



EUROPEAN COMMISSION
DG Competition

CASE AT.40588 – TEVA COPAXONE

(Only the English text is authentic)

ANTITRUST PROCEDURE

Council Regulation (EC) 1/2003

Article 7 Regulation (EC) 1/2003

Date: 31/10/2024

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Brussels, 31.10.2024
C(2024) 7448 final

COMMISSION DECISION

of 31.10.2024

**relating to a proceeding under Article 102 of the Treaty on the Functioning of the
European Union (the Treaty)**

(AT.40588 - Teva Copaxone)

(Only the English text is authentic)

TABLE OF CONTENTS

1.	Introduction.....	10
2.	Parties to the proceedings.....	11
2.1.	Teva.....	11
2.2.	Synthon	11
2.3.	{...}.....	12
2.4.	{...}.....	12
3.	Procedure.....	12
4.	Relevant regulatory framework.....	14
4.1.	Patent system.....	14
4.1.1.	The role of patents in the pharmaceutical sector.....	14
4.1.2.	Typology of patents in the pharmaceutical industry	15
4.1.3.	The EPC and divisional patents	16
4.1.4.	Challenging the validity of (divisional) patents	19
4.1.5.	Patent enforcement proceedings	21
4.2.	Marketing authorisations.....	22
4.2.1.	Decentralised Procedure.....	22
4.2.2.	Full, abbreviated and hybrid applications	22
4.3.	Pricing, reimbursement and substitution of medicinal products	23
4.4.	Promotion in the pharmaceutical sector	26
5.	Copaxone, its importance for Teva, and Teva’s strategy to confront entry of competing GA	28
5.1.	Product and business concerned – Copaxone	28
5.2.	The Copaxone Continuation Project	29
5.2.1.	Introduction	29
5.2.2.	The Copaxone Life Cycle Initiative and Teva’s attempts to tighten the regulatory requirements for the authorisation of competing GA	30
5.2.3.	The Copaxone Continuation Project, a strategy to confront the entry of competing GA.....	31
5.2.3.1.	Converting Copaxone patients to 40 mg to evade competition	33
5.2.3.2.	Patent enforcement and misuse of the (divisional) patent system	36
5.2.3.3.	Regulatory interventions to obstruct the launch of Synthon GA before Synthon obtained marketing authorisation	37
5.2.3.4.	Regulatory litigation against Marketing Authorisations	38
5.2.3.5.	Disparagement campaign targeting Synthon GA.....	40
5.2.3.6.	Further activities to counter market entry of Synthon GA.....	41
5.2.4.	The CCP strategy was carefully organised and centrally steered by Teva	42

5.2.4.1.	Many CCP activities shared the common objective to delay competition.....	43
5.2.4.2.	Teva was aware of antitrust compliance risks with the CCP and tried to avoid written traces	44
5.2.5.	The implementation of the CCP prevented and/or delayed market entry of competing GA, in particular Synthon GA	44
5.2.6.	Conclusion.....	45
6.	Relevant Market for Copaxone	46
6.1.	General principles regarding market definition	46
6.2.	Specific considerations on market definition in the pharmaceutical sector	48
6.2.1.	The conditions of competition and the complex structure of supply and demand in the pharmaceutical sector	48
6.2.2.	The life-cycle of pharmaceutical products as a key determinant of the definition of the relevant markets	49
6.2.3.	The emergence of generic-like competition may require a change of the definition of the relevant market to one limited to medicines that contain the same active ingredient.....	52
6.2.4.	The Commission’s approach to defining markets for pharmaceutical products in previous merger decisions.....	54
6.2.5.	Teva’s claims on the key precedents for defining relevant product markets in the pharmaceutical sector	56
6.3.	Relevant product market	58
6.3.1.	Multiple Sclerosis and available treatments.....	59
6.3.1.1.	Description of MS	59
6.3.1.2.	Approved DMT options for RRMS	62
6.3.2.	First step: assessment of therapeutic substitutability between Copaxone and other approved DMTs for the treatment of RRMS	64
6.3.2.1.	Synthon GA is not only therapeutically substitutable, but also therapeutically equivalent with Copaxone.....	65
6.3.2.2.	Non-GA first line DMTs are, at best, imperfect therapeutic substitutes for Copaxone	66
6.3.2.3.	Second-line and third-line DMTs are not in the relevant product market for Copaxone as they are not therapeutically substitutable	76
6.3.2.4.	Conclusion.....	77
6.3.3.	Second step: assessing which first-line DMTs effectively constrained Copaxone in the Relevant Period	78
6.3.3.1.	Synthon GA is in the same relevant product market as Copaxone and significantly changed the dynamics of the market.....	79
6.3.3.2.	Non-price competition from non-GA DMTs was not a significant driver of competition during the Relevant Period.....	87
6.3.3.3.	Teva’s competitive efforts were focussed on Synthon GA and it did not perceive non-GA first-line DMTs as a significant constraint during the Relevant Period.....	118

6.3.3.4.	A country-specific assessment shows that non-GA first-line DMTs have not been an effective and immediate constraint on Copaxone	128
6.3.3.5.	Conclusion: Synthon GA is the only first-line DMT that is capable of effectively and immediately constraining Copaxone.....	180
6.3.4.	Conclusion: the relevant product market is the market for glatiramer acetate	186
6.4.	Relevant geographic market.....	186
7.	Dominance	187
7.1.	Principles.....	187
7.2.	Assessment.....	188
7.2.1.	Market shares and profit margins.....	189
7.2.1.1.	Copaxone’s market shares and profit margins in Belgium	190
7.2.1.2.	Copaxone’s market shares and profit margins in Czechia	191
7.2.1.3.	Copaxone’s market shares and profit margins in Germany	192
7.2.1.4.	Copaxone’s market shares and profit margins in Italy.....	195
7.2.1.5.	Copaxone’s market shares and profit margins in the Netherlands.....	198
7.2.1.6.	Copaxone’s market shares and profit margins in Poland.....	199
7.2.1.7.	Copaxone’s market shares and profit margins in Spain.....	201
7.2.1.8.	Teva’s claims that market share evidence is not a reliable indicator for dominance in view of tenders	203
7.2.1.9.	Teva’s claim that the Commission considers market shares and pricing evidence in isolation.....	210
7.2.2.	Barriers to entry and expansion.....	212
7.2.3.	Payers did not exercise sufficient countervailing buyer power during the Relevant Period	217
7.2.4.	Teva’s acknowledgement of its own dominant position.....	224
7.3.	Conclusions on dominance	226
8.	First abuse: misuse of divisional patents.....	226
8.1.	Overview of Teva’s divisionals game.....	227
8.2.	The legal and economic context of Teva’s divisionals game	231
8.2.1.	General principles	231
8.2.2.	Specific principles concerning the investigated conduct in the context of intellectual property rights	233
8.2.3.	Particular features of divisional patents and their susceptibility to misuse	235
8.2.4.	Teva’s arguments and the Commission’s assessment.....	239
8.3.	Teva’s divisionals game falls outside the scope of competition on the merits	241
8.3.1.	Teva engaged in a comprehensive patenting conduct consisting of patent filings and withdrawals aimed at hindering the entry and/or expansion of GA competitors.....	242

8.3.2.	Teva filed staggered divisional patents with overlapping content to multiply its process and dosage patents, prevent parallel review and prolong legal uncertainty	249
8.3.2.1.	Creation of multiple divisional patents with significantly overlapping content	249
8.3.2.2.	Filings of divisional patents were staggered to prevent the parallel review of patents and to delay a final reasoned decision on their validity	265
8.3.3.	Teva obstructed effective legal review by withdrawing challenged patents thus avoiding damaging precedents	272
8.3.3.1.	Revocation decisions could have precedent effect for the whole patent family	273
8.3.3.2.	The legal proceedings concerning the validity of Teva’s Copaxone patents hinged on the same issues for each patent family	274
8.3.3.3.	Teva was concerned about the weakness of its patents and the resulting risk of their revocation.	281
8.3.3.4.	Teva was aware that a patent ruling would create a precedent for the remainder of the patent family and negatively influence the grant of preliminary injunctions	289
8.3.3.5.	The EPO and national courts confirmed the precedent effect of TBA’s decisions specifically for Teva’s dosage patents	291
8.3.3.6.	Teva strategically withdrew its patents before the adoption of a reasoned decision by the TBA, thus avoiding a “damaging” precedent for its remaining divisional patents	293
8.3.4.	The pattern of Teva’s carefully timed filings and withdrawals of patents demonstrates the existence of a strategy to maximise the delay of legal review	297
8.3.5.	Interim conclusion: Teva’s comprehensive patenting conduct obstructed and delayed the effective legal review of the validity of Teva’s patents and thus artificially prolonged legal uncertainty concerning Copaxone patents	301
8.3.6.	Teva’s explanations for its comprehensive patenting conduct cannot be accepted.	302
8.3.6.1.	Teva’s comprehensive patenting conduct goes against the objectives of the patent system.	302
8.3.6.2.	Teva clearly pursued and achieved the exact opposite from its claimed intent and instead sought to obstruct and delay the legal review process of its patents	304
8.3.6.3.	Teva’s conduct did not reduce Teva’s costs for maintaining its patents.	307
8.3.6.4.	Teva’s claimed reasons for withdrawing process patents EP ‘703 and EP ‘528 cannot be accepted.	308
8.3.6.5.	Teva’s claimed reasons for withdrawing its Original Dosage Patent EP ‘749 cannot be accepted.	308
8.3.7.	Conclusion: Teva’s comprehensive patenting conduct did not constitute competition on the merits.	315
8.4.	Teva’s divisionals game was capable of having anticompetitive effects.	316
8.4.1.	The direct anticompetitive effects of Teva’s comprehensive patenting conduct.	319
8.4.1.1.	Teva’s conduct contributed to artificially prolonging legal uncertainty for significant periods	319
8.4.1.2.	The artificially prolonged legal uncertainty was capable of hindering the market entry and expansion of Synthron GA	323

8.4.1.3.	The artificially prolonged legal uncertainty had a deterrent effect on potential further market entrants	325
8.4.2.	Effects from Teva’s increased ability to enforce its patents in national courts	326
8.4.2.1.	Teva used warning letters to deter market entry by Synthon GA	326
8.4.2.2.	Teva enforced its patents and sought preliminary injunctions against Synthon GA	327
8.4.2.3.	Teva’s divisionals game increased the obstacles Synthon’s licensees had to face to successfully launch their products in the Relevant Member States	330
8.4.2.4.	Teva’s patent enforcement prevented likely price competition in the Relevant Member States.....	331
8.4.3.	Effects of Teva’s comprehensive patenting conduct in the Relevant Member States	332
8.4.4.	Conclusion: Teva’s comprehensive patenting conduct was capable of having exclusionary effects.....	338
8.5.	Teva’s divisionals game has no objective justifications and generates no efficiencies	339
8.6.	Conclusion: Teva abused its dominant position in the Relevant Member States	339
9.	Second abuse: exclusionary disparagement	339
9.1.	Overview of Teva’s disparagement strategy and conduct	340
9.1.1.	Context of Teva’s disparagement campaign	341
9.1.2.	Overview of Teva’s disparagement strategy and campaign after the end of the Decentralised Procedure.....	344
9.2.	Applicable principles and analytical framework under Article 102 TFEU	347
9.2.1.	General principles	347
9.2.2.	Principles specifically applicable to exclusionary disparaging conduct on pharmaceutical markets.....	348
9.2.2.1.	Objectively misleading information capable of discrediting a competing product .	350
9.2.2.2.	Capability to produce exclusionary effects	352
9.2.2.3.	Lack of objective justification.....	355
9.2.3.	Teva’s arguments and the Commission’s assessment.....	356
9.2.3.1.	Teva’s claim that the Commission wrongly relied on Article 101 TFEU principles	356
9.2.3.2.	Teva’s claim that the Commission failed to apply the legal test of undue interference	356
9.2.3.3.	Teva’s claim that the Commission should apply a different test depending on the addressee of Teva’s disparaging messages	358
9.2.3.4.	Teva claims that messages are “misleading” only if they cast doubt on the safety of a competing product.....	359
9.2.3.5.	Teva’s claim that its communications were legitimate as they did not challenge therapeutic equivalence but focused on automatic substitution is unfounded	360

9.2.3.6.	Teva’s claims that the Commission should have carried out an in concreto assessment and established the likelihood of effects	365
9.2.3.7.	Teva’s claim that its communications concerning Synthon GA amount to an exercise of its freedom of speech	367
9.2.4.	Conclusion.....	368
9.3.	Teva disseminated objectively misleading information capable of discrediting Synthon GA.....	368
9.3.1.	Forms and expressions of Teva’s Complexity Message and their misleading and discrediting nature	370
9.3.1.1.	Teva emphasised clinically irrelevant differences in GA structures.....	370
9.3.1.2.	Teva implied that health risks observed in other glatiramer-related substances equally apply to Synthon GA.....	381
9.3.1.3.	Teva was casting doubt on the validity of the GATE study as the scientific basis for Synthon GA’s marketing authorisation, even after its endorsement by the competent authorities during the Decentralised Procedure	386
9.3.1.4.	Teva’s arguments and the Commission’s assessment.....	394
9.3.2.	Teva put in place effective mechanisms for disseminating the Misleading Complexity Message	401
9.3.2.1.	Multiple Teva teams were responsible for the dissemination of the Misleading Complexity Message.....	402
9.3.2.2.	Teva created an elaborate set of materials to disseminate the Misleading Complexity Message.....	403
9.3.2.3.	Teva’s other arguments and the Commission’s assessment	421
9.3.3.	Conclusion.....	424
9.4.	Teva’s Misleading Complexity Message was capable of producing exclusionary effects on the GA markets.....	425
9.4.1.	Teva targeted Payers and HCPs as key drivers of demand for GA products.....	425
9.4.1.1.	Teva targeted Payers to influence demand for Synthon GA on a systemic level	426
9.4.1.2.	Teva targeted HCPs to influence demand for Synthon GA at the level of individual patient prescriptions	429
9.4.1.3.	Teva further amplified the dissemination of the Misleading Complexity Message to Payers and HCPs by engaging Key Opinion Leaders	432
9.4.2.	Teva’s Misleading Complexity Message was capable of influencing demand by Payers and HCPs	435
9.4.3.	Teva enjoyed a special position in its communication with the Payers and HCPs..	437
9.4.4.	Teva’s dissemination of the Misleading Complexity Message was capable of producing exclusionary effects in at least seven Member States	440
9.4.4.1.	Centrally developed materials for the communication of misleading messages	440
9.4.4.2.	Teva’s dissemination of the Misleading Complexity Message in Belgium.....	442
9.4.4.3.	Teva’s dissemination of the Misleading Complexity Message in Italy	453
9.4.4.4.	Teva’s dissemination of the Misleading Complexity Message in Germany.....	463

9.4.4.5.	Teva’s dissemination of the Misleading Complexity Message in the Netherlands .	491
9.4.4.6.	Teva’s dissemination of the Misleading Complexity Message in Czechia.....	506
9.4.4.7.	Teva’s dissemination of the Misleading Complexity Message in Poland	512
9.4.4.8.	Teva’s dissemination of the Misleading Complexity Message in Spain	520
9.4.5.	Conclusion.....	526
9.5.	Teva’s conduct has no objective justification	526
9.6.	Conclusion: Teva’s conduct constitutes an abuse of its dominant position.....	530
10.	Effects on trade	531
10.1.	Principles.....	531
10.2.	Application to the present case	531
11.	Single and continuous infringement.....	532
11.1.	Principles.....	532
11.2.	Application to the present case	533
12.	Duration of the infringements	534
12.1.	First abuse: misuse of divisional patents.....	534
12.2.	Second abuse: exclusionary disparagement.....	536
12.3.	Duration of the single and continuous infringement.....	537
13.	Addressees.....	537
13.1.	Principles.....	537
13.2.	Application to the present case	538
14.	Teva’s claims related to rights of defence.....	538
14.1.	Teva’s claim that the Commission failed to provide minutes of all contacts between the Commission and the complainants.....	539
14.1.1.	Teva’s claim that it has not received access to all records of contacts with the complainants	540
14.1.2.	Teva’s claim that the minutes agreed after the Oral Hearing cannot represent an accurate record of the related contacts	542
14.1.3.	Teva’s claim that the agreed minutes are too vague to serve as complete records of the discussion	542
14.2.	Teva’s claim that the alleged violation of its rights of defence is irremediable	542
15.	Remedies and Fines.....	543
15.1.	Article 7(1) of Regulation (EC) No 1/2003	543
15.2.	Article 23(2) of Regulation (EC) No 1/2003	544
15.2.1.	General methodology of the Guidelines on Fines.....	545
15.2.2.	Imposition of a fine	545
15.2.2.1.	Intention or negligence.....	545
15.2.2.2.	Novelty.....	547

15.2.2.3. Legal certainty, legitimate expectations, nullum crimen, nulla poena sine lege and non-retroactivity 549

15.2.3. Amount of the fine to be imposed on Teva..... 550

15.2.3.1. Determination of the basic amount of the fine..... 550

15.2.3.2. Application of Article 23(2) of Regulation (EC) No 1/2003 562

15.2.3.3. Conclusion: final amount of the fine..... 562

16. Conclusion..... 562

COMMISSION DECISION

of 31.10.2024

relating to a proceeding under Article 102 of the Treaty on the Functioning of the European Union (the Treaty)

(AT.40588 - Teva Copaxone)

(Only the English text is authentic)

THE EUROPEAN COMMISSION,

Having regard to the Treaty on the Functioning of the European Union¹,

Having regard to Council Regulation (EC) No 1/2003, of 16 December 2002 on the implementation of the rules on competition laid down in Articles 81 and 82 of the Treaty², and in particular Article 7 and Article 23(2) thereof,

Having regard to the complaint lodged by Synthon B.V. and {...} on 7 October 2022, alleging infringements of Article 102 of the Treaty by Teva Pharmaceutical Industries Ltd (and other entities in the Teva group including Teva Pharmaceuticals Europe B.V.) and {...}, and requesting the Commission to put an end to those infringements,

Having regard to the complaint lodged by {...} on 8 December 2022, alleging infringements of Article 102 of the Treaty by Teva Pharmaceutical Industries Ltd (and other entities in the Teva group including Teva Pharmaceuticals Europe B.V.) and {...}, and requesting the Commission to put an end to those infringements,

Having regard to the Commission decision of 4 March 2021 to initiate proceedings in this case,

Having given the undertakings concerned the opportunity to make known their views on the objections raised by the Commission pursuant to Article 27(1) of Regulation No 1/2003 and Article 12 of Commission Regulation (EC) No 773/2004 of 7 April 2004 relating to the conduct of proceedings by the Commission pursuant to Articles 81 and 82 of the Treaty³,

After consulting the Advisory Committee on Restrictive Practices and Dominant Positions,

Having regard to the final report of the hearing officer in this case,

Whereas:

¹ OJ, C 115, 9.5.2008, p.47.

² OJ L 1, 4.1.2003, p. 1. With effect from 1 December 2009, Articles 81 and 82 of the EC Treaty have become Articles 101 and 102, respectively, of the Treaty on the Functioning of the European Union (“TFEU”). The two sets of provisions are, in substance, identical. For the purposes of this Decision, references to Articles 101 and 102 of the TFEU should be understood as references to Articles 81 and 82, respectively, of the EC Treaty when where appropriate. The TFEU also introduced certain changes in terminology, such as the replacement of “Community” by “Union” and “common market” by “internal market”. Where the meaning remains unchanged, the terminology of the TFEU will be used throughout this Decision.

³ OJ L 123, 27.4.2004, p. 18.

1. INTRODUCTION

- (1) This Decision pursuant to Article 7(1) of Council Regulation (EC) No 1/2003 is addressed to Teva Pharmaceutical Industries Ltd and Teva Pharmaceuticals Europe B.V., jointly referred to as “Teva”.
- (2) Teva is the originator producer of the medicine glatiramer acetate (“GA”) that is used to treat the most common form of multiple sclerosis (“MS”). Teva’s GA medicine is commercialised under the brand name Copaxone. It was, as long as Teva enjoyed patent protection and thus market exclusivity for the GA active substance, the best-selling and most profitable product of Teva. This Decision concerns Teva’s conduct that started when its basic patent for GA was approaching expiry and when competing manufacturers were trying to enter the market with their versions of GA. The Commission has reached the conclusion, based on the evidence on file, including Teva’s internal documents, and after a comprehensive assessment of all relevant legal and economic circumstances as set out in this Decision, that Teva has abused its dominant position in several markets for GA in the European Union.
- (3) Teva has committed two distinct abuses of its dominant position in the relevant markets for GA in Belgium, Czechia, Germany, Italy, the Netherlands, Poland and Spain (the “Relevant Member States”) that each infringe Article 102 of the Treaty on the Functioning of the European Union (“TFEU”) and that together constitute a single and continuous infringement of Article 102 TFEU. Both abuses pursued the same anticompetitive objective of artificially prolonging the exclusivity of Copaxone by hindering and/or delaying the market entry and uptake of Synthon’s product as the only competing GA in the EU, and thereby the start of significant price competition threatening to erode Teva’s large Copaxone revenues. The period during which these infringements took place started on 3 February 2015 and ended between 31 December 2018 and 7 February 2024.⁴
- (4) The first abuse concerns Teva’s abuse of its dominant position in the Relevant Member States by misusing regulatory patent procedures before the European Patent Office. Teva recurrently filed staggered divisional patents with overlapping content and then strategically withdrew the challenged patents before a reasoned decision on their validity could be issued. Teva thus artificially prolonged legal uncertainty about the validity of its exclusive rights and maintained Teva in a position to assert its remaining divisional patents against its competitors. Teva’s “divisionals game”, provided it with more “{...}” with the ultimate objective to “{...}” effective competition from competing GAs.⁵ This conduct cannot be considered as competition on the merits and is capable of hindering and/or delaying the market entry and expansion of competing GAs on the relevant markets, thereby eliminating or delaying price competition.
- (5) The second abuse of Teva’s dominant position consists in Teva’s systematic disparagement campaign targeting a competing GA developed by Synthon B.V. (“Synthon GA”) to hinder and/or delay its market entry and uptake in the Relevant Member States. In direct contradiction to the findings of the competent health

⁴ The single and continuous infringement addressed in this Decision started on 3 February 2015 and ended on 7 February 2024 in Belgium, Czechia, Germany and Spain, on 31 December 2022 in Poland, on 31 December 2021 in Italy and on 31 December 2018 in the Netherlands (see Chapter 12 on duration of the infringement).

⁵ ID 404-2555, Teva internal email dated 16 March 2016 from {...} to {...} and others. ID 404-1705, Teva internal email dated 27 September 2016 from {...}, p. 2.

authorities, Teva disseminated misleading messages to doctors, pharmacists, health insurances and other health bodies. Teva's communication campaign sought to manipulate the perception of the alleged risks arising from the use of Synthron GA and "{...}"⁶ in relation to Synthron GA's safety and efficacy, and its therapeutic equivalence⁷ with Copaxone, thus hindering and/or delaying the entry and uptake of the only product competing with Copaxone.

- (6) The Decision is structured as follows. Chapter 2 describes the undertakings concerned and Chapter 3 summarises the procedure in this case. Chapter 4 provides an overview of the relevant regulatory framework and Chapter 5 describes the product and business concerned and Teva's strategy and initiatives to "*defend*" the market exclusivity of Copaxone after expiry of its basic patent. Chapters 6 and 7 set out the Commission's conclusions on the relevant product and geographic markets concerned and Teva's dominant position on these markets. Chapters 8 and 9 contain, respectively, the Commission's comprehensive assessment of the first abuse (misuse of divisional patents) and the second abuse (exclusionary disparagement). Chapters 10 to 13 set out the Commission's conclusions on the effect on trade, the single and continuous nature of the infringements and their duration, as well as the addressees of this Decision. Chapter 14 summarise Teva's claims related to the respect of its rights of defence during the Commission's investigation. Chapter 15 sets out the remedies imposed by this Decision (order to desist), and sets out the methodology for calculating the fine and the final amount of the fine imposed on Teva. Finally, Chapter 16 presents the Commission's overall conclusion.

2. PARTIES TO THE PROCEEDINGS

2.1. Teva

- (7) Teva Pharmaceutical Industries Ltd., located at 124 Devorah Hanevia Tel Aviv 6944020, Israel, and its European holding subsidiary Teva Pharmaceuticals Europe B.V., located at Busweg 1, 2031 DA Haarlem, the Netherlands, are the addressees of this Decision. Teva is a worldwide pharmaceutical company which is active in the development, production and marketing of generic drugs as well as innovative and specialty pharmaceuticals, active pharmaceutical ingredients and over-the-counter products.
- (8) In 2023, Teva had a total worldwide consolidated turnover of USD {...} (approximately EUR {...}).⁸
- (9) {...} that has been marketed by Teva in the EU since 2000, with annual EU sales of c. {...} in 2015 and 2016 and of around {...} in 2020 and 2021.⁹

2.2. Synthron

- (10) Synthron B.V. (together with all entities belonging to the same group, "Synthron") is a pharmaceutical company headquartered in the Netherlands and specialised in developing and manufacturing generic and specialty medicines.
- (11) Synthron develops medicines for a variety of therapeutic areas, including for the treatment of multiple sclerosis where its generic-like product¹⁰ Synthron GA is to date

⁶ ID 404-2017, Teva internal email dated 27 October 2014 from {...}.

⁷ Medicines are considered therapeutic equivalents if they have the same (or similar) active ingredient and can be expected to have the same clinical effect and safety profile when administered to patients.

⁸ ID 5897, Certification of Teva's turnover data, p. 7.

⁹ ID 2149, Teva's reply to Article 18(2) Request of 13 July 2022.

the only GA alternative to Copaxone in Europe. Synthon commercialises GA in Europe through two main licensing agreements, described below.

2.3. {...}

(12) {...}

(13) {...}

2.4. {...}

(14) {...}

(15) {...}

3. PROCEDURE

(16) Based on market information, which suggested that Teva might be abusing its dominance through exclusionary conduct in the markets for the treatment of multiple sclerosis in breach of Article 102 TFEU, the Commission carried out unannounced inspections pursuant to Article 20(4) of Regulation 1/2003 at Teva's premises in the Netherlands, Germany and the United Kingdom from 24 to 28 October 2019.

(17) In the period from December 2019 until February 2020, a continued inspection of Teva's documents took place in the Commission's premises in the presence of Teva representatives.

(18) In view of Teva's claims relating to legal professional privilege, the Commission put a number of Teva documents into sealed envelopes during the inspections and requested Teva to state the reasons for its claims. Subsequently, Teva submitted its reply with the explanations of its claims. The Commission did not open these envelopes during the proceedings and returned them to Teva on 27 September 2024.

(19) On 3 June 2020, the Commission addressed a simple request for information pursuant to Article 18(2) of Regulation 1/2003 to Teva. Subsequent requests for information were sent to Teva on 8 January 2021, 3 June 2021, 22 October 2021, 18 November 2021, 13 July 2022, 20 July 2023, 4 October 2023 and 15 February 2024. On 25 May 2023, the Commission addressed a request for information by decision pursuant to Article 18(3) of Regulation 1/2003 to Teva. On Teva's request, the Commission granted several extensions of the deadlines to reply to these requests.

(20) On 4 March 2021, the Commission initiated proceedings against Teva Pharmaceutical Industries Limited and Teva Pharmaceuticals Europe B.V. pursuant to Article 2 of Regulation 773/2004¹¹ with a view to adopting a decision pursuant to Chapter III of Regulation 1/2003.

(21) On 5 May 2021, the case team invited Teva representatives to a state of play meeting for a preliminary exchange of views on the case.

(22) On 9 June 2021, 22 October 2021 and 11 February 2022, the Commission sent simple requests for information to a number of Teva's competitors for the supply of GA in the EEA.

¹⁰ See Section 4.2.2.

¹¹ Council Regulation (EC) No 773/2004 of 7 April 2004 relating to the conduct of proceedings by the Commission pursuant to Articles 81 and 82 of the EC Treaty, (OJ L 123, 27.04.2004, p.18-24).

- (23) In December 2021, the Commission sent simple requests for information to a number of national health care authorities and health insurance bodies in seven Member States (Belgium, Czechia, Germany, Italy, the Netherlands, Poland and Spain).
- (24) On 5 October 2022, the case team held another state of play meeting with Teva representatives to update them on the status of the Commission’s proceedings.
- (25) On 7 October 2022, {...} and Synthon submitted a joint formal complaint against Teva and {...}, claiming that Teva unlawfully delayed the market entry and uptake of generic GA to maintain its dominant position with Copaxone.¹²
- (26) On 10 October 2022, the Commission adopted a Statement of Objections addressed to Teva. Following Teva’s request of 18 October 2022, the Commission granted Teva access to the Commission’s file on 19 October 2022 by way of delivery of a DVD containing the evidence included in the Commission’s file prior to 7 October 2022.¹³
- (27) On 8 December 2022, {...} submitted a formal complaint against Teva and {...}, reiterating the claims made by {...} and Synthon.¹⁴
- (28) On 8 February 2023, Teva submitted a written reply to the Statement of Objections (“Teva’s Reply to the Statement of Objections”). Synthon, {...}, and {...} (in their capacity as complainants) submitted their comments on the Statement of Objections on 18 January 2023. Teva also further exercised its right to be heard by participating at an Oral Hearing on 24 March 2023.
- (29) On 19 July 2023, the Commission granted Teva supplemental access to the Commission’s file, and on 9 November 2023, Teva submitted its written observations thereon.
- (30) On 9 February 2024, the Commission issued a first Letter of Facts to Teva (“Letter of Facts I”). On the same day, the Commission granted Teva access to the additional evidence registered on the Commission’s file since the initial access to file. On 26 March 2024, Teva submitted a written reply to the Letter of Facts I.
- (31) On 17 May 2024, the Commission issued a second Letter of Facts to Teva (“Letter of Facts II”) and granted Teva access to the additional evidence registered in the Commission’s file since the Letter of Facts I. On 11 June 2024, Teva submitted a written reply to the Letter of Facts II.
- (32) On 5 July 2024, the Commission sent to Teva a letter addressing its requests for additional access to file submitted on 9 November 2023, as complemented by Teva’s reply to the Letter of Facts I submitted on 26 March 2024. On 19 July 2024, Teva replied and claimed that the Commission had committed procedural errors by failing to disclose adequate records of certain alleged contacts between the Commission and the complainants. The Commission replied to Teva on 2 September 2024, dismissing as unfounded Teva’s allegations and implied additional access to file requests. Teva

¹² Teva was provided access to a non-confidential version of the formal complaint submitted by {...} and Synthon on 3 November 2022.

¹³ On 30 September 2022, Teva signed a waiver for the Commission not to share again with Teva the documents submitted by Teva itself which had not been quoted or referred to in the Statement of Objections. On 12 December 2023, Teva also signed an additional waiver for the Commission not to share again with Teva the documents submitted by Teva itself which had not been quoted or referred to in any Letter(s) of Facts the Commission could adopt.

¹⁴ Teva was provided access to a non-confidential version of the formal complaint submitted by {...} on 16 December 2022.

submitted further arguments on 16 September 2024 and the Commission replied on 20 September 2024. Lastly, Teva indicated on 25 September 2024 that it considered that the Commission had not adequately addressed “*the central points raised in its prior correspondence*”. Teva’s main claims and the Commission’s position thereon are summarised in Chapter 14 below.

- (33) On 27 September 2024, the case team held a state of play meeting with Teva representatives to update them on the status of the Commission’s proceedings.
- (34) On 16 October 2024, the Commission issued a third Letter of Facts to Teva (“Letter of Facts III”) and granted Teva access to the specific items of evidence mentioned therein. On 28 October 2024, Teva submitted a written reply to the Letter of Facts III.

4. RELEVANT REGULATORY FRAMEWORK

- (35) This chapter summarises the various regulatory regimes relevant in the context of this case: (i) the patent system (Section 4.1), (ii) marketing authorisation (“MA”) procedures (Section 4.2), (iii) pricing and reimbursement systems in Member States (Section 4.3), and (iv) rules governing promotional activities for prescription medicines (Section 4.4).

4.1. Patent system

- (36) This section will present a brief overview of (i) the role of patent protection, (ii) the typology of patents in the pharmaceutical industry, (iii) the rules governing divisional patent applications, and (iv) how granted patents are challenged and (v) enforced.

4.1.1. The role of patents in the pharmaceutical sector

- (37) Patents play a key role in the pharmaceutical sector, which is characterised by high investments and a long and costly research and development phase necessary to bring new products to the market. A patent is an intellectual property right that confers on its holder the exclusive right to exploit the protected invention and a right to prevent third parties from using it, as well as from manufacturing, selling, importing, distributing or stocking the products embodying the invention without the patent holder’s consent.¹⁵ Patent rights and thereby the prospect of reaping rewards from the exclusive use of the invention on the market¹⁶ are limited in time and are granted in exchange for the public disclosure of the invention, which serves to disseminate the knowledge and provides further incentives to third parties to innovate.
- (38) In the EU, the full patent term is twenty years from the date of filing a patent application.¹⁷ To account for lengthy testing and trialling of medicinal products before they effectively reach the market and to preserve the incentives to innovate, the patent term of a specific medicinal product in the EU can be extended by a maximum of five years with a supplementary protection certificate (“SPC”). SPC is a

¹⁵ See Article 28(1) of the WTO Agreement on Trade-Related Aspects of Intellectual Property (“TRIPS”).

¹⁶ Either by commercialising the invention itself or through licensing it to the third parties.

¹⁷ See Article 63 of the European Patent Convention (the EPC).

sui generis intellectual property right provided for by EU legislation¹⁸, available to medicinal products that have been authorised by regulatory authorities.¹⁹

4.1.2. *Typology of patents in the pharmaceutical industry*

- (39) In the pharmaceutical industry, inventions relate for example, to new active ingredients, or to various (novel) aspects of existing active ingredients.
- (40) Patents covering new active pharmaceutical ingredients (“API”), the biologically active component of a medicinal product, provide the broadest protection (that is, in any form and for every use, whether known or unknown). API patents, referred to also as “primary”, “basic” or “compound” patents, apply to any product, which includes the protected active substance, irrespective of its formulation, dosage or application.
- (41) In addition to API patents, pharmaceutical companies typically apply for patents covering a specific aspect of a medicinal product. These so-called “secondary” patents may cover, amongst others, production processes, new therapeutic indications, novel forms of the compound (salt forms, enantiomers), dosing regimens, final formulations (tablets, intravenous etc.) combining the API with other ingredients, or providing for different ways of delivering the API (injectable drug, gel or a tablet).
- (42) For example, a process patent protects a particular way to manufacture the API. While there may be other ways to produce the product, the process patent confers protection only to the products directly obtained by the particular process.²⁰ A dosing regimen patent protects administration of a drug at a specific dose only. As such, for example, a patent may claim that at a certain dose the drug achieves higher tolerability, or that a specific low dose of API allows maintaining therapeutic effect with less adverse effects.
- (43) A secondary patent claiming a specific technical feature of the product confers a narrower protection than the claim to a compound itself, which is considered as conferring an “absolute protection”.²¹ Given that usually originators file for multiple secondary patents protecting different features of the invention, secondary patents are subject to more frequent legal challenges by the generic companies seeking to clear the way to the market. Secondary patenting is at the core of patenting strategies of pharmaceutical companies seeking, through filing of numerous patents covering different aspects of a drug, to extend market exclusivity beyond the protection period of their primary patent. In a testimony before the U.S. House of Representatives, Teva’s President and Chief Executive Officer recognised the issues arising from multiplications of secondary pharmaceutical patents and observed that “*exuberance*

¹⁸ Regulation (EC) No 469/2009 of the European Parliament and of the Council of 6 May 2009 concerning the supplementary protection certificate for medicinal products (OJ L 152, 16.6.2009, p.1-10) (as amended).

¹⁹ If the SPC relates to a medicinal product for paediatric use, a further six-month extension can be granted, provided data on the effects for children is submitted. See Regulation (EC) No 1901/2006 of the European Parliament and of the Council of 12 December 2006 on medicinal products for paediatric use and amending Regulation (EEC) No 1768/92, Directive 2001/20/EC, Directive 2001/83/EC and Regulation (EC) No 726/2004 (OJ L 378, 27.12.2006, p.1-19) (as amended).

²⁰ Article 64 EPC.

²¹ See for example, the decision of the Enlarged Board of Appeal of the EPO in case G 2/88.

of many surrounding minor patents” and companies making “a lot of patents which are not that substantiated” can delay generic competition.²²

4.1.3. *The EPC and divisional patents*

- (44) In the EEA, inventors may seek protection for their invention in several countries at once by applying for a European patent through a centralised and uniform procedure governed by the European Patent Convention (“EPC”)²³. If granted, a European patent gives its holder the same rights as would a national patent in each of the contracting parties of the EPC, for which patent protection was requested. That is to say, a European patent results in a bundle of national patents. Alternatively, inventors may apply for national patents by following separate procedures applicable in each Member State, where they seek protection for their invention.
- (45) A patent is granted upon examination of the patent application if the invention claimed is new, involves an inventive step and is susceptible of industrial application.²⁴ The scope of protection conferred by a European patent is determined by patent specific claims, which describe the features of the invention.²⁵
- (46) A divisional patent application (so called “divisional”) is a type of patent application, which claims subject-matter that has already been disclosed²⁶ in an earlier patent application (so called “parent application”). The parent application can be a primary or a secondary patent. Divisional applications are examined in the same way as other European patent applications.
- (47) Applicants may file for divisional applications in order to remedy a lack of unity of invention disclosed in an earlier application. This is the case where an earlier application claims more than one invention and the applicant splits the earlier application into one or several divisional applications each covering one invention (the so called “mandatory division” pursuant to Article 82 EPC).
- (48) Applicants may also file divisionals on a voluntary basis, including in cases where there is not necessarily more than one invention. The vast majority of divisional applications are filed on a voluntary basis rather than because the EPO identified a lack of unity of invention.²⁷ For example, applicants may seek to have separate patent applications covering different aspects of the same invention, such as distinct therapeutic uses, different production processes or dosage regimes. The divisional applications concerned in the present case were all voluntary.
- (49) One of the conditions for a divisional patent application is that it may only be filed if it relates to an earlier pending European patent application, be it the original parent

²² ID 4952, *Unsustainable Drug Prices: Testimony from the CEOs*, Hearing before the Committee on Oversight and Reform, U.S. House of Representatives, 30 September 2020, p. 52.

²³ The EPC is an international treaty binding all EU Member States as well as some other European countries (e.g. Switzerland, Norway).

²⁴ Article 52(1) EPC.

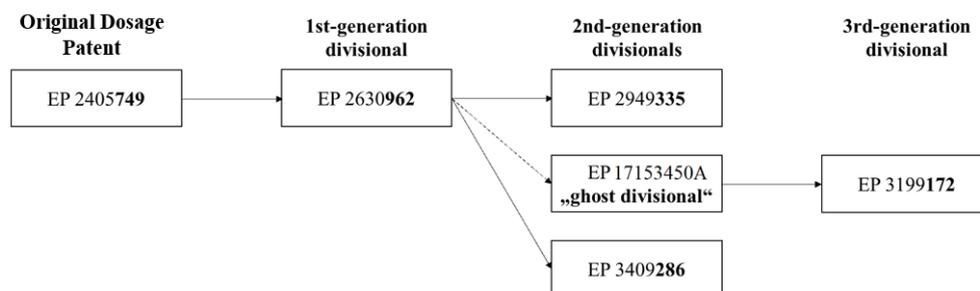
²⁵ Article 69 EPC.

²⁶ Subject matter describes technical features of the invention as well as the type of claim used to describe the invention (for example, product-by-process claim, and purpose limited product claim). Whether the conditions for filing a divisional application pursuant to Article 76(1) EPC are fulfilled, it has to be determined whether the skilled person can derive the subject matter of the claim directly and unambiguously, using common general knowledge, from the earlier application, as a whole. See the decision of the Enlarged Board of Appeal of the EPO in case G1/06; decision of the TBA in case T-1780/12, point 28.

²⁷ *Pharmaceutical Sector Inquiry*, Final report, Commission Staff Working Document, Part 1, 8 July 2009, paragraphs 433 and 1525.

patent application or an earlier divisional application.²⁸ A divisional patent can only be filed up to the date on which its (direct) parent patent is granted by the EPO. However, it is possible to file multiple generations of divisionals on the basis of an original parent patent. This is shown below on the example of one of Teva's divisional patent families (see also Section 8.3.2.1.2).

Figure 1: Example of a patent family with three generations of divisional patents



Source: Commission based on data from the European Patent Office website.

- (50) As is visible from Figure 1, one can distinguish between the original parent patent (the original patent which was not filed as a divisional) and the divisional patent, which in turn can be the (direct) parent patent to a later-generation divisional. A second-generation divisional can be filed up to the date on which its (direct) parent patent is granted by the EPO.²⁹
- (51) Although a divisional patent application is filed later than the parent application, it retains the filing date of the original parent application and benefits from the same priority date.³⁰ Similarly, each divisional application within the patent family will have the filing date of the original parent application and, if granted, will have a term of validity lasting twenty years from the date of the filing of the original parent application. In other words, the filing of divisional patents does not prolong the statutory end date for the lapse of the original parent patent.
- (52) Notably, an applicant may file divisional applications not only in relation to a pending parent patent application, but also in relation to another pending divisional patent application (see Figure 1).³¹ In such a case of sequenced divisional applications, it is not necessary that the initial parent application is pending in order to validly file later generations of divisionals. Even if the original parent (root) application is granted, withdrawn or refused (that is, not pending any more) and even after the original parent patent is revoked, it may be possible to continue filing further generations of divisional applications. For this purpose, it is sufficient that a divisional application is pending from which the later generation of divisionals is

²⁸ Article 76(1) EPC, for a brief period (2010-2013) the EPO had changed the rule limiting the possibility to introduce divisional patent application only within two years from the Examining Division's first communication concerning the earliest application for which a communication has been issued (usually the parent patent).

²⁹ A divisional application based on the parent application is referred to as first-generation divisional, while the divisional application based on a first-generation divisional is a second-generation divisional application, and this can continue further on. The parent application and all sequences of divisional applications stemming out of the same parent application constitute a patent family.

³⁰ Article 76(1) EPC.

³¹ There are generation-specific additional fees for divisionals, however, these additional costs are not considered to be significant enough to influence the decision whether to file for a further divisional, in particular when protecting blockbuster products such as Copaxone.

divided.³² Accordingly, by continuously filing divisional applications, it is possible to preserve the patent family pending throughout the initial exclusivity period of the original parent patent (even if the original parent patent has already been granted, revoked or withdrawn) and thereby extend the uncertainty as to the validity of relevant patents for potential or actual competitors.

- (53) Since a divisional application has the same filing and priority date as its original parent application, it may not claim any additional subject-matter to that disclosed in that parent application.³³ However, it is possible to file a divisional application, which has a scope that is very similar to the parent application (that is, with nearly identical claims).³⁴ Similarly, there can be a series of divisional applications pending with substantially overlapping claims. In case of a sequence of divisional applications, the content omitted on filing a divisional application cannot be re-introduced into the subsequent generations of divisionals derived from it.³⁵
- (54) While the EPC does not explicitly prohibit double patenting, the Guidelines for the examination by the EPO read on this point that “*it is an accepted principle in most patent systems that two patents cannot be granted to the same applicant for one invention*”.³⁶ In a case where two (or more) European patent applications from the same applicant relate to the same invention, the applicant may be requested during the examination proceedings to amend the claims to ensure that the subject-matter in the relevant applications is “not identical”, or choose which one of those applications to request for grant.³⁷ If the applicant does not act, once one patent application is granted, the other patent application will be refused.³⁸
- (55) However, pursuant to the EPO practice, if the claims of a parent patent and a divisional application do not fully overlap, there is no basis for refusing the divisional application.³⁹
- (56) Divisional applications are procedurally independent from their parent application. For example, a divisional application can be amended to the same extent as any other non-divisional application.⁴⁰ The procedural independence of divisional grant proceedings also determines that a refusal of the parent application will not have an effect on the content of a divisional application.⁴¹ The procedural independence of divisionals must be distinguished from the interdependence between the validity of the parent patents and their divisionals due to the precedent effect of EPO decisions.

³² A divisional application can also be an earlier application in the sense of Article 76(1) EPC for the purposes of one or more further divisional applications.

³³ Article 76(1) EPC.

³⁴ Despite the prohibition on double patenting (see G 4/19 (OJ 2022, A24)), it is possible to file identical divisional applications, as long as these applications are different from their (direct) parent patents.

³⁵ See the decision of the Enlarged Board of Appeal of the EPO in case G 1/06: “*anything disclosed in that divisional application be directly and unambiguously derivable from what is disclosed in each of the preceding applications as filed*”.

³⁶ Chapter G-IV, 5.4 of the Guidelines for Examination, see also a Decision of the Enlarged board of appeal in case G 1/05 accepting that objection of double patenting can be raised in order to refuse the European patent application.

³⁷ Chapter G-IV, 5.4 of the Guidelines for Examination in the EPO.

³⁸ See in this regard the decision of the TBA in case T-936/04.

³⁹ As noted above, the divisional application may not claim any additional subject matter to that disclosed in the parent application. See Guidelines for the Examination, Chapter C-IX, 1.6; see also the decision of the Enlarged Board of Appeal of the EPO in case G 4/19.

⁴⁰ Even if the earlier application is no longer pending, it is possible to amend the divisional so that its scope complies with the requirements of the EPC, Articles 76(1) and 123(2) EPC.

⁴¹ See decision of the TBA in case T-441/92.

A divisional will not be automatically revoked when its parent patent is revoked (procedural independence). However, if a parent patent is revoked with a reasoned decision, then this decision may have precedent value for the validity challenge of the divisional where the reasons for which the parent patent was invalidated also affect the divisionals (interdependence through precedent effect, see Recital (64) and Section 8.3.3.1).

4.1.4. Challenging the validity of (divisional) patents

- (57) The procedure to grant a patent is an *ex parte* procedure, in which third parties do not have any rights, except for the right to submit written observations concerning the patentability of a claimed invention (for example, comments relating to lack of novelty, inventive step or that the invention is not sufficiently disclosed).⁴² Third parties may challenge the validity of a patent only after the granting of the patent application, in opposition proceedings before the EPO or before a national court, which deals also with patent infringement cases.
- (58) An opposition against a patent in the EPO proceedings can be filed within nine months after the publication of the patent grant. Opposition proceedings, handled by the Opposition Division of the EPO (the “OD”), may result in a decision to declare the patent invalid and revoke the patent, to maintain the patent, or to maintain the patent in an amended form (narrowing of claims)⁴³. The party adversely affected by the decision of the OD may appeal the decision to the EPO Board of Appeal, specifically the Technical Board of Appeal (the “TBA”).
- (59) Based on the EPO statistics, in cases involving pharmaceutical preparations, the TBA revoked the patent and overturned the OD decisions upholding patents in 68% of cases.⁴⁴ Accordingly, the fact that an OD upheld the patent has limited indicative value as to whether the patent will ultimately be upheld by the TBA.
- (60) While a European patent is being challenged in opposition proceedings on substantive grounds with a view to having a patent revoked by a reasoned decision,⁴⁵ a patent holder may terminate the opposition proceedings with the same legal consequence (that is revocation *ab initio*⁴⁶). However, such termination does not entail the substantive examination as to the patentability of the patent concerned or the reasoned decision making the grounds for annulment publicly accessible.
- (61) Indeed, pursuant to Article 113(2) EPC, the EPO shall examine, and decide upon the European patent only in the text submitted to it, or agreed by the patent holder. Such agreement cannot be deemed to exist if the patent holder expressly states that it no

⁴² Article 115 EPC; Guidelines for Examination, Chapter E-VI, 3 and Rule 114 EPC.

⁴³ Articles 99-101 EPC.

⁴⁴ ID 413-11, Teva internal email dated March 2015 from {...} to {...} and others shows that Teva was aware of this, as it indicates chances of success distinguishing between the OD ({...} chance) and the TBA ({...}). The statistics are derived from the EPO Board of Appeal decisions database and concern all TBA decisions between 1 January 2017 and 3 April 2019 involving patents that are classified into the IPC codes A61K (Preparations for Medical, Dental or Toilet Purposes) or A61P (Specific Therapeutic Activity of Chemical Compounds or Medicinal Preparations) – which cover the majority of pharmaceutical patent cases. There were 67 TBA decisions falling into this category, 40 (60%) of which involved a TBA taking a decision in circumstances where the OD had maintained the patent as granted or in amended form. In 27 (68%) of these 40 cases, a TBA ultimately revoked the patent (i.e. overturning the OD’s decision to uphold the patent).

⁴⁵ Such as the claimed invention does not fulfil the patentability requirements of novelty, inventive step or does not disclose the invention sufficiently, see Article 100 EPC.

⁴⁶ Article 68 EPC.

longer approves the text of the patent as granted. Thus, in appellate proceedings where a patent holder declares that it does no longer approve the text of a patent as granted and withdraws its pending requests (such as, for instance, a request that the appeal be dismissed or the patent be upheld), the proceedings before the OD or TBA are to be terminated by a decision ordering the revocation of the patent, without going into the substantive issues. The OD or TBA no longer have legal ground to decide on the validity of the patent, as it implies that the patent has never existed.⁴⁷ Accordingly, in this case, the proceedings will be closed and the patent revoked without a reasoned decision.⁴⁸ Conversely, letting the patent lapse or surrendering it in all (designated) countries during the opposition proceedings would allow the opponent to request the continuation of proceedings (and a reasoned decision).⁴⁹

- (62) As regards the withdrawal of approval of the patent text in particular, the patent holder may withdraw the approved patent text very late in the proceedings, for example, just before the TBA renders a decision. Notably, in some cases the TBA may indicate in a preliminary opinion⁵⁰ matters of special significance that should be addressed during the oral proceedings (for example, that the claims in the divisional patent have added subject-matter which goes beyond the underlying parent patent application and could lead to invalidation of the divisional patent). A preliminary opinion does not substitute a reasoned decision of the TBA. However, it may provide guidance on the likely outcome of the case and thus directly trigger the patent holder to withdraw the approval of the text to avoid a negative reasoned assessment of its patent.⁵¹
- (63) While opponents may have an interest in a reasoned decision to be able to refer to it in opposition proceedings of another divisional patent of the same family, even where the opposed patent has been revoked, this is not possible where the patent holder causes its patent to be revoked by withdrawing the approval of the text.
- (64) While the EPC does not provide for rules on cross-procedural effect of final appeal decisions regarding the patents within the same patent family,⁵² in a few cases, the TBA explicitly relied on a binding effect of an earlier final appeal decision concerning the parent patent when deciding the appeal of a divisional application. In particular, the TBA explained in case T-51/08: “*Once a final judgment has been handed down, subsequent judges who are confronted with a suit that is identical to or substantially the same as the earlier one and between the same parties, are prevented from deciding on it a second time*” and “*since the aim of the res iudicata maxim is to avoid relitigation of the same subject matter by the same parties, it must inevitably apply to a divisional application*”.⁵³

⁴⁷ Article 113(2) EPC.

⁴⁸ Articles 101 and 113(2) EPC.

⁴⁹ See Rule 84.1 EPC.

⁵⁰ Under the Article 15 of the new rules of procedure of the Boards of Appeal, in force since 1 January 2020, the Board of Appeal is bound to issue a communication drawing attention to matters that seem to be of particular significance for the decision to be taken in every case, and may also provide a preliminary opinion.

⁵¹ Another explanation could relate to cost saving. However, the reimbursement of a full or partial appeal fee cannot be considered as sufficiently significant to explain the withdrawal.

⁵² See Article 111(2) EPC, which provides for *res iudicata* authority in cases where the TBA remits the case to the division whose decision was appealed.

⁵³ See the TBA decisions in cases T-51/08 and T-1155/13. See, however, also the TBA decisions questioning the cross-procedural *res iudicata* effect or the extent to which it applies: T-2084/11, T-1643/10, T-1666/14, and T-2145/11.

- (65) Accordingly, though *res iudicata* may only be invoked in narrow circumstances (such as in case of the same set of facts and between the same parties only), if opposition proceedings for parent patents end without a reasoned decision, that means that the opponents have to duplicate their arguments in subsequent opposition proceedings concerning divisional patents with substantially overlapping claims without being able to rely on an earlier (reasoned) decision in their favour. This not only increases the time and costs, but also prolongs the uncertainty about whether the products or processes protected by the patents are protected by valid patents.
- (66) The proceedings challenging the validity of a European patent before the EPO may run in parallel to national court proceedings. However, if the EPO revokes the patent, then there is no legal basis for the national court to exercise its jurisdiction in relation to patent invalidity (or infringement) claims. This is because the EPO decision to revoke the patent takes effect *ab initio* and in all designated states in respect of which the patent was granted. If the EPO maintains a patent in opposition proceedings, the patent validity challenge may continue before a national court.
- (67) A national court may consider the EPO's findings as a persuasive authority but it is not legally bound by its decisions and thus may arrive at a different outcome. If a national court annuls a patent based on the European patent, the effect of such a decision is limited to the single jurisdiction of the national court that took the decision.

4.1.5. *Patent enforcement proceedings*

- (68) After the issuance of a patent, patent holders may initiate patent infringement actions before national courts to, amongst others, prevent the entry or stop the marketing of a product allegedly infringing that patent. In the pharmaceutical industry, when a generic company launches or is about to launch a generic product on the market following the expiry of the primary patent, the patent holder often initiates lawsuits against the generic company (including possibly also other companies involved in manufacturing, stocking, or marketing of the allegedly infringing product) for alleged infringement of one or more secondary patents.
- (69) A patent holder may request a national court to issue a declaration of infringement, permanent and interim injunction, as well as request damages compensation. While specific conditions may apply depending on the procedural rules in a given jurisdiction, in principle, interim injunctions may be granted if the patent holder can show that patent infringement is likely or that such an infringement is imminent.⁵⁴ In the context of patents relevant for pharmaceutical products, the courts will consider that an infringement is imminent before any actual entry, if it can be shown, for example, that an alleged infringer has obtained a marketing authorisation. In some jurisdictions, before issuing an injunction, a national court may also conduct a preliminary assessment of the validity of the patent. Even where the validity of an asserted patent is contested (which occurs regularly with secondary patents), the courts often issue preliminary injunctions regarding pharmaceutical patents without assessing the validity of the patents concerned.
- (70) Interim measures in no way prejudice the merits of an infringement action brought by a patent holder and, if applicable, the merits of a counter claim challenging patent validity. However, litigation before national courts, often in several jurisdictions in parallel and concerning several secondary patents, is a significant burden in terms of

⁵⁴ The TBA decision in case T-51/08, points 3 and 3.1.

costs on a generic company intending to launch the generic product on the market. Such multiple proceedings, in particular in case of staggered divisional patents, not only significantly extend the uncertainty as to whether the generic product will be launched on the market but may actually delay (price) competition from generic alternatives, leading to significant harm to consumers and health systems.

4.2. Marketing authorisations

- (71) The requirements and procedures for acquiring an MA (marketing authorisation) are primarily laid down in Directive 2001/83/EC⁵⁵ and Regulation (EC) No 726/2004.⁵⁶ In the EEA, medicinal products for human use (whether originator or generic versions) may only be placed on the market after they have obtained an MA.⁵⁷
- (72) An MA can be obtained either through a centralised procedure before the European Medicines Agency (hereafter: “EMA”) or through national authorisation procedures. Non-central procedures include the so-called “Decentralised Procedure”, the “Mutual Recognition Procedure” and national procedures. The subsequent section describes the Decentralised Procedure, which was the one used for the assessment of the MA application for Synthon GA.

4.2.1. Decentralised Procedure

- (73) The Decentralised Procedure is used in cases where the applicant wishes to apply for MAs in more than one Member State and has not yet received an MA for its product in any Member State at the time of the application.⁵⁸ This procedure allows the common assessment of an application submitted simultaneously to several EU Member States, one being chosen as the reference Member State (“RMS”). The RMS prepares the draft assessment report, a draft summary of product characteristics and a draft of the labelling and package leaflet, while acting as central point for all concerned Member States and the applicant. The RMS proposes the abovementioned documents, which are approved by the concerned Member States.⁵⁹
- (74) After the procedure, each Member State issues an MA related to its territory. Should a country refuse to approve the RMS’s assessment, the issue is referred to a coordination group which should reach a consensus within 60 days. If no consensus is reached, the procedure is submitted to the appropriate EMA scientific committee for arbitration. The opinion of the EMA Committee is then forwarded to the Commission, which adopts a final decision on the application.

4.2.2. Full, abbreviated and hybrid applications

- (75) In order to obtain an MA for originator medicines, the applicant must submit a “full dossier” containing the data described in Article 8(3) of Directive 2001/83/EC, including among others detailed results of pharmaceutical tests, pre-clinical tests and

⁵⁵ Directive 2001/83/EC of the European Parliament and of the Council of 6 November 2001 on the Community code relating to medicinal products for human use (OJ 2001 L 311, p. 67) as amended.

⁵⁶ Regulation (EC) No 726/2004 of the European Parliament and of the Council of 31 March 2004 laying down Community procedures for the authorisation and supervision of medicinal products for human and veterinary use and establishing a European Medicines Agency, (OJ L 136, 30.4.2004, p. 1).

⁵⁷ Article 6(1) of Directive 2001/83/EC.

⁵⁸ Article 28(3) of Directive 2001/83/EC.

⁵⁹ For clarity, when this Decision refers to the “finalisation” or “completion” of a Decentralised Procedure, it means the approval by the concerned Member States of the draft assessment report, summary of product characteristics, and labelling and package leaflet proposed by the RMS. In the case of Synthon GA, as explained below, the Decentralised Procedure was therefore finalised on 11 March 2016.

clinical trials. At least eight years after an MA has been delivered in a Member State or in the EU for an innovator medicine (the “reference product”), generic companies can apply for MA for a generic version of the reference product through an “abbreviated procedure” set by Article 10(1) of Directive 2001/83/EC. This procedure does not require the applicant to provide the results of pre-clinical tests and clinical trials.

- (76) Hybrid medicines are developed as generic medicines that are based on a reference product. However, they do not satisfy the definition of a generic medicinal product⁶⁰ laid down for the abbreviated procedure. This is due to the fact that bioequivalence cannot be demonstrated or because of changes in the active substance(s), therapeutic indications, strength, pharmaceutical form or route of administration, vis-à-vis the reference medicinal product. In such a case, Article 10(3) of Directive 2001/83/EC requires that the applicant submits additional data compared to the abbreviated procedure set by Article 10(1) for generic medicines. These additional data include the results of pre-clinical tests or clinical trials.⁶¹ Therefore, authorisation of hybrid medicines depends partly on the results of tests on the reference medicine and partly on new data from clinical trials.
- (77) In the present case, as, due to certain compositional differences, bioequivalence with Copaxone could not be established for its GA, Synthon submitted in 2014 a hybrid application for an MA for GA on the basis of Article 10(3) of Directive 2001/83/EC⁶² with Copaxone as reference product. Synthon’s application was submitted via the Decentralised Procedure, with the Dutch Medicines Evaluation Board (“MEB”) acting as RMS and all other Member States of the EU as concerned Member States. The MEB examined the dossier submitted by Synthon and the Decentralised Procedure for the authorisation of Synthon GA was completed in 2016. National MAs were then subsequently issued.

4.3. Pricing, reimbursement and substitution of medicinal products

- (78) In addition to an MA, pharmaceutical companies must obtain a pricing and reimbursement decision in order to market a medicine in one of the Relevant Member States. The regulation on pricing, reimbursement and substitution of medicines is an exclusive competence of the Member States and can therefore differ. The relevant details for each Relevant Member State are explained in Section 6.3.3.4.
- (79) Together with the clinical practice, the rules on pricing and reimbursement of drugs, as well as the rules determining to which extent therapeutically equivalent generic or hybrid drugs can be automatically substituted for an originator product, co-shape the conditions of competition and the demand and supply structure of the market.

⁶⁰ A “generic” medicine is a medicine which has (i) the same qualitative and quantitative composition, in terms of active ingredients as the reference product, (ii) the same pharmaceutical form as the reference product and (iii) whose bioequivalence with the reference medicinal product has been demonstrated by appropriate bioavailability studies (see Article 10(2)(b) of Directive 2001/83/EC).

⁶¹ ID 2475, Notice to Applicants prepared by the European Commission, Volume 2A, Procedures for marketing authorisation, Chapter 1 Marketing Authorisation, July 2019, pp. 34-35.

⁶² Synthon has sought scientific advice on the dossier requirements both at centralized and national level in several Member States. The company was therefore advised by the EMA that the product should be subjected to a detailed comparative characterisation study with Copaxone, and to consider any additional data necessary to prove similarity. Therefore, Synthon made an application for a MA on the basis of Article 10(3) of Directive 2001/83/EC taking into account EMA’s scientific advice and submitted the additional studies required by Article 10(3) of Directive 2001/83/EC.

- (80) A particularity of supply and demand in markets for reimbursable drugs is that, generally, the person making the ultimate decision on the drug (usually the prescribing physician) is neither the entity that covers the costs of the treatment (which is usually the public health system or a health insurance company) nor the eventual consumer of the product, the patient. While pricing policies ensure that medicines are launched at reasonable prices (to balance the interest of health authorities in having access to affordable medicines with pharmaceutical companies' interest in recouping R&D costs), reimbursement and substitution policies ensure that patients receive the cheapest alternative out of several therapeutically equivalent medicines.⁶³ Patients are free to request an expensive treatment, but if more affordable and therapeutically equivalent medicines are available, then the more expensive medicine will usually not be (fully) reimbursed.
- (81) The pricing decision determines the commercial terms of a medicine's access to a Member State market. The requirement to obtain price approval before accessing a market aims to ensure (i) that patients have access to the necessary drugs and originator companies have adequate incentives to continue innovating, and (ii) that health budgets remain under control in order to ensure sustainability of the health system. Member States typically accord high price levels for innovative medicines, allowing the suppliers to enjoy high margins. This serves to preserve incentives for further innovation by allowing originators to enjoy a reward and recoup their investment in research and development of innovative medicines.
- (82) The pricing decision refers to the officially listed price of a medicine (list price) as agreed in a Member State. However, Member State authorities,⁶⁴ procurement bodies and health insurance companies (the "Payers") often negotiate rebates on the list price with pharmaceutical companies and eventually pay a lower price (net price). Both the list price and the net price can change over the life-cycle of a medicine. Member State laws often foresee mandatory list price reductions for medicines following the loss of exclusivity or the entry of generic/hybrid alternatives.⁶⁵
- (83) In addition, health systems rely on reimbursement policies to limit expenses on healthcare. The reimbursement price for a drug is set by the Payers.⁶⁶ Depending on the Member State, there can be a national reimbursement price or different reimbursement prices which are set by the different Payers (this would mostly be the case if the Payers are health insurers). The reimbursement price can be equal to the selling price of a medicine, meaning that patients will be fully reimbursed for their expenses on the medicine, or the reimbursement price can be lower than the drug's price, meaning that expenses on the drug are only partly reimbursed and patients have to cover the remaining amount.

⁶³ Payers are price-sensitive, see for example: ID 1251, Regione Liguria's reply to Article 18(2) Request of 15 December 2021, p. 2; ID 1258, GKV-Spitzenverband's reply to Article 18(2) Request of 15 December 2021, p. 2; ID 2203, Barmer's reply to Article 18(2) Request of 15 December 2021, p. 1; ID 1235, Zilveren Kruis' Reply to Article 18(2) Request of 15 December 2021, p. 2; ID 3621, Polish National Health Fund's reply to Article 18(2) Request of 15 December 2021, p. 3.

⁶⁴ Member State authorities includes not only the dedicated pricing and reimbursement authorities but all government bodies involved in the entire pricing and reimbursement process (see Recital (1766)).

⁶⁵ See ID 1288, Teva's reply to Article 18(2) Requests of 22 October and 18 November 2021, pp. 6-7; ID 1295-7, Teva's reply to Article 18(2) Requests of 22 October and 18 November 2021, p. 6; ID 1295-41, Teva's reply to Article 18(2) Requests of 22 October and 18 November 2021, p. 7.

⁶⁶ See ID 1288, Teva's reply to Article 18(2) Requests of 22 October and 18 November 2021, p. 6; ID 1295-25, Teva's reply to Article 18(2) Requests of 22 October and 18 November 2021, p. 6.

- (84) The reimbursement price often changes over the life-cycle of a medicine. During exclusivity and before the entry of generic or hybrid (generic-like) medicines, originator medicines are usually fully reimbursed.⁶⁷ After the launch of generic or hybrid (generic-like) medicines, Payers often reduce the reimbursement price to align it with the price of the generic or hybrid (generic-like) medicine. Medicines with the same active ingredient usually have the same reimbursement price.⁶⁸
- (85) A decrease in the reimbursement price of a medicine can indirectly lead to a decrease of its list or net price. Physicians may prefer to prescribe drugs that are fully reimbursed instead of drugs that require a (sometimes significant) co-payment from patients, for fear of lower patient adherence to an expensive therapy. Further, patients may request the prescription of a fully reimbursed drug to avoid a co-payment. For this reason, pharmaceutical companies have an incentive to adjust the price of their drug to the reimbursement price.
- (86) For the decision on or negotiation of list prices, net prices and reimbursement prices of medicines, Member State authorities often compare prices of the same medicine in other Member States or EEA states. This pricing mechanism is referred to as external (or international) price referencing. Because net prices are often confidential between Payers and the relevant pharmaceutical company, the price data from other countries available for comparison is often limited to the list price. This gives pharmaceutical companies an incentive to negotiate (non-public) low net prices with Payers instead of lowering the official list price.⁶⁹
- (87) Further to pricing and reimbursement policies, the Relevant Member States have rules in place that determine to which extent originator medicines can be automatically substituted with therapeutically equivalent generic or hybrid (generic-like) medicines. Automatic substitution is the practice of dispensing one medicine instead of another bioequivalent medicine at pharmacy level without having to consult the prescribing physician.⁷⁰ Physicians can facilitate automatic substitution by prescribing a medicine not by brand but by its international non-proprietary name (“INN”). Substitutable products are usually products with the same active ingredient, i.e. a formerly patent-protected originator medicine and its generic or hybrid (generic-like) alternative.
- (88) In the Relevant Member States, substitution rules usually apply by default to medicines with the same INN, meaning the same (or, in the case of hybrid products, a similar) active ingredient.⁷¹ The health authorities can exclude substitution by

⁶⁷ In most of the Relevant Member States (except Czechia and Germany, see footnote 68), Copaxone was the only medicine in its reimbursement group before Synthon GA entered the markets, or a reimbursement group was only opened upon Synthon GA’s entry. See, for example, ID 3612, Polish Ministry of Health’s reply to Article 18(2) Request of 16 December 2021, p. 2; ID 1326, RIZIV-INAMI’s reply to Article 18(2) Request of 16 December 2021, p. 2; ID 1295-9, Teva’s reply to Article 18(2) Requests of 22 October and 18 November 2021, p. 5.

⁶⁸ In some Member States, for example Czechia and Germany, medicines of different active ingredients can be grouped in a reimbursement group. As explained in Section 6.3.4.3.2.3 and footnote 956, this did not affect the reimbursement price of Copaxone.

⁶⁹ See for example ID 266-25, Copaxone/FoGA – P&MA outlook, 7 June 2017, p. 4.

⁷⁰ ID 2473, “Biosimilars in the EU: Information guide for healthcare professionals”, EMA & European Commission, 2019, p. 29.

⁷¹ See, for example, ID 1288, Teva’s reply to Article 18(2) Requests of 22 October and 18 November 2021, pp. 1-2; ID 1295-45, Teva’s reply to Article 18(2) Requests of 22 October and 18 November 2021, p. 2; ID 1295-7, Teva’s reply to Article 18(2) Requests of 22 October and 18 November 2021, p. 2, see also Article 129 of Volume V of the Social Insurance Code (SGB V); ID 1295-41, Teva’s reply to Article 18(2) Requests of 22 October and 18 November 2021, pp. 1-2.

placing an active ingredient on a “no substitution” or “no INN” list. In Belgium, for example, glatiramer acetate, the active ingredient of Copaxone and Synthron GA, was placed on the “no INN” list.⁷²

- (89) In some Relevant Member States (Czechia, Italy, Poland, Spain) disease modifying treatments for MS, such as Copaxone, are “hospital only” medicines, which means that they can only be prescribed in hospitals or specialised MS centres⁷³ and are either administered in the hospital or dispensed in hospital pharmacies. In other Relevant Member States (Belgium, Germany, the Netherlands)⁷⁴, Copaxone and other MS treatments are prescribed by non-hospital physicians and dispensed in regular pharmacies.
- (90) The classification of medicines as hospital or non-hospital medicine makes a difference for how Payers negotiate the reimbursement price. Hospitals and MS centres usually source medicines via tenders. In Italy and Spain, regional tender authorities carry out tenders for all hospitals in the region.⁷⁵ In Poland, a system of national tenders was recently introduced.⁷⁶
- (91) The reimbursement prices for non-hospital medicines can often be negotiated between health insurance bodies and pharmaceutical companies. In the Netherlands, for example, health insurers can enter exclusive tenders (so-called preference policies) with pharmaceutical companies to negotiate rebates for a medicine (on the basis of active ingredients). Patients will then only be reimbursed for medicines that fall under such a preference policy.⁷⁷ Similar rules apply in Germany.⁷⁸ In Belgium, a special committee for the reimbursement of drugs gives advice on the conditions of reimbursement and the reimbursement price. Representatives of all Belgian health insurers are members of this committee and can thereby influence the price of a drug but they cannot negotiate further rebates or hold tenders.⁷⁹

4.4. Promotion in the pharmaceutical sector

- (92) Directive 2001/83/EC on the Community code relating to medicinal products for human use also contains rules regarding the provision of information and advertising regarding medicinal products.⁸⁰ This Directive prohibits the advertising of medicinal products that have not been granted an MA in accordance with EU law. The Directive also provides that “*the advertising of a medicinal product: — shall encourage the rational use of the medicinal product, by presenting it objectively and without exaggerating its properties, — shall not be misleading*”.⁸¹

⁷² ID 1288, Teva’s reply to Article 18(2) Requests of 22 October and 18 November 2021, p. 3.

⁷³ ID 1295-45, Teva’s reply to Article 18(2) Requests of 22 October and 18 November 2021, p. 2; ID 1295-41, Teva’s reply to Article 18(2) Requests of 22 October and 18 November 2021, p. 1; ID 1295-25, Teva’s reply to Article 18(2) Requests of 22 October and 18 November 2021, p. 1; ID 1295-9, Teva’s reply to Article 18(2) Requests of 22 October and 18 November 2021, p. 1.

⁷⁴ ID 1288, Teva’s reply to Article 18(2) Requests of 22 October and 18 November 2021, pp. 1-2; ID 1295-7, Teva’s reply to Article 18(2) Requests of 22 October and 18 November 2021, pp. 2-3; ID 1295-64, Teva’s reply to Article 18(2) Requests of 22 October and 18 November 2021, pp. 1-2.

⁷⁵ ID 1295-41, Teva’s reply to Article 18(2) Requests of 22 October and 18 November 2021, p. 2; ID 1295-9, Teva’s reply to Article 18(2) Requests of 22 October and 18 November 2021, p. 1.

⁷⁶ ID 1295-25, Teva’s reply to Article 18(2) Requests of 22 October and 18 November 2021, p. 4.

⁷⁷ ID 1295-64, Teva’s reply to Article 18(2) Requests of 22 October and 18 November 2021, p. 2.

⁷⁸ ID 1295-7, Teva’s reply to Article 18(2) Requests of 22 October and 18 November 2021, p. 2.

⁷⁹ ID 1529, Solidarisis’ reply to Article 18(2) Request of 15 December 2021, pp. 2-3. The final reimbursement decision is taken by the Minister for Social Affairs and Public Health.

⁸⁰ Titles VIII and VIII bis of Directive 2001/83/EC.

⁸¹ Article 87 of Directive 2001/83/EC. See also Article 90(b) of Directive 2001/83/EC.

- (93) In this respect, misleading advertising is defined as “*any advertising which in any way, including its presentation, deceives or is likely to deceive the persons to whom it is addressed or whom it reaches and which, by reason of its deceptive nature, is likely to affect their economic behaviour or which, for those reasons, injures or is likely to injure a competitor*”.⁸² Similarly, a commercial practice is regarded as misleading if it involves “*any marketing of a product, including comparative advertising, which creates confusion with any products, trade marks, trade names or other distinguishing marks of a competitor*”.⁸³
- (94) In particular, Directive 2001/83/EC requires that all the information contained in the documentation transmitted as part of the promotion of a medicinal product to persons qualified to prescribe or supply it must be accurate, up-to-date, verifiable and sufficiently complete to enable the recipient to form his or her own opinion of the therapeutic value of the medicinal product concerned.⁸⁴ In this documentation, the quotations, tables and other illustrative matter taken from medical journals or other scientific works must be faithfully reproduced and the precise sources indicated.⁸⁵ The same objective of non-misleading information is required with regard to public announcements made by MA holders in order to inform the public and the competent authorities on pharmacovigilance concerns in relation to the use of a medicinal product.⁸⁶
- (95) Moreover, pharmaceutical industry associations issue their own codes of conduct that give guidance on the promotion of medicines.⁸⁷ According to the European Federation of Pharmaceutical Industries and Associations (EFPIA)’s Code of Practice⁸⁸, promotion must be accurate, balanced, fair, objective and sufficiently complete to enable the health care professionals to form their own opinion of the therapeutic value of the medicinal product. Promotion must be based on an up-to-date evaluation of all relevant evidence, without misleading by distortion, exaggeration, undue emphasis or omission. Comparisons of medicines must be based on relevant and comparable aspects, while the Code of Practice explicitly excludes misleading or disparaging comparative advertising.⁸⁹
- (96) Teva is a member of Medicines for Europe, which has its own Code of Conduct. According to this Code of Conduct, promotional claims and comparisons must be scientifically up-to-date, referenced, clinically relevant, balanced, fair, and sufficiently complete to enable the recipients to form their own opinion. Promotional

⁸² Article 2(b) of Directive 2006/114/EC of the European Parliament and of the Council of 12 December 2006 concerning misleading and comparative advertising (OJ L 376, 27.12.2006, pp. 21–27).

⁸³ Article 6(2)(a) of Directive 2005/29/EC of the European Parliament and of the Council of 11 May 2005 concerning unfair business-to-consumer commercial practices in the internal market (OJ L 149, 11.6.2005, p. 22–39) as amended.

⁸⁴ Article 92(2) of Directive 2001/83/EC.

⁸⁵ Article 92(3) of Directive 2001/83/EC.

⁸⁶ Article 106a of Directive 2001/83/EC.

⁸⁷ Similar guidance is provided by public authorities located outside the EU. For instance, in the USA, the Food and Drug Administration (FDA) issued a Draft Guidance on “Promotional Labeling and Advertising Considerations for Prescription Biological Reference and Biosimilar Products” in February 2020 and a CFL Guidance on “Medical Product Communications That Are Consistent With the FDA-Required Labeling” in June 2018.

⁸⁸ ID 2476, EFPIA Code of Practice, EFPIA, 2019, p. 9.

⁸⁹ ID 2476, EFPIA Code of Practice, EFPIA, 2019, chapter 1.

information must not be misleading and must encourage the rational use of medicinal products by presenting them objectively and without exaggeration.⁹⁰

- (97) Both EFPIA and Medicines for Europe endorsed the 2012 “*List of Guiding Principles Promoting Good Governance in the Pharmaceutical Sector*” under the Platform on Ethics and Transparency launched by the European Commission.⁹¹ Under these principles, the stakeholders committed to providing unbiased, fair, objective and complete information based on up-to-date scientific evidence, while banning misinformation campaigns and any misinformation on the quality, safety or efficacy of a competitor’s product. The information transmitted must not mention other medicines for which the pharmaceutical company is not the MA holder, or include comparisons of medicines related to their quality, safety and efficacy. Such comparisons must “*not go beyond the information that is in the patient information leaflet / summary of product characteristics*”.⁹²
- (98) The enforcement of rules for the promotion of medicines is regulated at the level of Member States. In certain countries, promotional (mal)practice may be subject to supervision by self-regulatory bodies, while in others, it may fall under the rules and procedures for unfair trading practices enforced by public authorities and/or courts.

5. COPAXONE, ITS IMPORTANCE FOR TEVA, AND TEVA’S STRATEGY TO CONFRONT ENTRY OF COMPETING GA

5.1. Product and business concerned – Copaxone

- (99) Copaxone is an immunomodulator indicated for the treatment of relapsing remitting multiple sclerosis (“RRMS”), the most common form of multiple sclerosis (MS).⁹³ Its active ingredient is glatiramer acetate (“GA”). Copaxone belongs to the so-called disease modifying therapies (“DMTs”) – therapies targeted at reducing the frequency and/or intensity of relapses and/or slowing down the course of the disease. It is used as a first-line treatment for RRMS.
- (100) GA was discovered during basic research on the immunological properties of synthetic polymers and copolymers of amino acids that started in 1968. It is a mixture of peptides that are randomly composed of the four amino acids found in myelin basic protein, namely glutamic acid, lysine, alanine and tyrosine. The mode of action of GA is not fully understood. It is believed to act by modifying immune processes that are currently believed to be responsible for the pathogenesis of MS.
- (101) Clinical trials on the use of GA to treat MS started in 1977. {...}. In 1995, the main patent protecting the composition of GA within specific molecular weight range – EP 0 762 888 (“EP ‘888”) was filed before the EPO. It was granted in 2002 and expired in 2015.
- (102) In the early 2000s, Teva started marketing Copaxone in the EU as one of the first disease modifying therapies for RRMS. Copaxone, a prescription-only drug, which is administered through injection, was initially launched in the EU as a 20 mg

⁹⁰ ID 2472, Medicines for Europe Code of Conduct, Medicines for Europe, 2020, section 5.3.

⁹¹ ID 2474, List of Guiding Principles Promoting Good Governance in the Pharmaceutical Sector under the Corporate Social Responsibility Platform by the European Commission endorsed by Medicines for Europe, https://www.eu-patient.eu/globalassets/news/list-guiding-principles_nov2012.pdf, accessed on 28 September 2022.

⁹² Ibid, Sections 4.6 and 4.7.

⁹³ See Section 6.3.1.1 below.

formulation requiring daily injections. Teva held, in particular, three process patents (a parent patent and two divisionals), which it started to file before EPO in 2005. These process patents were due to expire in 2025.

- (103) Starting from 2010, Teva ({...}) started to file dosage patents before the EPO (a parent patent and four divisionals).⁹⁴ These dosage patents were due to expire in 2030. In 2015, coinciding with the expiry of EP ‘888, Teva started to commercialise a 40 mg formulation of Copaxone in the EU - as part of its Copaxone Continuation Project⁹⁵- which has to be injected three times a week.
- (104) Copaxone developed into a blockbuster drug (globally grossing over USD {...} at the peak of the sales in 2015), while annual sales have in recent years stabilised at around {...} in the EU. Before the expiry of its main patent in 2015, Copaxone accounted for {...}.⁹⁶
- (105) Accordingly, hindering or delaying the entry and uptake of any competing GA had the potential to achieve very significant financial gains for Teva. A Teva presentation of June 2017 summarises the successes in countering the impact of competing GA by pointing to the following facts: at that time, Teva’s hindering the entry and uptake of competing GA had already brought about gains for Teva of EUR {...} since the loss of exclusivity of Copaxone 20 mg in Europe, and – in Teva’s estimate for Europe – revenues of “{...}”.⁹⁷

Figure 2: {...}

{...}

Source: ID 455-247, CCP DT, June 2017.

- (106) At the date of this Decision, there is only one generic-like version of Copaxone (developed by Synthon) commercialised in the EU. Synthon commercialises Synthon GA in the EU through two main licensees, i.e. Viatrix (formerly Mylan) and Zentiva (formerly Alvogen) under different brand names.⁹⁸

5.2. The Copaxone Continuation Project

5.2.1. Introduction

- (107) When the expiry of the exclusivity rights for Copaxone in 2015 approached and concerns mounted within Teva regarding the loss of revenues and profits following the market entry of competing GA, Teva developed a comprehensive strategy to prevent or limit the entry and uptake of these products. This strategy consisted of a broad range of practices and was named “Copaxone Continuation Project” or “CCP”.
- (108) The following sections describe Teva’s CCP strategy to counter the “risk” of competing GA entering the market. Section 5.2.2 below sets out Teva’s efforts to tighten the regulatory requirements for authorising competing GA that started years before generic companies would file applications for marketing authorisations in the EU. Section 5.2.3 describes the activities that Teva deployed to prevent or delay

⁹⁴ {...}.

⁹⁵ See Section 5.2 below.

⁹⁶ See ID 3541, Copaxone provided {...}% of Teva's operating profit – Globes, 12 February 2012, p. 1; ID 3536, Teva’s Form 20-F filing with the United States Securities and Exchange Commission for 2013, 10 February 2014.

⁹⁷ ID 455-247, CCP DT, June 2017, p. 9.

⁹⁸ In 2019, Teva launched its own duplicate (generic) version of Copaxone under the brand name AbZ in Germany in response to competition from Synthon GA (see Section 5.2.3.6 and Section 6.3.3.4.3.3.1).

entry or expansion of Synthron GA, including Teva's misuse of the divisional patents (Section 5.2.3.2) and the implementation of a disparagement campaign targeting Synthron GA (Section 5.2.3.5). Section 5.2.4 describes how the CCP strategy was carefully organised and centrally steered by Teva. Finally, Section 5.2.5 outlines the significant impact all these activities had on the launch of competing GA in the EU.

- (109) The Commission notes that, in this Decision, only Teva's misuse of the divisional patents and its exclusionary disparagement campaign are found to infringe Article 102 TFEU (see Chapters 8 and 9). This Decision does not take a position on whether any other Teva's activity comprised within the CCP could constitute an infringement of Teva's dominant position in the Relevant Member States pursuant to Article 102 TFEU. However, as all of these practices were an integral and indispensable part of Teva's broader CCP strategy it is necessary to describe all of them to place the two above-mentioned anticompetitive practices in their relevant context and to assess their objectives and effects.

5.2.2. *The Copaxone Life Cycle Initiative and Teva's attempts to tighten the regulatory requirements for the authorisation of competing GA*

- (110) Teva was aware of the potential advantage resulting from the fact that GA was not a conventional, small molecule synthetic drug, and that therefore regulatory barriers for competing GA could be significantly higher compared to those applicable to small molecule generics.⁹⁹ In view of the approaching patent expiry, Teva prompted scientific and regulatory discussions about the applicable regulatory framework for "purported generic versions of Copaxone" and took an active part in these discussions. In a series of activities ultimately aimed at influencing regulatory bodies, Teva pushed for a restrictive approach that would make the authorisation of such "generics" as costly and lengthy as possible.
- (111) Already in 2004, Teva put in place the Copaxone Life Cycle Initiative (LCI), which is the predecessor of the CCP. Its goal was to "{...}".¹⁰⁰ The LCI team had the objective to "{...}".¹⁰¹ The complexity of Copaxone was Teva's main argument to (successfully) lobby EU health authorities for "{...}" of risks allegedly connected to differences between Copaxone and its generic versions.¹⁰²
- (112) A central part of Teva's efforts was the creation and promotion of the terms "FoGA" (follow-on GA) and "NBCD" (non-biologic complex drug). An internal comment on the draft briefing document purporting to show a link between differences in GA active substances and patient safety shrewdly observed in 2014: "{...}".¹⁰³
- (113) Teva used the term "FoGA" both internally and externally, grouping together all competing GA worldwide (although only Synthron GA applied for a marketing authorisation in the EU). By grouping these numerous different products together under one term, Teva promoted the impression that all competing GA were one and the same product and consequently, concerns raised by any of these products would apply to all other "FoGAs" as well. The usage of the term was also designed to imply

⁹⁹ See for instance, ID 413-17, CP general version, 17 November 2008; ID 413-16, Copaxone White Paper, 16 March 2009; ID 404-2177, email dated 24 September 2014 from {...}, p. 1.

¹⁰⁰ ID 404-37, LCI Copaxone – EU, February 2014, p. 4.

¹⁰¹ ID 404-715, The Copaxone Life Cycle Initiative (LCI), 1 December 2012, p. 2; see also ID 404-712, Teva internal email dated 11 April 2013 from {...} and others, p. 1.

¹⁰² ID 404-1846, Regulatory Overview of Copaxone in Europe, 29 April 2011, p. 8.

¹⁰³ ID 455-705, FoGA White Paper, Copaxone and Follow-on Glatiramoids ("FoGAs"), September 2014, p. 1.

that competing GA were materially different from, and potentially not therapeutically equivalent to, Copaxone. Thereby Teva tried to artificially differentiate Copaxone from competing GA, including Synthon GA.¹⁰⁴

- (114) According to a Teva white paper of 16 March 2009, “{...}.”¹⁰⁵ Teva employees repeatedly emphasised that it would be virtually impossible for Teva’s competitors to meet the comparability requirements Teva was hoping to establish.¹⁰⁶
- (115) In an internal email sent on 6 December 2011, {...}: {...}.¹⁰⁷ as opposed to generics for which no new studies are required. An internal document from December 2012 claims that this objective was achieved and “{...}”.¹⁰⁸ Indeed, in the EEA, competing GA products could not be approved via the generic procedure, but had to follow the so-called hybrid procedure pursuant to Article 10(3) of Directive 2001/83, which also required Synthon to carry out a clinical study. Synthon submitted trial data showing that its drug is equivalent to Copaxone (namely the GATE study¹⁰⁹ and the GATE extension study¹¹⁰ (see also Recital (1604)). On the basis of the data presented, the Board of the RMS (reference Member State, see Recital (73)) concluded that Synthon GA can be regarded as a therapeutic equivalent to the reference product, Copaxone. Therapeutic equivalence means that the efficacy and safety of this hybrid formulation is similar to the efficacy and safety of the reference product.
- (116) Throughout this period, Teva closely monitored plans for the development and authorisation of competing GA.¹¹¹ On 14 November 2010 {...} justified a significant increase of the regulatory affairs budget for new products in 2011 as {their} “{...}.”¹¹²

5.2.3. *The Copaxone Continuation Project, a strategy to confront the entry of competing GA*

- (117) By 2012, Teva expected the market entry of Synthon GA shortly after the expiry of EP ‘888 on 23 May 2015. Throughout the years 2012-2014, Teva listed “{...}” and

¹⁰⁴ The same concepts and arguments were relied on by Teva in its disparagement campaign (see particularly Sections 9.3.1.1 and 9.3.1.2).

¹⁰⁵ ID 413-16, Copaxone White Paper DRAFT for Teva review MB cuts, 16 March 2009, p. 3.

¹⁰⁶ ID 413-17, CP general version, 17 November 2008; ID 413-16, Copaxone White Paper DRAFT for Teva review MB cuts, 16 March 2009; ID 404-2177, email dated 24 September 2014 from {...} to {...}, p. 1.

¹⁰⁷ ID 404-587, Teva internal email dated 7 December 2011 from {...} to {...}, p. 1, concerning “Audit Presentation – Condensed”. {...}.

¹⁰⁸ ID 404-715, The Copaxone Life Cycle Initiative (LCI), December 2012, p. 6, attached to the ID 404-712, Teva internal email dated 11 April 2013 from {...} to {...} and others.

¹⁰⁹ ID 3604, J. Cohen, A. Belova, K. Selmaj, C. Wolf, M. P. Sormani, J. Oberyé, E. van den Tweel, R. Mulder, N. Koper, G. Voortman, F. Barkhof, Equivalence of Generic Glatiramer Acetate in Multiple Sclerosis: A Randomized Clinical Trial - Glatiramer Acetate Clinical Trial to Assess Equivalence With Copaxone (GATE) Study Group, *JAMA Neurol.* 2015 Dec;72(12):1433-41. doi: 10.1001/jamaneurol.2015.2154.

¹¹⁰ ID 3548, Krzysztof Selmaj, Frederik Barkhof, Anna N Belova, Christian Wolf, Evelyn RW van den Tweel, Janine JL Oberyé, Roel Mulder, David F Egging, Norbert P Koper, Jeffrey A Cohen, Switching from branded to generic glatiramer acetate: 15-month GATE trial extension results, *Mult Scler.* 2017 Dec; 23(14): 1909–1917.

¹¹¹ ID 404-2092, Teva internal email dated 11 June 2008 from {...} to {...} and others, p. 2; ID 455-2000, email chain dated November – December 2011; ID 404-587, Teva internal email dated 6 December 2011 from {...} to {...}.

¹¹² ID 455-2462, Teva internal email dated 14 November 2010 from {...} to {...}, pp. 3-4. The Commission notes that Teva internally regularly referred to the “generics” of Copaxone regardless of a firm public line that these competing GA should be called “follow-on” GAs (FoGAs) (see Section 9.1).

the likely “{...}” as a primary market weakness and commercial threat for Teva.¹¹³ In April 2014, Teva identified Synthon as “{...}”.¹¹⁴

- (118) Teva therefore prepared for switching its focus from differentiation from non-GA first-line DMTs to activities to avoid losing sales to Synthon.¹¹⁵ In this context, Teva developed the “Copaxone Defence Europe” strategy that later became the Copaxone Continuation Project.
- (119) In June 2012, {...} outlined the central ideas of “Copaxone Defence Europe” and called for the rapid preparation of project plans and the division of tasks between geographies (country, region and global) and specialisations (medical, clinical, regulatory, legal, marketing and sales functions). Building on the earlier preparatory activities aimed at influencing regulatory bodies described in Section 5.2.2 (e.g. coining the terms “FoGA” and “NBCD”), the plans included convincing regulatory authorities that producers of competing GA would have to meet a legal threshold for marketing authorisation that was much higher than that for traditional generics (requirement to produce studies based on clinical trials) and moving patients to treatment forms for Copaxone for which Teva could still invoke legal exclusivity: “{...}” (emphasis added).¹¹⁶
- (120) On 5 November 2013, Teva’s holding company in Europe, Teva Pharmaceuticals Europe, organised the Copaxone Continuation Taskforce EU Kick-off meeting at its Amsterdam headquarters. The PowerPoint presentation used during this Kick-off meeting lists a series of tasks to implement as part of the CCP and defines the project objective as “{...}” (emphasis added).¹¹⁷
- (121) At the first stage of the CCP,¹¹⁸ emphasis was put on the conversion of patients to 40 mg Copaxone (Section 5.2.3.1), from which Teva was expecting to enjoy patent protection for a few more years owing to the later filing of, and consequently less advanced revocation proceedings concerning Teva’s dosage patents. This was also the economic rationale behind Teva’s misuse of both process and dosage divisional patents. Teva sought to first artificially prolong patent protection of the 20 mg product in order to complete the conversion of patients to Copaxone 40 mg before effective entry of competing GA, and then artificially prolong the patent protection of the 40 mg product (Section 5.2.3.2.). In parallel, Teva was using regulatory interventions and preliminary injunctions to obstruct Synthon GA’s launch once Synthon GA was about to obtain marketing authorisations (Section 5.2.3.3).

¹¹³ ID 455-9, Global Commercial Strategic Plan, 5 September 2012, p. 17; ID 455-2, Global Strategic Brand Plan Assumptions COPAXONE ® 2014-2017, 5 March 2013, p. 21; ID 455-55, TEVA European Brand Plan format, p. 39.

¹¹⁴ ID 455-2917, Copaxone enforcement strategy (commercial briefing note), 23 April 2014, p. 1.

¹¹⁵ ID 455-1003, LRP and Brand plan Copaxone review Spain, 25 April 2014, p. 6 (see Section 6.3.3.2.4 below) – “{...}”.

¹¹⁶ ID 455-1784, Teva internal email dated 24 June 2012 from {...} to {...} and others, p. 1, concerning “Copaxone defence europe”. See also ID 455-559, Copaxone Generics mitigation plan, 24 March 2017, p. 1: “{...}”.

¹¹⁷ ID 455-801, CCP Kick-off Meeting, 5 November 2013, p. 9.

¹¹⁸ Teva repeatedly referred to “pillars of the CCP”, although the exact delimitation and number of these varied, see ID 263-26, COPAXONE®/ FoGA, Overview Pricing and Market Access, 15 February 2017, p. 3; ID 455-473, EU COPAXONE Continuation Project Strategy, March 2017, p. 9.

- (122) As of April 2016, when the first marketing authorisations for Synthon GA were granted, the EU action plan moved into its next phase: “{...}”.¹¹⁹ This phase saw an intensification of practices to prevent or delay market entry by Synthon GA or limit its impact on Copaxone sales. Teva employees felt confident they had done their best in the previous phase and had prepared well for this new phase: “{...}” (emphasis added).¹²⁰
- (123) Teva had, in the words of the {...}, prepared “{...}”.¹²¹ Teva devised the legal defence to include multiple layers. First, Teva continued with delaying the entry and/or expansion of competing GA through the misuse of the (divisional) patent system before the EPO, also strengthening Teva’s capability to enforce its patents before national courts (aforementioned Section 5.2.3.2). In addition, the legal defence also comprised initiating legal challenges to marketing authorisations of Synthon GA at national level¹²² (Section 5.2.3.4). Finally, Teva carried out a comprehensive disparagement campaign to prevent or reduce the impact of Synthon GA’s market entry (Section 5.2.3.5).
- (124) The above described main activities under the CCP were complemented by several further activities aimed at limiting the expansion of competing GA, in particular Synthon GA, where it succeeded in entering the market, such as unfair competition litigation and the launch of a Copaxone duplicate (Section 5.2.3.6).¹²³

5.2.3.1. Converting Copaxone patients to 40 mg to evade competition

- (125) An important element of the CCP was the introduction of a new dosing regimen for Copaxone and converting patients from 20 mg to 40 mg. Teva had already successfully used such a conversion of patients to the 40 mg dosage in the US to react to the market entry of competing GA. An internal document describes how Teva converted nearly {...}% of users to a new formulation of Copaxone with “{...}” (as the new dosage would be covered by Copaxone’s 40 mg patents remaining in force for a longer time period) “{...}” in the US.¹²⁴
- (126) A report of the Committee on Oversight and Reform of the US House of Representatives describes that “[b]y December 2008, Teva’s business executives had decided to pursue research supporting a Copaxone dose of three times per week. Many of Teva’s scientists opposed this decision. One scientist wrote that Teva’s Innovative Research and Development (IR&D) management was “strongly against” Teva’s study into the less-frequent dosing of Copaxone “since it has no scientific rationale/value” [...] Teva implemented a comprehensive “generic defense strategy” to switch patients to Copaxone 40 mg/ml and avoid generic competition”.¹²⁵

¹¹⁹ ID 455-3076, Teva internal email dated 7 April 2016, from {...} to {...} concerning “COPAXONE EUROPE - LEGAL UPDATE”, p. 1.

¹²⁰ ID 404-778, Teva internal email dated 13 October 2016 from {...} to {...}, concerning “1st launch of FoGA”, p. 2.

¹²¹ ID 455-2502, Teva internal email dated 14 April 2016 from {...} to {...}, p. 1, full quote stating: “{...}” (emphasis added).

¹²² ID 455-3074, Teva internal email dated 13 July 2016 from {...} to Teva management board, {...} and others; ID 404-2555, Teva internal email dated 16 March 2016 from {...} to {...} and others.

¹²³ The Commission reiterates that the Decision does not take position on legality of any of Teva’s CCP activities except for those that are expressly addressed in the Chapter 8 (misuse of divisional patents) and Chapter 9 (exclusionary disparagement).

¹²⁴ ID 404-104, TEV-48125 LCM Meeting, 12 October 2016, p. 30.

¹²⁵ ID 3550, U.S. House of Representatives, Committee on Oversight and Reform, Staff Report “Drug Pricing Investigation, Teva—Copaxone”, September 2020, pp. 26-27, 30.

- (127) In June 2012, as an essential part of the Copaxone defence in Europe, {...} called for the implementation of a new dosing regimen in order to improve Copaxone’s patent protection.¹²⁶ Numerous internal documents confirm that Teva’s main incentive for introducing the 40 mg Copaxone was not to improve its product or meet a particular consumer demand,¹²⁷ but to “{...}”.¹²⁸ Accordingly, the objective was to “{...}”,¹²⁹ although the resulting reduction of the weekly overall dose from 40 mg to 20 mg meant that Teva had to offer Copaxone 40 mg for a lower price than Copaxone 20 mg.¹³⁰
- (128) In order to protect Copaxone revenue from the approaching market entry of Synthon GA Teva needed to “{...}” (emphasis added).¹³¹ A presentation slide on Copaxone 40 mg from January 2014 listed “price dynamics” as a benefit, which was explained in the notes as “{...}”.¹³² {...}.¹³³
- (129) From Teva’s perspective, the conversion primarily served the purpose of extending the market exclusivity for Copaxone. Notably, Copaxone 40 mg enjoyed the protection from several dosage divisional patents whose (overlapping) claims Teva was strategically shielding from timely and effective legal review, i.e. a final decision on their validity, before the EPO and national courts (see Section 5.2.3.2). For example, a Teva document made an explicit link between the conversion rate in a national market and the question whether there were any legal barriers to Synthon GA’s market entry.¹³⁴ Similarly, in April 2016, {...}.¹³⁵
- (130) The decision within Teva to convert patients from the 20 mg to the 40 mg dosage of Copaxone was thus not primarily driven by patient needs. For example, Teva considered temporarily converting patients back from 40 mg to 20 mg due to the reimbursement rules in Latvia: “{...}”.¹³⁶ If the conversion had been driven primarily by patients’ needs, then one would expect that Teva would have waited with the conversion until reimbursement of patients on Copaxone 40 mg was secured. Instead, Teva hastily converted patients from 20 mg to 40 mg and only considered the question of reimbursement afterwards. Alternatively, Teva could also have lowered the price of 40 mg Copaxone to be on a competitive level with Synthon GA but did not consider this option.

¹²⁶ ID 404-1946, Teva internal email dated 24 June 2016 from {...} to {...} and others, pp. 3-4, concerning “Copaxone defence europe”.

¹²⁷ Although Copaxone 40 mg was also considered to improve perceptions of convenience of Copaxone to better compete against oral MS treatments, see ID 455-2276, COPAXONE EU Strategic Brand Plan, 29 March 2016, p. 6.

¹²⁸ ID 404-1367, Copaxone BT Meeting Minutes, 30 June 2016, p. 3.

¹²⁹ ID 455-3415, Minutes BT Meeting, January 2014; ID 455-1318, BT Jan 2014 Copaxone® 40 mg, January 2014, p. 2.

¹³⁰ While price per mg of Copaxone remained the same for both dosages, a monthly pack of Copaxone 40 mg included smaller quantity of medicine than a monthly pack of Copaxone 20 mg (120 mg per week vs. 140 mg per week; see Recital (630) and footnote 802).

¹³¹ ID 455-3, 2014 COPAXONE® Annual Operating Plan, dated 16 December 2013, p. 3.

¹³² ID 455-610, Copaxone Brand Planning, 22 January 2014, p. 31.

¹³³ ID 834-32, Teva LRP 2015-2019 Overview, Board Meeting, July 2014, p. 5.

¹³⁴ ID 455-3128, Teva internal email dated 12 April 2016 from {...}.

¹³⁵ ID 404-1922, Teva internal email dated 16 April 2016 from {...}.

¹³⁶ ID 413-31, Teva internal email dated 6 October 2016 from {...} to {...} and others concerning “URGENT: Copaxone 20mg Net Price change request from 1st January – LATVIA”. The market entry of Synthon’s 20 mg GA would have significantly increased the cost of 40 mg Copaxone for patients who would no longer be fully reimbursed until new legislation on reimbursement would enter into force 3 months later, allowing for a separate reimbursement due to the different dosage of Copaxone 40 mg.

- (131) Similarly, in Germany, Teva employees responsible for Copaxone were concerned by the wish of doctors to start patients on 20 mg and then switch them to 40 mg instead of starting them on 40 mg directly.¹³⁷ This indicates that Teva’s efforts for converting patients to 40 mg were not primarily a reaction to customer demand, but part of its measures to defend Copaxone against generic competition.
- (132) The conversion of patients to 40 mg was carefully timed to pre-date the expected moment of Synthon GA’s market entry. As the conversion entailed a loss of revenue due to an inherent decrease in Copaxone daily dosage (at a weekly level, 40 mg thrice-a-week dosage was around {...}% lower than 20 mg daily dosage overall – see, for example, Recitals (136) and (137) below),¹³⁸ Teva planned the launch of Copaxone 40 mg close to the expiry of EP ‘888 (when the 40 mg divisional patent family was still in force). At the same time, Teva kept a close watch on the risk of possibly earlier market entry: a presentation from April 2014 mentions “{...}” as part of the Contingency Plan for reacting to “{...}”.¹³⁹ A slide entitled “{...}” from 2014 lists the Strategic Objective “{...}” with the following “{...}”.¹⁴⁰
- (133) An internal Teva presentation on timing of the 40 mg launch with the title “{...}” contained the warning “{...}” for three countries.¹⁴¹ One presentation from 2013 referred to limiting the “{...}”.¹⁴² An internal presentation from December 2015 lists the following under “{...}”.¹⁴³
- (134) When Synthon’s 20 mg GA obtained marketing authorisations in 2016, the importance of converting patients to 40 mg was emphasised again by Teva, calling on its staff to “{...}”¹⁴⁴ and “{...}” (emphasis added).¹⁴⁵
- (135) In email exchanges after Synthon GA’s market entry, Teva employees again emphasised the importance of converting patients to the (still) patent protected Copaxone 40 mg to reduce the impact on Copaxone pricing.¹⁴⁶ The personal notes of a Teva employee summarising a call concerning the CCP in September 2016 noted that “{...}” (emphasis added).¹⁴⁷
- (136) Without Synthon GA’s market entry, it is unlikely that Teva would have carried out its conversion strategy, i.e. a massive conversion of patients from 20 mg to 40 mg Copaxone. The conversion strategy was not implemented to in itself increase Copaxone revenues. On the contrary, Teva expected the conversion to reduce revenues. Commercially, this nonetheless made sense to Teva considering that Teva could count on additional patent protection for the 40 mg Copaxone, thereby protecting its sales from competing GA. Reduced revenue was thus considered a price worth paying for protecting future revenue from price competition from Synthon GA:

¹³⁷ “{...}.” ID 404-2405, Teva internal email dated 25 July 2016 from {...} to {...}.

¹³⁸ ID 2228, Teva reply to Article 18(2) Request of 13 July 2022, pp. 29-31.

¹³⁹ ID 455-562, LOCAL BRAND PLAN – Germany 2015-2017, pp. 3 and 80.

¹⁴⁰ ID 262-1669, Copaxone Brand Plan & LRP 2015-2017 NL, 14 April 2014, p. 149.

¹⁴¹ ID 263-20, Cop40launch_vs_FOGA_timing, 8 May 2014, p. 2.

¹⁴² ID 455-617, Copaxone40mg – three times weekly (TIW), September 2013, p. 15.

¹⁴³ ID 455-2523, Germany_GGM risk Mgmt_AOP 2016, 13 December 2015, p. 2.

¹⁴⁴ ID 263-54, CCP Meeting June 2016 final, p. 23.

¹⁴⁵ ID 404-778, Teva internal email dated 13 October 2016 from {...} to {...} and others, p. 2, concerning “1st launch of FoGA”.

¹⁴⁶ ID 404-2511, Teva internal email exchange dated 22-23 March 2017 from {...} to {...} and others.

¹⁴⁷ ID 404-1705, Teva internal email dated 27 September 2016 from {...}, p. 2.

“{...}”.¹⁴⁸

(137) A document from 2014 reaffirms the necessity to convert patients to 40 mg even if it entails lower sales: “{...}” (emphasis added).¹⁴⁹

(138) It follows that the main objective of Teva’s conversion to Copaxone 40 mg was to protect the Copaxone patient base from Synthon GA.¹⁵⁰ Teva was willing to accept a loss of revenue of around {...}% by systematically switching patients to a different Copaxone dosage, in order to protect itself from an even higher loss of Copaxone revenue that would result from price competition with Synthon GA.

5.2.3.2. Patent enforcement and misuse of the (divisional) patent system

(139) Teva had long identified the “{...}” as a primary market weakness of Copaxone.¹⁵¹ Following the expiry of EP’888,¹⁵² Teva relied on two secondary patents concerning the production process and a new dosing regimen (40 mg instead of 20 mg). Using the instrument of divisional patent applications (see Section 4.1.3), Teva multiplied its secondary patents to create two patent families, each comprising a number of divisional patents (“divisionals”) with significantly overlapping content covering, respectively, the same inventive concepts and suffering from the same key weaknesses.

(140) As explained in further detail in Chapter 8 below, Teva carefully timed the filing and withdrawal of these divisionals, using these patents to delay or prevent market entry of competing GA products and in particular Synthon GA. Correspondingly, Synthon and its licensees had to challenge the validity of each of those patents successively, as Teva repeatedly and in sequence decided to file and withdraw one patent only to rely on the next patent. Thus, instead of being able to obtain a final decision resolving the legal uncertainty concerning patent claims relevant for the entire divisional patent family, Synthon had to repeatedly re-start litigation from the very beginning before it could finally remove the patent barrier. This way, Teva managed to obstruct effective legal review of its patents and to prolong legal uncertainty surrounding their validity, thereby hindering Synthon GA’s entry on the markets. None of the patents relied on by Teva was confirmed as valid and enforceable in a final decision by the EPO.

(141) Teva’s misuse of the patent system after the expiry of EP ‘888 in May 2015 constitutes one of the key pillars of the CCP seeking to delay and/or prevent competition to Copaxone in the EEA. This divisional strategy was complemented by Teva’s conversion of Copaxone patients to the new Copaxone 40 mg product with longer-lasting patent protection. Although dosage patents were set to normally expire

¹⁴⁸ ID 455-617, Copaxone40mg – three times weekly (TIW), September 2013, pp. 9, 11, 12, 14, 15.

¹⁴⁹ ID 455-73, BP-LRP review Austria_answer_28.04.2014, p. 2.

¹⁵⁰ In this Decision, the Commission does not conclude on whether Teva’s conversion to Copaxone 40 mg constitutes anti-competitive conduct.

¹⁵¹ ID 455-9, Global Commercial Strategic Plan, 5 September 2012, p. 17.

¹⁵² The main patent protecting the specific composition of GA in Copaxone – EP ‘888 – was filed on 23 May 1995, granted on 6 February 2002 and expired on 23 May 2015. In 2005, Teva filed a secondary patent relating to claimed improvements in the manufacturing process, i.e. the process parent patent EP 1 799 703 before the EPO. This patent was granted by the EPO on 6 January 2010. In 2010, Teva started filing divisional process patents (EP ‘528 and EP ‘924). These patents form the “process patent family”. In 2010, Teva also filed a secondary patent relating to a new dosing regimen (40 mg instead of 20 mg) of GA, i.e. the dosage parent patent EP 2 405 749 before the EPO. This patent was granted by the EPO on 8 May 2013. In 2013, Teva started filing divisional dosage patents (EP ‘962, EP ‘335, EP ‘172 and EP ‘286). These patents form the “dosage patent family”.

in 2030, due to Synthon's challenges and their inherent weaknesses, Teva estimated that they would only remain in place until 2019 or 2020 (which was still longer than the estimated duration of protection for 20 mg dosage).¹⁵³

- (142) Teva launched a first series of patent enforcement actions, seeking to hinder or delay Synthon's preparations to launch competing GA, and targeting various links in Synthon's supply chain. Teva's patent litigation also undermined Synthon's ability to guarantee supply, {...}.¹⁵⁴
- (143) From September 2014, Teva tried to prevent the manufacturing of GA in the EEA. Synthon used to produce the GA active pharmaceutical ingredient (API) in Czechia and to send the API batches to {...} in Spain to be filled in injection syringes. Teva requested preliminary injunctions in both countries.¹⁵⁵ As a result, Synthon was forced to move its production facilities to Argentina, a country with which no mutual recognition agreement is in place. On this basis, Teva sent Synthon a warning letter stating that each imported API batch would have to undergo testing according to Article 51(1) (b) of Directive 2001/83/EC. In these actions, Teva claimed infringements of both its main patent (EP '888) as well as its overlapping divisional process patents (EP '924 and EP '528) and its (40 mg dosage parent patent (EP '749).¹⁵⁶
- (144) More importantly, after Synthon GA 20 mg successfully completed its Decentralised Procedure and then received the first MAs in April 2016, Teva relied on its divisional patents to pursue patent enforcement in 22 countries in the EEA from April 2016, including 23 infringement actions and 45 preliminary injunction filings.¹⁵⁷
- (145) Thus, Teva put in place an elaborate strategy to protect its dosage and process patents against a final decision on the validity of their claims. Teva enforced these patents actively, and often successfully, to bar Synthon GA from the market, {...}.
- 5.2.3.3. Regulatory interventions to obstruct the launch of Synthon GA before Synthon obtained marketing authorisation
- (146) In parallel to converting its patients from 20 mg to 40 mg Copaxone and the misuse of the patent system, Teva also intervened in the regulatory procedures for the granting of a marketing authorisation (MA) to Synthon GA with a view to raising regulatory barriers, thus further hindering, or delaying, the entry of Synthon GA.
- (147) From October 2014 until October 2018, Teva attempted to prevent the granting of an MA for Synthon GA in the Netherlands and elsewhere in the EU. In particular, Teva

¹⁵³ See Section 8.3.3.3.

¹⁵⁴ ID 455-2218, Copaxone/FoGA – P&MA outlook, 7 June 2017, p. 6.

¹⁵⁵ ID 2161, Teva's reply to Article 18(2) Request of 13 July 2022; ID 2150, Teva's reply to Article 18(2) Request of 13 July 2022; furthermore, Teva successfully obtained a court order to suspend Synthon's export licences in Chile and prevent Synthon from exporting GA produced there to the EU/EEA, see ID 455-2848, Teva internal email dated 8 February 2017 from {...} to {...} and others concerning "Synthon FoGA export from Chile - Good News".

¹⁵⁶ ID 2644, Synthon's Follow-Up Submission, p. 121; ID 2037, Annex 27 to follow-up submission, Letter sent by Teva's Dutch external counsel to Synthon (20160426), pp. 2-4.

¹⁵⁷ See Teva's replies to the Article 18(2) Request of 8 January 2021 (updated on 16 November 2021 and 29 July 2022): ID 741-4 Malta; ID 741-35 United Kingdom; ID 741-54 Austria; ID 741-55 Iceland; ID 741-56 Greece; ID 741-73 France; ID 741-76 Lithuania; ID 741-117; ID 741-122 Slovenia; ID 741-140 Finland; ID 741-141 Bulgaria; ID 741-163 Romania; ID 741-173 Ireland; ID 741-192 Norway; ID 741-193 Luxembourg; ID 1639 Estonia; ID 1641 Hungary; ID 1646 Portugal; ID 1649 Sweden; ID 2148 Latvia; ID 2150 Spain; ID 2151 Germany; ID 2152 Italy; ID 2153 Poland; ID 2154 Denmark; ID 2158 Netherlands; ID 2159 Croatia; ID 2160 Slovakia; ID 2161 Czechia; ID 2162 Belgium.

intervened extensively in the Decentralised Procedure for approving Synthron GA in which the Medicines Evaluation Board (MEB) in the Netherlands acted as RMS (reference Member State).¹⁵⁸ Teva attempted to convince the MEB as well as other national agencies involved in the Decentralised Procedure that Synthron GA did not satisfy the requirements for granting an MA.¹⁵⁹

- (148) Even after Synthron had applied for an MA, Teva continued to lobby for the strictest possible requirements for the approval of (generic-like) GAs. Among other things, Teva approached the EMA in an attempt “{...}” (emphasis added).¹⁶⁰ Thereby, Teva hoped to convince the EMA and national health bodies that “such products require a full application under Article 8(3), without extrapolation of the results of pre-clinical tests and clinical trials from the Copaxone MA dossier. Any less stringent approach places patient safety at risk” (emphasis added).¹⁶¹ At the very least, Teva hoped (and succeeded) in delaying the authorisation procedure.¹⁶²
- (149) For example, a slide relating to the CCP entitled “{...}” prominently hailed that “{...}” (due to Teva’s intervention in the procedure for MA in the Netherlands).¹⁶³
- (150) The measures taken to counter Synthron GA’s 20 mg were repeated in relation to Synthron GA 40 mg. Synthron applied for an MA for its 40 mg GA in June 2016. Teva intervened in the procedure, invoking the same grounds as in its previous, unsuccessful intervention regarding 20 mg GA. When Synthron obtained its MAs (from November 2017), Teva challenged these MAs in numerous Member States.

5.2.3.4. Regulatory litigation against Marketing Authorisations

- (151) Once the MAs for Synthron GA had been granted, despite Teva’s obstructive efforts, Teva embarked on a comprehensive, EEA-wide regulatory litigation campaign seeking to annul the MAs for Synthron GA and thus prevent or postpone its market entry. Teva planned and executed this litigation campaign as part of the overarching CCP strategy. From October 2014 to August 2019, Teva attempted to prevent (and then revoke) the grant of MAs first in the Netherlands as the RMS and then subsequently in nine concerned Member States.¹⁶⁴ In some countries, such as Germany, Finland and Austria, Teva’s actions triggered an automatic suspension of

¹⁵⁸ See Section 4.2.

¹⁵⁹ ID 455-1181, Teva internal email dated 1 May 2015 from {...} to {...} and others concerning “Copaxone - MEB Betapharm intervention and Hearings in PT and the NL”.

¹⁶⁰ ID 404-1893, Teva internal email dated 23 October 2014 from {...} to {...} and others, p. 2, concerning “Copaxone Update – EU submissions and Enforcement activities”.

¹⁶¹ ID 404-946, Teva letter to College ter Beoordeling van Geneesmiddelen, 15 October 2014, p. 4; ID 455-2735, letter to EMA, 22 October 2014, pp. 1-2.

¹⁶² ID 263-789, Copaxone Continuation Project (CCP), ECT June 7th, 7 June 2017, p. 8.

¹⁶³ ID 263-789, Copaxone Continuation Project (CCP), ECT June 7th, 7 June 2017, p. 8.

¹⁶⁴ ID 644-22, Teva’s reply to Article 18(2) Request of 3 June 2020 (entire document); ID 404-93, Copaxone EU Litigation Internal Update, 31 August 2018; ID 404-752, Teva internal email chain dated November 2017 – January 2018 from {...} to {...} and others concerning “FOGA MA challenge – Update Decision in the Netherlands”; ID 404-1637, Teva internal email chain dated 21 February 2018 from {...} and {...} concerning {...}; ID 404-1943, Teva internal email chain dated 8-16 December 2014 from {...} to {...} concerning “Copaxone EU Update – Today’s hearing at the Dutch Medicines Agency (MEB)”; ID 404-2134, Copaxone EU Litigation Update, 9 November 2018; ID 455-38, Copaxone/FoGA Overview, 7 February 2017, pp. 2-5; ID 455-461, Teva internal email chain dated December 2016 – May 2017 from {...} to {...} and others concerning meeting minutes from FoGA/Copaxone MA focus; ID 455-2597, Teva internal email chain dated December 2016 – February 2017 from {...} to {...} and others concerning meeting minutes from FoGA/Copaxone MA focus; ID 455-2647, Teva internal email chain dated December 2016 – February 2017 from {...} to {...} and others concerning meeting minutes from FoGA/Copaxone MA focus.

Synthon GA's MA under national administrative rules. Teva pursued this litigation although it was aware that the Decentralised Procedure allows challenges in the individual Member States only if there is a serious risk to public health and there was not enough evidence to robustly demonstrate the existence of such serious risk to public health.

- (152) Not a single one of Teva's legal actions against Synthon GA's MAs was successful in court.¹⁶⁵ In some jurisdictions, Teva's arguments were vigorously rejected by the courts. The Dutch Council of State held that "*the correct application of EU law is so evident in this case that there is no reasonable doubt*" (emphasis added) about the applicability of the authorisation procedure contested by Teva.¹⁶⁶ The German Federal Institute for Drugs & Medical Devices found that Teva's action was doomed to fail, not only because it did not find an infringement of Teva's rights under any conceivable viewpoint, but moreover because Germany (as concerned Member State) "*does not hold any independent right of assessment in respect of the possibility of the infringement of third parties' subjective rights*" (emphasis added).¹⁶⁷
- (153) {...}.¹⁶⁸ {...}.¹⁶⁹
- (154) However, numerous documents refer to the desired effect of delaying the market entry of Synthon GA, in particular through the suspension of MAs. The fact that an automatic suspension of an MA came into effect in case a legal challenge arose (which thus delayed market entry independently from whether the responsible

¹⁶⁵ Teva's actions in the Netherlands as the RMS are illustrative of Teva's expansive efforts to obstruct issuance of MAs for Synthon GA. On 13 June 2016, Teva raised an objection against the decisions to grant marketing authorisations to the companies Mylan B.V. and Synthon B.V. (objections raised under the Dutch Medicines Act dated 19 May 2016, published on 7 July 2016). On 3 November 2016, The Dutch Medicines Evaluation Board (MEB) issued a decision on Teva's objection notice rejecting Teva's claims (See ID 455-2193, the Decision of the Dutch Medicines Evaluation Board (NL version), pp. 1-16; ID 455-2197, the Decision of the Dutch Medicines Evaluation Board (EN version), pp. 2-16; ID 742-79, Assessment report with respect to quality Mylan and Synthon's glatiramer products (Registration numbers (RVG) 115987, 115980, 115993); ID 742-163, Klinisch beoordelingsrapport Glatirameerproducten van Mylan en Synthon (RVG 115987,115980,115993)). As detailed in Chapter 9, Teva continued to communicate those same claims and arguments to numerous stakeholders despite the MEB decision rejecting Teva's claims. Subsequently, on 9 January 2018, Teva's appeal against MEP's decision was rejected by the first instance Administrative Court Haarlem on procedural grounds related to Teva's lack of standing (Rechtbank Noord-Holland, zaaknummer: HAA 16/5166, Teva Pharmaceuticals Ltd. te Castleford v het College ter beoordeling van geneesmiddelen, ECLI:NL:RVS:2018:3298). Finally, on 10 October 2018 the second instance Council of State's Administrative Jurisdiction Division rejected Teva's appeal disputing the procedure that should have been followed by Synthon and Mylan also on substantive grounds (ID 3546, Dutch Council Of State, decision of 10 October 2018, Case No. 201801209/1/A3, Raad van State, zaaknummer 201801209/1/A3, *Teva Pharmaceuticals Ltd. te Castleford v het College ter beoordeling van geneesmiddelen*, NL:RVS:2018:3298, EN version)).

¹⁶⁶ ID 3546, Dutch Council Of State decision of 10 October 2018, Case No. 201801209/1/A3, Raad van State, zaaknummer 201801209/1/A3, *Teva Pharmaceuticals Ltd. te Castleford v het College ter beoordeling van geneesmiddelen*, NL:RVS:2018:3298, EN version, paragraph 52.

¹⁶⁷ ID 2019, Synthon's Follow-up Submission Annex 12(b), p. 6 (unofficial translation). Original text: "*Ein eigenständiges Prüfungsrecht hinsichtlich einer möglichen Verletzung von subjektiven Rechten Dritter steht dem Concerned Member State nach Abschluss des Verfahrens nicht zu*". Synthon GA was authorized at the EU level in the Decentralised Procedure (see Section 4.2.1). After completion of the Decentralised Procedure, the concerned Member States cannot reopen the procedure on a national level to assess whether the rights of a third party were infringed.

¹⁶⁸ ID 455-1422, Teva internal email dated 24 April 2014 from {...} to {...} and others, concerning "Synthon acknowledges complexity of Copaxone", p. 1.

¹⁶⁹ ID 455-493, Teva internal email dated 3 March 2015 from {...} to {...} and others, concerning "Copaxone - preparation of agency meetings - Updated legal slides", p. 3.

authority saw merit in Teva’s challenge) was an important factor for deciding in which Member States to initiate challenges.¹⁷⁰ Successful delays were considered as important achievements also in this part of the CCP. For example, upon receiving news of the suspension of the marketing authorisation in Germany, an employee emphasised that “{...}”.¹⁷¹

- (155) The regulatory litigation prolonged the legal uncertainty about the validity of the contested MAs and the safety and efficacy of Synthon GA, thus delaying market entry. Such uncertainty was then peddled in the framework of Teva’s disparagement campaign.¹⁷²

5.2.3.5. Disparagement campaign targeting Synthon GA

- (156) As set out in further detail in Chapter 9, Teva also planned and executed a comprehensive EEA-wide communication campaign targeting competing GA, in particular Synthon GA and aimed at both healthcare professionals (“HCPs”) as well as other actors who influence the demand for Copaxone, such as insurance funds, pricing and reimbursement authorities as well as other healthcare organisations. This campaign was based mainly on artificially emphasising physicochemical variations inherent to GA and aimed to “{...}”¹⁷³ regarding Synthon GA’s safety and efficacy and its therapeutic equivalence with Copaxone, in direct contradiction to the findings of the competent health authorities.
- (157) Teva specifically targeted the market players that could influence the demand for Synthon GA. Teva’s campaign covered a broad array of different types of Payers in the context of various types of pricing, reimbursement and other relevant decisions that would – at a systemic, aggregate demand level – encourage and establish direct price competition between Copaxone and Synthon GA and thus imperil Copaxone’s market position.
- (158) In addition, Teva’s extensive network of sales agents and medical officers also individually targeted HCPs, such as doctors, nurses and pharmacists to make them question the safety and efficacy and therapeutic equivalence of Synthon GA, despite the fact that the competent authorities found Synthon GA to be therapeutically equivalent to Copaxone. Teva thus sought to “{...}”¹⁷⁴ HCPs concerning their decisions to switch individual patients from Copaxone to Synthon GA.¹⁷⁵ Teva also sought to influence those HCPs who were also acting as Key Opinion Leaders (“KOLs”) advising authorities and bodies on substitution or were otherwise influential as regards MS, which is in their area of expertise.¹⁷⁶ Teva engaged certain

¹⁷⁰ ID 404-1599, Teva internal email dated 15 December 2015 from {...} to {...} and others concerning “Fwd: Privileged & Confidential - FOGA Update”; ID 263-30, Copaxone Legal Update, Regulatory litigations, {...}, February 2017; ID 455-2723, Teva internal email dated 20 April 2017 from {...} concerning CCP Meeting.

¹⁷¹ ID 455-2451, Teva internal email dated 20 July 2016 from by {...} to {...} and others, p. 1, concerning “Re: Copaxone Germany – Update”.

¹⁷² “{...}”, see ID 455-3158, Teva internal email dated 25 November 2017 from {...} to {...} and others concerning “Copaxone EU Legal Strategy - Proposed Changes and impact on 2018 EU Specialty AOP”.

¹⁷³ ID 404-2017, Teva internal email dated 27 October 2014 from {...} to {...} and others, p. 1, regarding “Afspraken tactics plan CPX 20” (unofficial translation): “{...}”.

¹⁷⁴ ID 455-893, Copaxone Global Strategic Marketing, Update for face 2 face meeting, 8 September 2014.

¹⁷⁵ ID 404-1883, email dated 10 April 2017 from {...} to {...} ({...} – Teva’s external representative) and to {...} and others (Teva); ID 455-2889, Teva internal email chain dated 14 April 2017 from {...} to {...} and others; ID 404-2409, Teva internal email dated 19 April 2017 from {...} to {...} and others.

¹⁷⁶ See section 9.4.1.3; see also Recitals (1948) to (1953).

KOLs to disseminate Teva’s misleading messages, as a seemingly neutral and independent position relating to the use of Synthron GA as a substitute for Copaxone, thereby supporting and reinforcing Teva’s official message on the topic.

5.2.3.6. Further activities to counter market entry of Synthron GA

(159) The above-described main activities under the CCP were complemented by several further activities aimed at limiting the expansion of Synthron GA in case and where it succeeded in entering the market (despite conversion of patients from Copaxone’s 20 mg to Copaxone’s 40 mg, Teva’s MA litigation, its divisional patent strategy and disparagement campaign).¹⁷⁷ Some more notable attempts to protect Copaxone’s sales include the following:

- Lobbying for price reference differentiation between 20 mg and 40 mg: Teva sought to avoid the spill over of price competition from the 20 mg product on its still patent protected 40 mg, to which it shifted most of the prescriptions of patients, by lobbying for price reference differentiation between 20 mg and 40 mg: “{...}”,¹⁷⁸ “{...}”.¹⁷⁹
- Unfair competition litigation: Teva pursued unfair competition litigation in numerous Member States to prohibit Synthron from advertising their GA without having received a market authorisation or from making certain claims about its safety and substitutability with Copaxone.¹⁸⁰ Specifically, Teva pursued actions against Synthron’s claim that its GA was of the same quality as Copaxone or a “well-known substance” as well as the presentation as “generic”.¹⁸¹
- Copaxone duplicate medicine: Teva also planned the launch of a Copaxone duplicate, i.e. applying for a second marketing authorisation for Copaxone under a different, “generic” brand name. The Copaxone duplicates could then be sold at a lower price to compete with Synthron GA in tenders without causing a general price reduction for Copaxone. Accordingly, Teva recalled that “{...}”.¹⁸² Eventually, the Copaxone duplicate was only introduced in Germany under the brand name AbZ.
- The SDD (single dose device for injecting Copaxone)¹⁸³ was also specifically designed to react to competing GA, specifically to the launch of Synthron GA in Germany, and hinder its uptake, with the objective to technically reduce substitution between Copaxone and Synthron GA: “{...}”.¹⁸⁴

¹⁷⁷ ID 455-751, MS update July 2017, 13 July 2017, p. 9.

¹⁷⁸ ID 455-1952, Copaxone/FoGA overview, 26 January 2017, p. 24.

¹⁷⁹ ID 455-2218, Copaxone/FoGA – P&MA outlook, 7 June 2017, p. 4.

¹⁸⁰ ID 455-797, Unfair Competition Copaxone, 27 April 2017; ID 455-1965, Teva internal email dated 2 June 2016 from {...} to {...} concerning “COPAXONE EUROPE - Unfair competition injunction against Synthron”; ID 455-3402, Teva internal email dated 10 November 2016 from {...} to {...} and others concerning “Copaxone - Unfair Competition litigation Germany”; ID 455-151, Brand Team MS, June 2017, p. 19.

¹⁸¹ ID 263-29, CCP Meeting, Amsterdam, February 2017, p. 24.

¹⁸² ID 404-385, Teva internal email dated 12 September 2017 from {...} to {...} and others concerning “Regulatory Route for Copaxone Duplicates - Your input is needed”, p. 1; also see ID 455-2081, Teva internal email dated 23 August 2018 from {...} to {...} and others concerning “Duplicate for Copaxone; delayed once again”.

¹⁸³ See Section 6.3.3.3.3 below.

¹⁸⁴ ID 263-1255, TPE Multiple Sclerosis: 2018, February 2018, p. 39.

5.2.4. *The CCP strategy was carefully organised and centrally steered by Teva*

- (160) In 2013, the CCP Taskforce, comprised of multidisciplinary representatives from various Teva departments dealing with Copaxone,¹⁸⁵ started developing an EU Action plan and a package of CCP promotional materials for Teva’s national subsidiaries in the EU/EEA. The “{...}”,¹⁸⁶ which also comprised the strategy related to divisional patents and the disparagement campaign aimed at Synthon GA, was developed by the CCP legal team in coordination with the regulatory team. The CCP was then “rolled out” across Teva’s national teams, responsible for formulating and implementing action plans based on CCP in their national markets, assisted by the CCP Taskforce.¹⁸⁷ This coordination was meant to lead to an “{...}” (emphasis added).¹⁸⁸ Teva also prepared detailed timelines for each country setting out various possible obstacles to the market entry of Synthon GA.¹⁸⁹
- (161) From 2014, CCP Materials with detailed instructions for local implementation were transmitted to CCP project teams in individual countries.¹⁹⁰ Based on these materials, the local teams developed CCP Action Plans for their local market “{...}”.¹⁹¹
- (162) In April 2016, when the Decentralised Procedure for Synthon’s 20 mg GA was concluded, Teva moved to the next phase by implementing the CCP Action Plans in each country: “{...}” (emphasis added).¹⁹² The CCP now required “{...}” (emphasis added).¹⁹³
- (163) These activities were complemented by “*constant vigilance*”,¹⁹⁴ in particular the extensive use of consultancies to gather information on generic market entry. Employees regularly discussed the fact that these intelligence services were expensive but unreplaceable: “{...}”¹⁹⁵; “{...}” (emphasis added).¹⁹⁶ IP enforcement was also designed to allow Teva to obtain information about generic products.¹⁹⁷

¹⁸⁵ Including Market Development, Medical LCI, Market Access, Governmental Affairs, Legal, Patient Services, Regulatory, CI, Branded Biosimilars, Generics, Compliance, see ID 455-801, Copaxone Continuation Taskforce EU – Kick-off meeting, 5 November 2013, p. 10.

¹⁸⁶ See Recital (123)

¹⁸⁷ ID 404-2198, Teva internal email dated 26 August 2014 from {...} to {...} and others concerning “CCP Materials Launch”.

¹⁸⁸ ID 455-2722, Teva internal email dated 13 April 2016 from {...} to {...} and others, concerning “EU Synthon approval + communication guidance and Q&A”, p. 1.

¹⁸⁹ ID 263-26, COPAXONE®/ FoGA, Overview Pricing and Market Access”, 15 February 2017, p. 9.

¹⁹⁰ ID 455-3288, Teva internal email dated 24 February 2014 from {...} to {...} and others, concerning “CCP Communication Slides”.

¹⁹¹ ID 404-2198, Teva internal email dated 26 August 2014 from {...} to {...} and others concerning “CCP Materials Launch”, p. 1.

¹⁹² ID 455-3076, Teva internal email dated 7 April 2016 from {...} to {...} and others concerning “COPAXONE EUROPE - LEGAL UPDATE”, p. 1.

¹⁹³ ID 455-2722, Teva internal email dated 13 April 2016 from {...} to {...} and others concerning “EU Synthon approval + communication guidance and Q&A”, p. 1.

¹⁹⁴ ID 455-473, EU COPAXONE Continuation Project Strategy, March 2017, p. 9.

¹⁹⁵ ID 455-3149, Teva internal emails dated 19 December 2014 from {...} to {...} and Teva internal email dated 6 January 2015 from {...} to {...} and others concerning “RE_ TPR Group and Teva EU”, pp. 1, 2.

¹⁹⁶ ID 455-3154, Teva internal email dated 6 December 2014 from {...}, concerning “{...}” and Teva internal email dated 6 December 2014 from {...} to {...}, p. 2.

¹⁹⁷ ID 404-872, Teva internal email dated 26 August 2012 from {...} to {...} and others concerning “Fw_ TEC Update 2012.09 dlt v5 w LCI slides.pptx”.

5.2.4.1. Many CCP activities shared the common objective to delay competition

(164) The objective to delay the entry of competing GA on the market was common to various Teva activities, ranging from regulatory interventions and litigation to filing preliminary injunctions, the divisional patent strategy and activities related to market access and (non-)substitutability of Copaxone with competing GA, and prominently features in numerous documents. Figure 3 illustrates CCP activities and reveals that the Teva legal team’s activities such as patenting, regulatory and promotional activities are intended to contain the emerging competition:

Figure 3: {...}

{...}

Source ID 263-1378, Understanding the Copaxone Continuation Project (CCP) – A total-disciplinary approach to lifecycle management, p. 20.

- (165) An internal note of a Teva employee concerning patent litigation explicitly noted that the “{...}”.¹⁹⁸ {...}.¹⁹⁹ Furthermore, delays bought Teva time for converting patients to 40 mg, where Teva would again be able to deploy the same activities to delay market entry and thereby protect its sales and profits.
- (166) Every delay achieved, such as the “regulatory clock stop” for over a year resulting from Teva’s intervention in the procedure for MA in the Netherlands, was celebrated as an important achievement.²⁰⁰ Suspensions due to challenges of marketing authorisations were also acclaimed as decisive achievements: “{...}”;²⁰¹ “{...}”.²⁰² In one email, an interruption and delay of Synthron’s assessment in the Netherlands was reported, and the recipient commented expressing the expectation that this may mean “{...}”.²⁰³
- (167) The central importance of delaying tactics to Teva’s strategy is also evident from two slides contained in two PowerPoint presentations for a Teva workshop held in June 2017.²⁰⁴ One slide describes a breakout session whose objective is “{...}”.²⁰⁵ Another slide, presented by an external consultant, emphasises the profits that can be achieved through delaying market entry.²⁰⁶ While this is not a statement expressed by a Teva employee, it is one that was presented, discussed and at least implicitly embraced by Teva via its inclusion in the overall document containing all presentations during the meeting:

¹⁹⁸ ID 455-439, Teva internal email dated 27 September 2016 from {...} concerning “personal notes CCP call”, p. 2.

¹⁹⁹ ID 455-848, presentation Europe, 26 May 2014, p. 20.

²⁰⁰ ID 263-789, Copaxone Continuation Project (CCP), 07 June 2017, p. 8.

²⁰¹ ID 455-1206, Teva internal email dated 19 July 2016 from {...} to {...} and others concerning “Re: Copaxone Germany – Update”, p. 1.

²⁰² ID 455-2451, Teva internal email dated 20 July 2016 from {...} to {...} concerning “Re: Copaxone Germany – Update”, p. 1.

²⁰³ ID 404-1943, Teva internal email chain dated 16 December 2014 between {...} and {...}, p. 1.

²⁰⁴ ID 264-892, Price competition workshop – COPAXONE & LONQUEx, June 20 – 21 2017, Amsterdam.

²⁰⁵ ID 264-892, Price competition workshop – COPAXONE & LONQUEx, June 20 – 21 2017, Amsterdam, presentation “Facing our FoGAs, {...} June 21st, 2017”, p. 115.

²⁰⁶ ID 264-892, Price competition workshop – COPAXONE & LONQUEx, June 20 – 21 2017, Amsterdam, presentation “{...}”, p. 72.

Figure 4: {...}

{...}

Source: ID 262-1695, Price competition workshop – Copaxone & Lonquex, 20-21 June 2017, p. 72.

(168) {...}.²⁰⁷

5.2.4.2. Teva was aware of antitrust compliance risks with the CCP and tried to avoid written traces

(169) From the very start of the CCP, Teva was aware that at least part of its activities under the CCP could raise concerns under EU competition law. The presentation at the Copaxone Continuation Taskforce EU Kick-off meeting on 5 November 2013 already includes a slide on “{...}”. The slide mentions, among others, the following points: “{...}” (emphasis added).²⁰⁸

(170) Accordingly, Teva employees were cautious about the language they used and asked their colleagues to avoid certain expressions, but without questioning the actual activities that gave rise to these expressions in the first place. For example, {...}.²⁰⁹

(171) In the review of national Brand Plans²¹⁰, {...}.²¹¹

(172) {...}

“{...}”,²¹² “{...}”.²¹³

(173) In an email exchange from February 2017, employees refer to “{...}” that should be discussed over the phone or in person: “{...}”.²¹⁴

5.2.5. *The implementation of the CCP prevented and/or delayed market entry of competing GA, in particular Synthon GA*

(174) Evidence suggests that the Copaxone defence strategy has been successful, ranging from delays to entry due to Teva’s interference in regulatory procedures and aggressive patent enforcement, to impacting the decisions to switch patients from Copaxone to Synthon GA. It was also capable of deterring other potential entrants from launching their competing GA products.

(175) Teva employees frequently affirmed that the CCP activities had delayed Synthon GA, for example: “{...}” (emphasis added).²¹⁵

²⁰⁷ ID 266-117, Price competition workshop – Copaxone&Lonquex, 20-21 June 2017, p. 1; See also ID 455-1982, Price competition workshop – Copaxone&Lonquex, 20-21 June 2017, p. 1.

²⁰⁸ ID 455-801, CCP Kick-off Meeting, 5 November 2013, p. 3.

²⁰⁹ ID 404-603, Teva internal email dated 10 February 2014 from {...} to {...} and others concerning “FW_ Copax single dose”, p. 1.

²¹⁰ Teva’s Brand Plans are commercial documents which set out proposed objectives regarding Copaxone’s business for the upcoming year(s), as well as underlying assumptions on the market and its evolution. Brand Plans are prepared at national and at European level. See ID 906, Teva’s reply to Article 18(2) Request of 3 June 2021, p. 6.

²¹¹ ID 455-74, Brand plan review 2015-2017 review, 16 April 2014, pp. 2, 5.

²¹² ID 404-2555, Teva internal email dated 16 March 2016 from {...} to {...} and others, p. 1.

²¹³ ID 404-2139, Teva internal email dated 16 March 2016 from {...} to {...} and others concerning “FoGA update”, p. 1.

²¹⁴ ID 455-2593, Teva internal email exchange dated 10 February 2017 between {...} and {...} concerning “TC 10th Feb 2017, Meeting minutes from FoGA/ Copaxone MA focus”, p. 1.

²¹⁵ ID 455-2844, Teva internal email exchange dated 2-3 January 2017 between {...} and {...} concerning “RE_ Copaxone figures”, p. 1.

- (176) A PowerPoint presentation entitled “EU CCP Strategy” of March 2017 contains a slide with the heading “{...}” (emphasis added)²¹⁶ {...}.²¹⁷ Similarly, in May 2017, the CCP activities were summarised thus: “{...}” (emphasis added).²¹⁸ In June 2017, a Teva employee referred to “{...}”.²¹⁹
- (177) One presentation celebrates that sales are increasing despite market entry of Synthon GA: “{...}” (emphasis added).²²⁰ Another presentation sets out net sales results for the fourth quarter of 2017 and comments these as “{...}” (emphasis added).²²¹

5.2.6. Conclusion

- (178) Teva’s various activities within the framework of the CCP were complementary and significantly increased the difficulties any competing GA producer would have to overcome to enter the market and successfully commercialise its GA. Since 2004, Teva has made significant efforts to tighten the regulatory requirements for the authorisation of competing GA. Building on these efforts, Teva intervened in the authorisation procedure for Synthon GA in 2014 and believed it succeeded in delaying the grant of its first MA until 2016. Teva subsequently engaged in extensive regulatory litigation to prevent or delay the grant of further MAs until 2019.
- (179) Meanwhile, Teva requested preliminary injunctions in patent litigations to first disrupt Synthon’s supply chain (in 2014 and 2015) and, following that, to prevent Synthon from marketing its 20 mg GA product once it was finally authorised and put on the market despite Teva’s legal actions against the MAs. In parallel, Teva started converting as many of its patients as possible from 20 mg to 40 mg Copaxone. On the one hand, patients already converted to 40 mg Copaxone would be less likely to be switched back to Synthon’s 20 mg GA. On the other hand, to address the threat that such patients would be switched to Synthon’s 40 mg GA, Teva was heavily relying on the divisional dosage patent family protecting its 40 mg product to exclude Synthon’s 40 mg GA from the market for as long as possible. To further avoid losing patients, Teva launched an extensive communication campaign to dissuade health authorities from authorising the generalised substitution of Copaxone to Synthon GA and HCPs from switching individual patients to Synthon GA. Teva was aware that in view of its dominant position, its activities to counter Synthon GA’s market entry may infringe competition law and avoid leaving written traces.
- (180) While a life-cycle management strategy to confront upcoming generic competition is not anticompetitive in itself, this Decision focuses on two major parts of Teva’s CCP (namely the misuse of the divisional patent system and its disparagement campaign) which have infringed Article 102 TFEU, as explained in detail in Chapters 8 and 9 below. The Commission does not take a position on the legality of Teva’s other practices, which are part of Teva’s overall strategy to hinder the entry and uptake of competing GA.

²¹⁶ ID 413-150, EU CCP Strategy, Amsterdam, March 2017, p. 14, attached to ID 455-823, email dated 17 February 2017 from {...} to {...}.

²¹⁷ ID 413-150, EU CCP Strategy, Amsterdam, March 2017, p. 9, attached to ID 455-823, email dated 17 February 2017 from {...} to {...}.

²¹⁸ ID 455-2280, Teva internal email dated 8 May 2017 from {...} to {...} and others concerning “FoGA country template”, p. 1.

²¹⁹ ID 404-1640, Teva internal email dated 6 June 2017 from {...} to {...} and others, p. 1.

²²⁰ ID 404-1087, Price competition workshop – COPAXONE & LONQUEx, June 20 – 21 2017, Amsterdam, pp. 3 and 4.

²²¹ ID 263-117, EU Q4 and full year 2017 review, January 2018, p. 3.

6. RELEVANT MARKET FOR COPAXONE

6.1. General principles regarding market definition

- (181) According to paragraph 6 of the Market Definition Notice²²² “[t]he main purpose of market definition is to identify in a systematic way the effective and immediate competitive constraints faced by the undertakings involved [...]. Only products that exert effective and immediate competitive constraints within the relevant timeframe form part of the same relevant market as those of the undertaking(s) involved”.
- (182) The concept of the relevant market implies that there can be effective competition between the products or services which form part of it and thus that there is a sufficient degree of interchangeability between all the products or services forming part of the same market in so far as a specific use of such products or services is concerned.²²³ It follows from paragraph 12 of the Market Definition Notice that “[t]he relevant product market comprises all those products that customers regard as interchangeable or substitutable to the product(s) of the undertaking(s) involved, based on the products’ characteristics, their prices and their intended use, taking into consideration the conditions of competition and the structure of supply and demand on the market”.²²⁴
- (183) The identification of relevant markets by the Commission derives from the existence of competitive constraints. Firms can be subject to three main sources of competitive constraints: demand substitutability, supply substitutability and potential competition. For the definition of the relevant market, demand substitution constitutes the most immediate and effective disciplinary force on the suppliers of a given product.²²⁵

²²² Commission Notice on the definition of relevant market for the purposes of Union competition law (OJ C, C/2024/1645, 22.2.2024, ELI: <http://data.europa.eu/eli/C/2024/1645/oj> – the “Market Definition Notice” or “2024 Market Definition Notice”. See also Judgment of the Court of Justice of 6 December 2012, *AstraZeneca v Commission*, C-457/10 P, EU:T:2012:770, paragraph 175; Judgment of the Court of Justice of 19 April 2012, *Tomra and Others v Commission*, C-549/10 P, EU:C:2012:221, paragraph 38. The Statement of Objections was adopted in 2022 and does therefore not refer to the 2024 Market Definition Notice but to the Commission Notice on the definition of relevant market for the purposes of Community competition law from 1997 (OJ C 372, 9.12.1997, p. 5 – the “1997 Market Definition Notice”). In the Statement of Objections, the Commission referred to “significant” or “sufficient” competitive constraints (see, for instance, Recitals 183, 187 of the Statement of Objections, relying on paragraphs 13 and 19 of the 1997 Market Definition Notice). In this Decision, the change in wording from “significant” or “sufficient” to “effective and immediate” merely serves the purpose of reflecting the wording that is more prominent in the Market Definition Notice in effect at the time of adoption of this Decision (i.e., the 2024 Market Definition Notice). The principles of defining relevant markets, as relied on in this Decision, remain unchanged: the relevance of immediate and effective competitive constraints is explained in both versions of the Notice (compare paragraph 13 of the 1997 Market Definition Notice to paragraph 6 of the 2024 Market Definition Notice). Accordingly, the Commission applies the same analytical framework for the finding of the relevant product market in this Decision as it did in the Statement of Objections.

²²³ Judgment of the Court of Justice of 13 February 1979, *Hoffmann-La Roche v Commission*, C-85/76, EU:C:1979:36, paragraph 28; Judgment of the Court of Justice of 23 January 2018, *F. Hoffmann-La Roche and Others*, C-179/16, EU:C:2018:25, paragraph 51; Judgment of the Court of Justice of 27 June 2024, *Commission v Servier and Others*, C-176/19 P, EU:C:2024:549, paragraph 383.

²²⁴ See also Judgment of the Court of Justice of 30 January 2020, *Generics (UK) and Others*, C-307/18, EU:C:2020:52, paragraph 129 and the case law cited.

²²⁵ Market Definition Notice, paragraphs 23(a), 25. See also paragraphs 23(b) and 23(c) for the other two types of competitive constraints.

- (184) It follows from the Market Definition Notice that “[s]ituations of sufficiently strong demand substitution arise when customers would switch easily from the products of the undertaking(s) involved to readily available alternative products”.²²⁶
- (185) For the purpose of determining the relevant market, “it is therefore necessary to identify in a systematic way the competitive constraints that the undertakings involved face with a view to identifying those actual competitors who are capable of constraining those undertakings’ behaviour or of preventing them from behaving independently of effective competitive pressure”.²²⁷
- (186) According to the Court of Justice, an assessment of economic substitutability is required when products are found to be functionally substitutable: “the assessment of the substitutability of two products is not limited to determining whether those products are, from a functional point of view, capable of satisfying the same need, but also requires a determination as to whether, from an economic point of view, those products are in fact substitutable. Economic substitutability between two products may be found where changes in their relative prices lead to a shift in the sales of one to the other”.²²⁸
- (187) In the assessment of demand substitutability, the Commission analyses to what extent and to what readily available substitute product (if any) the customers of the relevant product would switch in response to a deterioration in the conditions of supply of the relevant product relative to other products.²²⁹ The assessment usually focuses on reactions to price increases (other competitive parameters can be the quality of the product or its level of innovation).²³⁰ The price to take into account will be the prevailing market price. However, “this may not be the case where the focus is on the assessment of the existing market power of the undertaking(s) involved”.²³¹ Accordingly, “in the context of an assessment of dominance in an Article 102 TFEU case, the fact that the prevailing price may already be at a supra-competitive level needs to be taken into account.”²³² This reasoning is not limited to price as a competitive variable but also extends to other competitive variables. Accounting for the fact that current constraints on an undertaking may be the result of the exercise of market power by that undertaking is particularly important when the undertaking is the only supplier or has a very high market share in the candidate relevant market. Failure to do so may result in the well-known “cellophane fallacy” of wrongly inferring that the relevant market must be wider than the products of a dominant undertaking.²³³

²²⁶ Market Definition Notice, paragraph 25.

²²⁷ Opinion of AG Kokott of 14 July 2022, *Commission v Servier and Others*, C-176/19 P, EU:C:2022:576, paragraph 376.

²²⁸ C-176/19 P, *Commission v Servier and Others*, paragraph 384.

²²⁹ Market Definition Notice, paragraph 27.

²³⁰ Market Definition Notice, paragraph 27.

²³¹ Market Definition Notice, footnote 55.

²³² Market Definition Notice, footnote 55.

²³³ The “cellophane fallacy” is named after the US Supreme Court’s market definition involving cellophane and other wrapping products, see ID 3507, *United States v. E. I. du Pont de Nemours & Co.*, 351 U.S. 377 (1956). See also the explanations on this concept in the Market Definition Notice, footnote 55 and Commission Decision of 15 October 2014, *Slovak Telekom*, Case AT.39523, Recitals 158-171.

(188) Where the investigated conduct relates to exclusion, the competitive pressure from affected products should be taken into account for the assessment of the relevant market even in the absence of actual entry.²³⁴

(189) The definition of the relevant market does not require the Commission to follow a rigid hierarchy of different sources of information or types of evidence. Rather, the Commission must make an overall assessment of the relevant facts and can take account of a range of tools for the purposes of that assessment.²³⁵

6.2. Specific considerations on market definition in the pharmaceutical sector

(190) While the Market Definition Notice applies to all industry sectors, the assessment in the case at hand needs to take due account of features specific to pharmaceutical products differentiating them from products in other industry sectors. Those specific features of the pharmaceutical sector include that it is highly regulated and characterised by a complex structure both on the supply and on the demand side, in particular the fact that customers (consumers) of pharmaceutical products are often not deciding which product to consume, nor paying for its consumption (Section 6.2.1). Moreover, pharmaceutical products are normally characterised by a three-stage life-cycle that can impact the dynamics (and thus the definition) of the market over time (Section 6.2.2); in particular, it may become appropriate during the third stage of the product lifecycle to define a relevant product market that is limited to pharmaceutical products which contain the same active ingredient (Section 6.2.3).

6.2.1. The conditions of competition and the complex structure of supply and demand in the pharmaceutical sector

(191) Member States' regulations play a significant role in shaping the demand structure in the pharmaceutical sector. Various agencies decide on the marketing, pricing, procurement, reimbursement and substitution of pharmaceuticals. Governments aim to achieve several goals such as (i) maintaining a high quality, safety, efficiency and efficacy of pharmaceuticals; (ii) making pharmaceuticals affordable to everyone by negotiating prices and setting up public health insurance schemes; and (iii) promoting innovation and medical research.²³⁶

(192) Pharmaceutical markets are therefore highly regulated and characterised by a complex demand structure. The demand side in pharmaceutical markets is shaped by the presence of a multiplicity of stakeholders whose priorities are not necessarily aligned: patients and their medical needs; physicians who are responsible for the diagnosis and treatment of the patient but not for the cost thereof; and the reimbursement body and insurers, whose role is to ensure that medicine expenditure is sustainable for the collective benefit of the beneficiaries of health insurance schemes.

²³⁴ Case C-307/18, *Generics (UK) and Others*, paragraph 140.

²³⁵ Judgment of the Court of First Instance of 14 December 2005, *General Electric v Commission*, T-210/01, EU:T:2005:456, paragraph 519; Judgment of the General Court of 27 September 2012, *Shell Petroleum and Others v Commission*, T-343/06, EU:T:2012:478, paragraph 171; Judgment of the General Court of 6 July 2010, *Ryanair v Commission*, T-342/07, EU:T:2010:280, paragraph 136; Judgment of the General Court of 11 January 2017, *Topps Europe v Commission*, T-699/14, EU:T:2017:2, paragraph 82; Case T-584/19, *thyssenkrupp v Commission*, paragraphs 74-75.

²³⁶ Commission Report: Competition Enforcement in the Pharmaceutical Sector (2009-2017). European competition authorities working together for affordable and innovative medicines, 28.01.2019, COM(2019) 17 final, p. 17.

- (193) Physicians choose the appropriate therapy for their patients. If several treatments are therapeutically substitutable, it is the physician's responsibility to make the appropriate choice of treatment for each specific patient. In the case of chronic diseases such as MS (that can require indefinite and individualised treatment) physicians confer with patients and choose a treatment that takes into account the nature and gravity of the disease as well as, to a lesser extent, the patients' preferences and lifestyle. Neither physicians nor patients carry the (main) costs of treatment and thus have little incentive to take the cost of treatment into account in their choice.
- (194) National rules on pricing and reimbursement of drugs co-shape the demand side in pharmaceutical markets. The costs of prescription drugs are, fully or to a large part, covered by Member State authorities or by health insurance companies, which are funded, respectively, through taxes and insurance fees. In either case, they have a strong interest in containing the costs of healthcare. Health authorities and insurers are not (directly) involved in the treatment choice made by doctors and patients. National regulation provides price-control mechanisms applicable to pharmaceuticals, which usually differ depending on whether a medicine benefits from patent protection or faces generic competition.
- (195) On the supply side, there are manufacturers with distinct business models, such as suppliers of originator medicines, generic medicines or, increasingly, manufacturers of both types of products, wholesalers and pharmacies. Originators typically compete by investing into research and development to bring to the market new branded and patented medicines. Suppliers of generic medicines primarily compete on price.

6.2.2. *The life-cycle of pharmaceutical products as a key determinant of the definition of the relevant markets*

- (196) The Court of Justice held that economic substitutability needs to be assessed based on shifts in sales of therapeutically substitutable medicines based on changes in their relative price: *“irrespective of the specific characteristics of the pharmaceutical sector which are associated with the applicable legislation, with the role of prescribing doctors and with the fact that the price of medicinal products is covered by insurance mechanisms, the economic substitutability between medicinal products must be assessed in the light of the shifts in sales between medicinal products intended for the same therapeutic indication, brought about by the changes in the relative prices of those medicinal products. A finding that there is no such substitutability reveals the existence of a distinct market, whatever the reasons for that finding, whether it be the intrinsic quality of the medicinal product or products falling within that market or the promotional activities undertaken by their manufacturers”*.²³⁷
- (197) As held by the Court of Justice in the *Generics (UK)* case, the conditions of competition for a pharmaceutical product may change over its life-cycle and these changes can impact the definition of the relevant market over time. In *Generics (UK)*, the Court held that the interchangeability and substitutability of products are *“naturally dynamic, in that a new supply of products may alter the conception of the products considered to be interchangeable with a product already present on the market or as substitutable for that product and, in that way, justify a new definition of the parameters of the relevant market”*. It follows that *“a supply of generic medicines containing the same active ingredient [...] could lead to a situation where*

²³⁷ Case C-176/19 P, *Commission v Servier and Others*, paragraph 388.

*the originator medicine is considered, in the professional circles concerned, to be interchangeable only with those generic medicines and, consequently, to belong to a specific market, limited exclusively to medicines which contain that active ingredient”.*²³⁸

- (198) The Court of Justice further held that such a situation can exist even before actual entry of generic medicines if the generic medicines can be launched within a short period of time and with sufficient strength to constitute a serious counterbalance to the originator product.²³⁹
- (199) Three stages can be identified in the life-cycle of a pharmaceutical product.
- (200) First, in the stage before market launch, originator companies compete with each other through innovation, for example by developing new or better products with the goal of securing a patent-protected first-mover advantage in a therapeutic field.
- (201) Second, after a new medicine is placed on the market and enjoys legally protected market exclusivity, the originator company seeks to gain prescriptions by actively promoting its efficacy as well as potentially differentiating its product from alternative, therapeutically substitutable²⁴⁰ treatments. Originators distinguish their products from those of competitors on the basis of, for example, their efficacy, tolerability and safety profiles. In this context, therapeutically substitutable originator pharmaceutical products compete with each other through promotional efforts (or: non-price competition) such as conducting clinical studies, promotion activities vis-à-vis doctors, training of nurses, patient support programmes, etc. At this stage, prices are regulated, typically stable and relatively high (compared to the marginal costs of the manufacturers). Thus, at this stage, the price of the drugs plays a subordinate role in the competitive process.²⁴¹ Member State authorities and health insurers submit that, while they have a general interest in keeping prices low,²⁴² they have little bargaining power vis-à-vis originator companies as long as no generic version of a medicine is on the market.²⁴³

²³⁸ Case C-307/18, *Generics (UK) and Others*, paragraphs 130-131.

²³⁹ Case C-307/18, *Generics (UK) and Others*, paragraph 133.

²⁴⁰ Therapeutic substitutability means that medicines of the same or different active substances have the same therapeutic indication, e.g. treatment of RRMS. Therapeutically substitutable drugs can have different efficacy, safety and tolerability profiles. Therapeutic substitutability is to be distinguished from therapeutic equivalence and from automatic substitutability. Medicines are considered therapeutic equivalents if they have the same (or similar) active ingredient and can be expected to have the same clinical effect and safety profile when administered to patients. Automatic substitution is the practice of dispensing one medicine instead of another medicine at pharmacy level without having to consult the prescribing physician (see Recital (87)).

²⁴¹ ID 3508, OECD Health Policy Studies „Pharmaceutical Innovation and Access to Medicines“, 2018, pp. 19-20, 112-113.

²⁴² See ID 3625, Menzis' Reply to Article 18(2) Request of 15 December 2021, p. 1; ID 2203, Barmer's Reply to Article 18(2) Request of 15 December 2021, p. 1; ID 1251, Regione Liguria's Reply to Article 18(2) Request of 15 December 2021, p. 2; ID 3621, Polish National Health Fund's Reply to Article 18(2) Request of 15 December 2021, p. 3; ID 1133, Consorci Catalunya's Reply to Article 18(2) Request of 15 December 2021, p. 6.

²⁴³ In most of the Relevant Member States, payers are required to reimburse at least one drug of an active substance. See ID 1529, Solidaris' Reply to Article 18(2) Request of 15 December 2021, p. 3; ID 1258, GKV-Spitzenverband's Reply to Article 18(2) Request of 15 December 2021, p. 1; ID 1251, Regione Liguria's Reply to Article 18(2) Request of 15 December 2021, p. 3; ID 1235, Zilveren Kruis' Reply to Article 18(2) Request of 15 December 2021, p. 1; ID 3621, Polish National Health Fund's Reply to Article 18(2) Request of 15 December 2021, pp. 2-5; ID 1113, Servicio Navarro de Salud's Reply to Article 18(2) Request of 15 December 2021, p. 2. In Czechia, the authorities in theory only have to fully reimburse one drug of the interferons and GA drugs, but when the SUKL tried to apply this rule to

- (202) Third, when approaching loss of exclusivity and after the loss of exclusivity, the competitive constraints and related competitive dynamics of the market are typically transformed by the (prospective) entry of generic version(s) of the originator pharmaceutical product in question because of the significant price competition that these generic competitors usually bring to the market.
- (203) Generic versions of a pharmaceutical product are medicines that are bioequivalent (see Recital (76)) and therefore therapeutically equivalent to the originator product. They are therefore much closer substitutes than medicines that are merely therapeutically substitutable with the originator medicine. The prospect of entry of one or several generic versions of a medicine typically changes market dynamics. Supply and demand dynamics change already when the threat of generic entry emerges.
- (204) On the demand side, the health systems in the Member States have mechanisms in place which encourage price competition from the moment of actual generic entry. The Relevant Member States foresee various regulatory mechanisms that foster price competition, such as automatic price reductions for the originator product following entry of a therapeutically equivalent product and the possibility for health insurers, hospitals and (regional) tender authorities to negotiate additional price reductions through tenders²⁴⁴ and substitution rules. Under substitution rules, pharmacies and hospitals may be legally obliged to dispense the cheaper alternative of two or more therapeutically equivalent substitutable drugs, even if the treating physician has prescribed the originator (branded) product (“automatic substitution” or “blind substitution”). The demand side is thus prepared for market entry of generic or generic-like versions of pharmaceutical products in general through its regulatory framework. There is no need for further specific steps before demand dynamics regarding one specific product would change, except for implementation acts such as pricing and reimbursement decisions (see Recitals (81)-(86)) or decisions on automatic substitution (Recitals (87)-(88)).
- (205) On the supply side, the prospect of generic or generic-like competition may exercise a significant constraint on the originator product facing loss of exclusivity before it actually occurs. The threat of generic or generic-like competition can lead an originator company to start preparing a change of its business model from competition on promotion to price competition, and therefore often drives the commercial strategies for the originator product – so-called life-cycle management initiatives – already before that threat materialises. Such life-cycle initiatives can notably be the launch of product variations that are more difficult to mimic by generic or generic-like competition. In the present case, the expectation of generic-like entry and the price competition from such entrants led Teva to put in place the Copaxone Continuation Plan to respond to this new form of competition (see Section 5.2 and Section 6.3.3.2.2).
- (206) When generic or generic-like versions of an originator product enter the market, the originator is faced with a fundamental choice how to respond to the resulting price pressure: lower the prices of their medicine to retain their sales volumes, maintain

Copaxone, Teva challenged the decision and argued that Copaxone is not interchangeable with interferons (see Section 6.3.3.4.3.2).

²⁴⁴ See {...} Reply to Article 18(2) Request of 15 December 2021, p. 2: “*In our experience, tenders only make sense after loss of exclusivity.*” (unofficial translation). Original text: “*Erst mit dem ‘loss of exclusivity’ macht aus unserer Erfahrung eine Ausschreibung Sinn*”.

their price level and lose volume, or a combination of both.²⁴⁵ At this stage of the evolution of market dynamics, product differentiation and non-price competition become (even) less relevant due to the homogeneity (or strong similarity) of originator and generic products.²⁴⁶ At this stage, the competitive constraint from the actual or approaching generic competition normally far outweighs any pressure from other therapeutically substitutable drugs, as the competition now involves homogeneous products. In the case of Copaxone and the generic-like medicine Synthron GA (see Recital (77)), Teva stated in an internal document that {...}.²⁴⁷ As generics and originator products are, by definition, homogeneous products and thus in principle closely substitutable, any differentiation on qualitative standards is difficult. Provided that generic entry and expansion is not hindered by anticompetitive conduct, this leads to what can be called a “commoditisation” of the originator product as several suppliers offer a (quasi)-identical product. As a result, after the entry of generic versions of an originator product on the market, the key parameter of actual competition focuses on price differences.

(207) As a consequence, and as emphasised by the Court of Justice in *Generics (UK)*, the (approaching) introduction of generic products, which is the corollary of the fact that various exclusivities (patents/supplementary protection certificates, data exclusivity etc.) are limited in time, may change the market dynamics to such an extent that the assessment of the relevant market may have to be adapted as compared to the situation existing in the previous stage in the life-cycle of the originator product.²⁴⁸

6.2.3. *The emergence of generic-like competition may require a change of the definition of the relevant market to one limited to medicines that contain the same active ingredient*

(208) In the context of pharmaceutical products, therapeutic substitutability is a necessary precondition for two products to be potentially capable of exercising significant competitive constraints on each other (as provided by medical guidelines and/or actual prescription practices). However, the Commission already stated in its *AstraZeneca* decision, that “a properly defined market does not need to include all functionally interchangeable products, as such interchangeability between products normally only defines the outer boundaries of a product market but may not be a decisive criterion”.²⁴⁹ Therefore, while two medicines may be therapeutically substitutable to a certain extent, they do not necessarily exercise sufficient competitive constraints upon each other.²⁵⁰ This is particularly the case, as mentioned in Section 6.2.2 above, when a generic version of a pharmaceutical product effectively enters the market, as it usually leads to a market transformation from

²⁴⁵ The effect of upholding the same (high) price level as during exclusivity is usually that the originator loses significant sales volumes to the generic or generic-like competition because the demand side has become price-sensitive (tenders, substitution rules) and prefers to buy the cheaper product. The effects of price competition are therefore not limited to impact on prices but include impact on volumes instead of prices or impact on prices and volumes.

²⁴⁶ For a similar description of the life-cycle of a drug, including “Time-to-Collapse” after effective generic entry, see ID 263-1255, TPE Multiple Sclerosis: 2018, February 2018, p. 12.

²⁴⁷ ID 455-701, Regional Medical Plan: 2017-2019, 31 March 2016, p. 13.

²⁴⁸ Case C-307/18, *Generics (UK) and Others*, paragraph 131.

²⁴⁹ Commission Decision of 15 June 2005, *Astra Zeneca*, Case AT.37507, paragraph 370.

²⁵⁰ See Opinion of AG Kokott of 14 July 2022, *Commission v Servier and Others*, C-176/19 P, paragraph 378: “factors such as, in the present case, the evolution of the prices of perindopril and of the other ACE inhibitors, which show that products that can theoretically be substituted for the product at issue have not exerted a significant competitive constraint on that product, cannot be ignored”.

product differentiation and promotion-driven competition to product “commoditisation” and price-driven competition.

- (209) With regard to price-driven competition in pharmaceutical markets, the Court of Justice has recently confirmed in *Commission v Servier* that the particularities of pharmaceutical markets do not negate the relevance of price-related indicators for the assessment of the relevant product market: “*for the purposes of defining the relevant market, the price and quantity sold of a product are not the expression of a distinct type of competition, which could be contrasted with competition which depends on the quality of that product or the efforts made to ensure its commercial promotion. On the contrary, economic substitutability reflects all the characteristics of the products in question, including those relating to their promotional costs and their intrinsic or perceived quality*”.²⁵¹
- (210) The change in the market dynamics is explained by the fact that generics represent the closest and most significant constraint on an originator product’s price, in a way that differentiated (originator) products with different active substances do not, even when they can be considered therapeutically substitutable. Competition between differentiated originator products, where it effectively exists, tends to focus on promoting different product features. Promotion expenses and related costs can affect to some extent the volumes, and thereby the profits of the originator product (where competition between originators is effective), while competition from generic manufacturers leads to pricing constraints. On the one hand, generic products are (quasi-)identical to the originator products since they use the same active substance. On the other hand, generic products usually enter the market at significantly lower price points compared to the originator products. The constraint from generic products on the ability of the originator to set its prices and to maintain high profits is more often than not of an entirely different nature and magnitude than the competitive constraint that may emanate from differentiated originator products that are based on other active substances.²⁵²
- (211) Indeed, a number of national competition authorities in the Union have observed that, where medicines have lost their patent protection, medicines based on other active substances often do not constrain the off-patent medicine in a significant way.²⁵³ National competition authorities have observed that generic medicines based on the same active substance are typically the closest substitutes to off-patent originator medicines and that they are in fact specifically designed to compete with those originator medicines.²⁵⁴

²⁵¹ Case C-176/19 P, *Commission v Servier and Others*, paragraph 387. See also Opinion of AG Kokott of 14 July 2022, *Commission v Servier and Others*, C-176/19 P, paragraph 375.

²⁵² Synthron GA is therapeutically equivalent to Copaxone and therefore marketed as a generic-like (hybrid) alternative to Copaxone in the EEA (see Recitals (257)-(260)).

²⁵³ ID 2524, French Competition Authority (Autorité de la Concurrence) Decision of 14 May 2013, 13-D11, paragraph 301 on practices implemented in the pharmaceutical sector; Decision of the Autorité de la concurrence of 18 December 2013, *Buprénorphine*, 13-D-21, paragraph 329; Decision of the Competition and Markets Authority of 12 February 2016, *Paroxetine*, CE-9531/11, paragraphs 4.96-4.97; ID 2522, French Competition Authority Decision of 20 December 2017, 17-D-25, paragraph 391 regarding practices implemented in the sector of transdermal patches of fentanyl.

²⁵⁴ See ID 2525, Italian Competition Authority (Autorità Garante della Concorrenza e del Mercato) Decision of 11 January 2012, *Ratiopharm/Pfizer*, A 431, p. 5-56; ID 2524, French Competition Authority Decision of 14 May 2013, 13-D11 on practices implemented in the pharmaceutical sector; ID 2522, French Competition Authority Decision of 20 December 2017, 17-D-25 regarding practices implemented in the sector of transdermal patches of fentanyl in Case; ID 2523, Office of Fair Trading

(212) The dynamic nature of substitutability and hence market definition in the pharmaceutical sector was explicitly confirmed by the Court of Justice in the *Generics (UK)* case which stated that “a new supply of products may alter the conception of the products considered to be interchangeable with a product already present on the market or as substitutable for that product and, in that way, justify a new definition of the parameters of the relevant market”. The Court further noted that this “could lead to a situation where the originator medicine is considered, in the professional circles concerned, to be interchangeable only with those generic medicines and, consequently, to belong to a specific market, limited exclusively to medicines which contain that active ingredient.”²⁵⁵ In keeping with the approach in *Generics (UK)* judgment, the Commission will, amongst others, assess whether, in view of the steps Synthon and its licensees took to prepare for market entry, generic-like GA represented a significant competitive threat to Copaxone before and after actual market entry.²⁵⁶

6.2.4. *The Commission’s approach to defining markets for pharmaceutical products in previous merger decisions*

(213) According to Teva, the Commission’s approach to the definition of the Relevant Product market in this Decision contradicts the Commission’s decisional practice, in particular its decisional practice in merger decisions.²⁵⁷ These claims will be addressed in detail in Section 6.3. On a preliminary note and in view of Teva’s claims, the Commission first provides a short overview of its decisional practice in merger decisions.

(214) In previous merger decisions, a key determinant for the definition of the relevant product market for pharmaceutical products has been in which phase of its life-cycle a medicine was at the time the merger was assessed and what type of competition the relevant products were subject to.

(215) For the assessment of demand-side substitution between medicines, the starting point is the assessment of therapeutic substitutability. For this, the Commission usually looks at the so-called ATC levels of a medicine.²⁵⁸

(216) With regard to pharmaceutical products which do not face generic competition, the Commission has referred to the third ATC level (ATC3 - which groups pharmaceutical products by their specific therapeutic indication) as the starting point

Decision of 12 April 2011, *Reckitt Benckiser Healthcare (UK) Limited and Reckitt Benckiser Group plc*, CA98/02/2011. See also ID 3016, *Federal Trade Commission v. AbbVie Inc. et al.* (3d Cir.), 19 July 2019, Case 18-2621.

²⁵⁵ Case C-307/18, *Generics (UK) and Others*, paragraphs 130-131. Following paragraph 133 of that judgment, such a finding presupposes that “generic medicines are in a position to present themselves within a short period on the market concerned with sufficient strength to constitute a serious counterbalance to the manufacturer of the originator medicine already on the market.” This requirement will be addressed in Section 6.3.3.1.1.

²⁵⁶ See Section 6.3.3.1.2.

²⁵⁷ ID 4032, Teva’s Reply to the Statement of Objections, paras. 188, 275, 295, 302, 308, 325.

²⁵⁸ The ATC system is a hierarchical and coded four-level system which classifies medicinal products according to their indication, therapeutic use, composition and mode of action. In the first and broadest level (ATC1), medicinal products are divided into the 16 main anatomical groups. The second level (ATC2) represents either a pharmacological or therapeutic group. The third level (ATC3) further groups medicinal products by their specific therapeutic indications, meaning their intended use. The ATC4 level is the most detailed one (not available for all ATC3) and refers for instance to the mode of action or any other subdivision of the group. Finally, the level of the chemical substance is the so-called molecule level.

for assessing the relevant product market.²⁵⁹ Even where products belong to the same ATC class and/or have the same therapeutic use, further assessment is always required to conclude whether such products indeed exercise an effective competitive constraint on the product(s) in question.²⁶⁰ In a number of cases, the Commission thus found that the market could not be defined at ATC3 level. In such cases, the Commission has defined the relevant product market at a more granular level (ATC4 level or at the molecule level) because not all medicines with the same therapeutic indication were considered sufficiently interchangeable so as to exercise competitive pressure on one another. In assessing therapeutic interchangeability, the Commission's standard practice is to consider differences in composition, mode of action, as well as the safety, efficacy and tolerability profiles as a key factor when assessing the relevant market.²⁶¹ The key question is which medicines provide a "therapeutically equal outcome".²⁶² Depending on the specificities of the medicine for which the relevant product market is defined, a therapeutically equal outcome may be achieved with different active ingredients within the same ATC3 or ATC4 class, or it may only be achieved with medicines that have the same active ingredient.²⁶³ Another differentiating factor of medicines can be their route of administration. The Commission found in *Mylan/Meda* that "different routes of administration and the pharmaceutical form of a medicine may be designed to serve the needs of different patient groups and are therefore not interchangeable".²⁶⁴ It follows that the Commission has, in previous cases concerning medicines driven by non-price competition (differentiation, promotion), found medicines of different active ingredients to be part of the same market if they have similar safety, efficacy and tolerability profiles and/or the same or a similar route of administration.

- (217) For genericised products, competing primarily on price, the Commission has however regularly defined the relevant product market at the level of the active substance.²⁶⁵ For example, the Commission's merger decision in *Novartis/GSK Oncology Business* states that "for generic products the Commission typically defined the market at molecule level".²⁶⁶ Similarly, the Commission's merger decision in *CVC/Recordati* states "[a]s regards genericised products [...] the molecule level is the most plausible starting point for the product market definition, given that generic pharmaceutical companies typically produce copies of originator

²⁵⁹ Commission Decision of 15 June 2005, *Astra Zeneca*, Case AT.37507, paragraph 371.

²⁶⁰ Commission Decision of 20 July 2016, *Mylan/Meda*, Case M.7975, paragraph 11; Commission Decision of 2 March 2020, *GlaxoSmithKline/Pfizer Consumer Healthcare Business*, Case M.9274, paragraph 15.

²⁶¹ The Commission's standard practice is to rely on the mechanism of action precisely because medicines with the same mode of action typically have similar efficacy and safety profiles. See Commission Decision of 5 July 2021, *AZ/Alexion*, Case M.10165, paragraph 19; Commission Decision of 20 November 2018, *Takeda/Shire*, Case M.8955, paragraphs 39-49 (defining a market for anti-integrin due to its superior safety profile); Commission Decision of 10 January 2020, *AbbVie Allergan*, Case M.9461, paragraphs 33, 51; Commission Decision of 29 July 2019, *BMS/Celgene*, Case M.9294, paragraphs 37-42, 45.

²⁶² Commission Decision of 28 January 2015, *Mylan/Abbott*, Case M.7379, paragraph 35.

²⁶³ Case M.7379, *Mylan/Abbott*, paragraph 35.

²⁶⁴ Commission Decision of 20 July 2016, *Mylan/Meda*, Case M.7975, paragraph 22.

²⁶⁵ Commission Decision of 9 November 2012, *Teva/Cephalon*, COMP/M.6258, paragraphs 12, 37f., 64f., 94; Commission Decision of 3 August 2010, *Teva/Ratiopharm*, Case M.5865, paragraph 26; Commission Decision of 4 February 2009, *Sanofi-Aventis/Zentiva*, Case M.5253, paragraphs 25f.; Commission Decision of 19 December 2008, in Case *Teva/Barr*, Case M.5295, paragraph 17.

²⁶⁶ Commission Decision of 28 January 2015, *Novartis/GSK Oncology Business*, Case M.7275, paragraph 208.

drugs and thus it can be considered that a generic molecule is the closest substitute to the originator medicinal product based on the same molecule or APP.²⁶⁷

- (218) In some cases, the Commission has even considered that there may be differences in the demand for originator versus generic medicines, even though they are equivalent.²⁶⁸ However, the Commission clarified in *Mylan/Meda* that this is the case in particular countries in which the penetration of generics is lower and the importance of the brand is higher. In countries with regulatory incentives in favour of generic medicines (for example mandatory substitution at the pharmacy level and mandatory INN prescription), the originator medicines are more likely to be considered interchangeable with the generic versions.²⁶⁹
- (219) One previous merger decision concerns specifically the question whether Copaxone and Synthon GA²⁷⁰ are in the same relevant product market. In *Teva/Allergan*, the Commission considered that there is an “*originator-to-generic overlap*” between Copaxone and Synthon GA. In its decision, the Commission implicitly argued that Copaxone was not facing competition other than from generic-like GA, and raised serious doubts as to the compatibility of the concentration with the internal market on the ground that “*the merged entity [Teva/Allergan] may have the ability to delay, and possibly frustrate, the regulatory process leading to the granting of the marketing authorisation within the terms of the existing contractual arrangements. As such behaviour would result in a delayed entry of [...] generic glatiramer acetate on the market, it would extend the period in which Copaxone does not face competition. Given the importance of Copaxone in terms of sales and profits, it is clear that the merged entity would have the incentive to pursue such a strategy, which would lead to higher prices for patients and payers for a prolonged period of time*”.²⁷¹ The *Teva/Allergan* decision was not contested by Teva.

6.2.5. *Teva’s claims on the key precedents for defining relevant product markets in the pharmaceutical sector*

- (220) In its Reply to the Statement of Objections, Teva submits that the relevant product market could have only narrowed following the entry of Synthon GA if there is “*a finding that non-price competition efforts were no longer significant after [Synthon GA]’s entry*”.²⁷² According to Teva, this follows from the General Court’s *Servier*²⁷³ judgment in addition to the Court of Justice’s *Generics (UK)* judgment.²⁷⁴

²⁶⁷ Commission Decision of 4 December 2018, *CVC/Recordati*, Case M.9044, paragraph 12; See also Commission Decision of 22 April 2020, *Mylan/Upjohn*, Case M.9517, paragraphs 16-17 and 20; Commission Decision of 10 July 2019, *GSK/Pfizer Consumer Healthcare Business*, Case M.9274, paragraph 16.

²⁶⁸ Commission Decision of 3 August 2010, *Teva/Ratiopharm*, Case M.5865, paragraph 26; Case M.7379, *Mylan/Abbott*, paragraph 13.

²⁶⁹ Case M.7975, *Mylan/Meda*, paragraph 13. All Relevant Member States have regulatory incentives in favour of generic medicines (see Section 6.3.3.2.3 and the country-chapters in Section 6.3.3.4.). The Commission further explains in Recital (357) why the reasoning from *Mylan/Meda* is not applicable in the case at hand.

²⁷⁰ The Commission’s decision refers to Synthon GA as Synthon’s “*generic glatiramer acetate*”, see ID 2155, Case M.7746 – *Teva/Allergan Generics*, paragraphs 23, 668.

²⁷¹ ID 2155, Case M.7746 – *Teva/Allergan Generics*, paragraphs 587-588.

²⁷² ID 4032, Teva’s Reply to the Statement of Objections, para. 182.

²⁷³ Judgment of the Court of First Instance of 12 December 2018, *Servier and Others v Commission*, T-691/14, EU:T:2018:922. When Teva submitted its Reply to the Statement of Objections in February 2023, the Court of Justice had not yet ruled on the appeal in the case C-176/19 P *Commission v Servier*.

²⁷⁴ ID 4032, Teva’s Reply to the Statement of Objections, paras. 167, 182.

- (221) Teva submits that according to the General Court’s *Servier* judgment the starting point for the relevant product market definition is to consider whether there are other medicinal products that are substitutable with the drug that is the subject of the investigation, and to then examine whether these products exert significant competitive constraints with respect to non-price competition on the drug in question. If that is the case, Teva states that the relevant market should be found to include all such products, irrespective of the existence of price competition from a generic(-like) version of the drug.²⁷⁵
- (222) Teva further claims that *Generics UK* confirms the analytical framework applied by the General Court in *Servier*, which is to primarily base the analysis on therapeutic substitutability.²⁷⁶ Teva claims that *Generics (UK)* only foresees the “*theoretical possibility*” of a collapse in the scope of the relevant product market to a single molecule market and therefore requires a case-specific analysis of whether such a collapse has taken place.²⁷⁷ According to Teva, the criteria for this case-specific analysis should be taken from the General Court’s ruling in *Servier*.²⁷⁸ With this approach, Teva comes to the conclusion that the relevant product market could have only narrowed following Synthon GA’s entry if there is “*a finding that non-price competition efforts were no longer significant after [Synthon GA]’s entry*”.²⁷⁹
- (223) The Commission rejects Teva’s claims and its interpretation of the key precedents for defining relevant product markets in the pharmaceutical sector.
- (224) First, the interpretation suggested by Teva, relying on the General Court’s judgment in *Servier*, is flawed, and has as such been disproved by the Court of Justice in the same case. In its judgment, the Court of Justice held that it was economic, and not therapeutic substitution, that was decisive for the definition of the relevant product market. The Court clarified that “*economic substitutability between two products may be found where changes in their relative prices lead to a shift in the sales of one to the other*”.²⁸⁰ As will be shown in Section 6.3.3, only Synthon GA brought about such a shift in sales.
- (225) The General Court’s judgment in *Servier* held that the relevant product market in question comprises all therapeutically substitutable medicines because physicians make their prescribing decision based on product characteristics and not on price.²⁸¹ However, the Court of Justice annulled that finding, establishing that the General Court was wrong to hold “*that the relative price inelasticity of demand for perindopril was of little relevance for the purposes of determining the relevant market because it could be explained or justified by the quality of that medicinal product and the importance of its manufacturer’s promotional efforts*”.²⁸² The Court also stated that the price and quantity sold of a product are relevant parameters for the assessment of the market definition irrespective of whether competition depends on the quality, promotional competition or other aspects.²⁸³

²⁷⁵ ID 4032, Teva’s Reply to the Statement of Objections, para. 173.

²⁷⁶ ID 4032, Teva’s Reply to the Statement of Objections, para. 174.

²⁷⁷ ID 4032, Teva’s Reply to the Statement of Objections, para. 177.

²⁷⁸ ID 4032, Teva’s Reply to the Statement of Objections, para. 179.

²⁷⁹ ID 4032, Teva’s Reply to the Statement of Objections, para. 182.

²⁸⁰ Case C-176/19 P, *Commission v Servier*, paragraph 384.

²⁸¹ Case T-691/14, *Servier and Others v Commission*, paragraphs 1574-1575, 1590-1591.

²⁸² Case C-176/19 P, *Commission v Servier*, paragraph 390.

²⁸³ Case C-176/19 P, *Commission v Servier*, paragraph 387.

- (226) Teva’s reasoning also contradicts the earlier Court findings in *Generics (UK)*. The Court of Justice found in *Generics (UK)* that the “*that interchangeability or substitutability is not assessed solely in relation to the objective characteristics of the products and services at issue*” and that “*conditions of competition and the structure of supply and demand on the market*” need also to be taken into account.²⁸⁴ The Court also confirmed that “*the interchangeability or substitutability of products are naturally dynamic, in that a new supply of products may alter the conception of the products considered to be interchangeable with a product already present on the market or as substitutable for that product and, in that way, justify a new definition of the parameters of the relevant market*”.²⁸⁵ Consequently, the relevant product market may not (anymore) include all therapeutically substitutable medicines but be limited to the active ingredient: “*a supply of generic medicines containing the same active ingredient [...] could lead to a situation where the originator medicine is considered [...] to be interchangeable only with those generic medicines*”²⁸⁶.
- (227) Thus, also in the *Generics (UK)* judgment, the Court of Justice differentiates between therapeutically substitutable medicines (medicines of the same therapeutic class) and interchangeability or substitutability of products.²⁸⁷ The Court found that establishing therapeutic substitutability of medicinal products is only the first step of assessing the relevant market. In a second step, it is necessary to assess whether, and which therapeutically substitutable products exert significant competitive constraints on a medicinal product.
- (228) It follows that in a market that, in view of Copaxone’s loss of exclusivity, transforms into one driven by price competition, Teva’s approach cannot explain how non-price competition from other DMTs would be capable of significantly constraining Copaxone’s in the absence of an impact on prices, volumes and/or profits as demonstrated in Section 6.3.3. And if it made sense for Teva to invest in non-price competition with non-GA DMTs as it claims, this is only because Teva managed to prevent, or at least delay the effective entry of its generic-like competitor and thereby also the onset of price competition. In so doing, Teva artificially froze market conditions in a state where it still made sense for Teva to invest in its brand to grow its revenue or confront limited competitive constraints from other brands.
- (229) Thus, in order to assess which therapeutically substitutable products are also economic substitutes as they exert significant competitive constraints on Copaxone, the Commission carries out a comprehensive assessment of competitive constraints (price and non-price constraints) at the relevant time when Teva engaged in the conduct that is the subject of this Decision.

6.3. Relevant product market

- (230) For the purpose of the present case, the definition of the relevant product market seeks not only to assess whether other pharmaceutical products are therapeutically substitutable, but also whether the competitive constraint they exercise is sufficient to discipline Teva’s commercial strategy for Copaxone. In particular, in line with the *Servier* judgment²⁸⁸, the question is which products are economically substitutable

²⁸⁴ Case C-307/18, *Generics (UK) and Others*, paragraph 129.

²⁸⁵ Case C-307/18, *Generics (UK) and Others*, paragraph 130.

²⁸⁶ Case C-307/18, *Generics (UK) and Others*, paragraph 131.

²⁸⁷ Case C-307/18, *Generics (UK) and Others*, paragraph 131.

²⁸⁸ C-176/19 P, *Commission v Servier and Others*, paragraph 384.

with Copaxone constraining its pricing such as to lead to a decrease in revenue and profits due to reduced volumes and/or prices.

- (231) As set out above, in the *Generics (UK)* case, the Court explicitly confirmed that in pharmaceutical markets the entry of generic versions of a pharmaceutical product may lead to a market limited exclusively to medicines which contain the same active ingredient, even if other medicines might also be therapeutically substitutable.²⁸⁹ In the present case, the Commission’s finding is that when Teva’s conduct started, in February 2015, the structure of the relevant market had already shifted to one where the competitive constraints that Teva faced, as regards Copaxone, were mainly those exercised by the threat of generic-like competition.²⁹⁰
- (232) In this Section, the Commission first describes MS and the available treatment options (Section 6.3.1), and then, following the Court’s approach in *Generics (UK) and Servier*²⁹¹, analyses the competitive constraints on Copaxone in two steps:
- The first step is an assessment of product characteristics and therapeutic use of different MS medicines to establish which treatments are therapeutically substitutable with Copaxone. Only therapeutically substitutable medicines, and those for which therapeutic substitutability cannot be excluded, need to be considered under the second step (Section 6.3.2).
 - The second step is an assessment of the competitive conditions and the demand and supply structure for Copaxone. The aim of this second step is to establish which of the therapeutically substitutable treatments actually exert an effective competitive constraint on prices, volumes and profits of Copaxone within the relevant timeframe (Section 6.3.3).
- (233) The Commission’s assessment is not split by distribution channels – sales to hospitals and specialised clinics on the one hand and retail sales through pharmacies on the other hand. This is because, with regard to Copaxone, the distinction between retail and hospital sales is not relevant for the purpose of the present case, as in the Relevant Member States, Copaxone is sold either through one or the other channel, but not through both.²⁹² Therefore, no separate assessment is needed per distribution channel. This finding is not contested by Teva.

6.3.1. Multiple Sclerosis and available treatments

- (234) Copaxone is an immunomodulator indicated for the treatment of Relapsing-Remitting MS (RRMS), the most common form of MS. Its active ingredient is glatiramer acetate (GA). GA is a mixture of random-sized peptides that are composed of the four amino acids found in myelin basic protein, namely glutamic acid, lysine, alanine and tyrosine. As regards GA’s mode of action, Teva describes that “[i]t is believed to act by modifying immune processes that are currently believed to be responsible for the pathogenesis of MS.”²⁹³

6.3.1.1. Description of MS

- (235) MS is a chronic autoimmune disease in which the body immune system attacks the nerve fibres in the central nervous system, degenerating the myelin coating that

²⁸⁹ Case C-307/18, *Generics (UK) and Others*, paragraph 131.

²⁹⁰ See Section 6.3.3.2.2.

²⁹¹ Case C-176/19 P, *Commission v Servier*, paragraph 388.

²⁹² The market structure and regulatory system of each Relevant Member State is explained in Section 6.3.3.4.

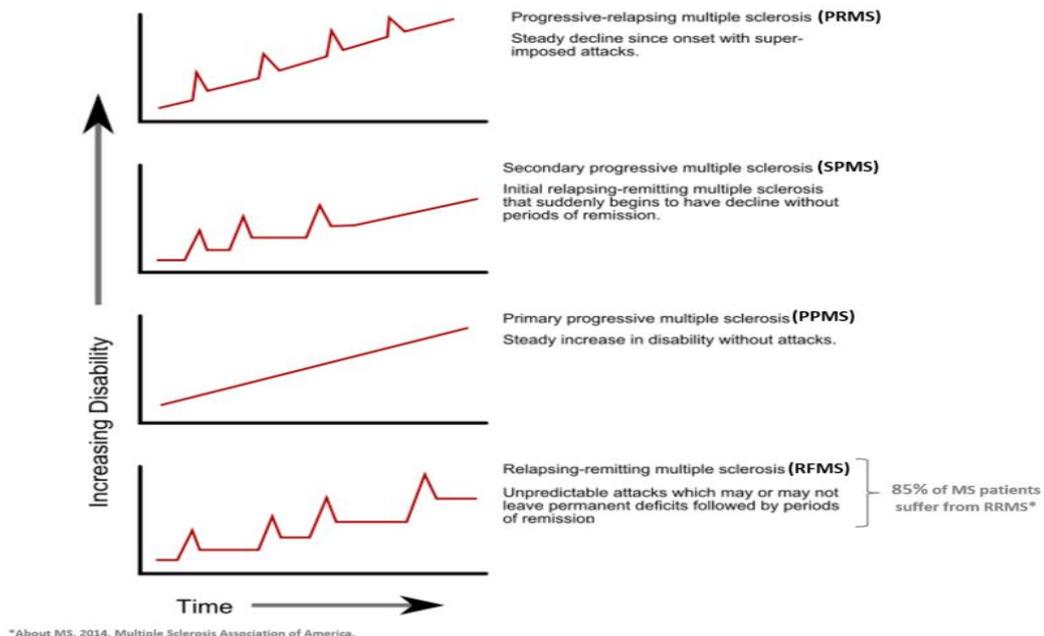
²⁹³ ID 660, Teva’s reply to Article 18(2) Request of 3 June 2020, p. 11.

insulates the nerves and helps the transmission of nerve impulses between the brain and other parts of the body.

- (236) According to the European Multiple Sclerosis Platform (EMSP) more than 1 million people in Europe are affected by MS. It constitutes the most frequent cause of non-traumatic disability in the young adult population (the average age of onset of first symptoms of the disease is 32 years).
- (237) As shown in Figure 5 below, MS can be divided into four sub-types:²⁹⁴ relapsing remitting MS (RRMS) – also referred to as relapsing forms of MS (RFMS), secondary-progressive MS (SPMS), primary-progressive MS (PPMS) and progressive relapsing MS (PRMS).²⁹⁵

Figure 5: The four sub-types of MS

Relapsing-Remitting MS is the most common form of MS



Source: ID 263-1255, *TPE Multiple Sclerosis: 2018, February 2018, p. 4.*

- (238) RRMS is the most common form of MS, affecting around 85% of MS patients.²⁹⁶ It is characterised by clear episodes of inflammatory activity (relapses) alternated with periods in which the illness appears to fade or even disappear (remittances). Relapses can last for varying periods (days or months) and there is a partial or total recovery (remission). The disease may then be inactive for months or years.

²⁹⁴ See also ID 3472, “Defining the clinical course of multiple sclerosis: results of an international survey”, National Multiple Sclerosis Society (USA) Advisory Committee on Clinical Trials of New Agents in Multiple Sclerosis, 1996, F D Lublin 1, S C Reingold.

²⁹⁵ In 2013, the International Committee on Clinical Trials of MS added a new disease course to its disease typology. Clinically Isolated Syndrome (“CIS”) is recognised as the first clinical presentation of a disease that could be MS because it shows characteristics of inflammatory demyelination, but that has yet to fulfil the criteria of dissemination in time. CIS, if subsequently clinically active and fulfilling MS diagnostic criteria, becomes RRMS. As a result of the inclusion of two modifiers (i.e. activity and progression of the disease over time), the PRMS category became redundant.

²⁹⁶ ID 4032, Teva’s Reply to the Statement of Objections, para. 49; ID 660, Teva’s reply to Article 18(2) Request of 3 June 2020, p. 10.

- (239) Given that the investigated medicine (Copaxone) is an immunomodulator indicated for the treatment of RRMS and holds no SPMS, PPMS or PRMS indications, the Commission will focus its analysis on RRMS only.
- (240) There is currently no curative treatment available for RRMS. The key clinical goals of current RRMS treatments are the reduction of relapse rates and the permanent delay of the disability progression.²⁹⁷ For patients, independence and the ability to continue working or studying are the key priorities.²⁹⁸
- (241) According to the EMA Guidelines,²⁹⁹ the current therapeutic approach for the treatment of MS, including RRMS, encompasses the following:
- symptomatic treatment – refers to all therapies applied to improve symptoms and complications caused by the disease;
 - treatment of acute relapses – the standard of care for acute relapses is methylprednisolone which shortens the duration of a relapse but has no influence on its sequelae; and
 - DMT(s) (disease modifying therapy/ies) – therapies targeted at reducing the frequency and/or intensity of relapses and/or slowing down the course of the disease.³⁰⁰
- (242) Almost all RRMS patients (96%) can be classified as having mild-moderate RRMS.³⁰¹ Patients with RRMS who have had two or more clinical relapses in the previous two years are considered to suffer from an “active” disease that warrants consideration for treatment with a DMT. The majority of RRMS patients that are diagnosed and presented to HCPs are treated with a DMT.³⁰²
- (243) In previous merger cases, the Commission found that DMTs that address the immunological causes of MS, aimed at reducing the disease activity, and products that relieve only the symptoms of MS patients belonged to separate relevant product markets.³⁰³ Teva itself focuses its claims regarding the relevant product market for Copaxone on DMTs only.³⁰⁴
- (244) Given that the investigated medicine (Copaxone) is indicated as a DMT for the treatment of RRMS, the starting point for the Commission’s assessment of the relevant market for Copaxone are DMTs for the treatment of RRMS. Teva does not claim that treatments other than DMTs for the treatment of RRMS should be included in the assessment.³⁰⁵

²⁹⁷ ID 2632, “Guideline on clinical investigation of medicinal products for the treatment of Multiple Sclerosis”, *EMA*, EMA/CHMP/771815/2011, Rev. 2, 26 March 2015 or “EMA Guidelines”.

²⁹⁸ According to a patient survey by the Multiple Sclerosis International Federation (MSIF): ID 2703, MS in focus – Young people with MS, *MSIF*, January 2013, p. 27.

²⁹⁹ See footnote 297.

³⁰⁰ EMA Guidelines, p. 5.

³⁰¹ ID 660, Teva’s reply to Article 18(2) Request of 3 June 2020, p. 10; ID 4032, Teva’s Reply to the Statement of Objections, para. 49.

³⁰² ID 741-79, Teva’s reply to Article 18(2) Request of 8 January 2021, p. 5.

³⁰³ E.g. Commission Decision of 6 February 2006, *Novartis/Chiron*, M.4049; Commission Decision of 12 January 2011, *Sanofi-Aventis/Genzyme*, Case M.5999; Commission Decision of 18 December 2015, *Novartis/GSK*, Case M.7872; Commission Decision of 9 June 2017, *Johnson & Johnson /Actelion*, Case M.8401.

³⁰⁴ ID 660, Teva’s reply to Article 18(2) Request of 3 June 2020, p. 10.

³⁰⁵ See ID 4032, Teva’s Reply to the Statement of Objections, para. 271; ID 660, Teva’s reply to Article 18(2) Request of 3 June 2020, p. 19-20.

6.3.1.2. Approved DMT options for RRMS

- (245) All the approved DMTs for RRMS reduce relapse rates and the accumulation of lesions of the brain that are discernible through magnetic resonance imaging (MRI lesions). Based on their individual risk-benefit profile, DMTs are categorised into first-line, second-line, and third-line treatments.³⁰⁶ DMTs are also categorised by their route of administration. The categorisations by line of treatment and by route of administration are not mutually exclusive but complementary.
- (246) Patients suffering from RRMS usually start their treatment with one of the first-line DMTs. Treatments belong to the first-line if they are considered the preferred treatment for RRMS. Second line-DMTs are usually indicated only for patients who do not respond to first-line treatments, or for patients with rapid disease progression.³⁰⁷ If a first-line treatment fails to treat disease symptoms in a patient, physicians may prescribe a different first-line treatments before moving the patient to a second-line treatment (treatment switching between first-line DMTs is addressed in Section 6.3.2.2.3). Third-line DMTs are indicated only after a patient has tried one or several second-line treatments and the treatment has failed.
- (247) Some DMTs, such as Gilenya and Ocrevus, are categorised as second-line treatments for patients with mild-moderate RRMS but can be first-line treatments for patients with highly active RRMS. Teva itself distinguishes between first-line treatments for mild-moderate RRMS and first-line treatments for highly active disease.³⁰⁸ The Commission focuses its analysis on mild-moderate RRMS, as this includes almost all RRMS patients.
- (248) The currently approved DMTs can also be categorised based on their route of administration:
- injectable therapies – are administered subcutaneously, provide for moderate efficacy and have a good long-term safety profile (interferons beta and glatiramer acetate); injectable therapies are either based on an interferon beta as the active substance (there are several different active substances based on interferon beta) or on GA. In the following, the Commission therefore refers to all non-GA injectables as interferons;
 - oral therapies – offer improved efficacy but also lead to increased serious side effects and have only been available to patients more recently than injectable therapies (active substances for oral therapies are, for example, teriflunomide, dimethyl fumarate and fingolimod);
 - intravenous therapies – therapies administered by intravenous infusion which deliver further improved efficacy but have significant increased risks of side effects. All intravenous RRMS therapies are monoclonal antibodies.

³⁰⁶ The risk-benefit profile describes the weighing of the risks and benefits for the patient associated with a treatment. High drug efficacy is a benefit, while adverse effects are a risk. Typically, first-line treatments are preferred treatments because they have less adverse effects than the second-line treatments and a comparable efficacy. However, when considering this categorisation between DMTs, one needs to take into account that formal approvals do not necessarily coincide in different countries and the concepts of first-line and second-line treatments are constantly evolving (e.g. although Gilenya is arguably a second line treatment, it is indicated as first line treatment in some jurisdictions such as France and Switzerland).

³⁰⁷ ID 4032, Teva's Reply to the Statement of Objections, para. 45.

³⁰⁸ ID 660, Teva's reply to Article 18(2) Request of 3 June 2020, pp. 31-38.

(249) Table 1 below provides an overview of all approved DMTs for the treatment of RRMS. It is based on information submitted by Teva in reply to the Commission's Article 18(2) Request of 3 June 2020.

Table 1: Currently approved DMTs for the treatment of RRMS

Name of the medicine	Active substance	Line of treatment (LoT)	Route of administration	Launch in the EEA
Copaxone	GA	1 st LoT	Injectable	Pre-2010
Synthon GA	GA	1 st LoT	Injectable	May 2016
Avonex	interferon beta-1a	1 st LoT	Injectable	Pre-2010
Rebif	interferon beta-1a	1 st LoT	Injectable	Pre-2010
Betaferon	interferon beta-1b	1 st LoT	Injectable	Pre-2010
Plegridy	interferon beta-1a	1 st LoT	Injectable	July 2014
Extavia	interferon beta-1b	1 st LoT	Injectable	Pre-2010
Aubagio	Teriflunomide	1 st LoT	Oral	Aug. 2013
Tecfidera	dimethyl fumarate	1 st LoT	Oral	Jan. 2014
Gilenya ³⁰⁹	Fingolimod	2 nd LoT	Oral	March 2011
Tysabri	Natalizumab	2 nd LoT	Intravenous	Pre-2010
Ocrevus	Ocrelizumab	2 nd LoT	Intravenous	Jan. 2016
Zeposia	Ozanimod	2 nd LoT	Oral	May 2020
Mavenclad	Cladribine	2 nd LoT	Oral	Aug. 2017
Lemtrada ³¹⁰	Alemtuzumab	2 nd LoT	Intravenous	Sept. 2013
Mayzent	Siponimod	3 rd LoT	Oral	Jan. 2017

Source: ID 660, Teva's reply to Article 18(2) Request of 3 June 2020, pp. 31-38; ID 2222, Teva's reply to Article 18(2) Request of 13 July 2022.

(250) The categorization of interferon beta 1a and 1b, GA, dimethyl fumarate and teriflunomide as first-line treatment for RRMS is largely supported by the results of

³⁰⁹ Gilenya is indicated as a first-line treatment in some national medical guidelines, such as in France and in the UK.

³¹⁰ Lemtrada is formally approved as first-line treatment, but used as second-line, in light of the more serious risk profile. See ID 2624 Coyle, P.K., "Current evaluation of alemtuzumab in multiple sclerosis", *Expert Opin Biol Ther*, 2014; 14:127-35.

the market investigations in earlier merger cases³¹¹ and also fully aligned with national medical guidelines.³¹² In the course of the investigation, no information was raised, or otherwise came to the Commission's attention, which would lead to a different conclusion.

6.3.2. *First step: assessment of therapeutic substitutability between Copaxone and other approved DMTs for the treatment of RRMS*

- (251) In the first step of assessing the competitive constraints on Copaxone, the Commission assesses to which extent other pharmaceutical products are therapeutic substitutes with Copaxone (from the patients' and the physicians' perspective). As explained above (see footnote 240), therapeutic substitutability means that medicines of the same or different active substances have the same therapeutic indication, in this case the (disease-modifying) treatment of RRMS. This does not mean that all therapeutically substitutable medicines are indicated and suitable for every patient. Depending on a medicine's mode of action, mode of administration, safety profile and side effect, it may be indicated for different patient groups and contra-indicated (or a less optimal treatment) for others.
- (252) Most importantly, not all therapeutically substitutable medicines are therapeutically equivalent. Medicines are considered therapeutic equivalents if they have the same (or similar) active ingredient and can be expected to have an equivalent clinical effect and safety profile when administered to patients. Usually, only an originator (reference) medicine and its generic, generic-like or biosimilar competition are considered therapeutically equivalent medicines.³¹³
- (253) Teva submits that Copaxone is substitutable with the non-GA first-line treatments (orals and interferons) and certain second-line treatments, including at least Gilenya, Ocrevus and Tysabri.³¹⁴
- (254) In the following sections, the Commission analyses and demonstrates that (i) Copaxone and Synthon GA, as the only product with the same active ingredient, are therapeutically equivalent, and therefore also fully therapeutically substitutable (Section 6.3.2.1), that (ii) non-GA first-line DMTs are, at best, imperfect therapeutic substitutes for Copaxone (Section 6.3.2.2), and that (iii) second-line DMTs are not sufficiently therapeutically substitutable with Copaxone and therefore do not belong to the same relevant product market (Section 6.3.3).

³¹¹ See for example: Case M.8401, *Johnson & Johnson/ Actelion*, paragraph 59.

³¹² See, for example, ID 2717, *Traitements immunomodulateurs de la sclérose en plaques, Guide à l'usage des patients, de leur famille et de leurs soignants*, 2022, pp. 4-6; ID 3242, *Patientenleitlinie Multiple Sklerose*, Deutsche Gesellschaft für Neurologie e.V., 2022, p. 26; ID 2502, *Guideline database of the Federatie Medisch Specialisten*, 2022, p.3; ID 2496, García Merino *et al.*, "Consensus statement on the treatment of multiple sclerosis by the Spanish Society of Neurology in 2016", *Neurología*, 2017, 32(2):113-119, p. 117.

³¹³ As explained in Recital (76), originator and generic medicines are usually considered therapeutically equivalent because they have the same active substance and are bioequivalent. For hybrid medicines and biosimilars, it may be necessary to prove equivalence with the reference medicine by submitting additional (clinical) data. In practice, this means that the manufacturer of the hybrid medicine/biosimilar could need to carry out additional pre-clinical tests or clinical trials to prove equivalence.

³¹⁴ ID 660, Teva's reply to Article 18(2) Request of 3 June 2020, p. 19; ID 758, Teva's reply to Article 18(2) Request of 8 January 2021, pp. 2-3.

6.3.2.1. Synthron GA is not only therapeutically substitutable, but also therapeutically equivalent with Copaxone

- (255) To date, Synthron GA is the only other product on the EEA market with GA as its active ingredient. Synthron GA is the generic-like version of Copaxone on the EEA market (developed by Synthron and approved under the hybrid procedure³¹⁵) which entered the market in 2016, following the expiry of Teva's EP '888 patent in 2015.
- (256) Teva submits that GA is a complex active ingredient whose exact composition cannot be fully characterised and that any changes in the manufacturing process, for example by another manufacturer, such as Synthron, may impact the properties of GA.³¹⁶ Teva further submits that there are differences in the physicochemical and biological attributes of Copaxone and Synthron GA.³¹⁷
- (257) The Commission considers that Synthron GA is therapeutically substitutable with Copaxone as it is therapeutically equivalent to Copaxone according to, *inter alia*, the respective summaries of product characteristics (SmPCs), as approved by the competent public health authorities. Because it is a therapeutically equivalent medicine, Synthron GA is marketed as a generic-like (hybrid) alternative to Copaxone.
- (258) First, the respective SmPCs for Copaxone and Synthron GA are identical, which shows that the products are therapeutically equivalent.³¹⁸ According to the SmPCs, the mode of action, clinical efficacy, safety, contra-indications and side effects of the two medicines are identical. They are both indicated for the treatment of RRMS with the same route of administration (subcutaneous use, self-injection by patients).³¹⁹ Therapeutic equivalence between Copaxone and Synthron GA is not contested by Teva in these proceedings.³²⁰ No other first-line DMT is therapeutically equivalent to Copaxone (see Section 6.3.3.1.1).
- (259) Second, Synthron GA was developed to be marketed as a generic alternative to Copaxone.³²¹ Its marketing authorisation was assessed in a procedure for hybrid drugs with Copaxone as the reference product (see Section 4.2.2). Hybrid drugs are medicines for which the strict definition of a generic medicinal product is not met because there are certain differences between the hybrid and the reference originator drug, such as in their strength, indication or pharmaceutical form, preventing the demonstration of their bioequivalence. However, they nonetheless are therapeutically

³¹⁵ See Section 4.2.2 for explanation of the hybrid application procedure.

³¹⁶ ID 1866, Teva's spontaneous submission of 25 May 2022, pp. 1-2; ID 4032, Teva's Reply to the Statement of Objections, paras. 58-61.

³¹⁷ ID 1866, Teva's spontaneous submission of 25 May 2022, p. 8.

³¹⁸ See, e.g., for the Netherlands (RMS): ID 3505, Samenvatting van de productkenmerken (SmPC) – Copaxone; ID 3509, Samenvatting van de productkenmerken (SmPC) – Synthron GA.

³¹⁹ Copaxone and Synthron GA have the same ATC code (L03AX13). Anatomical therapeutic classification ("ATC") is devised by the European Pharmaceutical Marketing Research Association ("**EphMRA**") and maintained by EphMRA and Intercontinental Medical Statistics ("**IMS**"). In the EphMRA ATC system, medicines are classified into groups at four different levels. In the first and broadest level (ATC1), medicinal products are divided into the 16 main anatomical groups. The second level (ATC2) represents either a pharmacological or therapeutic group. The third level (ATC3) further groups medicinal products by their specific therapeutic indications, i.e. their intended use. The ATC4 level is the most detailed one (not available for all ATC3) and refers for instance to the mode of action (e.g. distinction of some ATC3 classes into topical and systemic depending on their way of action) or any other subdivision of the group. Finally, the level of the chemical substance is the so-called molecule level.

³²⁰ ID 4032, Teva's Reply to the Statement of Objections, para. 25.

³²¹ ID 2644, Synthron's Follow-Up Submission, pp. 12-13.

equivalent.³²² Synthon submitted trial data showing that its drug is therapeutically equivalent to Copaxone (namely the GATE study³²³ and the GATE extension study³²⁴) and its GA was approved as a hybrid drug with Copaxone as the reference drug. Moreover, Synthon GA is referred to as a “Generic of Copaxone” in the list of DMTs approved by the EMA that is available on the European Multiple Sclerosis Platform.³²⁵ Accordingly, the Commission’s market investigation in the *Teva/Allergan* case from 2016 identified the overlap between Copaxone and Synthon GA as an “*originator-to-generic pipeline overlap*”.³²⁶

(260) Third, due to the therapeutic equivalence between Copaxone and Synthon GA, significant switching between the two medicines can occur for cost saving considerations (as opposed to switching on medical grounds).

(261) In view of the above, the Commission concludes that Copaxone and Synthon GA are not only therapeutically substitutable but also therapeutically equivalent.

6.3.2.2. Non-GA first line DMTs are, at best, imperfect therapeutic substitutes for Copaxone

(262) To assess whether non-GA first-line DMTs are therapeutically substitutable with Copaxone, the Commission assesses the efficacy, safety and tolerability profiles of Copaxone and non-GA first-line DMTs, which shows that the different profiles cater to different patient needs (Section 6.3.2.2.1). The Commission then shows that Teva itself has emphasised significant therapeutic differences between Copaxone and non-GA first-line DMTs in submissions to Member State authorities (Section 6.3.2.2.2) and that switching patterns between different first-line DMTs confirm that non-GA first-line DMTs have differentiated therapeutic profiles (Section 6.3.2.2.3).

(263) From this analysis, the Commission concludes that non-GA first-line DMTs are, at best, imperfect substitutes for Copaxone.

6.3.2.2.1. Different first-line DMTs cater to different patient needs

(264) Teva submits that non-GA first-line treatments are “*at least equally attractive*” treatment options as Copaxone,³²⁷ and that the oral first-line treatments Tecfidera and Aubagio, because of their more convenient form of administration, their safety profile, and their efficacy, may be a preferred option for doctors and patients alike.³²⁸

³²² ID 2497, EMA glossary, <https://www.ema.europa.eu/en/glossary/hybrid-medicine#:~:text=Hybrid%20medicine%20A%20medicine%20that%20is%20similar%20to,information%20can%20be%20found%20under%C2%A0Generic%20and%20hybrid%20medicines>, accessed on 26 September 2022.

³²³ ID 3604, J. Cohen, A. Belova, K. Selmaj, C. Wolf, M. P. Sormani, J. Oberyé, E. van den Tweel, R. Mulder, N. Koper, G. Voortman, F. Barkhof, Equivalence of Generic Glatiramer Acetate in Multiple Sclerosis: A Randomized Clinical Trial - Glatiramer Acetate Clinical Trial to Assess Equivalence With Copaxone (GATE) Study Group, *JAMA Neurol.* 2015 Dec;72(12):1433-41. doi: 10.1001/jamaneurol.2015.2154.

³²⁴ ID 3548, Krzysztof Selmaj, Frederik Barkhof, Anna N Belova, Christian Wolf, Evelyn RW van den Tweel, Janine JL Oberyé, Roel Mulder, David F Egging, Norbert P Koper, Jeffrey A Cohen, Switching from branded to generic glatiramer acetate: 15-month GATE trial extension results, *Mult Scler.* 2017 Dec; 23(14): 1909–1917.

³²⁵ ID 2501, European Multiple Sclerosis Platform, <https://emsp.org/about-ms/ms-treatments/>, accessed on 26 September 2022.

³²⁶ ID 2155, Commission decision of 10 March 2016, *Teva/Allergan Generics*, Case M.7746, paragraph 62. The decision refers to Synthon GA as a pipeline product because it was issued in March 2016, which was shortly before the launch of Synthon GA in the first EEA countries.

³²⁷ ID 758, Teva’s reply to Article 18(2) Request of 8 January 2021, p. 3.

³²⁸ ID 660, Teva’s reply to Article 18(2) Request of 3 June 2020, p. 14.

Teva further submits that physicians consider the non-GA first-line DMTs as therapeutically substitutable with Copaxone.³²⁹

- (265) The Commission finds that first-line DMTs are different from each other concerning their efficacy and safety (including tolerability and route of administration). When choosing a treatment, HCPs, conferring with patients, not only consider a drug's efficacy profile but they take all of the abovementioned aspects into account as well as the patients' preferences and lifestyle. As Teva explains "*physicians are focused primarily on [annualised relapse rate] efficacy, but also need to manage long-term safety and tolerability for the patient; patient buy-in is important as it can boost treatment adherence over the course of treatment*".³³⁰
- (266) Notwithstanding a high efficacy profile, different DMTs can be contraindicated for some patient groups because of, for example, hypersensitivities or comorbidities.³³¹ Thus, some patients may forego a drug with a high efficacy profile in order to avoid the accompanying side effects. In addition, the patient's lifestyle plays an important role in the choice of treatment. For example, a patient who travels a lot can find it burdensome to use a drug that needs refrigerated storage and patients with an active lifestyle may give more importance to the frequency of administration to avoid frequent side effects. The choice of treatment will therefore depend on each patient's priorities, lifestyle, and health profile (including potential comorbidities). Consequently, all characteristics of a DMT have to be taken into account for the assessment of therapeutic substitutability between different DMTs.
- (267) Teva's internal documents confirm that not every first-line DMT is appropriate for all patients. For example, {...}.³³² In the same vein, the MS Treatment Decisions and Positioning Research report prepared for Teva by a third party finds that {...}.³³³

6.3.2.2.1.1. Efficacy profile

- (268) Copaxone benefits from a well-established efficacy profile. Studies concluded that Copaxone reduces relapses³³⁴ and lesions³³⁵. Some studies suggest that Copaxone has a better efficacy profile than interferons,³³⁶ that switching from interferons to

³²⁹ ID 4032, Teva's Reply to the Statement of Objections, para. 276.

³³⁰ ID 644-199, Global Customers Insight-Multiple Sclerosis Fact Book, November 2016, p. 87.

³³¹ Every first-line DMT has a contraindication for some patient groups; see Table 2 below for an overview of the contraindications per DMT.

³³² ID 741-185, 2021 E.U. Brandplan & High level GTMAP Copaxone, p. 11.

³³³ ID 644-192, MS treatment decisions and positioning research – Phase 1: BUILD workshop, 9th April 2019, pp. 44, 47, 77.

³³⁴ ID 3631, Bornstein *et al.*, "A pilot trial of Cop 1 in exacerbating-relapsing multiple sclerosis, *N. Engl. J. Med.*, 1987, 317(7):408-14; Johnson *et al.*, "Copolymer 1 reduces relapse rate and improves disability in relapsing-relapsing multiple sclerosis: results of a phase III multicenter, double-blind placebo-controlled trial. The Copolymer 1 Multiple Sclerosis Study Group", *Neurology*, 1995, 45(7):1268-76; ID 3643, Khan *et al.*, "Three times weekly glatiramer acetate in relapsing-relapsing multiple sclerosis", *Ann. Neurol.*, 2013, 73(6):705-13.

³³⁵ ID 3632, Comi G., Filippi M., Wolinsky J.S., "European/Canadian multicenter, double-blind, randomized, placebo-controlled study of the effects of glatiramer acetate on magnetic resonance imaging--measured disease activity and burden in patients with relapsing multiple sclerosis", *Ann Neurol.*, 2001, 49(3):290-297.

³³⁶ ID 3460, Lindsey *et al.*, "The CombiRx trial of combined therapy with interferon and glatiramer acetate in relapsing remitting MS: Design and baseline characteristics", *Mult Scler Relat Disord.*, 2012, 1(2): 81-86.

Copaxone is beneficial to patients in terms of efficacy³³⁷ and that Copaxone has a better long-term efficacy profile than interferons³³⁸.

- (269) Teva submits that the efficacy profile of first-line treatments other than Copaxone is comparable or superior to Copaxone's efficacy profile, with interferons being comparable to Copaxone while the oral first-line treatments have a better efficacy profile than Copaxone.³³⁹ Teva's internal documents partly confirm this submission. {...}.³⁴⁰
- (270) There is therefore no conclusive evidence that Copaxone's efficacy would be significantly different from, or superior to, the efficacy of other DMTs.

6.3.2.2.1.2. Safety profile

- (271) Another important criterion for treatment choices is the safety profile of a drug. Teva's internal documents, as well as a comparison of contraindications for first-line DMTs, suggest that the safety profile of Copaxone is superior to the safety profiles of non-GA first-line DMTs.
- (272) First, even though Teva submitted that Copaxone's safety profile is similar to that of non-GA first-line treatments,³⁴¹ evidence from Teva's contemporaneous documents pre-dating the investigation (thus *in tempore non suspecto*) does not support this claim. According to the "Multiple Sclerosis Fact Book" prepared by Teva in 2016, {...}.³⁴² The above-mentioned product comparator table from Teva's 2018 EU Strategic Brand Plan for Copaxone (see Section 6.3.2.2.1.2) suggests that {...}.³⁴³ While Teva submits that the safety profile of orals is allegedly no longer perceived as inferior to that of Copaxone, internal documents show that, {...}.³⁴⁴ According to Teva, {...}.³⁴⁵ {...}.³⁴⁶
- (273) Second, the benefits of Copaxone's safety profile are visible from comparing the contraindications of first-line DMTs (see Table 2 below). Copaxone is only contraindicated for patients with "*hypersensitivity to the active substance or excipients*"³⁴⁷, a contraindication that all first-line DMTs have concerning their respective active substances and excipients. The non-GA first-line DMTs have a number of additional contraindications.

³³⁷ ID 3459, Meca-Lallana *et al.*, "Spasticity improvement in patients with relapsing-remitting multiple sclerosis switching from interferon- β to glatiramer acetate: the Escala Study", *J Neurol Sci.*, 2012, 315(1-2):123-8; See also ID 3480, Zwibel *et al.*, "A multicenter study of the predictors of adherence to self-injected glatiramer acetate for treatment of relapsing-remitting multiple sclerosis", *J Neurol.*, 2011, 258(3):402-11.

³³⁸ The long-term efficacy of GA is not compromised by treatment-related antibodies, in contrast to interferon-beta treatments, see ID 3504, Ford *et al.*, "A prospective open-label study of glatiramer acetate: over a decade of continuous use in multiple sclerosis patients", *Mult Scler.*, 2006 12(3):309-20.

³³⁹ ID 660, Teva's reply to Article 18(2) Request of 3 June 2020, pp. 12-13.

³⁴⁰ ID 263-439, 2018 EU Strategic Brand Plan COPAXONE, 5 May 2017, p. 26.

³⁴¹ ID 660, Teva's reply to Article 18(2) Request of 3 June 2020, pp. 12-13.

³⁴² ID 644-199, Global Customers Insight-Multiple Sclerosis Fact Book, November 2016, p. 5.

³⁴³ ID 263-439, 2018 EU Strategic Brand Plan COPAXONE, 5 May 2017, p. 26.

³⁴⁴ The second main driver being pregnancy, see ID 644-192, MS treatment decisions and positioning research – Phase 1: BUILD workshop, 9th April 2019, p. 38.

³⁴⁵ ID 644-192, MS treatment decisions and positioning research – Phase 1: BUILD workshop, 9th April 2019, p. 38.

³⁴⁶ ID 644-192, MS treatment decisions and positioning research – Phase 1: BUILD workshop, 9th April 2019, p. 38.

³⁴⁷ ID 3505, Samenvatting van de productkenmerken (SmPC) – Copaxone, section 4.3.

Table 2: Contraindications of first-line DMTs

Contraindication	Copaxone³⁴⁸		<ul style="list-style-type: none"> hypersensitivity to the active substance or excipients
	Interferons	Rebif, Plegridy, Avonex³⁴⁹	<ul style="list-style-type: none"> hypersensitivity to the active substance or excipients severe depression and/or suicidal ideation
		Extavia, Betaferon,³⁵⁰	<ul style="list-style-type: none"> hypersensitivity to the active substance or excipients severe depression and/or suicidal ideation decompensated liver disease
	Orals	Tecfidera³⁵¹	<ul style="list-style-type: none"> hypersensitivity to the active substance or to any of the excipients in its composition suspected or confirmed Progressive Multifocal Leukoencephalopathy (PML)
		Aubagio³⁵²	<ul style="list-style-type: none"> hypersensitivity to the active substance or excipients severe hepatic impairment pregnant women, or women of childbearing potential who are not using reliable contraception during treatment with teriflunomide and thereafter as long as its plasma levels are above 0.02 mg/l breast-feeding women patients with severe immunodeficiency states, e.g. acquired immunodeficiency syndrome (AIDS) patients with significantly impaired bone marrow function or significant anaemia, leucopenia, neutropenia or thrombocytopenia patients with severe active infection until resolution patients with severe renal impairment undergoing dialysis, because insufficient clinical experience is available in this patient group patients with severe hypoproteinaemia, e.g. in nephrotic syndrome

Source: SmPCs of the respective medicines, as approved by the competent public health authorities

³⁴⁸ ID 3505, Samenvatting van de productkenmerken (SmPC) – Copaxone, section 4.3.

³⁴⁹ ID 3473, Rebif SmPC, section 4.3; ID 3476, Avonex SmPC, section 4.3; ID 3475, Plegridy SmPC, section 4.3.

³⁵⁰ ID 3458, Extavia SmPC, section 4.3; ID 3461, Betaferon SmPC, section 4.3.

³⁵¹ ID 3468, Tecfidera SmPC, section 4.3 and 4.6.

³⁵² ID 3474, Aubagio SmPC, section 4.3.

- (274) Third, another reason for patients to be treated with Copaxone is its *proven* safety during pregnancy and breastfeeding.³⁵³ Orals are not recommended (Tecfidera) or even contra-indicated (Aubagio) for women wishing to become pregnant³⁵⁴ and interferons should only be considered during pregnancy “*if clinically needed*” because it cannot be excluded that they increase the risk of a miscarriage.³⁵⁵ Teva is very clear in emphasising this comparative advantage stating how “*Copaxone offers great value from its safety heritage – especially in pregnancy*”.³⁵⁶
- (275) Proven safety for pregnancy and breastfeeding is a significant drug characteristic for first-line DMTs because women of childbearing age represent a particularly large part of MS patients. In Europe, 69% of patients with MS are women; the average age of diagnosis of MS is 34 years old in Europe;³⁵⁷ and approximately 43% of women diagnosed with MS start a family after diagnosis³⁵⁸. Teva notes in an internal document that {...}.³⁵⁹
- (276) The abovementioned points suggest that Copaxone’s safety profile is not only comparable but potentially superior to those of non-GA first-line DMTs.

6.3.2.2.1.3. Tolerability and other factors

- (277) Tolerability is another important factor in the choice of treatment. Due to the very different tolerability profile of the first-line DMTs, the choice of the appropriate treatment for a patient is an individual decision depending on the patient’s capacity to tolerate adverse effects and the patient’s lifestyle.
- (278) In essence, tolerability is a sub-category of a medicine’s safety profile. Drug tolerability refers to the degree to which the adverse effects of a treatment can be tolerated by patients. The tolerability profile largely determines whether patients adhere to their treatment, and therefore ultimately influences whether a treatment is successful.³⁶⁰ As explained above, therapeutically equivalent medicines, such as Copaxone and Synthon GA, are expected to have the same clinical effects (see footnote 240). Therefore, they are expected to have an identical tolerability profile.³⁶¹
- (279) Several factors determine a medicine’s tolerability profile. First, the tolerability of a medicine is closely linked to its route of administration. For example, certain patients

³⁵³ ID 644-192, MS treatment decisions and positioning research – Phase 1: BUILD workshop, 9th April 2019, pp. 38, 69.

³⁵⁴ ID 3468, Tecfidera SmPC, section 4.6: “*animal studies have shown reproductive toxicity (...). Tecfidera is not recommended during pregnancy and in women of childbearing potential not using appropriate contraception*”. ID 3474, Aubagio SmPC, section 4.6: “*Teriflunomide may cause serious birth defects when administered during pregnancy. Teriflunomide is contraindicated in pregnancy*”.

³⁵⁵ ID 3473, Rebif SmPC, section 4.6; ID 3476, Avonex SmPC, section 4.6; ID 3475, Plegridy SmPC, section 4.6; ID 3458, Extavia SmPC, section 4.6; ID 3461, Betaferon SmPC, section 4.6.

³⁵⁶ ID 644-192, MS treatment decisions and positioning research – Phase 1: BUILD workshop, 9th April 2019, p. 4.

³⁵⁷ ID 2504, MS map published by the MS International Federation, <https://www.atlasofms.org/chart/united-kingdom/epidemiology/average-age-people-start-to-develop-ms>, accessed on 26 September 2022.

³⁵⁸ ID 644-285, EU Strategic Brand Plan, Copaxone, 23rd March 2017, p. 3.

³⁵⁹ ID 644-192, MS treatment decisions and positioning research – Phase 1: BUILD workshop, 9th April 2019, p. 4.

³⁶⁰ Stanulović *et al.*, “Drug tolerability: How much ambiguity can be tolerated? A systematic review of the assessment of tolerability in clinical studies”, *British Journal of Clinical Pharmacology*, 2022, 88(2):551-565.

³⁶¹ ID 3505, Samenvatting van de productkenmerken (SmPC) – Copaxone; ID 3509, Samenvatting van de productkenmerken (SmPC) – Synthon GA.

may want to avoid self-injecting their treatment, or suffer from injection site reactions, while others cannot tolerate the side effects of oral treatments.

- (280) Second, every first-line DMT has different adverse effects. Apart from injection site reactions, the use of interferons can cause flu-like headaches and fatigue.³⁶² The use of orals can lead to gastro-intestinal disorders³⁶³ and Copaxone can cause injection site reactions³⁶⁴. The tolerability of those adverse effects depends on the patient but also on his/her lifestyle. For example, interferons are to be avoided by patients that like to engage in sports because they can cause flu-like symptoms and weakness three days after the administration.³⁶⁵
- (281) While the tolerability of a medicine is different to each individual patient, it is still possible to make some general statements on the tolerability of medicines based on statistical data. For example, Teva refers to orals having a {...}, while stating that Copaxone has a {...}.³⁶⁶ Tolerability considerations can both draw patients to Copaxone³⁶⁷ as well as lead them to switch to another first-line treatment instead³⁶⁸.
- (282) Third, each medicine comes with certain constraints, be it adverse effects or the route of administration. If the choice of treatment suitable for an individual patient allows it, patients will be inclined to choose a treatment with constraints that are reconcilable with their lifestyle. As explained by Teva {...}.³⁶⁹ {...}.³⁷⁰
- (283) Other factors that can influence the choice of treatment are the frequency of administration, whether a medicine needs refrigerated storage and whether treatment with a medicine requires regular monitoring by doctors. For instance, patients that regularly travel will not be able to follow a treatment that requires refrigerated storage or regular monitoring and would tend to favour medicines that require less frequent administration.³⁷¹ In this regard, the different first-line DMTs have different advantages and disadvantages that can cater for different needs of individual patients. Copaxone is a medicine that needs refrigerated storage but does not require special monitoring of patients. The oral DMT Aubagio, for example, requires extensive monitoring but does not require any special storage conditions.³⁷² Regarding frequency of administration, some interferons are only administered once a week (Avonex) or every two weeks (Plegridy),³⁷³ while the first-line oral DMTs have to be

³⁶² ID 644-192, MS treatment decisions and positioning research – Phase 1: BUILD workshop, 9th April 2019, p. 38.

³⁶³ ID 644-192, MS treatment decisions and positioning research – Phase 1: BUILD workshop, 9th April 2019, p. 38.

³⁶⁴ ID 644-192, MS treatment decisions and positioning research – Phase 1: BUILD workshop, 9th April 2019, p. 94.

³⁶⁵ ID 644-192, MS treatment decisions and positioning research – Phase 1: BUILD workshop, 9th April 2019, p. 29.

³⁶⁶ ID 263-2763, COPAXONE – Strategic Brand Plan and Medical Plan Review, 5 May 2015, pp. 10, 23.

³⁶⁷ {...}, see ID 644-192, MS treatment decisions and positioning research – Phase 1: BUILD workshop, 9th April 2019, p. 38.

³⁶⁸ {...} see ID 644-192, MS treatment decisions and positioning research – Phase 1: BUILD workshop, 9th April 2019, p. 39.

³⁶⁹ ID 644-199, Global Customers Insight-Multiple Sclerosis Fact Book, November 2016, p. 88.

³⁷⁰ ID 644-192, MS treatment decisions and positioning research – Phase 1: BUILD workshop, 9th April 2019, pp. 4, 29.

³⁷¹ ID 644-192, MS treatment decisions and positioning research – Phase 1: BUILD workshop, 9th April 2019, p. 29.

³⁷² ID 3474, Aubagio SmPC, pp. 4, 21.

³⁷³ ID 3476, Avonex SmPC, p. 2; ID 3475, Plegridy SmPC, p. 3.

administered once (Aubagio) or twice (Tecfidera) per day³⁷⁴ and Copaxone has to be administered at least three times per week.

(284) In conclusion, Copaxone is a medicine that is administered daily (20 mg dosage) or three times a week (40 mg dosage) by subcutaneous injection and that requires refrigerated storage but no special monitoring of patients. The most common adverse effects of Copaxone are injection site reactions. Copaxone's tolerability profile is different from the tolerability profiles of other (non-GA) first-line DMTs. These differences are all the more apparent when taking into account other factors that influence the choice of DMT.

6.3.2.2.2. Teva emphasised significant therapeutic differences between Copaxone and interferons in submissions to Member States' authorities

(285) In its RFI responses, Teva submits that Copaxone's safety and efficacy is comparable to that of interferons and orals.³⁷⁵ However, this claim is contradicted by Teva's submissions to Member State authorities in which it sought to differentiate Copaxone from interferons on factors such as safety and tolerability. This is notable because interferons are the product group whose treatment regime is closest to Copaxone because they have the same route of administration (Copaxone and interferons are injectables, see Recital (248)).

(286) Teva sought to differentiate Copaxone from interferons during administrative proceedings in Czechia aimed at revising (and potentially lowering) the reimbursement price of Copaxone. The reimbursement authority, the Czech institute for Drug Control ("SUKL"), uses so-called "reference groups" to determine the reimbursement price of medicines. The drug with the lowest price in the reference group (the reference product) determines the reimbursement price for all members of the group. From its inclusion in the reference group in 2010 to 2018, Copaxone was the reference product in its group.³⁷⁶ Teva challenged the conditions of reimbursement in this reference group several times (in 2010, 2018 and 2020).

(287) In the 2010 challenge, Teva communicated in writing to SUKL, with concerns that the safety profile of Copaxone was too different from the other products for it to be included in the same reference group.³⁷⁷ Specifically, Teva claimed that {...}.³⁷⁸ Teva's challenge in 2010 was unsuccessful.

(288) In 2018, SUKL decided to replace Copaxone by the interferon Extavia as the reference product in the group. Teva successfully challenged SUKL's decision stating {...}.³⁷⁹ It follows that Teva claimed that Copaxone and interferons are not substitutable for certain patients and Teva's appeal was successful on that basis.

(289) In October 2020, Teva asked SUKL to review the reference group based on new clinical guidelines for MS therapies but its request was rejected. Teva argued that the different DMTs were not therapeutically substitutable and should be classified in separate groups due to their different tolerability profiles (side effects, pregnancy-related contraindication) and their different modes and frequency of

³⁷⁴ ID 3474, Aubagio SmPC, p. 3; ID 3468, Tecfidera SmPC, p. 2.

³⁷⁵ ID 660, Teva's reply to Article 18(2) Request of 3 June 2020, pp. 12-14.

³⁷⁶ ID 1295-45, Teva's reply to Article 18(2) Requests of 22 October and 18 November 2021, p. 12.

³⁷⁷ ID 1295-45, Teva's reply to Article 18(2) Requests of 22 October and 18 November 2021, p. 8.

³⁷⁸ ID 1295-61, Teva's reply to Article 18(2) Requests of 22 October and 18 November 2021, p. 2 (unofficial translation). Original text: {...}.

³⁷⁹ ID 1295-45, Teva's reply to Article 18(2) Requests of 22 October and 18 November 2021, p. 9.

administration.³⁸⁰ Teva quoted the new clinical guidelines, which state: “*Due to the different tolerability of DMTs (flu-like symptoms, skin reactions, hepatotoxicity rate, etc.), the frequency of administration (once in two weeks, once weekly, three times a week, every other day, daily) and the form of application (s.c. [subcutaneous injection], i.m. [intramuscular injection], p.o. [oral administration]), each individual DMT has its specific indicator status, and therefore, due to such nature of individual DMTs, their mutual substitution is not possible*” (emphasis added).³⁸¹

- (290) In its submission to SUKL, Teva further quotes the Czech Neurological Society with the statement: {...}.³⁸² Following this logic, the only therapeutically substitutable product for Copaxone can be Synthron GA.
- (291) Teva further sought to differentiate Copaxone from interferons in a 2013 submission to the Belgian Commission for authorisation of medicines (CTG). The CTG had expressed its intention to revise the reimbursement criteria for Copaxone, which prompted Teva to proactively defend the price level of Copaxone. In this submission, Teva argued, in keeping also with its statements to the Czech authorities, that Copaxone had a better tolerability profile and a better risk/efficacy ratio than the interferons.³⁸³
- (292) Teva submits that these statements were made in an effort to differentiate Copaxone from the interferons and that such actions are fully consistent with its claim that significant (non-price) competition occurred between Copaxone and non-GA first-line DMTs.³⁸⁴ Teva further submits that the statements were made in the context of the specific rules of the Czech price referencing system, which places Copaxone and interferons in the same reference group. According to Teva, this shows that the SUKL considered Copaxone and interferons as substitutable.³⁸⁵
- (293) The Commission notes that, regardless of the context of Teva’s statements towards SUKL, it is clear that Teva explicitly challenged that Copaxone and interferons are therapeutically substitutable treatments for RRMS patients due to each DMT’s different characteristics. In this regard, Teva’s statements to the SUKL are in line with the Commission’s finding that interferons (and oral DMTs) are only imperfect substitutes for Copaxone.

6.3.2.2.3. Switching patterns confirm the high degree of differentiation between first-line DMTs

- (294) Teva submits that patients often switch across DMTs and that doctors are inclined to react to patients’ requests for switching in order to improve the treatment and avoid blame for failure to take action.³⁸⁶ Teva further submits that switching evidence indicates substitutability between Copaxone and non-GA first-line DMTs.³⁸⁷ The Commission addresses this argument in step two of its analysis (Section 6.3.3), which analyses competitive interactions between Copaxone and non-GA first-line DMTs.

³⁸⁰ ID 1295-30, Teva’s reply to Article 18(2) Requests of 22 October and 18 November 2021, pp. 4-5.

³⁸¹ ID 1295-30, Teva’s reply to Article 18(2) Requests of 22 October and 18 November 2021, p. 4 (unofficial translation). Original text: {...}

³⁸² ID 1295-30, Teva’s reply to Article 18(2) Requests of 22 October and 18 November 2021, p. 5 (unofficial translation). Original text: {...}

³⁸³ ID 1295-50, Teva’s reply to Article 18(2) Requests of 22 October and 18 November 2021, p. 13.

³⁸⁴ ID 4032, Teva’s Reply to the Statement of Objections, para. 278.

³⁸⁵ ID 4032, Teva’s Reply to the Statement of Objections, paras. 282-283.

³⁸⁶ ID 660, Teva’s reply to Article 18(2) Request of 3 June 2020, p. 15.

³⁸⁷ ID 4032, Teva’s Reply to the Statement of Objections, para. 286.

- (295) The Commission’s investigation in this case shows that, when patients switch from one first-line DMT treatment regime to another, this is not because they are readily interchangeable but rather because of the high degree of differentiation between DMTs. Switches within first-line DMTs mainly occur because the current treatment is no longer effective, or is not well tolerated by the patient.³⁸⁸ A scientific paper cited by Teva in one of its internal presentations states: “*Movement from one disease-modifying therapy to another should occur only for medically appropriate reasons as determined by the treating clinician and patient*”.³⁸⁹ Some patients may switch for reasons of convenience and easier compliance with the treatment.³⁹⁰ However, convenience switches account for only a fraction of overall patients that are prescribed another DMT and there is no evidence reporting actual economic or cost-driven switches to another DMT product on the Commission’s file (with the exception of switches from an originator drug to a generic or generic-like version of that drug). The predominance of switches for “*medically appropriate reasons*” over switches for convenience indicates that MS drugs involved in the switch are often not functional substitutes for a specific patient but are chosen precisely because their therapeutic characteristics are so different that they address different patient needs.
- (296) This finding is explained by the reasons mentioned below. First, it is the responsibility of the attending physician, in discussion with the patient, to choose the appropriate treatment for a patient. In this respect, physicians will take into account patient characteristics and comorbidities, disease severity/activity, drug safety profile, effectiveness, tolerability and accessibility of the drug.³⁹¹ For patients, convenience, tolerability and effectiveness, as well as their physician’s advice, are the most important factors in the decision for a treatment.³⁹² Given that the progress, severity and specific symptoms of MS vary from one person to another and because no single optimal treatment exists, medical publications emphasise the importance of personalised treatment for MS patients.³⁹³ In the same vein, clinical guidelines in Italy state that it is “*appropriate that the therapeutic choice is the result of a weighted judgment for the individual patient on the basis of clinical-radiological elements, the safety profile of the drugs, the monitoring required and the lifestyle of the patient*”.³⁹⁴

³⁸⁸ ID 758, Teva’s reply to Article 18(2) Request of 8 January 2021, p. 7.

³⁸⁹ ID 264-180, document entitled “Die Komplexität von COPAXNONE” [sic], 28 October 2016, p. 24 (unofficial translation). Original text: “*Ein Wechsel von einem DMT auf ein anderes sollte nur erfolgen, wenn es aus Sicht des behandelnden Arztes und des Patienten aus medizinischen Gründen angemessen ist*”.

³⁹⁰ ID 660, Teva’s reply to Article 18(2) Request of 3 June 2020, pp. 15-16; ID 758, Teva’s reply to Article 18(2) Request of 8 January 2021, pp. 8-9.

³⁹¹ ID 3518, Kanavos *et al.*, “Towards Better Outcomes in Multiple Sclerosis by Addressing Policy Change: The International MultiPIE Sclerosis Study (IMPrESS)”, LSE Consulting, March 2016, p. 24.

³⁹² ID 3518, Kanavos *et al.*, “Towards Better Outcomes in Multiple Sclerosis by Addressing Policy Change: The International MultiPIE Sclerosis Study (IMPrESS)”, LSE Consulting, March 2016, p. 24.

³⁹³ ID 3517, Jonker *et al.*, “Summarizing Patient Preferences for the Competitive Landscape of Multiple Sclerosis Treatment Options”, *Medical Decision Making*, 2020, 40(2):198-211.

³⁹⁴ ID 3519, “Percorso Regionale di Diagnosi e Terapia della Sclerosi Multipla”, Version 1.1, *Regione Emilia-Romagna*, March 2011, p. 67 (unofficial translation). Original text: “*è opportuno che la scelta terapeutica sia frutto di un giudizio ponderato per il singolo paziente sulla base di elementi clinico-radiologici, del profilo di sicurezza dei farmaci, del monitoraggio richiesto e dello stile di vita del paziente*”.

(297) Second, Teva’s studies confirm that the main reasons why patients switch away from Copaxone are therapeutic ones. {...}³⁹⁵

Figure 6: {...}

{...}

Source: ID 660, Teva’s reply to Article 18(2) Request of 3 June 2020, p. 16.

(298) {...}. Teva itself classifies relapses as a medical switching reason; adverse events and efficacy perception as “*mostly medical*” reasons; and submits that pregnancies can be considered as both medical and non-medical reasons “*as it involves a patient’s lifestyle changes*”.³⁹⁶

(299) Third, treatment-stable patients, in other words patients that are doing well on the treatment that they are currently receiving, are usually not switched to a different treatment because of the risk of reducing the efficacy of the treatments and/or increasing side effects, considering the differentiation between different DMTs. Indeed, as shown in Section 6.3.2.2.1 above, non-GA first-line DMTs do not have the same safety and tolerability profiles and thus do not target the exact same patient groups. In its White Paper on “The Complexity of Copaxone”, Teva noted: {...}³⁹⁷

(300) An Ipsos Healthcare presentation from 2013 (before Synthon GA was launched) suggests that more than 50% of RRMS patients are treatment-stable (meaning that they have been on their current treatment for longer than 12 months).³⁹⁸ Only 25-29% of patients are either naïve (meaning that they have never received RRMS treatment) or have been initiated on a first-line treatment in the last 12 months. The remaining patients either discontinued their treatment or have been escalated to second- or third-line treatments. Internally, Teva used the term “*dynamic market*” to refer to patients that are not treatment stable, stating that {...}.³⁹⁹ {...},⁴⁰⁰ {...}.⁴⁰¹

(301) In light of the above, the Commission concludes that non-GA first-line DMTs are, at best, imperfect substitutes for Copaxone. While Synthon GA is therapeutically substitutable and even therapeutically equivalent with Copaxone (see Section 6.3.2.1), the non-GA first-line DMTs have different safety and tolerability profiles (while the analysis of the efficacy profiles was inconclusive). In contradiction to its submission in this investigation, Teva itself has questioned the substitutability of Copaxone and other treatments in internal documents and in statements to Member State authorities. The different DMT profiles cater to different patient needs. Due to these different (medical) needs, patients are not able to switch between Copaxone and any other DMT and most patients will be limited in the choice of alternative DMTs. In fact, treatment guidelines advise against treatment switches for non-medical reasons. {...}

³⁹⁵ ID 660, Teva’s reply to Article 18(2) Request of 3 June 2020, p. 16.

³⁹⁶ ID 758, Teva’s reply to Article 18(2) Request of 8 January 2021, pp. 9-10.

³⁹⁷ ID 455-1506, Considering the value of COPAXONE® in an era of Follow-on Glatiramer Acetate, 6 May 2016, p. 6. On treatment-stable patients, see also ID 1314, AOK NordWest’s reply to Article 18(2) Request of 15 December 2021, pp. 3, 5.

³⁹⁸ ID 263-1589, EU5 Multiple Sclerosis Monitor Q4 2013 – final report, 13 January 2014, p. 23.

³⁹⁹ ID 886-31, Global Brand Work Plan Assumptions Copaxone, June 2012, p. 22.

⁴⁰⁰ ID 886-31, Global Brand Work Plan Assumptions Copaxone, June 2012, p. 22.

⁴⁰¹ ID 263-385, MS Market Monthly Summary & Highlights, September 2013, p. 13 (see p. 8 for explanations of the terminology).

- 6.3.2.3. Second-line and third-line DMTs are not in the relevant product market for Copaxone as they are not therapeutically substitutable
- (302) Teva submits that Copaxone is not only competing with all first-line DMTs⁴⁰² but also with the second-line DMTs Gilenya, Ocrevus and Tysabri.⁴⁰³ The Commission finds that second-line DMTs are not therapeutic substitutes for Copaxone as they are destined for patients with more serious forms of RRMS. Teva does not claim that Copaxone competes with third-line DMTs.
- (303) In support of its claim about competition with second-line DMTs, Teva highlights the increased trend towards “escalation”. Originally, when a first-line DMT failed, physicians would switch patients to another first-line DMT before escalating to second-line DMTs; but “*there is now an increasing trend towards immediately escalating patients to second line treatments*”.⁴⁰⁴ Teva’s internal documents confirm that Teva was worried about an increase in treatment escalation. {...}.⁴⁰⁵
- (304) Teva concludes that, “*boundaries between first and second line have thus been blurred and there is not only competition between first line treatments but also between first line and second line treatments*”.⁴⁰⁶
- (305) Notwithstanding, the Commission finds that second-line DMTs are not therapeutic substitutes for Copaxone, as they are not destined for the same patient population.
- (306) Copaxone is used for patients with mild to moderate forms of RRMS while second-line DMTs are reserved for patients with (highly) active forms of RRMS.
- (307) This is apparent from the SmPCs of the second-line treatments (as listed in Table 1 above), including Gilenya, Ocrevus and Tysabri. Furthermore, according to their SmPCs, Ocrevus, Mavenclad and Zeposia are indicated for RRMS patients with an active or highly active disease.⁴⁰⁷ The threshold for Gilenya, Tysabri and Lemtrada is even higher. They are only indicated for patients with a highly active RRMS, who have already been treated with at least one DMT, or who have a rapidly evolving severe RRMS.⁴⁰⁸ Mayzent is only indicated for the treatment of patients with a secondary progressive MS with an active disease evidenced by relapses or imaging features of inflammatory activity.⁴⁰⁹
- (308) Accordingly, the EMA assessed Tysabri as “*a medicine for treating adults with multiple sclerosis (MS) that is not sufficiently controlled with another disease-modifying therapy or is rapidly getting worse*”⁴¹⁰ and Gilenya as a medicine that “*is used when the disease remains active despite appropriate treatment with at least one other disease-modifying therapy, or is severe and getting worse rapidly*”.⁴¹¹

⁴⁰² See Table 1 for an overview of the first-line treatments.

⁴⁰³ ID 660, Teva’s reply to Article 18(2) Request of 3 June 2020, pp. 14-15; ID 4032, Teva’s Reply to the Statement of Objections, para. 67.

⁴⁰⁴ ID 660, Teva’s reply to Article 18(2) Request of 3 June 2020, p. 15.

⁴⁰⁵ ID 644-285, EU Strategic Brand Plan, Copaxone, 23rd March 2017, p. 3.

⁴⁰⁶ ID 660, Teva’s reply to Article 18(2) Request of 3 June 2020, p. 15; see also ID 4032, Teva’s Reply to the Statement of Objections, paras. 45, 67.

⁴⁰⁷ ID 3514, Ocrevus SmPC, p. 2; ID 3512, Zeposia SmPC, p. 3.

⁴⁰⁸ ID 3513, Gilenya SmPC, p. 2; ID 3516, Tysabri SmPC, p. 2.

⁴⁰⁹ ID 3511, Mayzent SmPC, p. 3.

⁴¹⁰ ID 3515, European public assessment report (EPAR) – Tysabri, <https://www.ema.europa.eu/en/medicines/human/EPAR/tysabri>, accessed on 27 September 2022.

⁴¹¹ ID 3510, European public assessment report (EPAR) – Gilenya, <https://www.ema.europa.eu/en/medicines/human/EPAR/gilenya>, accessed on 27 September 2022.

- (309) On the other hand, Copaxone is simply “*indicated for the treatment of relapsing forms of multiple sclerosis*”.⁴¹² Neurologists prescribe Copaxone to patients with a mild to moderate form of RRMS in order to preserve the patient’s quality of life and to minimise treatment-related risks.⁴¹³
- (310) The Commission’s position takes into account that some doctors may follow a “*hit hard, hit early*” approach to treating patients with mild-moderate RRMS.⁴¹⁴ Such an approach, as laid out in Teva’s internal document cited above, consists of first using a second- or third-line DMT for a patient and then replacing it with a lighter therapy. The first- and second-line DMTs, respectively, thus remain complementary to one another. This confirms the Commission’s finding that second- and third-line DMTs are not used as long-term therapy for patients with less severe forms of RRMS and that first-line DMTs are generally used differently from second- and third-line DMTs.
- (311) The Commission’s findings are in line with the General Court’s finding in AstraZeneca that “*the fact that [certain first-line treatments] were prescribed at the start of treatment or at a later stage, according to whether a “step-down” or “step-up” approach was chosen, does not change the finding that [alternative first-line treatments] were prescribed in different situations, in the context of gradation of treatments*”,⁴¹⁵ and that “*although they were prescribed to treat the same conditions, [these alternative treatments] were used differently*”.⁴¹⁶
- (312) Based on the above, the Commission finds that second-line and third-line DMTs are not therapeutic substitutes for the same patient population as Copaxone.

6.3.2.4. Conclusion

- (313) As a result of the first step in the analysis of the relevant product market for Copaxone, the Commission finds that:
- Copaxone and Synthon GA are therapeutically substitutable and are even therapeutically equivalent;
 - Non-GA first-line DMTs (oral first-line DMTs and interferon first-line DMTs) are, at best, imperfect substitutes for Copaxone. Nevertheless, for the purposes of the assessment – in the subsequent sections – the Commission analyses the competitive constraint exercised on Copaxone by all first-line DMTs⁴¹⁷; and
 - Second-line and third-line DMTs are not therapeutic substitutes for Copaxone. They are therefore not included in the second step of the market definition assessment.

⁴¹² ID 3505, Samenvatting van de productkenmerken (SmPC) – Copaxone, p. 1 (unofficial translation). Original text: “...geïndiceerd voor de behandeling van relapsing vormen van multipele sclerose.”

⁴¹³ ID 644-199, Global Customers Insight-Multiple Sclerosis Fact Book, November 2016, p. 88.

⁴¹⁴ ID 660, Teva’s reply to Article 18(2) Request of 3 June 2020, p. 24.

⁴¹⁵ Judgment of the General Court of 1 July 2010, *AstraZeneca v Commission*, T-321/05, EU:T:2010:266, paragraph 70.

⁴¹⁶ T-321/05, *AstraZeneca AB and AstraZeneca plc v European Commission*, paragraph 72.

⁴¹⁷ Teva claims that the Commission failed to properly investigate relevant market definition in view of Teva’s position that the relevant product market comprised all first line DMTs (ID 4032, Teva’s Reply to the Statement of Objections, para. 106(d)(i)). However, considering that (i) this Decision, in line with Teva’s arguments, does not exclude other first-line DMTs as therapeutic substitutes to GA, and (ii) the assessment of whether other first-line DMTs effectively constrained Copaxone’s prices, volumes and profits (and were thus economic substitutes) could be carried out based on publicly available (IQVIA) as well as Teva’s own data, it was not necessary to gather information from suppliers of other first-line DMTs.

6.3.3. *Second step: assessing which first-line DMTs effectively constrained Copaxone in the Relevant Period*

- (314) Having established which treatments are or could be therapeutically substitutable (at least to some extent) with Copaxone, it is still necessary in a second step to verify if they actually constrain Teva's commercial strategy for Copaxone (economic substitutability). This is because even if non-GA first-line DMTs may be, to a certain extent, therapeutically substitutable with Copaxone, they may, in view of the actual market structure and the prevailing conditions of competition, nonetheless not (or no longer) represent an effective and immediate competitive constraint in the context of the conduct under investigation. This may be determined by the prevailing conditions of competition at the relevant time, such as when price competition replaces non-price competition as the main driver of demand for Copaxone.
- (315) Therefore, defining the relevant product market to which Copaxone belonged during the period in which the conduct took place (from 3 February 2015 to 7 February 2024, hereafter also referred to as the "Relevant Period") requires assessing the conditions of competition and the demand and supply structure for Copaxone at the time of the investigated practices. The aim of this assessment is to identify whether, during the Relevant Period, the first-line DMTs exercised an effective and immediate competitive constraint on Copaxone, or whether the (approaching) loss of exclusivity for Copaxone and the market entry of Synthon GA, which initiated price competition, has "[led] to a situation where the originator medicine is considered, in the professional circles concerned, to be interchangeable only with those generic medicines and, consequently, to belong to a specific market, limited exclusively to medicines which contain that active ingredient".⁴¹⁸
- (316) The Commission notes that the "*professional circles concerned*" are not limited to doctors but can also include Payers, such as national health authorities and health insurers. As Advocate General Kokott stated in her opinion on *Commission v Servier*, "*the purpose of the market definition is not to scrutinise the doctors' choices as such, but rather to analyse their implications for the scope of the competitive constraints on [an undertaking]*".⁴¹⁹ The extent to which Payers can shape the structure of demand, and influence competitive constraints on an undertaking, are detailed in Section 6.3.3.2.2 below.
- (317) Teva submits that the (approaching) entry of Synthon GA did not alter in any material way the conditions of supply and did not change how the professional circles concerned considered the substitutability between Copaxone and other DMTs.⁴²⁰ According to Teva, the relevant product market to which Copaxone belonged at the time of the investigated practices includes at least all first-line DMTs for the treatment of RRMS (meaning the interferons and the orals Tecfidera and Aubagio).
- (318) In its assessment, the Commission concludes that Synthon GA belongs to the same relevant product market as Copaxone. Having established that Synthon GA and Copaxone are not only therapeutically substitutable but also therapeutically equivalent, the Commission finds that Synthon GA introduced, for the first time, price competition to Copaxone. As a result, price became the main driver of competition, thus changing the structure of the market (Section 6.3.3.1). In this

⁴¹⁸ Case C-307/18, *Generics (UK) and Others*, paragraph 131.

⁴¹⁹ Opinion of AG Kokott of 14 July 2022, *Commission v Servier and Others*, C-176/19 P, paragraph 386.

⁴²⁰ ID 758, Teva's reply to Article 18(2) Request of 8 January 2021, p. 3.

transformed market, Synthon GA was apt to exert (or exerted) price pressure on Copaxone. Moreover, it was the only product capable of contesting the entire patient base of Copaxone.

(319) Conversely, the Commission finds that non-GA first-line DMTs did not exercise an effective and immediate constraint on Copaxone during the Relevant Period and should therefore not be included in the same relevant market. The Commission's finding is irrespective of the question whether such products may (or may not) have exercised a certain constraint on Copaxone before the Relevant Period (Section 6.3.3.2).⁴²¹

(320) The Commission further demonstrates that Teva was aware of this development and perceived the competitive threat from Synthon GA differently compared to competitive pressure from non-GA first-line DMTs (Section 6.3.3.2.4).

(321) Finally, the Commission shows for each Relevant Member State that, unlike non-GA DMTs, Synthon GA effectively and immediately constrained (or was capable of effectively and immediately constraining) Copaxone during the Relevant Period. Synthon GA caused actual changes in the structure of the relevant market, or would have been apt to introduce such actual changes had it not been for Teva's conduct to defend Copaxone's market position (Section 6.3.3.4.).

6.3.3.1. Synthon GA is in the same relevant product market as Copaxone and significantly changed the dynamics of the market

(322) The Commission has already established in Section 6.3.2.1 above that Synthon GA and Copaxone are therapeutically substitutable products. As explained above in Recital (208), therapeutic substitutability is a necessary precondition in pharmaceutical markets for the finding of economic substitutability in the sense of paragraph 12(a) of the Market Definition Notice. However, therapeutic substitutability between medicines alone is not sufficient to establish that they belong to the same relevant product market. While two medicines may be therapeutically substitutable to a certain extent, that does not necessarily mean that they are capable of exercising effective and immediate competitive constraints on each other.⁴²²

(323) The Commission reaches the conclusion that Synthon GA and Copaxone belonged to the same product market during the Relevant Period, because (i) Synthon GA is the only medicine that is therapeutically equivalent to Copaxone, (ii) Synthon GA exerted an effective and immediate competitive constraint on Copaxone even before its launch (Section 6.3.3.1.1.) and (iii) Synthon GA contests the entire Copaxone patient base and changed the market dynamics (Section 6.3.3.1.2.).

6.3.3.1.1. Synthon GA is the only medicine that is therapeutically equivalent to Copaxone

(324) As explained in Recital (258) above, Synthon GA is therapeutically equivalent to Copaxone. This means that the product characteristics of Copaxone and Synthon GA are the same, in particular the efficacy and safety (including tolerability) profiles.

⁴²¹ The Commission does not take a position on whether non-GA first-line DMTs were able to exert sufficient competitive pressure on Copaxone before the Relevant Period.

⁴²² Case C-307/18, *Generics (UK) and Others*, paragraph 129 and the case law cited; Opinion of AG Kokott of 14 July 2022, *Commission v Servier and Others*, C-176/19 P, paragraph 376; see Recitals (184) and (185).

(325) Synthon GA is the only medicine in the EEA that is therapeutically equivalent to Copaxone. While non-GA first-line DMTs could be (at least to some extent) therapeutically substitutable with Copaxone (see Recital (313)), they are not therapeutically equivalent to it.⁴²³

6.3.3.1.2. Synthon GA exerted an effective and immediate competitive constraint on Copaxone even before its launch

(326) In the earlier stages of the Relevant Period (which starts in February 2015), Copaxone was still protected by its main patent EP ‘888 and Synthon GA was yet to be launched. According to the *Generics (UK)* judgment, a medicine should be taken into account in the assessment of the market if it demonstrated “a sufficient degree of interchangeability” and actually entered the market or was “in a position to present [itself] within a short period on the market concerned with sufficient strength to constitute a serious counterbalance to the manufacturer of the originator medicine already on the market.”⁴²⁴

(327) Teva claims that Synthon GA could not have exerted competitive constraints on Copaxone before it effectively entered the Relevant Member State markets (or at the earliest at the time of the relevant MA approvals). Teva argues that the 1997 Market Definition Notice does not provide for the taking into account of potential competition when defining the relevant product market.⁴²⁵ Teva further submits that the Commission cannot rely on the Court of Justice’s findings in *Generics (UK)* concerning potential competition because Synthon GA does not fulfil the requirements for entry within a short period as set out in *Generics (UK)*.⁴²⁶

(328) Teva’s arguments are unfounded. The Commission finds that Synthon GA exerted effective and immediate competitive constraints on Copaxone already before its launch in the Relevant Member States. In that respect, expected changes in the structure of a market can be taken into account for the definition of the relevant product market.

(329) The Court of Justice has clarified in *Generics (UK)* that competition from a manufacturer of generic medicines is to be taken into account for the definition of the relevant market of the originator medicine if that manufacturer is in a position to present itself within a short period on the market concerned with a sufficient strength to constitute a serious counterbalance to the originator.⁴²⁷ The situation is applicable to that of Synthon GA and Copaxone. Synthon GA was developed as a generic alternative to the originator product Copaxone (see Recital (259)). Synthon GA was therefore designed to compete with Copaxone.

(330) In particular, and in line with the elements considered relevant in the *Generics (UK)* judgment⁴²⁸, the Commission finds that, by the start of the Relevant Period, in February 2015, Synthon GA was in a position to present itself within a short period on the market concerned with sufficient strength to constitute a serious

⁴²³ See footnote 240 concerning the distinction between therapeutic substitutability and therapeutic equivalence.

⁴²⁴ Case C-307/18, *Generics (UK) and Others*, paragraph 132.

⁴²⁵ ID 4032, Teva’s Reply to the Statement of Objections, para. 349. The reply to the Statement of Objections was submitted in February 2023, before the adoption of the 2024 Market Definition Notice in February 2024. Teva’s argument therefore refers to 1997 Market Definition Notice. Teva’s argument likewise applies to the text of paragraph 23(c) of the 2024 Market Definition Notice.

⁴²⁶ ID 4032, Teva’s Reply to the Statement of Objections, paras. 348-349.

⁴²⁷ Case C-307/18, *Generics (UK) and Others*, paragraph 133.

⁴²⁸ Case C-307/18, *Generics (UK) and Others*, paragraphs 44-46 and 134.

counterbalance to the originator. This conclusion is based on the following findings: (i) Synthon had a prior strategy for effective entry with its GA product, (ii) Synthon had taken the steps necessary to achieve effective entry by applying for and obtaining marketing authorisations, (iii) Synthon GA concluded licence contracts with third-party licensees, and (iv) there were no insurmountable entry barriers regarding intellectual property rights or other barriers to the launch of Synthon GA.

- (331) First, Synthon (through its licensees) had a strategy for effective entry of Synthon GA in each of the Relevant Member States.⁴²⁹ Synthon began developing its generic-like version of Copaxone in 2006.⁴³⁰ In 2012, a meeting with EMA took place to discuss Synthon’s proposed application for a marketing authorisation in the EU.⁴³¹ Following EMA’s feedback, Synthon conducted a study to show the therapeutic equivalence of its GA with Copaxone (“the GATE study”), which was successfully concluded in 2014.⁴³²
- (332) Second, Synthon (and/or its licensees) took the necessary steps to achieve effective entry by applying for MAs and, in Teva’s own perception, Synthon’s entry was imminent.
- (333) In the first place, Synthon applied for MAs in all EU Member States in 2014⁴³³ and expected final approvals in the Relevant Member States by the {...}.⁴³⁴ Synthon’s licensees foresaw launch dates {...} and {...} for Synthon GA in the Relevant Member States.⁴³⁵ Contrary to Teva’s claims,⁴³⁶ it is not necessary that a pharmaceutical company has already obtained the relevant MAs to find that it could present itself on a market within a short period of time. In fact, *Generics (UK)*, explicitly considers “lodging of an MA application” as an example of taking the necessary steps for market entry within a short period.⁴³⁷
- (334) In the second place, it follows from *Generics (UK)* that competition from a generic manufacturer could even be taken into account earlier than its application for an MA based on the originator’s perception: “evidence of the perception, by the manufacturer of originator medicines, of the immediacy of the threat of market entry by the manufacturers of generic medicines might also be taken into account in order to assess the significance of the competitive constraints imposed by the latter”.⁴³⁸ Internal documents show that Teva was preparing for Synthon GA’s market entry by May 2015 {...}.⁴³⁹ Already in 2011, {...} monitored the progress of trials and authorisation endeavours for Synthon GA and stated that {...}.⁴⁴⁰ Emails from {...} show that, as of 2014 at the latest, Teva closely followed Synthon’s activities leading

⁴²⁹ ID 3289, {...} Reply to Article 18(2) Request of 9 June 2021; ID 3095, {...}.

⁴³⁰ ID 2644, Synthon’s Follow-Up Submission, p. 14.

⁴³¹ ID 2644, Synthon’s Follow-Up Submission, pp. 83-85.

⁴³² ID 2493, Synthon press release, <https://www.synthon.com/press-releases/synthon-announces-successful-outcome-phase-iii-gate-study-its-generic-glatiramer-acetate>, accessed on 28 September 2022.

⁴³³ ID 2644, Synthon’s Follow-Up Submission, p. 83.

⁴³⁴ ID 2644, Synthon’s Follow-Up Submission, p. 83; see also ID 1727, {...} Reply to Article 18(2) Request of 9 June 2021, p. 6; ID 3095, {...}, p. 6.

⁴³⁵ ID 1727, {...} Reply to Article 18(2) Request of 9 June 2021, p. 7; ID 3095, {...}, p. 6.

⁴³⁶ ID 4032, Teva’s Reply to the Statement of Objections, paras. 351-352.

⁴³⁷ Case C-307/18, *Generics (UK) and Others*, paragraph 134.

⁴³⁸ Case C-307/18, *Generics (UK) and Others*, paragraph 135.

⁴³⁹ ID 455-801, CCP Kick-off Meeting, 5 November 2013, p. 9. See also Recital (120).

⁴⁴⁰ ID 455-2000, Teva internal email exchange dated November – December 2011 from {...} to {...}, p. 2.

up to the launch of Synthon GA⁴⁴¹ (see also Section 5.2.3 and Section 6.3.3.2.2). An internal email chain of meeting minutes for several meetings on “*FoGA/ Copaxone MA focus*”, sent by {...}, shows that Teva continued to closely monitor the progress of national MA approvals after approval in the Reference Member State, as well as pricing and reimbursement decisions, patent challenges and other relevant events related to the market entry of Synthon GA.⁴⁴² This evidence shows that Teva perceived the market entry of Synthon GA to be imminent.

- (335) Third, Synthon concluded supply contracts with third-party licensees for distribution in the Relevant Member States starting from {...}. For Belgium, Germany, Italy, the Netherlands and Spain, the licensee was the generics company Mylan, now part of the US-based healthcare company Viatriis. The licensee for Czechia and Poland between 2015-2020 was Alvogen. In April 2020, the Czech generic company Zentiva took over the distribution of Synthon GA from Alvogen for these two countries.
- (336) Fourth, there were no insurmountable entry barriers regarding intellectual property rights or other barriers to the launch of Synthon GA. The active ingredient for Copaxone was in the public domain since May 2015, i.e. before the projected launch dates for Synthon GA, and the only relevant patents still in force were patents for the manufacturing process and the dosing regimen of Copaxone (and their divisional patents, the filing of which is part of Teva’s abusive conduct, see Chapter 8). Synthon questioned the validity of these patents and challenged them before the EPO. As the Advocate General found in her opinion for *Generics (UK)* “*uncertainty as to the validity of patents [...] is not such as to demonstrate that [...] a generic manufacturer does not have real concrete possibilities to enter that market. That uncertainty is, on the contrary, a fundamental characteristic of competitive relationships in the pharmaceutical sector*”.⁴⁴³
- (337) In view of the above, the Commission concludes that Synthon GA exerted an effective and immediate competitive constraint on Copaxone even before its launch, and at the latest by February 2015.

6.3.3.1.3. Synthon GA was capable of entering with sufficient strength to constitute a serious counterbalance to Copaxone

- (338) The Commission finds that, absent the investigated practices, Synthon GA would have entered, and in several occasions did ultimately enter still during the Relevant Period, the relevant product market of Copaxone with sufficient strength to constitute a serious counterbalance to Copaxone. This is demonstrated by the following: (i) Synthon’s business model is the production of generic or generic-like drugs that differ from the originator product only in price, and to enter markets with a strategy of price competition; (ii) Teva perceived Synthon GA as a generic alternative to Copaxone; and (iii) Synthon GA is the only treatment that poses a competitive threat to Teva’s entire patient base.
- (339) First, in view of their therapeutic equivalence, the key differentiator between Copaxone and Synthon GA would be price, leading to strong (price) competition

⁴⁴¹ ID 262-1481, Teva internal email dated 23 October 2014 from {...} to {...}; ID 4513-55017, Teva internal email dated 7 September 2014 from {...} to {...}; ID 327, Copaxone Europe: Recent Developments and Activities, September 2014 (attachment to 4513-55017).

⁴⁴² ID 455-461, Teva internal email exchange from 9 December 2016 to 12 May 2017 from {...} to {...} and others.

⁴⁴³ Opinion of AG Kokott of 22 January 2020, *Generics (UK) and Others*, C-307/18, EU:C:2020:28, paragraph 67. See also Case C-307/18, *Generics (UK) and Others*, paragraphs 136-140.

between the two medicines. This is shown, for example, by the fact that in Italy and the Netherlands, the entry of Synthron GA was followed by an erosion of Copaxone's prices (in Italy, see 6.3.3.4.2.1) and volumes (in the Netherlands, see 6.3.3.4.2.2).

- (340) Second, Teva perceived Synthron GA as a generic alternative to Copaxone. In internal, as well as public documents, Teva referred to Synthron GA as, for example, “*generic competition*”,⁴⁴⁴ “*generic GA*”⁴⁴⁵ or “*generic Copaxone*”.⁴⁴⁶ Teva was aware of the risk that competition between Copaxone and Synthron GA could follow the model of generic competition, which means the introduction of automatic substitution (see Recital (204)) and price-based tenders. In an internal document that compares different DMTs to Copaxone it was noted that the {...}.⁴⁴⁷ The impending market entry of Synthron GA was considered a {...}⁴⁴⁸ {...} and Teva employees repeatedly {...}⁴⁴⁹ {...}.
- (341) Third, the Commission finds that Synthron GA is the only RRMS medicine that poses a competitive threat to Teva's entire patient base. Other DMTs are imperfect substitutes for Copaxone (see Section 6.3.2.4), at best, and cannot compete with Copaxone for its entire patient base.
- (342) The contestable (or in Teva's terms, “dynamic”) part of the Copaxone market open to other DMTs is limited to naïve and treatment-switching patients because (i) the choice of DMT is first and foremost driven by medical considerations, (ii) a significant share of patients is treatment-stable and unlikely to switch to a different DMT, (iii) even if switching occurs between Copaxone and non-GA DMTs, it is primarily for medical reasons, {...} (what promotional activities may be taking place aimed at portraying other non-GA DMTs as superior to Copaxone, lack relevance once GA has already been chosen as the primary treatment but a patient needs to abandon it for medical reasons, see Section 6.3.2.2.3, in particular Recitals (297)-(298)). For these reasons, (iv) promotional activities by other non-GA DMTs are primarily directed at prescriptions for new patients.
- (343) In the first place, the choice of DMT to treat RRMS patients is highly personalised and driven primarily by medical considerations as explained in Section 6.3.2. Patients are therefore unlikely to switch (i.e., be prescribed a different DMT) without compelling (usually medical) reasons.
- (344) In the second place, Copaxone and other DMTs acquire a broad patient base over time due to the chronic nature of RRMS and the need for personalised treatment. As explained in Section 6.3.2.2.3, neurologists are disinclined from switching patients who are reacting well to their treatment. This population, which accounts for the majority of RRMS patients, and thus a very high portion of overall sales of the

⁴⁴⁴ ID 263-123, Business Review Teva Germany, 24 October 2018, p. 6; ID 455-2521, Risk Management Germany Commercial, 15 September 2015, p. 6.

⁴⁴⁵ ID 741-143, Copaxone Brand Plan UK 2014-2017, April 2013, p. 5; ID 404-715, The Copaxone Life Cycle Initiative (LCI), December 2012, pp. 3, 6-7.

⁴⁴⁶ ID 834-133, Teva's reply to Article 18(2) Request of 3 June 2021, pp. 2-3.

⁴⁴⁷ ID 455-701, Regional Medical Plan: 2017-2019, 2016, p. 13.

⁴⁴⁸ ID 455-1005, internal email dated 14 August 2017 from {...} to {...} and others, pp. 1-2.

⁴⁴⁹ ID 266-25, Copaxone/FoGA – P&MA outlook, 7 June 2017, p. 4; ID 262-1695, Price competition workshop – Copaxone & Lonquex, 20-21 June 2017, p. 9; ID 455-2359, internal email dated 20 September 2018 from {...} to {...} and others, p. 4; ID 886-20, 2020 E.U. Brandplan & High level GTMAP Copaxone, p. 17; ID 886-19, 2019 EU Strategic Brand Plan Copaxone, p. 15.

product, therefore represents a rather stable customer base. {...}.⁴⁵⁰ Moreover, patients can remain on Copaxone for a long time. {...}.⁴⁵¹ These treatment-stable patients are less susceptible to switch treatment in response to promotional efforts.⁴⁵²

- (345) In the third place, switching between DMTs such as Copaxone occurs primarily for medical reasons, such as relapses, adverse events and efficacy perception (as per Teva’s classification of medical switching reasons, see Recital (298)), as demonstrated in Section 6.3.2.2.3.
- (346) In the fourth place, it follows that promotional activities, the main means of competition between different active substances (such as interferons, dimethyl fumarate, etc.), concern primarily competition for new, treatment naïve (and, to a lesser extent, treatment-switching) patients, but do not pose an immediate and significant threat to Copaxone’s base of existing patients.
- (347) On the contrary, generic competition not only contests the portion of new prescriptions, but can effectively erode the entire patient base of Copaxone (for example, because doctors may prescribe by active substance, or via more favourable reimbursement conditions that require a (lower) co-pay from the patient or via automatic substitution between the two medicines).⁴⁵³ In all Relevant Member States, there are mechanisms for the automatic substitution of originator medicines with generic alternatives. Automatic substitution rules in the Relevant Member States allow health insurers and hospitals to switch all of their patients with Copaxone prescriptions to Synthon GA, with a view of minimising costs, without requiring the approval of the relevant treating physician (see Recital (204)). Teva was aware of this and the threat of “price wars” following tenders and substitution rules (see Recitals (340), (519)-(526)). This threat materialised in six out of seven Relevant Member States, where the relevant authorities eventually decided that Synthon GA and Copaxone are considered automatically substitutable.⁴⁵⁴ In Belgium, Copaxone and Synthon GA are not considered to be automatically substitutable.⁴⁵⁵

⁴⁵⁰ {...}. See ID 644-199, Global Customers Insight-Multiple Sclerosis Fact Book, p. 28; ID 263-439, EU Strategic Brand Plan COPAXONE, p. 27; ID 886-1, Copaxone Brand Plan Europe 2014-2017, April 2013, p. 98.

⁴⁵¹ ID 266-355, Copaxone (Glatiramer Acetate) for the treatment of relapsing forms of multiple sclerosis, September 2016, p. 59. As shown in Figure 5, MS is a progressive disease that can increase the disability of MS patients over time. It is therefore not unusual that, within 20 years, a considerable number of patients would have to switch to a second-line DMT because of disease progression.

⁴⁵² See ID 262-1669, Copaxone Brand Plan & LRP 2015-2017 NL, 14 April 2014, p. 23 (including the notes): {...}

⁴⁵³ ID 262-1669, Copaxone Brand Plan & LRP 2015-2017 NL, 14 April 2014, p. 89; ID 262-1586, 2019 GTMAP Template –The Netherlands, 4 September 2018, p. 5.

⁴⁵⁴ Czechia: ID 1295-45, Teva’s reply to Article 18(2) Requests of 22 October and 18 November 2021, p. 4; Germany: ID 1255, GKV-SV’s reply to Article 18(2) Request of 15 December 2021 – Annex IV, p. 3; Italy: ID 1295-41, Teva’s reply to Article 18(2) Requests of 22 October and 18 November 2021, p. 1; Poland: ID 1295-25, Teva’s reply to Article 18(2) Requests of 22 October and 18 November 2021, p. 2; the Netherlands: ID 1295-64, Teva’s reply to Article 18(2) Requests of 22 October and 18 November 2021, p. 4; Spain: ID 1295-9, Teva’s reply to Article 18(2) Requests of 22 October and 18 November 2021, pp. 1-2.

⁴⁵⁵ The competent Belgian medicines agency FAMHP generally discourages INN prescription for biological medicinal products. The authority considers GA to be strongly related to biological drugs due to the complexity of the active substance and its immunogenic potential. See ID 1306, FAMHP’s reply to Article 18(2) Request of 16 December 2021, pp. 1-2.

- (348) As many Teva documents suggest, Teva’s actions differ depending on whether they are aimed at protecting the existing patient base or competing for new patients.⁴⁵⁶
- (349) The Commission acknowledges that competing for naïve patients is an important element of competition in pharmaceutical markets and necessary in order to grow, or at least maintain, a medicine’s patient base. However, in comparison to competition, contesting the entire patient base of a product, as is the case for generic or generic-like products, competition for naïve patients only is a significantly weaker competitive threat, if it is perceived as a threat at all. Generic or generic-like competition may also reduce incentives for an originator to invest in promotional efforts to win new patients, as the originator normally has limited means to ensure that the patients get the branded product, and not the cheaper generic or generic-like medicine (the so-called free-riding problem whereby investments by the originator manufacturer benefit also the generic offerings).
- (350) Therefore, due to the limited therapeutic substitutability of Copaxone with other DMTs, non-GA DMTs can at most contest a limited portion of prescriptions, while generic alternatives such as Synthon GA can contest the entirety of Copaxone prescriptions.
- (351) Teva claims that, while Synthon GA may be able to compete for a larger proportion of Copaxone’s patient base than each of the non-GA first-line DMTs, it is also differentiated from Copaxone and therefore cannot compete for all of the Copaxone demand.⁴⁵⁷ In support of its claim, Teva argues that (i) hybrid medicinal products are not necessarily deemed automatically substitutable with their reference product,⁴⁵⁸ (ii) where Copaxone and Synthon GA are deemed automatically substitutable, there is a portion of Copaxone prescriptions for which Synthon GA cannot be automatically substituted,⁴⁵⁹ and (iii) that the Commission has found in *Mylan/Meda* that there can be differences in demand for bioequivalent drugs⁴⁶⁰.
- (352) The Commission rejects Teva’s claims that Synthon GA cannot compete for the entirety of Copaxone’s patient base. First, the fact that Synthon GA is a hybrid product is unable to support Teva’s argument because Synthon GA was found to be therapeutically equivalent to Copaxone and there was a possibility (or from Teva’s perspective, the threat, see Recitals (519)-(526)) that Copaxone and Synthon GA would be found automatically substitutable. This threat materialised as Copaxone and Synthon GA were found to be automatically substitutable in all Relevant Member States (except in Belgium) under national rules despite Synthon GA’s status as a hybrid product.⁴⁶¹

⁴⁵⁶ See, for example, ID 262-1586, 2019 GTMAP Template –The Netherlands, 4 September 2018, pp. 3, 14; ID 263-1255, TPE Multiple Sclerosis: 2018, February 2018, p. 15; ID 263-2037, Brand Plan Copaxone – Belgium, pp. 8-12.

⁴⁵⁷ ID 4032, Teva’s Reply to the Statement of Objections, para. 326.

⁴⁵⁸ ID 4032, Teva’s Reply to the Statement of Objections, para. 321.

⁴⁵⁹ ID 4032, Teva’s Reply to the Statement of Objections, para. 323.

⁴⁶⁰ ID 4032, Teva’s Reply to the Statement of Objections, para. 325.

⁴⁶¹ Czechia: ID 1295-45, Teva’s reply to Article 18 Requests of 22 October and 18 November 2021, p. 4; Germany: ID 1255, GKV-SV’s reply to Article 18(2) Request of 15 December 2021 – Annex IV, p. 3; Italy: ID 1295-41, Teva’s reply to Article 18(2) Requests of 22 October and 18 November 2021, p. 1; Poland: ID 1295-25, Teva’s reply to Article 18(2) Requests of 22 October and 18 November 2021, p. 2; the Netherlands: ID 1295-64, Teva’s reply to Article 18(2) Requests of 22 October and 18 November 2021, p. 4; Spain: ID 1295-9, Teva’s reply to Article 18(2) Requests of 22 October and 18 November 2021, pp. 1-2.

- (353) Second, Teva argues that, in each of the Relevant Member States, there is a portion of Copaxone prescriptions which cannot be automatically substituted by Synthon GA. With this argument, Teva refers to the fact that physicians can exclude automatic substitution on the prescription. According to Teva, the fact that doctors make use of the possibility to exclude substitution of Copaxone with Synthon GA shows a lack of substitutability at least for those patients.⁴⁶²
- (354) The exclusion of substitution, while theoretically possible, is very uncommon in Czechia, Italy, Poland and Spain.⁴⁶³ The only Relevant Member States in which exclusion of automatic substitution appears to have a measurable effect on prescriptions are Germany and the Netherlands.
- (355) In Germany, doctors can exclude substitution by ticking the box “*aut idem*”⁴⁶⁴ on the prescription form. It follows from an internal Teva document from January 2019 that the quota of *aut idem* prescriptions {...}% of Copaxone sales in 2016 to {...}% by 2019.⁴⁶⁵ Teva submitted to the Commission in 2021 that, on average, circa {...} of Copaxone prescriptions in Germany exclude substitution.⁴⁶⁶ This percentage of *aut idem* prescriptions has to be seen in the context of Teva’s strategy to hinder Synthon GA’s success on the German market. Teva explicitly targeted German HCPs and Payers with an “*aut idem*” campaign, which formed part of the “Copaxone Continuation Programme” and aimed at convincing doctors to exclude substitution of Copaxone with Synthon GA.⁴⁶⁷
- (356) In the Netherlands, physicians are allowed to exclude substitution for medical reasons, and pharmacies are allowed to dispense products that are not covered by the preference policy, if it doesn’t exceed 10-15% of all prescriptions.⁴⁶⁸ The Commission therefore concludes that, if there is a part of the Copaxone demand in the Netherlands that Synthon GA cannot compete for, this would be at most 10-15% of the entire Copaxone demand. However, even this percentage has to be seen in the context of Teva’s disparagement of Synthon GA to HCPs in the Netherlands (see Section 9.4.4.5.2).
- (357) Third, as regards the Commission decision in *Mylan/Meda*, Teva relies on a sentence in that decision stating that “*there may be differences in the demand for originator versus generic drugs*”.⁴⁶⁹ As explained in Recital (218), the *Mylan/Meda* decision clarifies that such differentiation can only be considered in countries in which penetration of generics is low and the importance of the brand is higher, and not in countries which incentivise generic substitution with regulatory mechanisms. As the Commission shows in Sections 6.3.3.2.3 and 6.3.3.4, such regulatory mechanisms to

⁴⁶² ID 4032, Teva’s Reply to the Statement of Objections, para. 323.

⁴⁶³ Italy: see Recital (558); Poland: see Recital (619); Spain: see Recital (650); Czechia: ID 1295-45, Teva’s reply to Article 18(2) Requests of 22 October and 18 November 2021, pp. 2, 4. In Czechia, DMTs are prescribed in MS centres, which use the “order method” to prescribe medicines. Typically, doctors will prescribe the product which the hospital has sourced via a tender (and tenders are usually on molecule basis, meaning for GA products). In the case of the order method, substitution cannot be excluded by the doctor. While exclusion of substitution would be possible with the “receipt method”, this is not the method that is normally used in MS centres.

⁴⁶⁴ See footnote 915 for a detailed explanation of the *aut-idem* mechanism in Germany.

⁴⁶⁵ ID 264-1517, Copaxone: Performanceanalyse, January 2019, p. 12 (see Recital (1975)).

⁴⁶⁶ ID 1295-7, Teva’s Reply to Article 18(2) Requests of 22 October and 18 November 2021, p. 3 (see Recital (778)).

⁴⁶⁷ See Recital (1969).

⁴⁶⁸ See ID 1295-64, Teva’s reply to Article 18(2) Requests of 22 October and 18 November 2021, p. 2, 4.

⁴⁶⁹ Case M.7975, *Mylan/Meda*, paragraph 13.

increase generic substitution exist in all Relevant Member States and are applicable to Copaxone and Synthon GA. The differentiation referred to by Teva is thus not relevant for the purposes of this Decision. The Commission further concluded in the *Mylan/Meda* decision that the product market includes both generic and originator versions of the relevant molecule because “*the present case specifically concerns a combination of an ex-originator with a generic producer competing head-to-head in many markets*”.⁴⁷⁰ It follows that the Commission did not establish any relevant differences in demand for originator medicines and their generic versions in situations where both products compete head-to-head, as is the case with Copaxone and Synthon GA.

(358) For the abovementioned reasons, the Commission maintains its finding that Synthon GA can contest virtually the entirety of Copaxone prescriptions. The Commission finds that, during the Relevant Period, the market for Copaxone includes all GA products authorised for sale in the EEA, that is to say Copaxone and Synthon GA. In what follows, the Commission examines whether first-line DMTs other than GA also exerted an effective and immediate competitive constrain on Copaxone at the time of the investigated conduct so as to be included in the same relevant product market as Copaxone and Synthon GA.

6.3.3.2. Non-price competition from non-GA DMTs was not a significant driver of competition during the Relevant Period.

(359) The Commission understands non-price competition as essentially comprising activities to differentiate the therapeutic characteristics of a medicine from other, alternative treatments, by, for example, investing into clinical studies, and disseminating the resulting findings to HCPs. While non-price competition can effectively and immediately constrain a product in a way that is not necessarily reflected in price developments, such constraint ought to have an observable effect on a product’s volumes and/or its profitability.⁴⁷¹

(360) Teva submits that Copaxone faces strong non-price competition from non-GA DMTs. Teva submits that the market definition analysis should take into account evidence suggesting the existence of non-price competition, such as the efforts made by pharmaceutical companies to convince doctors that their drugs should be prescribed to patients, switching patterns between treatments and the intensity of promotional activities.⁴⁷²

(361) However, unlike generic-like competition on price from Synthon GA, promotion based non-price competition has not been a significant driver for competition with Copaxone during the Relevant Period. Even before the Relevant Period, when competitive constraints from non-GA DMTs were primarily based on promotional activities, these constraints did not translate into price or profitability changes and the volume changes for Copaxone were limited as a result of these promotional efforts (Section 6.3.3.2.1). The (approaching) loss of patent protection and entry of Synthon GA in the Relevant Member States changed the nature of competition not only on the supply side, but also on the demand side. It introduced price competition as the main driver of competition for Copaxone (Section 6.3.3.2.2). The loss of exclusivity for

⁴⁷⁰ Case M.7975, *Mylan/Meda*, paragraph 14.

⁴⁷¹ Effects on volumes would be indicative of (economic) substitutability, while effects on profitability would indicate that an undertaking incurred increased costs due to the increased expenditures on non-price competition for a product that would in turn erode its profit margins with that product.

⁴⁷² ID 758, Teva’s reply to Article 18(2) Request of 8 January 2021, p. 1.

Copaxone and the launch of Synthon GA led to changes in the demand structure in the relevant national health systems, which resulted in intensive price pressure for Copaxone (Section 6.3.3.2.3). Teva's claims of significant competition between Copaxone and non-GA first-line DMTs are unfounded (Section 6.3.3.2.4).

6.3.3.2.1. Already before the Relevant Period, non-GA first-line DMTs exerted only limited competitive constraints on Copaxone primarily based on non-price competition

(362) The Commission does not contest that, prior to the Relevant Period, competition may have been driven primarily by promotional efforts, i.e., by companies investing in clinical studies and a sales force to disseminate their findings to HCPs and thus differentiate their product. In order to assess the change in the nature of competition (see Section 6.3.3.2.2), the Commission also briefly examines the time before the Relevant Period, the time during which any potential competitive constraint could only stem from first-line non-GA DMTs.

(363) The Commission finds that, in the years preceding the Relevant Period, Copaxone was subject to only limited competitive constraints from first-line DMTs. National health systems exercised only very limited price pressure on Copaxone while it was patent-protected (Section 6.3.3.2.1.1). Competitive constraints for Copaxone were thus primarily of promotional nature and further limited by the fact that first-line DMTs (other than GA) are, at best, imperfect therapeutic substitutes (Section 6.3.3.2.1.2).

6.3.3.2.1.1. National health systems already exercised only very limited price pressure on Copaxone preceding the Relevant Period

(364) Even before the Relevant Period, price pressure from bodies responsible for pricing and reimbursement as well as from health insurers, (regional) tender authorities and hospitals was generally limited and Copaxone's prices in the relevant Member States were stable. The following shows that even if certain non-GA first-line DMTs may have influenced the initial price of Copaxone, this was a one-off consequence of price regulation, and did not exercise a continued and lasting constraint on Copaxone any more once the initial price was set, for example, due to review clauses to take into account competition from other DMTs that were applied to Copaxone (see Section 6.3.2.2.2 and 6.3.3.4.3.2).

(365) First, despite price benchmarking by the national health bodies with existing first-line DMTs for RRMS, initial pricing negotiations allowed Teva to maintain prices far above variable costs for Copaxone.⁴⁷³ In pricing negotiations for the launch of a new product (often referred to as "market access"), the competent bodies usually take into account the therapeutic efficacy and prices of the treatments already on the market for the same indication. Furthermore, a comparison of Copaxone's official list prices in other countries where the drug has already been launched (external reference pricing) may also be an important element in pricing negotiations.⁴⁷⁴ At launch, Copaxone was benchmarked against the prices and efficacy of the

⁴⁷³ Commission calculations based on internal data from Teva (ID 1674, Teva's reply to Article 18(2) Request of 25 April 2022), see footnote 746. See also ID 2644, Synthon's Follow-Up Submission, p. 77.

⁴⁷⁴ In Belgium, Czechia, Italy, the Netherlands and Poland, external reference pricing is common. In Spain, it can be relied on in price negotiations. In Germany, external reference pricing appears to play a smaller role.

interferons.⁴⁷⁵ It cannot be excluded that such benchmarking exercised some price pressure on Copaxone to align its launch price with the prices of interferons. However, such price pressure would have remained a singular event at Copaxone's launch and still allowed Teva to maintain Copaxone's price far above variable costs.⁴⁷⁶

- (366) Second, once its prices were set, there was virtually no price pressure throughout Copaxone's exclusivity period from non-GA DMTs. The price agreed on between Teva and the Member State authorities upon product launch was by and large not revisited for a long time period. For example, in Germany, Italy, the Netherlands, and Spain, there were no changes in the price of Copaxone between 2010 and the entry of Synthon GA⁴⁷⁷ – except for a small price increase in Germany to adjust for inflation.⁴⁷⁸ In Belgium, price decreases were only applied after Copaxone lost exclusivity⁴⁷⁹ and in Czechia, Teva successfully appealed against the SUKL's attempts to lower Copaxone's price to the level of Extavia's price by arguing that a price decrease could compromise the supply of patients that depend on treatment with GA (see Sections 6.2.2.2 and 6.3.6.4.1.).⁴⁸⁰
- (367) Pricing developments in Poland show a limited exception. There, the prices for Copaxone were renegotiated on a regular basis but the actual constraint of these negotiations on Copaxone's price before generic entry was limited and the price of Copaxone was stable until the entry of Synthon GA in Poland (see 6.3.6.2.2. below for a detailed account of price adjustments in Poland).
- (368) Third, Payers such as hospitals and health insurance companies have limited or no means to put price pressure on suppliers of patented medicines. In all of the Relevant Member States, at least one medicine of each active substance for MS treatment has to be reimbursed by health insurers and tenders have to be organised by active substance (or by brand).⁴⁸¹ As long as only one medicine of an active substance is available, this medicine has to be reimbursed, and will be the only one to compete in the relevant tenders. Until Synthon GA entered the Relevant Member State markets, Copaxone was the only medicine containing the active substance GA in the Relevant Member States and did not face competition in tenders. The tendering organisations therefore had little to no negotiation power to obtain lower prices for Copaxone. A

⁴⁷⁵ An exception was Germany, where – under the law before 2011 – Teva was free to set the price of Copaxone without negotiations. See responses to ID 1295-7, Teva's reply to Article 18(2) Requests of 22 October and 18 November 2021, p. 10.

⁴⁷⁶ For a detailed description of how Copaxone variable profit margins developed in the Relevant Member States since 2013, see Figure 31 and Table 12.

⁴⁷⁷ Germany: A mandatory {...} rebate due to the launch of a therapeutically equivalent drug (Synthon GA) was applied to Copaxone from July 2018 on, see ID 1295-7, Teva's reply to Article 18(2) Requests of 22 October and 18 November 2021, p. 6. Italy: Copaxone's price in Italy was aligned with the price of Synthon GA after it was included in the transparency list in 2019, see ID 1295-41, Teva's reply to Article 18(2) Requests of 22 October and 18 November 2021, p. 6. Netherlands: a cluster was created for Copaxone and Synthon GA in January 2018. Teva submits that the creation of this cluster did not impact Copaxone's prices, see ID 1295-55, Teva's reply to Article 18(2) Requests of 22 October and 18 November 2021, p. 6. Spain: a reference group was created for Copaxone and Synthon GA in 2017, see ID 1295-48, Teva's reply to Article 18(2) Requests of 22 October and 18 November 2021, p. 5.

⁴⁷⁸ ID 906, Teva's reply to Article 18(2) Request of 3 June 2021, p. 20.

⁴⁷⁹ ID 906, Teva's reply to Article 18(2) Request of 3 June 2021, p. 15; ID 2228, Teva's reply to Article 18(2) Request of 13 July 2022, p. 29.

⁴⁸⁰ ID 1295-45, Teva's reply to Article 18(2) Requests of 22 October and 18 November 2021, p. 8-9. Teva submits that price changes in Czechia between 2010 and 2020 were due to external reference pricing, i.e. to lower prices of Copaxone in other countries.

⁴⁸¹ See footnote 243.

health insurer in the Netherlands reports that suppliers of patented drugs “*have no incentive at all in our system to lower prices for a health insurance. They are directing their efforts to prescribers through visits, advertising etc. Only when a generic became available was there price pressure*”.⁴⁸² Similarly, a Spanish regional tender authority stated that “*where market exclusivity for medicines is concerned, the administration’s margin for ‘negotiation’ is more or less non-existent*”.⁴⁸³

(369) Fourth, doctors are generally reluctant to switch patients that are stable on their treatment to another DMT (see Recital (299)), and are unlikely to switch a patient’s treatment to save costs. Even where national systems incentivise doctors to prescribe cheaper, alternative DMTs,⁴⁸⁴ price-driven prescriptions are not common as the physicians’ decisions are based primarily on the medical needs of the specific patient.⁴⁸⁵ As concluded above in the first step of the analysis, the non-GA first-line DMTs are imperfect substitutes for Copaxone at best and in any event not therapeutically equivalent to Copaxone (see Recital (313)). Czech health insurers report that switching patients to a cheaper DMT in order to achieve savings would be an “*unnecessary and unacceptable risk for the patient’s health*”.⁴⁸⁶ Similarly, an Italian regional tender authority submits that “*these are medicinal products with indications which are not always exactly overlapping and any therapeutic switch would be at the discretion of the prescriber*”.⁴⁸⁷

6.3.3.2.1.2. Non-price constraints from non-GA first-line DMTs were further limited because non-GA first-line DMTs are only imperfect therapeutic substitutes for GA

(370) During the time when Teva enjoyed market exclusivity and Copaxone faced little to no price competition, the main source of competition was promotional activity from companies marketing non-GA first-line DMTs, with a view to present their benefits and differentiate them from, inter alia, Copaxone. Teva’s internal documents suggest that such activities from other companies could comprise post-approval scientific studies and the dissemination of medical and other information to key opinion

⁴⁸² ID 3625, Menzis’ Reply to Article 18(2) Request of 15 December 2021, p. 3-4 (unofficial translation). Original text: “*hebben geen enkele prikkel in ons systeem om hun prijs te verlagen voor een zorgverzekeraar zodat hun geneesmiddel meer wordt voorgeschreven. Ze richten zich middels bezoek, reclame etc. wel op de voorschrijvers. Pas toen er een generiek beschikbaar kwam, was er prijsdruk.*”

⁴⁸³ ID 3624, Region of Asturias’ Reply to Article 18(2) Request of 15 December 2021, p. 4 (unofficial translation). Original text: “*cuando nos encontramos en un régimen de exclusividad en el consumo de un medicamento el margen de “negociación” de la administración es más bien inexistente*”.

⁴⁸⁴ This is the case in Belgium, Germany and the Netherlands, see ID 1288, Teva’s Reply to Article 18(2) Requests of 22 October and 18 November 2021, pp. 1-2; ID 1295-7, Teva’s Reply to Article 18(2) Requests of 22 October and 18 November 2021, pp. 1-2; ID 2438, Minutes of DG COMP’s call with VGZ, p. 2; ID 1295-55, Teva’s Reply to Article 18(2) Requests of 22 October and 18 November 2021, p. 1.

⁴⁸⁵ This confirms the findings from the Commission’s market investigation in the *Teva/Barr* case, where hospitals stated that in particular for serious illnesses, they would not consider switching from drugs based on one molecule to drugs based on another, even if the price for the molecule would increase significantly (Case M.5295, *Teva/Barr*, paragraph 17).

⁴⁸⁶ ID 1338, Zaměstnanecká pojišťovna Škoda’s Reply to Article 18(2) Request of 15 December 2021, p. 2; ID 1276, Vojenska Zdravotni Pojistovna’s Reply to Article 18(2) Request of 15 December 2021, p. 2; ID 1303, RBP Zdravotni Pojistovna’s Reply to Article 18(2) Request of 15 December 2021, p. 2; ID 1155, Oborová zdravotní pojišťovna zaměstnanců bank’s Reply to Article 18(2) Request of 15 December 2021, p. 3.

⁴⁸⁷ ID 1324, Regione Campania’s Reply to Article 18(2) Request of 15 December 2021, p. 3 (unofficial translation). Original text: “*trattasi di specialità medicinali con indicazioni non sempre esattamente sovrapponibili e l’eventuale switch terapeutico sarebbe a discrezione del prescrittore*”.

leaders, health care professionals and patients in order to inform them about the advantages of a DMT concerning inter alia its efficacy, safety and tolerability.⁴⁸⁸

- (371) These promotional activities had two types of effects. On the one hand, they contributed to growing the overall pool of patients that receive first-line DMTs by, for example, addressing previously unmet medical needs and advances in diagnosing⁴⁸⁹ (market expansion). On the other hand, they were also a form of non-price competition between different first-line DMTs, which however was limited in scope and intensity already before the Relevant Period for the following reasons.
- (372) First, non-GA first-line DMTs may be considered as potentially therapeutically substitutable with Copaxone in general – in the sense that they are all suitable as potential first-line RRMS treatments. But unlike Synthron GA (see Section 6.3.2.1.), they are not therapeutically equivalent to Copaxone and are therefore not considered to be fully interchangeable with Copaxone in professional circles.⁴⁹⁰ Due to the heterogeneity of patients’ medical needs and individual situations, not all treatments are therapeutically suitable for every single patient. Non-GA first-line DMTs do not compete for all RRMS patients but only for naïve patients and patients that change their treatment (as explained in Section 6.3.2.2.3). The majority of patients at any given point in time are not part of the contestable market because they are doing well on their treatment. This is confirmed by Teva’s “EU Strategic Plan for Copaxone”, which states under the title {...}.⁴⁹¹
- (373) Second, in cases of treatment switches for medical reasons, no commercial activity or promotion could convince a doctor or a patient to initiate or maintain a treatment that is ineffective, unsafe and/or intolerable for the patient. If switching patients are nonetheless eligible for treatment by a number of different DMTs, due to, for example, comparable efficacy but different side effect profiles, a situation of promotion-based competition could arise.
- (374) Therefore, to the extent that Copaxone faced any competitive constraints before the Relevant Period, those were limited to promotional efforts aimed at differentiating Copaxone from non-GA first-line DMTs in the eyes of doctors and patients. In principle, where a medicine enjoys prices high above variable costs and corresponding high and stable margins, a price inelastic demand, and a broad base of prescribers and treatment-stable patients, this could in itself be an indication that the product faces limited competitive constraints and can consequently operate to a large extent independently of other medicines. In any event, this Decision does not draw any conclusions concerning the relevant product market for Copaxone or Teva’s market position for the period preceding the Relevant Period.
- (375) Teva claims that differentiation between Copaxone and non-GA first-line DMTs does not suggest that the treatments belong to separate relevant markets (neither before nor during the Relevant Period).⁴⁹² In support of this claim, Teva submits that

⁴⁸⁸ ID 644-461, Copaxone EU Strategic Brand Plan – March 29, 2016, pp. 14-16, ID 644-343, Copaxone 3 x weekly launch tracker – Germany – post-launch W2, JN 260121698-3 – Updated 4th October 2016, pp. 18, 52.

⁴⁸⁹ See ID 906, Teva’s Reply to Article 18(2) Request of 3 June 2021, pp. 1-3.

⁴⁹⁰ ID 1279, VDEK’s Reply to Article 18(2) Request of 15 December 2021, p. 8; ID 1324, Regione Campania’s Reply to Article 18(2) Request of 15 December 2021, p. 2; ID 2441, Regione Siciliana’s Reply to Article 18(2) Request of 15 December 2021, p. 3.

⁴⁹¹ ID 741-25, EU Strategic Brand Plan Copaxone – Approved and Launched Relapsing forms of MS, p. 12.

⁴⁹² ID 4032, Teva’s Reply to the Statement of Objections, para. 266.

(i) evidence suggests that physicians consider first-line DMTs as substitutable, (ii) Teva's efforts to differentiate Copaxone from non-GA first-line DMTs is direct evidence of competition, (iii) switching evidence indicates competition between Copaxone and non-GA first-line DMTs and (iv) rivals do not need to be able to compete for the entirety of each other's demand to form part of the same relevant market.

- (376) The Commission rejects Teva's claims. As Teva's claims concern alleged competition between Copaxone and non-GA first-line DMTs per se, the below references do not only refer to the competitive environment of Copaxone before the Relevant Period but also during the Relevant Period.
- (377) First, Teva submits that evidence suggests that doctors consider first-line DMTs as substitutable.⁴⁹³ According to Teva, the "*key question is thus whether doctors consider the various first-line DMTs as interchangeable*"⁴⁹⁴. Teva also points to evidence from internal documents which supposedly show the competitive threat from non-GA first-line DMTs and sales and marketing efforts to convince physicians to prescribe Copaxone.⁴⁹⁵
- (378) In its argumentation, Teva uses the terms (economic) substitutability and interchangeability to refer to therapeutic substitutability, implying that these terms have the same meaning. This is not correct. The terms "substitutability" and "interchangeability", as used in the Market Definition Notice,⁴⁹⁶ have to be distinguished from the term "therapeutic substitutability". As explained above (see footnote 240), medicines are considered therapeutically substitutable if they have the same therapeutic indication (here: first-line DMTs for RRMS).
- (379) In the competition law sense, therapeutic substitutability is in itself not a sufficient condition to find that medicines belong to the same relevant product market. Whether physicians consider Copaxone and non-GA first-line DMTs as therapeutically substitutable is a pre-requisite for even considering whether these substances are substitutes, in the sense of the Market Definition Notice. But it is only a first step of the assessment which needs to also consider the wider therapeutic and economic context.
- (380) As explained in Recital (186), such further assessment requires a determination whether, from an economic point of view, the products are in fact substitutable. This can comprise an assessment of the degree to which medicines are considered, in the professional circles concerned, to be substitutable (see Recital (315)). AG Kokott's opinion in *Servier* clarifies that "*the professional circles concerned*" are not necessarily limited to doctors, by stating that "*the purpose of the market definition is not to scrutinise the doctors' choices as such, but rather to analyse their implications for the scope of the competitive constraints on [an undertaking]*".⁴⁹⁷ Payers can shape the structure of demand and influence the competitive constraints exercised on an undertaking in a significant manner. Therefore, Payers' perception of the degree of substitutability of first-line DMTs, and their ability to influence the demand for Copaxone, have to be taken into account as well.

⁴⁹³ ID 4032, Teva's Reply to the Statement of Objections, para. 276.

⁴⁹⁴ ID 4032, Teva's Reply to the Statement of Objections, para. 270.

⁴⁹⁵ ID 4032, Teva's Reply to the Statement of Objections, para. 273.

⁴⁹⁶ Market Definition Notice, para. 12(a).

⁴⁹⁷ Opinion of AG Kokott, *Commission v Servier and Others*, C 176/19 P, paragraph 386.

- (381) In that respect, it is important to distinguish therapeutic substitutability from therapeutic equivalence. To be considered therapeutically equivalent, medicines need to have the same clinical effect (efficacy) and safety profile when administered to patients. Therapeutically substitutable medicines can have different active ingredients, different modes of actions and different modes of administration (resulting in different efficacy, safety and tolerability profiles). It follows that the degree to which medicines are economically substitutable or interchangeable is higher for therapeutically equivalent medicines than for therapeutically substitutable medicines.
- (382) Teva argues that the Commission decisions *Mylan/Abbott* and *Mylan/Meda* support its position that the relevant market should include all first-line DMTs for the treatment of RRMS.⁴⁹⁸ As explained above in Recital (216), the Commission stated in past decisions – including *Mylan/Meda* and *Mylan/Abbott* – that the relevant market for a pharmaceutical product can include medicines of different active ingredients (even though, after the launch of a generic alternative, the relevant product market would usually be considered at the level of the active substance of the genericised medicine). However, even under that scenario, medicines of different active ingredients are usually considered to be part of the same relevant product market only if they have similar safety, efficacy and tolerability profiles. The findings in Section 6.3.2.2.1 show that the first-line DMTs differ in their combined safety, efficacy and tolerability profiles, so that they are only imperfect therapeutic substitutes. Further, contrary to Synthon GA, non-GA first-line DMTs are not therapeutically equivalent to Copaxone. Similarly, in *Mylan/Abbott*, the Commission found that medicines of different active ingredients can be in the same market, while at the same time stating that for some of the medicines, “*the market investigation provided clear indications that the markets are limited to the molecule based on the specificities of those molecules pointing to the lack of alternatives providing therapeutically equal outcome*”.⁴⁹⁹ The Commission’s approach in this Decision does therefore not contradict its findings in past decisions. While it is not *per se* excluded that differentiated medicines compete in the same market, it is the Commission’s standard practice to consider differences in the safety, efficacy and tolerability profiles as a key factor when assessing the relevant product market for medicines (see Section 6.2.4). In any event, the Commission is not bound to apply the definition of a relevant market from its past decisions.⁵⁰⁰
- (383) Second, Teva claims that evidence from internal documents shows the competitive threat from non-GA first-line DMTs and Teva’s sales and marketing efforts to convince physicians to prescribe Copaxone.⁵⁰¹ The Commission notes that the evidence submitted by Teva only shows that Teva engaged in promotional activities for Copaxone, whereas the claim that the entirety of those activities can be attributed to competitive rivalry between Copaxone and non-GA first-line DMTs is unfounded (see Recital (474)). As shown in Section 6.3.3.3.1 below, Teva’s concerns over competition from Synthon GA dwarfed any concern over competition from non-GA first-line DMTs in the period before the Relevant Period as well as during it.
- (384) Furthermore, the Commission notes that any purported competition between Copaxone and non-GA first-line DMTs did not effectively constrain Teva’s volumes,

⁴⁹⁸ ID 4032, Teva’s Reply to the Statement of Objections, para. 275(c).

⁴⁹⁹ Case M.7379, *Mylan/Abbott*, paragraph 35.

⁵⁰⁰ Market Definition Notice, para. 14 and the case-law cited.

⁵⁰¹ ID 4032, Teva’s Reply to the Statement of Objections, para. 260.

prices and profits (which are the relevant metrics to assess economic substitutability, see Recital (186)), as the Commission shows in the specific country-by-country assessment in Section 6.3.3.4. As explained above, differences in safety, efficacy and tolerability usually indicate that medicines do not have similar therapeutic effects, thereby indicating that they belong to different markets.

- (385) Third, concerning Teva’s argument that switching evidence indicates competition between Copaxone and no-GA first-line DMTs,⁵⁰² the Commission does not deny that switching does happen. Also, the Commission does not contest that the entry of orals may have had some (minor) impact on Copaxone’s sales. This minor impact is, however, dwarfed by the significant impact on Copaxone’s sales volumes, prices and profits that can be observed following the entry of Synthron GA. While patients do on occasions switch from one treatment regime to another, such switches mainly occur “for medically appropriate reasons” because the initial treatment is no longer effective or not well tolerated by the patient, rather than due to promotional efforts of competing first-line DMTs (see Recital (295)).
- (386) The data submitted by Teva⁵⁰³ only prove that switches take place (which is undisputed) but does not provide additional information on the frequency of switches or whether they were driven by non-price competition, for example in reaction to a promotional campaign, or rather due to (unavoidable) medical reasons, which means that they would have happened regardless of any promotional efforts and do not demonstrate the existence of competition. The data (for which some explanation has been provided)⁵⁰⁴ show that Copaxone patients that had to switch treatment for medical reasons had indeed to switch to a non-GA treatment.
- (387) At any rate, the study submitted by Teva is based on only 120 Copaxone patients (over a span of seven years; 2013-2017) and does not answer the question of how often such switches happen, and in particular, how likely they are to take place due to competition rather than medical reasons (which, as discussed, is the main reason patients may switch a treatment regime). They are therefore not particularly informative as to the relevance of the competitive constraints of non-price competition exercised by non-GA first-line DMTs on Copaxone.⁵⁰⁵
- (388) Fourth and last, concerning Teva’s argument that rivals do not need to be able to compete for the entirety of each other’s demand to form part of the same relevant market,⁵⁰⁶ it should be noted that Teva does not contest the Commission’s finding that only 25-29% of RRMS patients are “contestable” to non-GA first-line DMTs because they are naïve patients or have started treatment within the last 12 months.

⁵⁰² ID 4032, Teva’s Reply to the Statement of Objections, paras. 286-287.

⁵⁰³ ID 660, Teva’s Reply to Article 18(2) Request of 3 June 2020, p. 17, Figure 4 (for the underlying data, see: ID 644-355, Teva’s reply to Article 18(2) Request of 3 June 2020, Annex Q75); ID 4032, Teva’s Reply to the Statement of Objections, paras. 287-288; ID 4049; Teva’s Reply to the Statement of Objections, Annex 4.17; ID 4050, Teva’s Reply to the Statement of Objections, Annex 4.18; ID 4051, Teva’s Reply to the Statement of Objections, Annex 4.19; ID 4052, Teva’s Reply to the Statement of Objections, Annex 4.20.

⁵⁰⁴ The data analyses {...}, see ID 644-355, Teva’s reply to Article 18(2) Request of 3 June 2020, Annex Q75.

⁵⁰⁵ Teva submitted additional switching data in its reply to the Statement of Objections (ID 4049, ID 4050, ID 4051, ID 4052). Teva does not provide explanations on how this data supports its claim, and the Commission finds that this data merely shows that switching does take place. It does not provide information on how often such switches happen or on how likely they are to take place due to competition rather than medical reasons.

⁵⁰⁶ ID 4032, Teva’s Reply to the Statement of Objections, para. 267(d).

The Commission maintains its position that the fact that only Synthron GA can contest the entire Copaxone demand demonstrates the shift in market dynamics. Internal documents suggest that {...} (see Recital (300)). With the approaching entry of Synthron GA, this profitable patient base was under threat.

- (389) In support of its claim, Teva argues that “*the nature of non-price competition in this market means that Teva is unable to vary its non-price offering by patient, and hence is unable to discriminate as between the 25-29% of its demand [...] (i.e., the so-called contestable demand) and the rest of its demand*”.⁵⁰⁷ This statement is contradicted by Teva’s internal documents, which show that {...}.⁵⁰⁸

Figure 7: {...}

{...}

Source: ID 4835, GTMAP MS 2017 Italy, 15 September 2016, p. 2.

- (390) Teva claims that, even if such a differentiation was possible, there would be “*forms of non-price competition*” in which differentiation between groups of patients is not possible. The examples that Teva mentions are investments into patient support, into the launch of the 40 mg dosage, and into the pregnancy and breastfeeding label change.⁵⁰⁹ These examples, however, are not convincing. As explained above in Section 5.2.3.1, the launch of the 40 mg dosage was part of Teva’s strategy to artificially prolong the exclusivity of Copaxone (see also Section 6.3.3.2.4.3.1). Concerning the pregnancy and breastfeeding label change, there are no indications that Teva differentiated its promotional efforts in this regard, but internal documents show {...} (see Recital (422) and Section 6.3.3.2.4.3.2). As regards Teva’s investments into patient support, it follows from internal documents and from Teva’s own submission in Teva’s Reply to the Statement of Objections that Teva’s investments in Copaxone’s patient-support programme (PSP) were at least partly motivated by competition with Synthron GA and not, as Teva claims, solely to compete with non-GA DMTs (see Recital (481)). Teva’s examples of alleged non-price competition in which differentiation between groups of patients is not possible are therefore not apt to show “*significant non-price competition with other first-line DMTs*”⁵¹⁰ because either they are not an example of competitive efforts targeted at competition with non-GA first-line DMTs (launch of the 40 mg dosage), they are examples of competitive efforts that were de-prioritized in favour of Teva’s CCP campaign against Synthron GA (pregnancy and breastfeeding label change) or they are an example of competitive efforts that were at least partly motivated by competition with Synthron GA.
- (391) Teva further argues that patients would have at least been contestable when first diagnosed (when they were treatment-naïve patients).⁵¹¹ The Commission

⁵⁰⁷ ID 4032, Teva’s Reply to the Statement of Objections, para. 300. Teva further claims in its Reply to the Letter of Facts I of 9 February 2024 (ID 5695, para. 131) that “[p]romotional efforts to doctors are therefore aimed at impacting doctors’ prescribing choices for both existing and potential new Copaxone patients. As such, the differentiation that the [Commission] seeks to highlight is simply not relevant to the issue of market definition”. The Commission notes that Teva’s internal documents cited in Recital (389) and Figure 7 do not support this claim.

⁵⁰⁸ ID 4835, GTMAP MS 2017 Italy, 15 September 2016, p. 2; ID 4823, 2019 GTMAP Template – Germany, 11 September 2018, p. 5; ID 4850, 2022 GTMAP Poland, 8 December 2021, pp. 13-14. See also Recital (372) and footnote 491.

⁵⁰⁹ ID 5695, Teva’s Reply to the Letter of Facts I of 9 February 2024, para. 131.

⁵¹⁰ ID 4032, Teva’s Reply to the Statement of Objections, para. 183.

⁵¹¹ ID 4032, Teva’s Reply to the Statement of Objections, para. 301.

acknowledges that there may be an element of (non-price) competition in convincing doctors and patients to choose the treatment for a first-time patient. However, this can only be limited competition because (i) not every first-line DMT fits for every patient and (ii) the potential constraint from this competition is much smaller than the constraint from Synthon GA, which can contest the entire Copaxone demand.

- (392) Teva also alleges that the Commission has, in recent merger decisions, defined relevant product markets in which rivals products cannot contest the entirety of one another's prospective customer bases (inter alia, *Mylan/Meda*).⁵¹² As explained above in Recitals (216) and (382), the Commission's market definition in the *Mylan/Meda* case is based on the finding that the two relevant medicines are closely substitutable (similar efficacy and comparable side effects and contraindications). While the decision finds that it is "*possible to use [the relevant medicines] interchangeably at the very least for new patients*"⁵¹³, the next paragraph of the decision finds that there are indications that the two products are also substitutable for patients already on the treatment.⁵¹⁴
- (393) The Commission therefore rejects Teva's claim that differentiation between Copaxone and non-GA DMTs is not relevant for the analysis of competitive constraints.
- (394) The Commission maintains its finding that non-price constraints from non-GA first-line DMTs were already limited before the Relevant Period because the treatments are only imperfect therapeutic substitutes for GA.

6.3.3.2.2. The prospect of generic-like entry has changed the nature of competition for Copaxone

- (395) The Commission finds that a change in the relevant product market for Copaxone occurred with the approaching loss of exclusivity and the prospect of entry of Synthon GA in the EEA. This change had occurred by the time that Teva commenced its abusive conduct assessed in Chapters 8 and 9 of this Decision, i.e. by February 2015. As explained in Section 6.2.2, the prospect of generic or generic-like competition may exercise an effective and immediate constraint on an originator product facing loss of exclusivity before it actually occurs.
- (396) On the demand side of the market, the health systems in the Relevant Member States have established processes to take the necessary steps to encourage the use of generic medicines as soon as these are available. The same processes were in place when Synthon GA entered the Relevant Member States. Therefore, the health systems in the Relevant Member States were ready for the entry of a competing generic-like GA and additional specific steps to prepare for a change in the demand dynamics were not necessary as regards Copaxone (see Recital (204)).
- (397) On the supply side of the market, Teva started preparing for potential competition from generic-like GA as early as 2004 by starting a "Copaxone Life Cycle Initiative" with the aim to artificially differentiate Copaxone from competing GA (see Section 5.2.2). An email exchange from late 2011 shows that Teva's management monitored the progress of trials and authorisation endeavours for Synthon GA because the launch of a generic GA was considered {...}.⁵¹⁵ {...}.⁵¹⁶ This defence strategy for

⁵¹² ID 4032, Teva's Reply to the Statement of Objections, para. 302.

⁵¹³ Case M.7975, *Mylan/Meda*, paragraph 48.

⁵¹⁴ Case M.7975, *Mylan/Meda*, paragraph 49.

⁵¹⁵ ID 455-2000, Teva internal email exchange dated November – December 2011 from {...} to {...}, p. 2.

Copaxone developed into the CCP, the Copaxone Continuation Project (see Section 5.2).

- (398) As part of the CCP, the so-called “Copaxone Continuation Taskforce” met for a “kick-off meeting” in Teva’s European headquarters in November 2013. The aim of the taskforce was to {...}.⁵¹⁷ {...}.⁵¹⁸
- (399) Teva’s Brand Plans for Copaxone further confirm that Teva’s commercial strategy already considered the “*lifecycle management*” of Copaxone several years before the actual entry.⁵¹⁹ In a 2012 analysis of Copaxone’s strengths, weaknesses, opportunities and threats, Teva notes {...}. The launch of Copaxone 40 mg, an action aimed at defending Copaxone from competition from competing GA, is mentioned {...}.⁵²⁰
- (400) Already from 2013 onwards, Teva’s internal documents show a clear awareness of the competitive threat of competing GA. In March 2013, the Copaxone “Brand Team” had a meeting to discuss {...}.⁵²¹ {...}, even though the first-line DMTs Plegridy, Tecfidera and Aubagio were to be launched in the Relevant Member States shortly and before Synthron GA (Aubagio was first launched in the EEA in August 2013 and the first launches of Tecfidera and Plegridy in the EEA were in 2014, see Table 1). In a “Strategic Brand Plan Europe” dated March 2015, the switch to Copaxone 40 mg is described as {...}.⁵²² {...} (despite the launch of Aubagio, Tecfidera and Plegridy in some of Copaxone’s biggest EEA markets in late 2014 and early 2015⁵²³).
- (401) Emails from Teva’s {...} to Teva’s higher management show that, as of 2014 at the latest, {...}.⁵²⁴ In an email from September 2014, Teva’s {...} and {...} shared a document titled “*Copaxone Europe: Recent Developments and* {...}.⁵²⁵ {...}.⁵²⁶ The document does not mention any non-GA DMTs and the Commission is not aware of any similar {...} concerning non-GA DMTs.
- (402) A 2014 country Brand Plan for Spain shows that already in 2014 a local team changed its competitive focus from competition on promotion to price competition.

⁵¹⁶ ID 455-1784, internal email dated 24 June 2012 from {...} to {...} and others, p. 1; See also Recital (119).

⁵¹⁷ ID 455-801, CCP Kick-off Meeting, 5 November 2013, p. 9. See also Recital (120).

⁵¹⁸ As explained in Section 5.2.3.1, the main purpose of the switch from Copaxone 20 mg to Copaxone 40 mg was to evade competition from potential generic-like competition for Copaxone 20 mg and especially to avoid automatic substitution with any 20 mg competing GA.

⁵¹⁹ In June 2020, the Commission issued an Article 18(2) request to Teva to, inter alia, submit Copaxone Brand Plans for Europe and for each of the Relevant Member States for each year of the period 2010-2020. In its response, Teva explained that the earliest available documents dated from 2012 onwards and did not submit documents for 2010-2011, see ID 906, Teva’s reply to Article 18(2) Request of 3 June 2021, p. 8.

⁵²⁰ ID 886-31, Global Brand Work Plan Assumptions Copaxone, June 2012, p. 11.

⁵²¹ ID 455-2, Global Strategic Brand Plan Assumptions – COPAXONE 2014-2017, Amsterdam BT March 5 2013, 3 March 2013, p. 3.

⁵²² ID 886-27, Strategic Brand Plan Europe 2016-2019, March 2015, p. 11 and Section 5.2.3.1.

⁵²³ For example, Aubagio and Tecfidera were launched in Italy in the second half of 2014 and Plegridy was launched in 2015, see Figure 13. In Spain, Aubagio was launched in late 2014 and Tecfidera and Plegridy were launched in 2015, see Figure 19.

⁵²⁴ ID 262-1481, Teva internal email dated 23 October 2014 from {...} to {...} and others; ID 4513-55017, Teva internal email dated 7 September 2014 from {...} to {...} and others; ID 327, Copaxone Europe: Recent Developments and Activities, September 2014 (attachment to ID 4513-55017).

⁵²⁵ ID 4513-55017, Teva internal email dated 7 September 2014 from {...} to {...} and others, p. 1.

⁵²⁶ ID 327, Copaxone Europe: Recent Developments and Activities, September 2014.

In the local Brand Plan, the Spanish Copaxone team explains that {...}.⁵²⁷ It follows from a 2018 internal document from Teva Netherlands that {...}.⁵²⁸ {...}.

- (403) Teva claims that Synthon GA could not have exercised a competitive constraint on Copaxone before it obtained MAs in the Relevant Member States because Synthon GA could not legally be sold in the Relevant Member States without national MAs. The national MAs were granted in May/June 2016 and January 2017.⁵²⁹
- (404) The Commission rejects Teva’s claim for the reasons set out below.
- (405) First, it is recognised by the Court of Justice that a medicine can exert competitive pressure already before its launch and even before it has an MA (see Recitals (329), (333)-(334)).
- (406) Second, the Commission has shown above in Recitals (397)-(402) that, by February 2015, the competitive constraint from approaching loss of exclusivity and Synthon GA’s entry, and the ensuing prospect of price competition, had become the predominant driver of competition for Copaxone.
- (407) Third, the Commission notes that legal challenges to Synthon’s process for obtaining MAs were part of Teva’s CCP strategy (see footnote 116 and Section 5.2.3.4). {...}.⁵³⁰ {...}.⁵³¹ Teva’s perceived need to delay Synthon GA and the costs and efforts attributed to these legal challenges to the MAs are in themselves evidence of the competitive constraint Synthon GA already exercised.
- (408) Internal Teva documents support the finding that Teva engaged in various efforts related to MA approvals for Synthon GA, which shows that Teva perceived the threat of Synthon GA’s market entry as imminent already before its effective MA grant. As part of the “Copaxone Life Cycle Initiative”, Teva communicated to regulators about the “complexity” of Copaxone. When several authorities, including EMA, indicated that they would require clinical trials for the approval of a generic GA product, {...}.⁵³² Teva also intervened in the MA process for Synthon GA, resulting in a clock-stop for Synthon GA’s MA,⁵³³ which was in place for one year.⁵³⁴ {...}.⁵³⁵
- (409) The Commission finds that Teva’s extensive efforts to challenge or delay Synthon GA’s MA approvals, including a “*substantial*”⁵³⁶ spend on legal activities, show that Teva perceived Synthon GA’s market entry as an imminent threat already well

⁵²⁷ ID 455-1003, LRP and Brand plan Copaxone review Spain, 25 April 2014, p. 6.

⁵²⁸ ID 262-1284, Memo from Teva NL’s management to the Works Council, 23 January 2018, p. 11.

⁵²⁹ ID 4032, Teva’s Reply to the Statement of Objections, para. 352(b). The national MAs were approved in May 2016 for Belgium, Czechia, Germany, the Netherlands and Spain, in June 2016 for Poland and in January 2017 in Italy.

⁵³⁰ ID 455-38, Copaxone/FoGA Overview, 7 February 2017, pp. 3, 10. See also: ID 404-1599, Teva internal email dated 15 December 2015 from {...} to {...} and others concerning “Fwd: Privileged & Confidential – FOGA Update”; ID 455-2844, Teva internal email exchange between {...} and others dated 2-3 January 2017 concerning “RE_Copaxone figures”.

⁵³¹ ID 455-38, Copaxone/FoGA Overview, 7 February 2017, p. 11.

⁵³² ID 404-715, The Copaxone Life Cycle Initiative (LCI), December 2012, pp. 4-6, 13, 18-26. Communications directed at EMA and the Relevant Member States started as of October 2009.

⁵³³ ID 404-1943, Teva internal email exchange dated 8-16 December 2014 from {...} to {...} and others.

⁵³⁴ ID 404-1599, Teva internal email dated 15 December 2015 from {...} to {...} and others concerning “Fwd: Privileged & Confidential – FOGA Update”.

⁵³⁵ ID 455-2844, Teva internal email exchange between {...} and others dated 2-3 January 2017 concerning “RE_Copaxone figures”, p. 1.

⁵³⁶ ID 455-2844, Teva internal email exchange between {...} and others dated 2-3 January 2017 concerning “RE_Copaxone figures”, p. 4.

before the national MA grants in the Relevant Member States in May/June 2016 and January 2017.

(410) From the above, the Commission finds that by February 2015 (the start of the Relevant Period) the competitive constraint from the approaching loss of exclusivity of Copaxone and Synthon GA's entry, and the ensuing prospect of price competition, had become the predominant driver of competition.

6.3.3.2.3. With the (approaching) loss of exclusivity, markets for Copaxone are driven by price competition with Synthon GA and no longer by non-price competition with non-GA first-line DMTs

(411) With the loss of exclusivity, originator medicines are normally exposed to strong price pressure in all Relevant Member States due to a wide array of measures designed to stimulate price competition, such as (i) legally mandated price decreases; (ii) tenders for medicines with the same active substance organised by health insurers and hospitals; (iii) rules mandating automatic substitution for generic or generic-like products; (iv) the combination of tenders and automatic substitution rules affecting the entire patient base for a medicine; and (v) external reference pricing. In contrast, (vi) promotional efforts are losing their relevance for effective competition, consistent with the findings in the *Teva/Allergan* decision from 2016.⁵³⁷ These points are discussed in what follows.

(412) First, the loss of exclusivity and the entry of a generic version of Copaxone led to significant mandatory price reductions in most of the Relevant Member States. In Belgium, Germany and Poland, Copaxone was subject to a mandatory list price decrease of {...}%, {...}% and {...}%, respectively, after loss of exclusivity and the entry of Synthon GA. In Italy and Spain, reimbursement prices for Copaxone 20 mg and 40 mg were reduced by {...}% upon generic entry.⁵³⁸

(413) Second, entry of generic or therapeutically equivalent products enables State authorities, hospitals and/or health insurers, i.e. the ultimate payers for pharmaceutical products, to organise competitive tenders for an active substance.⁵³⁹ Health insurers and tender authorities report that the resulting "*direct competition*"⁵⁴⁰ between two medicines of the same active substance improves the conditions at which they buy medicines.⁵⁴¹ A Spanish regional tender authority states that "*the arrival of generic medicines helps the sustainability of the public system by offering the medicine at the best price, for the generic as well as for the original, due to competition*".⁵⁴²

⁵³⁷ ID 2155, Case M.7746, *Teva/Allergan Generics*.

⁵³⁸ In the Netherlands, the market entry of Synthon GA did not in itself lead to a change in Copaxone's list or reimbursement price (see Sections 6.3.3.4.2.2). Synthon GA has not yet entered the Czech market and could thus not have an impact on Copaxone's prices in Czechia (see 6.3.3.4.3.2).

⁵³⁹ Tenders are held on molecule basis in all Relevant Member States (see the country-specific assessment in Section 6.3.3.4. This statement does not apply to Belgium, where Copaxone and Synthon GA are not tender products.

⁵⁴⁰ See ID 1178, DAK's Reply to Article 18(2) Request of 15 December 2021, p. 2 (unofficial translation). Original text: "*direkter Wettbewerb*".

⁵⁴¹ ID 1312, AOK Plus's Reply to Article 18(2) Request of 15 December 2021, p. 6; ID 1113, Servicio Navarro de Salud's Reply to Article 18(2) Request of 15 December 2021, p. 3; ID 1143, IKK's Reply to Article 18(2) Request of 15 December 2021, pp. 4-5.

⁵⁴² ID 1340, Servicio Extremeño de Salud's Reply to Article 18(2) Request of 15 December 2021, p. 5 (unofficial translation). Original text: "*la llegada de los medicamentos genéricos supone una ayuda a la sostenibilidad de los sistemas públicos al ofrecer el medicamento a mejor precio, tanto del genérico como del "original" por competencia.*"

- (414) Third, if put in place, automatic substitution rules mean that doctors prescribing GA no longer decide which GA product will be dispensed to patients. Six out of seven Relevant Member States introduced automatic substitution for Copaxone during the Relevant Period. Automatic substitution means that a patient with a prescription for GA receives the cheapest (or one of the cheapest) GA medicines in the pharmacy, regardless of whether the prescription is by INN or by brand, which means that the patient may receive Synthron GA even on a prescription for a branded Copaxone product. {...}.⁵⁴³ This means that if the patient’s health insurer or the regional administration have tendered the supply of GA, only the tender-winning product will be dispensed (even if the doctor has prescribed a different brand). Health care professionals and patients, who are the main targets of Teva’s promotional efforts, thus lose their influence over which medicines will ultimately be dispensed to the patient. {...}.⁵⁴⁴ In cases of medical necessity, however, doctors can indicate on the prescription that the prescribed brand should not be substituted with a generic (e.g. *aut idem* in Germany). In most Relevant Member States, exclusion of substitution is a mere theoretical possibility rather than an actual practice by physicians (see Recital (354)).
- (415) Fourth, the combination of tenders and automatic substitution rules exerts strong pressure on either the prices or the volumes of originator medicines, or both. Originators have the choice between engaging in price competition with generics, leading to what one German health insurer called a “*price spiral*”⁵⁴⁵ {...}.⁵⁴⁶, or maintaining their prices and profit margins but losing significant volumes. Either way, this leads to a decrease in the revenues and profits of originator medicines. In combination with substitution rules, tenders do not only affect prescriptions for new patients but existing patients as well. {...}.⁵⁴⁷
- (416) For example, such pressure on the prices and/or volumes of Copaxone was particularly strong in the Netherlands and in Italy. In the Netherlands, the main health insurers entered exclusive “preference policies”⁵⁴⁸ with Mylan for Synthron GA in 2018 (see Recital (598)). The preference policy includes new and existing patients, meaning that – after a transition period – existing patients have to switch from Copaxone to Synthron GA, regardless of their prescription. {...}.⁵⁴⁹
- (417) Fifth, price pressure on Copaxone was further increased by the system of external reference pricing. External reference pricing, also called international price referencing, is a mechanism that national pricing authorities employ to ensure that prices for pharmaceutical products in their country are not significantly higher than in certain selected reference countries. Czechia, Italy, the Netherlands, Poland and

⁵⁴³ ID 644-199, Global Customers Insight-Multiple Sclerosis Fact Book, November 2016, p. 100.

⁵⁴⁴ ID 262-1601, Price Competition Workshop Amsterdam, 20-21 June 2017, p. 2.

⁵⁴⁵ ID 1143, IKK’s Reply to Article 18(2) Request of 15 December 2021, pp. 4-5.

⁵⁴⁶ ID 266-25, Copaxone/FoGA – P&MA outlook, 7 June 2017, p. 4; ID 262-1695, Price competition workshop – Copaxone & Lonquex, 20-21 June 2017, p. 9; ID 455-2359, internal email dated 20 September 2018 from {...} to {...} and others, p. 4; ID 886-20, 2020 E.U. Brandplan & High level GTMAP Copaxone, p. 17; ID 886-19, 2019 EU Strategic Brand Plan Copaxone, p. 15.

⁵⁴⁷ ID 262-1695, Price competition workshop – Copaxone & Lonquex, 20-21 June 2017, p. 9.

⁵⁴⁸ Health insurers can set up preference policies for drugs, which means that they can negotiate preferential rates with pharmaceutical companies for one or several drugs of an active substance. If a preference policy exists with a patient’s health insurer, pharmacies dispense only the preferred product to the patient, regardless of the doctor’s prescription (see Recital (592)).

⁵⁴⁹ ID 1295-41, Teva’s reply to Article 18(2) Requests of 22 October and 18 November 2021, pp. 6, 10.

Spain are countries that foresee a price comparison through external price referencing when negotiating medicines prices.⁵⁵⁰

- (418) Czechia, for example, compares its national Copaxone list prices to Copaxone list prices in 17 reference countries.⁵⁵¹ The authority can lower the maximum selling price for Copaxone to match the average of the three lowest prices of the drug in the reference countries. Price decreases in a reference country can therefore indirectly influence the prices in Czechia.
- (419) The potential impact of external price referencing can be further illustrated with the example of Belgium. Before 2020, the launch of a generic or hybrid medicine on the Belgian market implied a mandatory 44% price decrease on both the generic/hybrid and the originator product. Because Belgium is a reference country for several other Member States (for example Czechia, the Netherlands and Poland), this 44% price reduction would have had a spill-over effect into other national markets.
- (420) Teva was aware of the effects of external price referencing. In internal documents, Teva discussed {...}.⁵⁵² The downside of delisting a medicine from the list of reimbursable products is that health insurers will no longer reimburse patients for the product. In other words, the strategy of delisting a product would entail a loss of some sales in one country so as to maintain higher prices in a different country.
- (421) Sixth, with the entry of generic (or generic-like) competition, promotional efforts are generally losing their relevance as a tool for effective competition. As long as a medicine enjoys exclusivity and competes, if at all, with other active substances, promotional efforts are important to differentiate one branded product from another. However, promotional efforts are less useful for differentiating a branded medicine from the generic alternative because the products are therapeutically equivalent. Rather, originator companies have to take into consideration that their promotional efforts may not only benefit their branded product but the generic competitor as well, as, with the existence of automatic substitution, any promotional efforts would ultimately benefit the generic(-like) product instead of the originator (the so-called “free-riding” problem). In view of that, an originator may significantly reduce or even abandon promotional efforts for its branded medicine to reduce costs and focus on price competition with generics.
- (422) Internal documents suggest {...}.⁵⁵³ {...}.⁵⁵⁴ {...}.⁵⁵⁵ {...}.⁵⁵⁶ {...}.⁵⁵⁷
- (423) The shift from promotion-driven competition to price competition is also visible from {...}. Contrary to Teva’s claims, internal documents do not suggest significant

⁵⁵⁰ ID 1295-45, Teva’s reply to Article 18(2) Requests of 22 October and 18 November 2021, p. 5; ID 1295-41 Teva’s reply to Article 18(2) Requests of 22 October and 18 November 2021, p. 6; ID 1295-64, Teva’s reply to Article 18(2) Requests of 22 October and 18 November 2021, p. 6; ID 1295-25, Teva’s reply to Article 18(2) Requests of 22 October and 18 November 2021, p. 9; ID 1295-9, Teva’s reply to Article 18(2) Requests of 22 October and 18 November 2021, p. 6.

⁵⁵¹ The 17 reference countries for Czechia are Belgium, Croatia, Denmark, Finland, France, Hungary, Ireland, Italy, Latvia, Lithuania, the Netherlands, Poland, Portugal, Slovakia, Slovenia, Spain, and Sweden, see ID 1295-45, Teva’s reply to Article 18(2) Requests of 22 October and 18 November 2021, p. 5.

⁵⁵² ID 404-2469, Copaxone in Belgium/Impact in the NL, 24 April 2018, p. 4.

⁵⁵³ ID 263-2408, Strategic priorities and roadmap, June 2016, p. 6.

⁵⁵⁴ ID 263-2408, Strategic priorities and roadmap, June 2016, p. 7.

⁵⁵⁵ ID 263-2408, Strategic priorities and roadmap, June 2016, p. 8.

⁵⁵⁶ ID 263-1255, TPE Multiple Sclerosis: 2018, February 2018, p. 25; see also ID 455-1934, internal email conversation dated 6/7 April 2016 between {...} and {...}.

⁵⁵⁷ ID 263-1255, TPE Multiple Sclerosis: 2018, February 2018, pp. 39-40.

competition between Copaxone and non-GA DMTs during the Relevant Period.⁵⁵⁸ {...}. After the launch of Synthon GA, {...},⁵⁵⁹ {...}⁵⁶⁰ {...}⁵⁶¹ {...}. This is discussed in more detail in the following Sections, in particular in Section 6.3.3.3.1.

- (424) Finally, in *Teva/Allergan*, the Commission found that the overlap between Teva's Copaxone and Synthon GA⁵⁶² constituted an “*originator-to-generic overlap*”, and raised serious doubts as to the compatibility of that concentration with the internal market (see Recital (219)) The Commission found that a practice aimed at delaying the entry of a “*generic glatiramer acetate on the market*” would extend the period in which Copaxone does not face competition on prices. The finding of the Commission in this case could not be clearer: Synthon GA was the only pharmaceutical product able to exert price competition on Copaxone. This finding was not contested by Teva since the company submitted remedies in order to dispel the serious doubts raised by the Commission in the *Teva/Allergan* case in relation to Copaxone.⁵⁶³
- (425) In view of the foregoing, the Commission concludes that the (approaching) loss of patent protection and the related exclusivity for Copaxone and the launch of Synthon GA led to changes in the demand structure in the relevant national health systems, thereby introducing price competition for Copaxone as the main driver of competition.

6.3.3.2.4. Teva's claims on significant competition between Copaxone and non-GA first-line DMTs

- (426) Teva claims that Copaxone faced significant competitive constraints from non-GA first-line DMTs prior to the Relevant Period, constraints that continued to have an impact on Teva's market conduct with respect to Copaxone sales also during the Relevant Period. The sub-sections that follow address each of these arguments in turn.

6.3.3.2.4.1. Teva's argument on price versus non-price competition

- (427) In Teva's view, the Commission's analysis means that only price competition can impose an effective competitive constraint on Copaxone and that, accordingly, the absence of price competition implies a lack of competition in general.⁵⁶⁴ According to Teva, this fails to acknowledge that price competition is only one element of competition in the pharmaceutical sector, which also takes the form of R&D investments and seeking to gain prescriptions from alternative treatments by actively differentiating products on the basis of, for example, their efficacy and tolerability and safety profiles, which, according to Teva, is achieved through promotional efforts such as conducting clinical studies, promotion activities with doctors, training of nurses, and Teva's patient support program (PSP).⁵⁶⁵ Teva further submits that, in other cases, the Commission has acknowledged the importance of elements of

⁵⁵⁸ ID 4032, Teva's Reply to the Statement of Objections, paras. 247-248. See also Recitals (510)-(515).

⁵⁵⁹ ID 806-32, TPE Board Mtg – April 2019 – Finance, Amsterdam, April 4, p. 7.

⁵⁶⁰ ID 806-4, TPE Board Meeting Finance – Q2 2020, 9 July 2020, p. 20.

⁵⁶¹ ID 806-13, TPE Board Mtg – January 2020 Finance, Amsterdam, Jan 9th 2020, p. 14.

⁵⁶² The Commission's decision does not specifically refer to Synthon GA but to Synthon's “*generic glatiramer acetate*”, see ID 2155, Case M.7746, *Teva/Allergan Generics*, paragraphs 23, 668.

⁵⁶³ ID 2155, Case M.7746, *Teva/Allergan Generics*, paragraph 668.

⁵⁶⁴ ID 4032, Teva's Reply to the Statement of Objections, para. 186.

⁵⁶⁵ ID 4032, Teva's Reply to the Statement of Objections, para. 187.

competition other than price (referring to previous merger decisions).⁵⁶⁶ These claims are unfounded for the following reasons.

- (428) First, Teva tends to unduly focus on whether and to what extent first-line DMTs exercised a competitive constraint on Copaxone prior to the Relevant Period and to only summarily consider the situation during the Relevant Period. The Commission's assessment is limited to the Relevant Period, during which Teva undertook significant activities to specifically confront competition from Synthon GA. The Commission does not take a position as to the delineation of the relevant product market before the Relevant Period. In line with *Generics (UK)*, it cannot be excluded that the market was broader before the (threat of) generic entry and potentially driven (at that time) by non-price competition. Instead, the Commission's assessment focuses on the constraints Teva was facing once generic entry was imminent. In any event, a comparison of the competitive constraints faced by Copaxone before and during the Relevant Period, supports the conclusion that any non-price constraints that non-GA first-line DMTs may have exercised before the beginning of the start of the Relevant Period were significantly reduced with the threat of generic entry at the start of the Relevant Period (see Sections 6.3.3.2.4.3.3. and 6.3.3.3.1).
- (429) Second, the Commission does not consider that only price competition can impose an effective competitive constraint on Copaxone. The Commission accepts that non-price competition may be capable of imposing an effective competitive constraint on a product or firm, not only in pharmaceutical industries but also more generally.⁵⁶⁷ However, the Commission's analysis shows that no such effect is observable in the specific case of Copaxone in terms of the metrics analysed (price, sales and profits, see Recitals (224)-(225), (359)) following the entry of non-GA first-line DMTs (particularly orals) and prior to the entry of Synthon GA (see Section 6.3.3.4). In Section 6.3.3.4., the Commission does not only analyse Copaxone's pricing power but also the evolution of Copaxone sales, profits and profit margins in order to conclude that the entry of Synthon GA had a significant and lasting impact on Copaxone's prices, volumes and profits (or was capable of having such impact) whereas any effect that may have followed the entry of orals was either insignificant, or merely transitory (or both).
- (430) The Commission notes that non-price competition of the type discussed by Teva, if effective in constraining Copaxone's market conduct, ought to have at least some observable effect if not on Copaxone prices at least on Copaxone volumes or profitability.⁵⁶⁸ Effects on volumes would be indicative of (economic) substitutability, while effects on profitability would indicate that Teva incurred increased costs due to the increased expenditures on non-price competition with non-GA DMTs that would in turn erode Copaxone's profit margins. However, as discussed in the previous paragraph, no such significant, non-transitory effects are observed on Copaxone sales, prices and/or profits in relation to non-GA first-line DMTs and certainly no effects comparable to those that followed the entry of Synthon GA in the market.
- (431) Third, concerning Teva's claim that the Commission has acknowledged the importance of elements of competition other than price in previous cases, it is important to note that the Commission's assessment is always done on a case-by-

⁵⁶⁶ ID 4032, Teva's Reply to the Statement of Objections, para. 188.

⁵⁶⁷ See Market Definition Notice, para. 15.

⁵⁶⁸ See also case C-176/19 P, *Commission v Servier*, paragraph 387.

case basis, considering the specifics and facts of each case. The Commission is not bound to apply the definition of a relevant market from its past decisions.⁵⁶⁹

- (432) In addition, Teva misrepresents the Commission’s approach to market definition in previous cases by (i) omitting to mention cases that concern the pharmaceutical sector and confirm the Commission’s approach, (ii) selectively quoting statements from a previous decision out of context, and (iii) relying on previous cases that have little relevance for the case at hand.
- (433) In the first place, Teva’s references to previous cases is highly selective. Teva omits to mention that the Commission regularly defines the relevant product market for genericised medicinal products at the level of the active substance (see Recital (217)). Already in 2008, the Commission found in *Teva/Barr* that, even though the starting point for market definition is often to look at all pharmaceuticals with the same therapeutic indication (ATC3 level), *“it is appropriate to carry out analyses also at other ATC levels, or a mixture thereof, if the circumstances of a case show that sufficiently strong competitive constraints faced by the undertakings involved are situated at another level [...] for example the ATC4 class or medicines based on the same active pharmaceutical ingredient (molecule level)”* (emphasis added).⁵⁷⁰
- (434) The Commission has followed this approach in several recent decisions.⁵⁷¹ Notably, the Commission took price-setting modalities into account in the *Mylan/Upjohn* decision: *“different genericized molecules, including from the same ATC3 class, do not form part of the same product market, in particular since they are not interchangeable for patients and pharmacies and their price-setting modalities differ”* (emphasis added).⁵⁷²
- (435) In the second place, Teva’s argument relating to the Commission’s decision in *Mylan/Meda*, relies on a statement that does not concern MS medicines and reads: *“products based on different molecules may competitively constrain one another [as] the prescriber would typically choose between different molecules based on his/her assessment of therapeutic efficacy, preference and experience, before even considering a generic version of the chosen molecule”*.⁵⁷³
- (436) This quote is presented out of context and omits relevant parts of the quoted paragraph, namely that *“products based on the same molecule are typically closer substitutes than products based on different molecules”* and that, only *“in certain circumstances”*, products based on different molecules may constrain one another, provided that they have *“an equivalent therapeutic profile”*. In the case of Copaxone, the Commission’s assessment shows that the therapeutic profiles of first-line DMTs differ significantly (e.g. concerning safety, tolerability and mode of administration, see Section 6.3.2.2) which means they are, at best, imperfect substitutes, and are in any case not therapeutically equivalent. The *Mylan/Meda* decision does therefore not provide a basis for Teva’s claims.
- (437) In the third place, the other previous Commission decisions mentioned by Teva in support of its claim have little relevance for the case at hand. Only one case,

⁵⁶⁹ Market Definition Notice, para. 14 and the case-law cited.

⁵⁷⁰ Case M.5295, *Teva/Barr*, paragraph 11 (quote) and paragraphs 34, 42, 49, 56, 66, 71, 78, 85.

⁵⁷¹ Case M.9044, *CVC/Recordati*, paragraph 11; Case M.9274, *GlaxoSmithKline/Pfizer Consumer Healthcare Business*, paragraph 15; Case M.7275, *Novartis/GSK Oncology Business*, paragraph 208.

⁵⁷² Case No. M.9517, *Mylan/Upjohn*, paragraph 21.

⁵⁷³ ID 4032, Teva’s Reply to the Statement of Objections para. 188(a); quoting Case M.7975, *Mylan/Meda*, paragraph 45.

Mylan/Meda, concerns the same sector (pharmaceutical products) but relates to different products. Due to the specificities of pharmaceutical markets compared to other industries (see Section 6.2), the market definition findings from other cases are not necessarily transferable.

- (438) As regards the Commission's decisions in *Dow/Dupont*⁵⁷⁴ and *GE/Alstom*⁵⁷⁵, *Teva* argues that the Commission acknowledged the importance of analysing innovation-related effects and their impact on competition for the definition of the relevant market.⁵⁷⁶ As the decision excerpts on which *Teva* relies for its claim do not refer to market definition but to the competitive assessment, the evidential value of these excerpts for the case at hand is limited to the statement that innovation is an important parameter of competition in certain industries. While this is true for pharmaceutical markets as well (see Recital (200)), the relevance of innovation as a parameter of competition for an originator medicine decreases significantly with (approaching) loss of exclusivity. Also, the Commission has taken non-price elements such as innovation into account for its assessment (see Recital (429)).
- (439) *Teva* further states that the Commission identified privacy as an important parameter of competition in the *Microsoft/LinkedIn*⁵⁷⁷ decision. While there is no apparent link between privacy as a parameter of competition and the case at hand, the Commission understands this to be an argument that parameters other than price can be taken into account for the purposes of defining the relevant market. As stated above, the Commission does not deny the relevance of parameters other than price for market definition in general. However, the Commission finds that, as regards the case at hand, with (approaching) loss of exclusivity, price has become the main parameter for competition for Copaxone.

6.3.3.2.4.2. *Teva's* argument on volume movements

- (440) *Teva* claims that the entry of orals shortly before and after the Relevant Period (between August 2013 and August 2015) led to a material reduction in Copaxone's sales volumes which suggests that orals won a material number of prescriptions from Copaxone before and during the Relevant Period.⁵⁷⁸ This, according to *Teva*, demonstrates that first-line oral DMTs are engaged in significant competition for prescriptions with Copaxone.⁵⁷⁹ To reach that conclusion, *Teva* developed a methodology according to which one needs to first accept that Copaxone's sales were steadily growing prior to oral entry and therefore any impact of oral entry on Copaxone's volumes must be assessed against this counterfactual and second that the launch of Copaxone 40 mg was a competitive reaction by *Teva* against the entry of orals, that stemmed Copaxone's volume loss.⁵⁸⁰

⁵⁷⁴ Commission Decision of 27 March 2017, *Dow/DuPont*, Case M.7932, paragraph 2003.

⁵⁷⁵ Commission Decision of 8 September 2015, *General Electric/Alstom*, Case M.7278, paragraph 1128.

⁵⁷⁶ ID 4032, *Teva's* Reply to the Statement of Objections, para. 188.

⁵⁷⁷ Commission Decision of 6 December 2016, *Microsoft/LinkedIn*, Case M.8124.

⁵⁷⁸ ID 4032, *Teva's* Reply to the Statement of Objections, para. 190; ID 5695, *Teva's* Reply to the Letter of Facts I of 9 February 2024, para. 55. In ID 5909, *Teva's* Reply to the Letter of Facts II of 17 May 2024, para.17, *Teva* expands its argument about purported volume losses by also estimating the corresponding profit (in absolute terms) losses. Since this profit loss analysis depends on the flawed volume loss analysis, it is similarly dismissed.

⁵⁷⁹ ID 4032, *Teva's* Reply to the Statement of Objections, para. 190.

⁵⁸⁰ ID 4032, *Teva's* Reply to the Statement of Objections, para. 193.

- (441) The Commission notes that the premises of this analysis are flawed and the conclusions that Teva wants to draw from it for the Relevant Period, accordingly, cannot stand either.
- (442) First, Teva’s entire analysis focuses mainly on the time before the Relevant Period and therefore provides little to no insights as to the competitive landscape following the (approaching) loss of exclusivity and entry of Synthon GA. The Commission does not take a position as to the market delineation prior to the Relevant Period.
- (443) Second, Teva’s claim that Copaxone’s sales were steadily growing prior to oral entry is demonstrably wrong. As the Commission shows in Section 6.3.3.4, Copaxone sales growth had slowed down already before the entry of orals, in particular in Italy (Section 6.3.3.4.2.1, where the growth rate of Copaxone sales decreased every year between 2010 and 2013) and Germany (Section 6.3.3.4.3.3, where sales decreased already between 2013 and 2014), the two largest markets considered. Technically, the sales curve appears to be closer to a quadratic one than a linear one as suggested by Teva.⁵⁸¹ Teva does not consider the overall pattern that Copaxone’s sales exhibit in the period but rather draws a straight line connecting only two data points that it then calls a trend line ignoring all data points in between. Teva essentially bases its analysis (i) on the claim that Copaxone sales exhibited, on average, a constant growth, prior to the entry of orals, a claim which is not true, and (ii) on the assumption that absent the entry of orals, Copaxone sales would continue growing at this (erroneous) constant rate, an assumption for which there is no support. A careful reading of the relevant figures shows that Copaxone growth rate was not constant during this period and rather slowed down (even turning negative on several instances) prior to the entry of orals.⁵⁸²
- (444) The Commission notes that a continuous, linear growth trend for a legacy medicine, which had been launched two decades ago and was approaching the end of its exclusivity, would be uncommon for the pharmaceutical industry.⁵⁸³ Similarly, Teva acknowledges, in internal documents as well as in public statements that a

⁵⁸¹ A linear fit assumes a constant relationship between the two variables being considered, here sales and time, such as $y = a + b * t$. Here, a and b are constants and b captures the slope of the linear curve (meaning how steep the relationship between y and t is). The main drawback of a linear fit is that it assumes that the relationship between y and t is constant (as captured by the slope, b) throughout the entire period considered. A quadratic fit is much more flexible because it also includes a quadratic term and has the form $y = a + b * t + c * t^2$. The quadratic term ($c * t^2$) allows the relationship between y and t to either grow or decrease as t grows, meaning that it allows the relationship to have a curved rather than a linear shape (in other words, it does not assume that sales will always grow or always decline). A quadratic fit (that is usually a curved rather than a straight line) is more flexible and is a better fit for data that have a U-shaped relationship (growth followed by decline, or vice versa), while at the same time simply collapses back to a linear fit if c is found to be equal to zero.

⁵⁸² In ID 5695, Teva’s Reply to the Letter of Facts I of 9 February 2024, para. 58, Teva claims that Copaxone’s volumes steadily increased by {...}% to {...}% from 2009 until the year of oral entry across the different Relevant Member States assessed. The claim that Copaxone sales grew monotonically (“*steadily*”) is true if aggregate annual figures are considered, however this approach again only focuses on two figures, the start and end of period sales, and deliberately obscures the non-monotonic shape of the more detailed quarterly sales figures in between (see Section 6.3.3.4).

⁵⁸³ Teva claims in its Reply to the Letter of Facts I that the Commission finds the entry of Synthon GA to be the reason for changes in Teva’s sales curve (ID 5695, paras. 60-62). This is incorrect. The Commission merely states that it would be uncommon for Copaxone’s volumes to steadily grow late in its life cycle.

continuous growth trend for a legacy medicine would be uncommon for a product like Copaxone.⁵⁸⁴

- (445) Also, the break in trend of Copaxone’s volume growth coincides with Copaxone’s loss of exclusivity. Teva provides no evidence to support its assumption that Copaxone’s volumes would keep growing even after loss of exclusivity. In short, there is no evidence supporting Teva’s claim that absent the entry of orals, Copaxone’s sales would enjoy a steady and continuous growth rate and the observable sales data do not support this claim either. Focusing the analysis on Copaxone’s actual sales volumes, as the Commission does in Section 6.3.3.4., instead of an assumed counterfactual of unconstrained linear growth shows that Teva’s claim is misguided.
- (446) Third, Teva’s approach of considering the launch of Copaxone 40 mg purely as a competitive response to orals is not borne out by facts. Evidence from Teva’s internal documents demonstrates that the main reason for the switch from Copaxone 20 mg to Copaxone 40 mg was the competitive threat from Synthon GA (see Section 5.2.3.1 and Section 6.3.3.2.4.3.1 below). Therefore, the uptake in Teva’s volume’s following the launch of Copaxone 40 mg cannot be considered as the consequence of Teva’s actions in reply to competition from orals.
- (447) In short, both key premises of Teva’s analysis are flawed. Teva greatly exaggerates the impact that the entry of orals might have had on Copaxone sales. In any event, the Commission does not contest that the entry of orals appears to correlate with some small setback on Copaxone sales prior to the Relevant Period but, as previously discussed, this potential impact was transitory, relatively small (definitely not as great as Teva’s flawed methodology would suggest) and limited primarily to sales volumes, with no significant impact on Copaxone pricing (market) power. On the contrary, the entry of Synthon GA, in those markets where it took place, was followed by sizeable non-transitory decreases in Copaxone sales, prices and profits.

6.3.3.2.4.3. Teva’s claims on evidence of “*significant competitive reactions*” between Copaxone and non-GA first-line DMTs before and during the Relevant Period

- (448) Teva puts forward a number of claims that purportedly demonstrate that significant competitive interactions took place between Copaxone and non-GA first-line DMTs both before and during the Relevant Period.⁵⁸⁵

6.3.3.2.4.3.1. Teva’s argument with respect to the launch of Copaxone 40 mg

- (449) Teva claims that the launch of Copaxone 40 mg was a competitive reaction to non-GA first-line DMTs and not (only) a reaction to the upcoming entry of Synthon GA.⁵⁸⁶ In support of its claim, Teva argues that (i) the decision to develop Copaxone 40 mg was taken many years before the contemplated launch of Synthon GA and before Teva was responsible for the marketing of Copaxone in the EU; (ii) Copaxone 40 mg was developed to generate patient benefits and to make Copaxone more attractive to patients (compared to oral DMTs); and (iii) that the introduction of

⁵⁸⁴ ID 262-1695, Price competition workshop – Copaxone & Lonquex, 20-21 June 2017, p. 73 (see Figure 4); ID 834-138, Teva’s Strategy – creating a sustainable path forward, July 2018, p. 2; ID 5200, Teva Earnings Call Q4 2018, 13 February 2019, pp. 3-4; ID 5198, Teva Earnings Call Q2 2019, 7 August 2019, p. 3; ID 5201, Teva Earnings Call Q3 2020, 5 November 2020, p. 34; ID 5202, Teva Earnings Call Q1 2021, 28 April 2021, pp. 39-40; 2 ID 5202, Teva Earnings Call Q4 2021, 9 February 2022, pp. 57-58.

⁵⁸⁵ ID 4032, Teva’s Reply to the Statement of Objections, para. 205.

⁵⁸⁶ ID 4032, Teva’s Reply to the Statement of Objections, para. 208.

Copaxone 40 mg had a significant impact on stemming Copaxone’s loss of volumes to orals. Teva further (iv) brings forward quotes from internal documents to purportedly support its claims.

- (450) The Commission notes that it is not disputed that the Copaxone 40 mg dosage may be perceived as an improvement of the medicine by some patients (and physicians). However, the Commission disputes Teva’s claim that pressure from non-GA DMTs or patient benefits were what primarily drove Teva’s decision to commercialise the 40 mg dosage of Copaxone.
- (451) First, evidence from internal documents clearly refutes Teva’s claim that since the decision to develop Copaxone 40 mg was taken before 2010 and therefore before the launch of Synthon GA was contemplated, no connection between the two therefore exists.⁵⁸⁷ Teva was already planning for generic(-like) competition following Copaxone’s eventual loss of exclusivity before 2010, and even as early as 2004 (see Section 5.2.2.).
- (452) {...}.⁵⁸⁸ {...}.⁵⁸⁹ {...}.⁵⁹⁰ {...}.⁵⁹¹ {...}.⁵⁹²
- (453) This evidence shows that Teva was already preparing for Copaxone’s loss of exclusivity and generic(-like) entry in the early days of Copaxone 40 mg’s development and long before its commercialisation.
- (454) Second, concerning Teva’s argument that Copaxone 40 mg was introduced to make Copaxone more attractive to patients (compared to oral DMTs), Teva points to the fact that Copaxone 40 mg reduced the frequency of self-injections for patients.⁵⁹³
- (455) However, numerous internal documents confirm that Teva’s main incentive for introducing the 40 mg Copaxone was to {...}.⁵⁹⁴ (see also Section 5.2.3.1.).
- (456) A 2020 drug pricing investigation by the U.S. House of Representatives (“U.S. Staff Report”) equally came to the conclusion that Teva’s real intention for the launch of the 40 mg dosage was a “*generic defense strategy*” for Copaxone and not competition with non-GA first-line DMTs.⁵⁹⁵ While these findings may not refer to decision-making on the level of Teva’s European management, they are nonetheless relevant because the development of Copaxone 40 mg was steered centrally for the US, EU and Canada.⁵⁹⁶
- (457) Teva claims that clinical trial reports show that improving the experience for Copaxone patients was always a key driver for the development of Copaxone 40 mg. To support its claim, Teva points to the fact that it initially tested whether a 40 mg daily dosage of Copaxone would increase the drug’s efficacy.⁵⁹⁷ A Teva press release from 2008 confirms that the FORTE trial could not show that a 40 mg dosage of GA

⁵⁸⁷ ID 4032, Teva’s Reply to the Statement of Objections, para. 211.

⁵⁸⁸ ID 4032, Teva’s Reply to the Statement of Objections, para. 216(a).

⁵⁸⁹ ID 404-37, LCI Copaxone – EU, February 2014, p. 4 (see also Section 5.2.2.).

⁵⁹⁰ ID 404-37, LCI Copaxone – EU, February 2014, p. 3.

⁵⁹¹ ID 404-2092, Teva internal email dated 16 September 2009 from {...} to {...} and others, p. 1.

⁵⁹² ID 404-2092, Teva internal email dated 16 September 2009 from {...} to {...} and others.

⁵⁹³ ID 4032, Teva’s Reply to the Statement of Objections, paras. 210, 213.

⁵⁹⁴ ID 404-1367, Copaxone BT Meeting Minutes, 30 June 2016, p. 3 (see Recital (127)).

⁵⁹⁵ ID 3550, U.S. House of Representatives, Committee on Oversight and Reform, Staff Report “Drug Pricing Investigation, Teva—Copaxone”, September 2020, p. 25-29.

⁵⁹⁶ ID 455-2910, Teva internal email dated 5 December 2007 from {...} to {...} and others.

⁵⁹⁷ ID 4032, Teva’s Reply to the Statement of Objections, para. 216(a).

would increase Copaxone’s efficacy.⁵⁹⁸ This further suggests that, while patient benefits may have been a reason to start the development of Copaxone 40 mg, it was not the reason for the final decision to launch Copaxone 40 mg.

- (458) Internal documents quoted in the U.S. Staff Report show that patient benefits were not a deciding factor for Teva when deciding whether to launch Copaxone with a new dosing regimen. One executive is quoted saying: “The reason I’ve been given why less frequent dosing of a higher dose of glatiramer should not even be considered is pricing: for the 40 mg once daily, one can not [sic] double the price, let alone when 40 mg would be used less frequent dosing ie [sic] once a week” (emphasis added).⁵⁹⁹ A slide on “GA Life Cycle Initiatives” states “*How do we justify the use of higher doses after Forte?*” and notes that higher doses lead to “*increased injection site reactions*”.⁶⁰⁰ This contradicts Teva’s claim that this new dosage, by reducing the frequency of administration, resulted in patient benefits.
- (459) Instead, an internal document cited in the U.S. Staff Report demonstrates that Teva considered “*barrier to Generic entrance*” and “*extension of Life Cycle and new IP*” as opportunities stemming from launching a 40 mg dosage of Copaxone.⁶⁰¹ Noted as “*threats*” are “*physicians not ready to accept additional ‘minor’ innovation/benefit*” and “*fragmentation of the market*”. While the document notes that a 40 mg dosage of Copaxone might be interesting to patients currently treated with interferons and despite a mention of oral treatments in the document, no connection is made between Copaxone 40 mg and Copaxone’s alleged increased competitiveness vis-à-vis orals.⁶⁰²
- (460) Further, Teva put great effort into switching Copaxone 20 mg patients to Copaxone 40 mg specifically before the entry of Synthon GA 20 mg in the Relevant Member States (see Section 5.2.3.1). This is illustrated by a presentation titled {...}, in which Teva notes under the headline {...}: {...}.⁶⁰³
- (461) Teva claims that “*the success of 40mg Copaxone and the Copaxone Pen in and of itself demonstrates the existence of patient benefits versus 20mg Copaxone and other first-line DMTs*” because there would be no reason for doctors to prescribe Copaxone 40 mg or the SDD/Pen if there were no benefits for patients.⁶⁰⁴ As stated above in Recital (450), it is not disputed that patients or doctors may perceive the Copaxone 40 mg dosage as an improvement. However, that does not mean that such patient benefits were what primarily drove Teva’s decision to commercialise the 40 mg dosage of Copaxone. Moreover, the Commission notes that doctors’ decisions to prescribe Copaxone 40 mg and the SDD/Pen was likely influenced by Teva’s strategic conversion campaign for Copaxone 40 mg in the Relevant Member States

⁵⁹⁸ ID 4962, Teva Press Release: Teva Provides Update on FORTE Trial, 7 July 2008, p. 1.

⁵⁹⁹ ID 3550, U.S. House of Representatives, Committee on Oversight and Reform, Staff Report “Drug Pricing Investigation, Teva – Copaxone”, September 2020, p. 25.

⁶⁰⁰ ID 3550, U.S. House of Representatives, Committee on Oversight and Reform, Staff Report “Drug Pricing Investigation, Teva – Copaxone”, September 2020, p. 26.

⁶⁰¹ ID 3550, U.S. House of Representatives, Committee on Oversight and Reform, Staff Report “Drug Pricing Investigation, Teva – Copaxone”, September 2020, p. 29.

⁶⁰² ID 3550, U.S. House of Representatives, Committee on Oversight and Reform, Staff Report “Drug Pricing Investigation, Teva – Copaxone”, September 2020, p. 29.

⁶⁰³ ID 1062-43, Deep Dive Session TPE – CNS BeLux 2016, p. 8.

⁶⁰⁴ ID 5695, Teva’s Reply to the Letter of Facts I of 9 February 2024, para. 74.

{...},⁶⁰⁵ see Section 5.2.3.1) and the efforts to promote the Copaxone Pen in Germany (see Recitals (811) and (812)).

- (462) It follows that Teva’s claim that Copaxone 40 mg was introduced to make Copaxone more attractive to patients (compared to non-GA first-line DMTs) is not supported by evidence.
- (463) Third, Teva claims that the entry of oral first-line DMTs caused Teva’s sales volumes to flatten or decline.⁶⁰⁶ According to Teva, these declines were at least partially stemmed when Copaxone 40 mg was launched.⁶⁰⁷
- (464) The shortcomings of Teva’s analysis of Copaxone’s sales volumes have already been addressed above in Section 6.3.3.2.4.2. Moreover, the Commission notes that the decrease of injection frequency can only offset a competitive disadvantage vis-à-vis other first-line injectable drugs, i.e. interferons. For patients that want to avoid self-injection altogether, self-injecting three times weekly instead of every day is not a significant improvement in convenience. For these patients, the only available first-line treatment options are oral DMTs and the switch to Copaxone 40 mg therefore could not stem any alleged volume losses to oral DMTs. This is confirmed by a statement from a Teva representative, quoted in the U.S. Staff Report saying that “*every other day over once daily does not represent a significant improvement in convenience*”.⁶⁰⁸
- (465) Fourth, Teva’s claims are not supported by internal documents either.
- (466) In the first place, Teva claims that clinical trial reports show that improving the experience for Copaxone patients was always the key driver for the development of Copaxone 40 mg.⁶⁰⁹ {...}⁶¹⁰ {...}.
- (467) Moreover, the U.S Staff Report quotes an internal document suggesting that Teva executives opted against research on the efficacy of a once-weekly dosage of Copaxone 40 mg, which would have led to even less injections and more patient benefits.⁶¹¹ According to the findings of the report, the reason for this decision was that Teva’s CEO feared that patients would inject a cheaper generic 20 mg dosage of GA twice per week instead of injecting Copaxone 40 mg once per week.⁶¹² A reduction of injections to only once a week would have further offset the alleged competitive disadvantages of Copaxone vis-à-vis non-GA first-line DMTs, but not against Synthon GA.
- (468) In the second place, Teva points to Brand Plans to show that the launch of Copaxone 40 mg was allegedly expected to, and influenced by the desire to, {...}.⁶¹³ The referenced internal documents cannot support the finding of such an “expectation” and “desire” to offset advantages of first-line DMTs. The documents merely show

⁶⁰⁵ ID 404-1922, Teva internal email dated 16 April 2016 from {...} to {...}, p. 1, see Recital (129).

⁶⁰⁶ ID 4032, Teva’s Reply to the Statement of Objections, para. 212.

⁶⁰⁷ ID 4032, Teva’s Reply to the Statement of Objections, para. 212.

⁶⁰⁸ ID 3550, U.S. House of Representatives, Committee on Oversight and Reform, Staff Report “Drug Pricing Investigation, Teva – Copaxone”, September 2020, p. 25.

⁶⁰⁹ ID 4032, Teva’s Reply to the Statement of Objections, para. 216.

⁶¹⁰ ID 4962, Teva Press Release: Teva Provides Update on FORTE Trial, p. 1.

⁶¹¹ ID 3550, U.S. House of Representatives, Committee on Oversight and Reform, Staff Report “Drug Pricing Investigation, Teva – Copaxone”, September 2020, p. 28.

⁶¹² ID 3550, U.S. House of Representatives, Committee on Oversight and Reform, Staff Report “Drug Pricing Investigation, Teva – Copaxone”, September 2020, p. 28.

⁶¹³ ID 4032, Teva’s Reply to the Statement of Objections, para. 217; See also ID 5695, Teva’s Reply to the Letter of Facts I of 9 February 2024, para. 72.

that Teva considered the {...}.⁶¹⁴ In fact, one of the Brand Plans does not show, as Teva claims, {...}, but instead states {...}.⁶¹⁵ Conversely, the same Brand Plan states (on the same page) that the driver for the launch of Copaxone 40 mg is to {...}.⁶¹⁶ Even if the Brand Plans showed an “expectation” or a “desire” to offset advantages of first-line DMTs with the introduction of Copaxone 40 mg, that would not be sufficient to support Teva’s claim that Copaxone 40 mg was developed to generate patient benefits and to make Copaxone more attractive to patients (compared to oral DMTs). This Decision demonstrates in detail that the key driver for Teva’s decision to launch Copaxone 40 mg was competition from competing GA, especially Synthon GA (see Section 5.2.3.1 and Recitals (451) to (461) in this Section).

- (469) In summary, the Commission concludes that, contrary to Teva’s claims, the launch of Copaxone 40 mg was not a competitive reaction to non-GA first-line DMTs. Instead, it was a reaction to the upcoming entry of Synthon GA.

6.3.3.2.4.3.2. Teva’s argument with respect to the removal of the pregnancy and breastfeeding contra-indication

- (470) Teva cites its investments and efforts to obtain label changes for Copaxone in relation to pregnancy and breastfeeding as another example of its reaction to competition from non-GA first-line DMTs. Teva claims that these investments were “*evidently driven by competition from other first-line DMTs only*” because label changes apply to Synthon GA as well.⁶¹⁷ As explained in Recital (274) of this Decision, proven safety for pregnancy and breastfeeding is an advantage for first-line DMTs because women of childbearing age represent a particularly large part of MS patients. It is therefore indeed possible that Teva expected to gain a competitive advantage over non-GA first-line DMTs with these label changes.

- (471) However, internal evidence suggests that Teva expected the removal of the pregnancy contra-indication to also be a competitive advantage vis-à-vis Synthon GA.⁶¹⁸ For example, Teva’s Director for {...} asked Copaxone’s legal team in November 2016 to {...}.⁶¹⁹ In an email exchange from June 2018, Teva’s Head of {...} asked Teva’s Director Head {...}, to which one of the answers was {...}.⁶²⁰ This contradicts Teva’s statement in the Reply to the Statement of Objections that the label changes were “*evidently driven by competition from other first-line DMTs only*”.⁶²¹

- (472) Moreover, the Commission shows in Recital (422) of this Decision that Teva prioritised the investment of resources in “*FoGA planning*”, meaning preparation for the launch of Synthon GA, over promotion of the new label for safe use of Copaxone

⁶¹⁴ ID 4032, Teva’s Reply to the Statement of Objections, para. 217(a), quoting ID 891-2, Copaxone EU Strategic Brand Plan, 29 March 2016, p. 21; ID 4032, Teva’s Reply to the Statement of Objections, para. 217(c), quoting ID 891-35, EU Strategic Brand Plan – Copaxone, p. 25.

⁶¹⁵ ID 4032, Teva’s Reply to the Statement of Objections, para. 217(b), quoting ID 891-1, Copaxone Brand Plan Europe 2014-2017, April 2013, p. 28.

⁶¹⁶ ID 891-1, Copaxone Brand Plan Europe 2014-2017, April 2013, p. 28.

⁶¹⁷ ID 4032, Teva’s Reply to the Statement of Objections, para. 219; See also ID 5695, Teva’s Reply to the Letter of Facts I of 9 February 2024, para. 78.

⁶¹⁸ ID 455-3001, Teva internal email exchange dated 18 July 2017 between {...} and others; ID 404-2435, Teva internal email exchange dated 2 December 2016 between {...} and others; ID 404-1756, Teva internal email dated 15 May 2017 {...} to {...} and others.

⁶¹⁹ ID 266-252, internal Teva email dated 8 November 2016 from {...} to {...} and others, p. 3.

⁶²⁰ ID 404-537, Teva internal email exchange dated 15 June 2018 between {...} and {...}, p. 2.

⁶²¹ ID 4032, Teva’s Reply to the Statement of Objections, para. 219.

during pregnancy or breastfeeding {...}⁶²²). Teva claims that this evidence “*only suggests that [Synthon GA] was a closer rival to Copaxone than other first-line DMTs*” and that “*other first-line DMTs are also material rivals to Copaxone*” (original emphasis).⁶²³ However, to the contrary, the evidence shows that non-GA first-line DMTs were not (anymore) “material rivals” to Copaxone during the Relevant Period. As the Commission shows in Recital (422), the evidence shows a clear shift from promotion-driven competition to price-driven competition, exemplified by how Teva made promotion on the label change a subordinate aim (“{...}”⁶²⁴) compared to efforts to compete with Synthon GA. This further supports the Commission’s finding that Synthon GA was not just “*a closer rival*” to Copaxone but the only medicine able to effectively and immediately constrain Copaxone during the Relevant Period.

6.3.3.2.4.3.3. Teva’s argument with respect to sales, marketing and medical costs

- (473) Teva submits that it made significant investments in sales, marketing and medical costs both prior to as well as during the Relevant Period.⁶²⁵ According to Teva, the goal of these investments was to differentiate Copaxone from non-GA first-line DMTs (indicating non-price competition).⁶²⁶ Teva submits that these investment costs primarily capture competition against non-GA first-line DMTs because Copaxone competes with Synthon GA primarily on price.⁶²⁷ Teva further underlines, first, that these significant investments still do not capture the full extent of non-price competition between Copaxone and non-GA first-line DMTs since they do not include R&D costs, such as those attributable to the development of Copaxone 40 mg,⁶²⁸ and second, that the observed decrease in sales, marketing and medical costs that coincide with the onset of the Relevant Period are at least partly attributable to general cost-cutting measures across all of Teva’s products and are not observed exclusively for Copaxone.⁶²⁹ Finally, Teva also considers that its sales, marketing and medical costs are evidence that Teva sacrificed around {...}% of its profit margin to compete with other first-line DMTs.⁶³⁰ Teva concludes that this data supports the claim that Copaxone faced significant non-price competition from non-GA first-line DMTs also during the Relevant Period.⁶³¹
- (474) First, the Commission rejects Teva’s claim that all evidence of non-price competition must necessarily be attributed primarily to competition against non-GA first-line DMTs. As stated in Recital (422) of this Decision, evidence from an internal document suggests that {...}.⁶³² As explained in Recital (119) of this Decision, the project to “defend” Copaxone, including the introduction of the 40 mg dosage and the disparagement campaign, required the input from several teams within Teva (medical, clinical, regulatory, legal, marketing, sales). Teva can therefore not claim

⁶²² ID 455-1934, internal email conversation dated 6/7 April 2016 between {...} and {...}, p. 8.

⁶²³ ID 5695, Teva’s Reply to the Letter of Facts I of 9 February 2024, paras. 86-87.

⁶²⁴ ID 455-1934, internal email conversation dated 6/7 April 2016 between {...} and {...}.

⁶²⁵ ID 4032, Teva’s Reply to the Statement of Objections, para. 228.

⁶²⁶ ID 4032, Teva’s Reply to the Statement of Objections, para. 229.

⁶²⁷ ID 4032, Teva’s Reply to the Statement of Objections, para. 233; ID 5695, Teva’s Reply to the Letter of Facts I of 9 February 2024, para. 104.

⁶²⁸ ID 4032, Teva’s Reply to the Statement of Objections, para. 232.

⁶²⁹ ID 4032, Teva’s Reply to the Statement of Objections, para. 235.

⁶³⁰ ID 5909, Teva’s Reply to the Letter of Facts II of 17 May 2024, para. 24.

⁶³¹ ID 4032, Teva’s Reply to the Statement of Objections, para. 237; ID 5695, Teva’s Reply to the Letter of Facts I of 9 February 2024, para. 90.

⁶³² ID 263-1255, TPE Multiple Sclerosis: 2018, February 2018, pp. 39-40.

that non-price competition, and in particular expenses incurred for non-price competition, must be attributed practically exclusively to competition against non-GA first-line DMTs.

- (475) Second, the Commission notes that it carefully and closely scrutinises the competitive constraints exercised on Copaxone by non-GA first-line DMTs during the Relevant Period in this Chapter and also carefully compares them to those that followed the entry of Synthon GA (in the Relevant Member States where entry took place) in order to conclude that any competition that may have existed between Copaxone and non-GA first-line DMTs was not effective in constraining Copaxone's market conduct in a meaningful way (see country-by-country analysis in Section 6.3.3.4). The fact that some investments in sales, marketing and medical costs have persisted during the Relevant Period is not surprising, especially since a significant portion of those can credibly be attributed to the CCP. This does not alter the fact that no significant effect on Copaxone prices, sales and profitability can be detected that can credibly be attributed to non-price competition stemming from sources other than Synthon GA.
- (476) Third, the Commission notes that the data on sales, marketing and medical cost expenditures that Teva puts forward clearly show a significant qualitative change in the nature of competition with a sharp and continuous decrease in this type of investments starting already before the beginning of the Relevant Period. This becomes particularly clear if one considers the percentage change of the absolute value of EUR spent on sales, marketing and medical costs, instead of the change of these costs as proportion of net sales. Figure 8 below presents the percentage change of the absolute value of EUR spent on sales, marketing and medical costs using the peak year of 2013 as the index year (= 100), which shows that the decrease between 2013 and 2021 was approximately {...}% in absolute terms.
- (477) In its Reply to the Letter of Facts I, Teva reiterates that the proportion of net revenues for which sales and marketing cost investments account for is more informative than considering the absolute values of these costs and that sales and marketing costs decreased for all Teva products, not just Copaxone.⁶³³ The Commission notes that it is not necessary to conclude which metric is superior to the other since both exhibit the same pattern. Copaxone sales and marketing costs (both in absolute terms and as well as a proportion of net revenues) have greatly decreased since their peak in 2013, much more than for the rest of Teva's products (the discrepancy is more evident in absolute rather than relevant terms, but the comparison is not, in any event, informative since there is no information about the competitive landscape and dynamics of those other products), even though they have not completely disappeared. In this context, the Commission notes how Teva, in arguing why the ratio of sales and marketing cost investments over revenues is a more relevant metric than the absolute level of sales and marketing cost investments, claims that "*the extent to which a firm invests into marketing efforts and patient support program will depend on the number of sales that are being made*".⁶³⁴ However, it is far from obvious what the direction of the causality is and whether it is increased sales that cause sales and marketing costs to increase or the other way around.

⁶³³ ID 5695, Teva's Reply to the Letter of Facts I of 9 February 2024, para. 99.

⁶³⁴ ID 5695, Teva's Reply to the Letter of Facts I of 9 February 2024, para. 98.

Figure 8: {...}

{...}

Source: Annex Q2 submitted in response to the Article 18(2) Request of 3 June 2021.

- (478) Teva’s argument essentially amounts to claiming that as long as Copaxone sales, marketing and medical cost expenditures do not approach zero one has to conclude that Copaxone faces (non-price) competitive constraints from non-GA first-line DMTs significant enough so as to support the inclusion of those products in the same relevant product market. This cannot be accepted as non-GA first line DMTs can only be considered to be part of the same relevant market as Copaxone if they exercise an effective competitive constraint, and not just a barely measurable one.
- (479) The Commission further rejects Teva’s claim that it would be incorrect to attribute all of the observed decline to a reduced focus on competition with non-GA first-line DMTs because Teva carried out a broader set of cuts to the promotional budgets of various products.⁶³⁵ In this context Teva submits that in Europe, sales and marketing costs as a proportion of net sales on all other Teva products also fell by {...} across this period.⁶³⁶ This argument does not convince. First, the comparison with promotional expenditures of all other Teva products is uninformative since Teva does not provide any information on the competitive landscape of these other products and what role promotional expenditures play in that context. Second, the decrease of the actual absolute EUR value spent on sales, marketing and medical costs for all other Teva products in the EEA between 2013 and 2021 is of just {...},⁶³⁷ almost {...} times ({...}%) smaller than the corresponding decrease in the case of Copaxone. These figures, if anything, further support the Commission’s finding that the nature of competition faced by Copaxone changed radically once the entry of Synthron GA was imminent.
- (480) Moreover, Teva puts forward Copaxone’s patient-support-programme (PSP) as an example of significant investment during the Relevant Period to effectively compete with non-GA first-line DMTs.⁶³⁸ Teva claims that it would not have invested in the PSP if Copaxone was only competing with Synthron GA.
- (481) While the Commission does not dispute that PSPs can be an example of non-price competition (see Recital (201)), evidence suggests that Teva’s investments in Copaxone’s PSP were at least partly motivated by competition with Synthron GA.⁶³⁹

⁶³⁵ ID 4032, Teva’s Reply to the Statement of Objections, para. 235.

⁶³⁶ ID 4032, Teva’s Reply to the Statement of Objections, para. 235.

⁶³⁷ Teva correctly pointed out (ID 5695, Teva’s Reply to the Letter of Facts I of 9 February 2024, para. 93) that the Commission’s calculation of the decrease of the actual absolute EUR value spent on sales, marketing and medical costs for all other Teva products in the EEA between 2013 and 2021 first included in the Commission’s Letter of Facts I of 9 February 2024 (para. 58) was incorrect because the data was not properly harmonised to EUR (but compared EUR amounts to USD amounts). However, the Commission’s assessment still holds even after the correction since it is still true that sales & marketing spending for Copaxone has decreased significantly more than for all other Teva products. The error that Teva identified means that the decrease in Copaxone spending is almost three rather than more than five times that of all other products. Teva’s statement that the difference is only {...}% rather than more than {...}% is misleading since it reverses the nominator and denominator of the two ratios it compares to make the error seem more consequential than it was. In any event, the Commission reiterates that the comparison is largely uninformative in the absence of information about the competitive landscape of the other Teva products.

⁶³⁸ ID 4032, Teva’s Reply to the Statement of Objections, para. 206c), para. 228.

⁶³⁹ ID 404-1977, presentation titled “Copaxone Continuation Plan – Project Charter”, 20 February 2017, pp. 5-6; ID 404-1756, Teva internal email dated 15 May 2017 from {...} to {...} and others.

In particular, an internal Teva presentation titled “{...}” shows that Teva’s PSP activities were closely linked to its CCP activities, as it states inter alia: “{...}”.⁶⁴⁰ This is confirmed by Teva’s submission in the Reply to the Statement of Objections, where Teva explains that Copaxone and Synthon GA competed via improvements on their PSP’s in Belgium.⁶⁴¹

- (482) In summary, the assessment of Copaxone sales, marketing and medical costs does not support Teva’s claim that Copaxone faced significant competitive constraints from non-GA first-line DMTs during the Relevant Period. That is because these costs greatly decreased once Synthon GA’s entry became imminent, especially when compared to corresponding decreases for other Teva products, marking an evident change in the nature of competition. Evidence on the file suggest that significant parts of the remaining expenditures can more credibly be attributed to Teva’s efforts to compete against Synthon GA rather than non-GA first-line DMTs; and in any event, these expenditures have had no significant non-transitory effect on Copaxone prices, sales and/or profitability.

6.3.3.2.4.3.4. Teva’s argument with respect to the price constraints exercised by non-GA first-line DMTs on Copaxone

- (483) Teva further argues that although competition among first-line DMTs primarily takes place via non-price competition, there are also instances in which the price of Copaxone has constrained that of non-GA first-line DMTs and vice versa.⁶⁴² In support of this claim Teva refers to (i) reference-pricing in general, (ii) the regulatory framework in Czechia; and (iii) pricing decisions taken by Teva in Germany.
- (484) First, with respect to reference-pricing, Teva submits that when Copaxone was launched, the existing products in the market were interferons, and that the pricing of Copaxone was (at least) initially constrained by interferons.⁶⁴³ Teva concludes from this that, similarly, when Tecfidera and Aubagio were launched, the prices of Copaxone and interferons likely acted as a constraint on these two oral products.⁶⁴⁴ Relatedly, Teva presents a figure that purportedly shows that with the exception of a few outliers, the prices of the various first-line DMTs were broadly similar in each of the Relevant Member States at the start of the Relevant Period.⁶⁴⁵
- (485) In the first place, the Commission has shown in Section 6.3.3.2.1.1 that national health systems exercised very limited price pressure on Copaxone preceding the Relevant Period (and Synthon GA’s entry). Price pressure from bodies responsible for pricing and reimbursement as well as from health insurers, (regional) tender authorities and hospitals was generally limited and Copaxone’s prices in the Relevant Member States were stable. Even if certain non-GA first-line DMTs may have influenced the initial price of Copaxone, this was a one-off consequence of price regulation, and did not exercise a continued and lasting constraint on Copaxone any more once the initial price was set.
- (486) In the second place, even if the launch prices of orals had been to some extent constrained by the prices of Copaxone and the interferons at the time, such a finding

⁶⁴⁰ ID 455-2088, FoGA 2017 – PSP EU activities, 12 May 2017, pp. 3-4, 7, 9, 11-15, 32-34, 49-52.

⁶⁴¹ ID 4032, Teva’s Reply to the Statement of Objections, para. 330.

⁶⁴² ID 4032, Teva’s Reply to the Statement of Objections, para. 238; ID 5695, Teva’s Reply to the Letter of Facts I of 9 February 2024, para. 106.

⁶⁴³ ID 4032, Teva’s Reply to the Statement of Objections, para. 239.

⁶⁴⁴ ID 4032, Teva’s Reply to the Statement of Objections, para. 240.

⁶⁴⁵ ID 4032, Teva’s Reply to the Statement of Objections, Figure 3.

only concerns constraints on oral DMTs and would be irrelevant for determining whether Copaxone’s pricing is constrained in any meaningful manner by orals or interferons.⁶⁴⁶ Teva does not claim that these alleged constraints on oral DMTs then lead to further constraints on Copaxone.

- (487) In the third place, Teva submits that the prices of various first-line DMTs were “*broadly similar*” in 2015, the year of Synthon GA’s launch, indicating that pricing constraints imposed at the time of launch of the respective products have an ongoing impact.⁶⁴⁷ The Commission rejects this argument. Contrary to Teva’s claims, Copaxone was not closely competing on price with the various first-line DMTs. Teva relies on a comparison of public list prices in a single year (2015) to substantiate its claims. However, public list prices are often uninformative because they normally differ significantly from real net prices.⁶⁴⁸
- (488) The Commission further notes that, in any event, even these public list prices are not “*broadly similar*”, as Teva contends, but differ very significantly.⁶⁴⁹ These differences are obscured by the scale that Teva uses in Figure 3 of the Reply to the Statement of Objections. For example, in Poland, that appears to have the smallest difference between the lowest and highest observed prices, the difference between Copaxone (at 17 EUR/DOT) and the cheapest “alternative” considered (Extavia at 12.6 EUR/DOT) is about {...}%, whereas the difference between Copaxone and the most expensive “alternative” considered (Tecfidera at 34.3 EUR/DOT) is roughly {...}%. These large differences in the list prices of first-line DMTs in Poland in 2015, which are far from “*broadly similar*”, are shown in Figure 9 below.⁶⁵⁰ It is noteworthy that Copaxone, a medicine at the end of its lifecycle, could maintain prices at a similar level as the new oral products – without any significant impact on profits.
- (489) In the Reply to the Letter of Facts I,⁶⁵¹ Teva argues that the price differences of Copaxone versus other first-line DMTs “*are entirely consistent with other first-line DMTs imposing a price constraint one [sic] Copaxone’s prices when it was first launched*”.⁶⁵² Teva fails to clarify which are the first-line DMTs that purportedly exercised such a constraint and which ones are the ones that did not. Teva further claims that reference pricing “*evidently does not mean that these negotiations will result in all products having the same price*” (original emphasis) and that “*the mere existence of a price differential clearly does not mean the reference products did not*

⁶⁴⁶ In Germany, the prices of Tecfidera and Aubagio were indeed referenced against the price of Copaxone (see footnote 956) and this had no mentionable impact on Copaxone’s prices in Germany. While the treatment costs for Tecfidera more than halved between 2014 and 2020 and the treatment cost of Aubagio was reduced by nearly 40%, Copaxone’s prices remained largely stable and were reduced by around {...}% only once Clift was launched.

⁶⁴⁷ See ID 4032, Teva’s Reply to the Statement of Objections, para. 241 and Figure 3.

⁶⁴⁸ This is a common feature of pharmaceutical markets where pricing and reimbursement rules and policies remain an exclusive competence of Member States and regulation, public procurement and related negotiations influence the price of a medicine. List prices of medicinal products rarely, if ever, include the rebates resulting from these processes and tend to be significantly higher than realised prices.

⁶⁴⁹ This holds true even when excluding the outlier of Tecfidera’s price in Belgium.

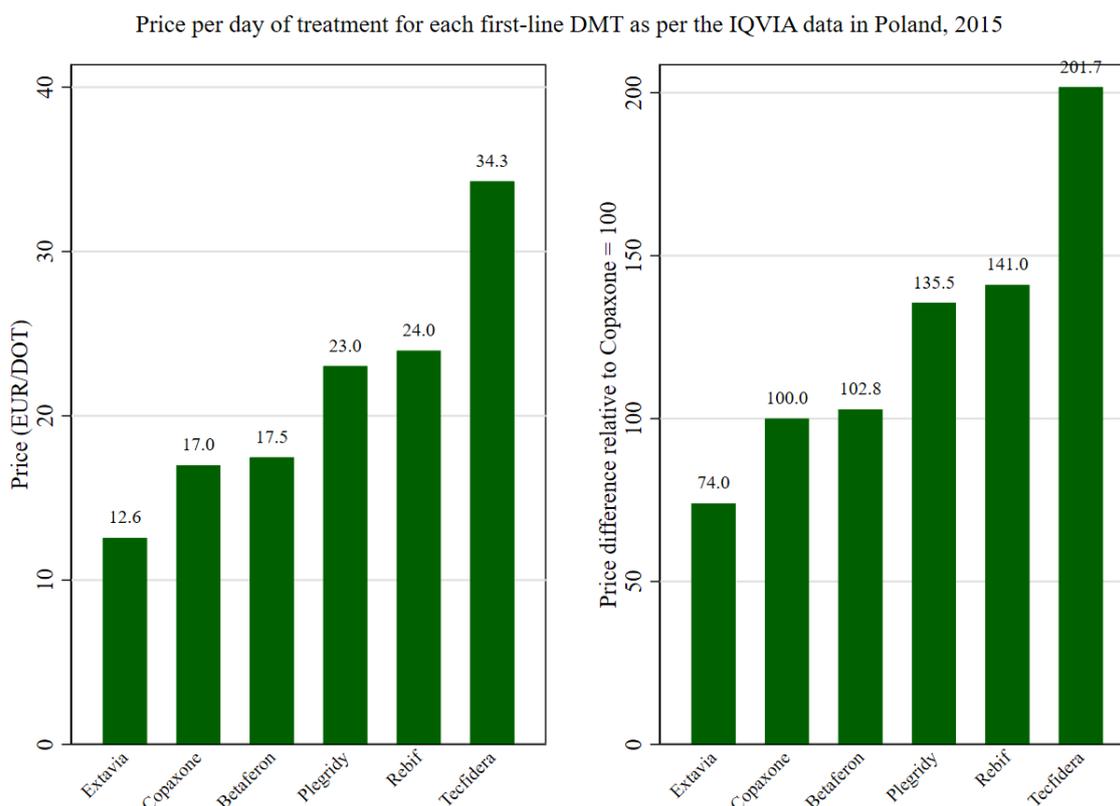
⁶⁵⁰ Only one of the interferons, Betaferon, has a list price close to, but still higher than, Copaxone’s list price. However, no evidence on file exists to suggest that Betaferon in particular exercises a uniquely significant competitive constraint on Copaxone.

⁶⁵¹ ID 5695, Teva’s Reply to the Letter of Facts I of 9 February 2024, paras. 108-111; ID 4032, Teva’s Reply to the Statement of Objections, Figure 3.

⁶⁵² ID 5695, Teva’s Reply to the Letter of Facts I of 9 February 2024, para. 110.

impact the final price negotiated”.⁶⁵³ The Commission reiterates that it was Teva that first suggested that the list prices put forward were “broadly similar” and that that was evidence of other first-line DMTs exercising a significant pricing constraint on Copaxone. The Commission simply noted that these prices were anything but similar. Teva’s reply in the Reply to the Letter of Facts I essentially amounts to admitting that no evidence exists that reference pricing has constrained Copaxone prices, but still arguing that one should simply assume that this has taken place. The Commission has explained why one cannot simply assume that that is the case in Recitals (485) and (486) above.

Figure 9: Price per day of treatment for each first line DMT as per the IQVIA data in Poland, 2015



Source: IQVIA data included in “SO Response datapack - 10 February”

(490) Second, with respect to the regulatory framework in Czechia, Teva claims that Copaxone’s price is directly constrained by interferons because Copaxone is included in the same reference group as interferons.⁶⁵⁴ While it is correct that Copaxone and interferons are included in the same reference group, the Commission rejects Teva’s claim that Copaxone’s prices are directly constrained by interferons. As explained in more detail in the country-chapter on Czechia (specifically in Section 6.3.3.4.3.2.3), Teva managed to avoid price constraints from the reference group until at least October 2021.⁶⁵⁵ An analysis of Copaxone’s prices in Czechia

⁶⁵³ ID 5695, Teva’s Reply to the Letter of Facts I of 9 February 2024, para. 111.

⁶⁵⁴ ID 4032, Teva’s Reply to the Statement of Objections, para. 243.

⁶⁵⁵ ID 4896, Teva’s Reply to Article 18(2) Request of 20 July 2023 (question 3), pp. 5-6.

between 2013 and 2023 shows that the pricing and reimbursement rules in Czechia did not significantly affect Copaxone's prices at least until 2022.⁶⁵⁶

(491) Third, with respect to pricing decisions taken by Teva in Germany, Teva claims that it implemented a voluntary price reduction of {...}% for Copaxone in Germany in reaction to price decreases for Tecfidera and Aubagio.⁶⁵⁷ However, this claim is inconsistent with Teva's own statements in its reply to the Article 18(2) Requests of 22 October and 18 November 2021 that the price decrease of {...}% was implemented to avoid a mandatory price decrease due to the launch of Synthon GA/Clift.⁶⁵⁸ Internal documents confirm that the reason for the price decrease in Germany was the launch of Synthon GA and not the price decreases for Tecfidera and Aubagio.⁶⁵⁹

(492) In summary, the evidence put forward by Teva does not provide any support for the claim that non-GA first-line DMTs exercised meaningful price constraints on Copaxone.

6.3.3.2.4.4. Conclusion: No evidence of significant competitive reactions between Copaxone and non-GA first-line DMTs during the Relevant Period

(493) The Commission carefully assessed the arguments put forward by Teva that purportedly show that significant competitive reactions can be observed between Copaxone and non-GA first-line DMTs during the Relevant Period. The result of the Commission's analysis is that Teva's claims are unfounded. There is no evidence of significant competitive reactions between Copaxone and non-GA first-line DMTs during the Relevant Period.

6.3.3.3. Teva's competitive efforts were focussed on Synthon GA and it did not perceive non-GA first-line DMTs as a significant constraint during the Relevant Period

(494) Teva's reporting, actions and plans show that, *in tempore non suspecto*, Teva itself perceived generic-like competition as an unparalleled competitive threat. No evidence exists on file that Teva harboured similarly strong concerns for non-GA first-line DMTs. Reports of Teva's top management meetings show that concerns regarding any perceived constraints from non-GA DMTs were dwarfed by concerns over Synthon GA (Section 6.3.3.3.1); that Teva closely monitored price developments in EEA markets and prepared, for the first time, its local Copaxone

⁶⁵⁶ ID 4805, Teva's Reply to Article 18(2) Request of 20 July 2023 – Czechia (question 1b). For completeness, Teva sold Copaxone in several different packages. Teva reports in its reply to the Article 18(2) Request of 20 July 2023 (see footnote 655 above) that pricing decisions by the Czech relevant authority related to one specific package and not to all Copaxone packages. While these pricing decisions led to reduced prices for some other Copaxone packages, these packages represented a relatively small number of Copaxone's overall sales in Czechia. The pricing decisions did not significantly affect the prices of the Copaxone packages which generated the most sales at least until 2022.

⁶⁵⁷ ID 4032, Teva's Reply to the Statement of Objections, para. 244; ID 906, Teva's Reply to the Article 18(2) Request of 3 June 2021, p. 20; ID 1295-7, Teva's Reply to the Article 18(2) Requests of 22 October and 18 November 2021, p. 9.

⁶⁵⁸ ID 1295-7, Teva's reply to Article 18(2) Requests of 22 October and 18 November 2021, p. 8, see Recital (789). Notably, the Commission informed Teva of its view of the facts in the Statement of Objections. In its Reply to the Statement of Objections, Teva claims that the Commission misunderstood or even disregarded the facts but it does not attempt to explain or reconcile its own contradicting statements.

⁶⁵⁹ Internal documents suggest that Teva {...}, see ID 404-1631, Teva internal email exchange dated 29-30 May 2018 between {...} and others; ID 404-93, Copaxone® EU Litigation Internal Update, 31 August 2018, pp. 1-2.

teams for price competition in anticipation of the launch of Synthon GA, marking a change in the nature of the competitive environment Copaxone operated in (Section 6.3.3.3.2.); as well as that Teva implemented comprehensive commercial strategies to avoid or mitigate the impact of generic-like entry (Section 6.3.3.3.3). In contrast, Teva has failed to provide evidence of significant competitive reactions between Copaxone and non-GA DMTs (as concluded in Recital (493)), let alone comparable monitoring efforts or commercial strategies as it employed with Synthon GA. In fact, Teva's reporting, actions and plans show that Teva's competitive efforts were focused on Synthon GA and that Teva did not perceive non-price competition from non-GA DMTs as an effective competitive constraint for Copaxone during the Relevant Period. Indeed, contrary to Teva's claims, price competition was not only one element of competition for Copaxone but it became the predominant, if not the only, element of competition when entry of Synthon GA was approaching.

6.3.3.3.1. Teva management's concerns regarding any perceived constraints from other DMTs were dwarfed by its concerns over Synthon GA

(495) An analysis of the topics discussed in Teva's top management meetings at European and global level in the Relevant Period shows that Teva's management {...}.

Discussion of Synthon GA in board meetings

(496) The Commission has reviewed and analysed 201 meeting minutes from the management board of Teva Pharmaceuticals International ("TPI" and "TPI minutes") related to meetings that took place between November 2010 and April 2021 and 26 meeting minutes from the management board of Teva Pharmaceuticals Europe ("TPE" and "TPE minutes") related to meetings that took place between March 2016 and December 2020 that Teva submitted in reply to a Commission's request for information. The Commission requested Teva to provide documents for the period 2010 to 2020. While this includes a period before the start of the Relevant Period in 2015, the Commission considers it appropriate to take into account the period before the nature of competition changed for Copaxone due to the threat of Synthon GA's entry, with the sole view to providing the full context to assess Teva's conduct during the Relevant Period without reaching any finding as regards that earlier period (see Section 6.3.3.2.2). The Commission expects that this period is when Teva would have concentrated the most on its non-GA first-line DMTs rivals (if ever).⁶⁶⁰ Constraints from competing generic(-like) products were (directly or indirectly) mentioned in 106 out of 201 TPI minutes⁶⁶¹ and in 19 out of 26 TPE minutes⁶⁶², often accompanied by an analysis of financial impact of such generic(-like) competition (see next point). {...}.⁶⁶³

⁶⁶⁰ See, to that effect, the following statement from Teva from its Reply to the Statement of Objections (ID 4032, Teva's Reply to the Statement of Objections, para. 251): "It is only to be expected that when a new product enters the market, more time in meetings and more space in internal documents will be devoted to that new product".

⁶⁶¹ The few documents which include statements referring to other DMTs but not to competing GA all stem from before the Relevant Period.

⁶⁶² Based on the review of the minutes provided by Teva in response to the Commission's Article 18(2) Request of 3 June 2021 (ID 778, p. 5).

⁶⁶³ IDs 815-20, 815-58, 834-6, 834-8, 834-16, 834-21, 834-23, 834-27, 834-35, 834-42, 834-49, 834-56, 834-65, 834-71, 834-82, 834-101, 834-108, 834-113, 834-118, 834-133, 834-135, Teva's Reply to Article 18(2) Request of 3 June 2021.

- (497) Teva’s management started discussing the launch of competing GA in Europe and potential scenarios resulting from it in February 2013.⁶⁶⁴ Since then, it constantly monitored and updated scenarios on generic entry. A first estimation was that the impact of competing GA in Europe would lead to a “{...}”.⁶⁶⁵ For comparison, Copaxone’s overall sales in the EEA in 2015 were {...},⁶⁶⁶ which means that, according to Teva’s estimates in 2013, the impact of competing GA in Europe would mean a loss equivalent to two full years of sales in the EEA. In 2019, it was estimated that “{...}”.⁶⁶⁷
- (498) The entry of competing GA was perceived as a serious threat to Teva’s overall profitability because Copaxone was Teva’s “{...}”.⁶⁶⁸ In 2017, Teva’s management warned that “{...}”.⁶⁶⁹ In its 2018 annual report, Teva mentioned adverse court rulings for Copaxone and alerted that “{...}”.⁶⁷⁰
- (499) Accordingly, the TPI minutes, on multiple occasions, state the need to defend Copaxone. For example, one set of minutes reads “{...}”.⁶⁷¹ From 2016 onwards, Teva’s management regularly reported on the achievements of the Copaxone Continuation Project (CCP, see Section 5.3.). In particular, Copaxone 40 mg was perceived as an effective tool to “{...}”⁶⁷² and TPI’s management qualified the approval of Copaxone 40 mg in the EU as “{...}”.⁶⁷³
- (500) After the launch of Synthon GA in Europe, the TPI and TPE minutes show that the price development of Copaxone and Synthon GA was closely followed in European and international management meetings. The European management observed that “{...}”,⁶⁷⁴ {...}.⁶⁷⁵ The management found that Teva’s main tool to compete is “{...}”.⁶⁷⁶ A document discussed in a board meeting in 2019 of Teva’s European management concluded: “{...}”.⁶⁷⁷
- (501) The TPI and TPE minutes show that Teva saw a direct link between {...}. According to TPI minutes, {...}.⁶⁷⁸ TPE minutes from 2020 state “{...}”⁶⁷⁹ and explain that “{...}”⁶⁸⁰.

⁶⁶⁴ ID 834-27, Copaxone Board Discussion, February 2013, pp. 55-58, 66.

⁶⁶⁵ ID 834-27, Copaxone Board Discussion, February 2013, p. 66.

⁶⁶⁶ ID 2149, Teva’s reply to Article 18(2) Request of 13 July 2022.

⁶⁶⁷ ID 834-9, February 2019 Board meeting – Europe Business Update, p. 14.

⁶⁶⁸ ID 834-69, Annual Report on Form 10-K: 2019 – Reading Materials, Part I, January 10, 2019, p. 22.

⁶⁶⁹ ID 834-75, Teva Pharmaceutical Industries Limited – Consolidated Financial Statements – For The Year Ended December 31, 2017, p. 47; see also ID 834-21, Q3 2016 Financial Results Audit Committee Meeting, November 7th 2016, p. 29.

⁶⁷⁰ ID 834-69, Annual Report on Form 10-K: 2019 – Reading Materials, Part I, January 10, 2019, p. 22.

⁶⁷¹ ID 834-21, Q3 2016 Financial Results Audit Committee Meeting, November 7th 2016, p. 29; see also ID 834-27, Copaxone Board Discussion, February 2013; ID 815-45, Teva Pharmaceutical Industries LTD, Minutes of the Meeting of the Board Directors (8/15), April 28, 2015.

⁶⁷² ID 815-69, Teva Pharmaceutical Industries LTD, Minutes of the Meeting of the Board Directors (14/14), September 17, 2014, p. 3.

⁶⁷³ ID 834-140, 2015 Financial Outlook, December 11, 2014, p. 10.

⁶⁷⁴ ID 806-34, Minutes of the Management Board, 25 November 2016, p. 2.

⁶⁷⁵ ID 806-29, Minutes of the Management Board, 12 December 2018, p. 1.

⁶⁷⁶ ID 806-36, TPE Board Meeting – Finance – Q3 2020, 5 October 2020, p. 6.

⁶⁷⁷ ID 806-32, TPE Board Mtg – April 2019 – Finance, Amsterdam, April 4, p. 7.

⁶⁷⁸ ID 834-29, Teva Q1 2018 Financial Review and Analysis Executive Summary; ID 834-90, Audit Committee & Board meeting, Q1 2018 Results, May 1, 2018; ID 834-47, Q2 2018 Results, 30/31 July 2018; ID 834-52, Q1 2018 Draft Financial Results – Board of Directors and Audit Committee Meeting, May 1, 2018; ID 834-46, Q3 2018 Draft Financial Results – Board of Directors and Audit Committee Meeting, October 29, 2018; ID 834-25, Teva Q2 2018 Financial Review and Analysis Executive Summary; ID 834-38, Q2 2018 Draft Financial Results – Board of Directors and Audit Committee

(502) The importance of delaying generic entry, for example through patent enforcement, for Teva Europe’s profitability is demonstrated by the fact that the status of EPO proceedings and preliminary injunctions was discussed in detail in meetings of both TPE and TPI.⁶⁸¹ In a 2020 TPE board meeting that took place shortly after the EPO revoked Teva’s dosage patent EP ‘335 and the preliminary injunction against Synthron GA in Germany was lifted, Teva estimated the impact of this “{...}” on {...},⁶⁸² which is {...}.⁶⁸³

(503) Consequently, the board documents contain a clear acknowledgement that competition from Synthron GA was the primary reason for the decline in Copaxone revenues: “{...}”.⁶⁸⁴

Discussion of other (non-GA) DMTs, especially orals, in board meetings

(504) {...}.⁶⁸⁵

(505) {...}. This analysis demonstrates that even during the period where interferons were the only other first-line treatments in the RRMS segment (before 2014), Teva’s management did not discuss a potential impact of interferons on Teva’s business in any meaningful detail. Moreover, while impact from “generic” GA competition was discussed and analysed at length by Teva’s top management,⁶⁸⁶ references to other DMTs were terse and rarely contained any analysis (as exemplified by the quotation in Recital (504)).

(506) There is stark contrast between the prevalence and nature of discussion, as well as depth of analysis, concerning, respectively, Synthron GA and oral DMTs. {...}.

Figure 10: Excerpt from TPE Board Meeting Minutes (July 2020)

{...}

Source: {...}.

(507) {...}.⁶⁸⁷ {...}.⁶⁸⁸ {...}.

Meeting, July 30, 2018; ID 834-59, Q3 2018 Draft Financial Results – Board of Directors and Audit Committee Meeting, October 30, 2018.

⁶⁷⁹ ID 806-1, TPE Board Mtg – April 2020 - Finance, April 2nd 2020, p. 10; ID 806-4, TPE Board Meeting Finance – Q2 2020, 9 July 2020, p. 10.

⁶⁸⁰ ID 806-1, TPE Board Mtg – April 2020 - Finance, April 2nd 2020, p. 10; ID 806-4, TPE Board Meeting Finance – Q2 2020, 9 July 2020, p. 10.

⁶⁸¹ ID 834-29, Teva Q1 2018 Financial Review and Analysis Executive Summary; ID 806-15, TPE Board Meeting – EU Management Financials, Amsterdam, October 2018.

⁶⁸² ID 806-36, TPE Board Meeting – Finance – Q3 2020, 5 October 2020, p. 14.

⁶⁸³ Assuming Teva’s quarterly operating profits are one fourth of the annual operating profits (after R&D, GD and other income) in 2020 in the EEA were USD {...}. See ID 1674, Teva’s reply to Article 18(2) Request of 25 April 2022.

⁶⁸⁴ ID 834-82, United States Securities and Exchange Commission – Form 10-K, for the fiscal year ended December 31, 2019, p. 29. On p. 68 of the document, Teva refers specifically to {...}. See also: ID 834-30, United States Securities and Exchange Commission – Form 10-Q, for the quarterly period ended March 31, 2020, p. 40; ID 834-68, United States Securities and Exchange Commission – Form 10-Q, for the quarterly period ended September 30, 2020, p. 64; ID 834-74, Teva Q3 2019 Financial Review and Analysis – Executive Summary, October 31, 2019, p. 8; ID 834-138, Teva’s Strategy – creating a sustainable path forward, Draft Version 8.0, May 2018, p. 2

⁶⁸⁵ ID 806-13, TPE Board Mtg – January 2020 Finance, Amsterdam, Jan 9th 2020, p. 13.

⁶⁸⁶ See Recital (497) and subsequent.

⁶⁸⁷ ID 806-4, TPE Board Meeting Finance – Q2 2020, 9 July 2020, p. 20.

⁶⁸⁸ ID 806-4, TPE Board Meeting Finance – Q2 2020, 9 July 2020, p. 20.

Figure 11: Excerpt from TPE Board Meeting Minutes (April 2019)

{...}

Source: ID 806-32, TPE Board Mtg – April 2019 – Finance, Amsterdam, April 4, p. 7.

(508) {...}

(509) {...}.⁶⁸⁹ {...}.⁶⁹⁰

Teva claims to have continuously discussed non-GA DMTs in internal documents

(510) Teva claims that non-GA first-line DMTs are consistently raised in internal documents, namely in Teva’s board meeting minutes, in strategic internal Copaxone Brand Plans, and in recent promotional materials for physicians.⁶⁹¹ Teva claims that this is evidence that significant competition exists between Copaxone and non-GA first-line DMTs both prior to as well as during the Relevant Period⁶⁹² because “*these references would make no sense if [...] these products had not remained material rivals to Copaxone throughout the period*”.⁶⁹³

(511) Teva’s claim does not convince. First, Teva suggests that the fact that non-GA first-line DMTs were mentioned at all in internal documents is evidence of significant competitive constraints.

(512) Teva does not demonstrate that the context of references to non-GA first-line DMTs shows that they were considered a significant competitive threat to Copaxone (comparable to Synthon GA). According to Teva, any indication that Copaxone may also face some competition from non-GA first-line DMTs, no matter how negligible, must necessarily mean that those remain a significant competitive threat to Teva and therefore belong to the same relevant market. The Commission rejects this premise. Teva does not demonstrate that the interactions are significant enough to exercise a meaningful constraint on the market conduct of Copaxone. The Commission does not find that such competitive interactions are non-existent, but they are limited (see Recitals (363), (493)). The evidence that Teva puts forward indicating (indirectly) that these interactions might in fact exist, albeit to a limited extent, does not undermine the Commission’s overall analysis, findings and/or conclusions in this Chapter.

(513) Second, Teva’s claim is based solely on the basis of prevalence of mentions of Synthon GA and non-GA first-line DMTs without considering the context in which a treatment is mentioned. While non-GA first-line DMTs may be mentioned in internal documents, there is a stark contrast between the nature of discussion and the depth of analysis of Synthon GA (as shown above in Recitals (497)-(503)) and non-GA DMTs (as shown above in Recitals (504)-(509)). For example, Teva’s 2018 annual report states concerning Synthon GA that “*the loss of patent protection or regulatory exclusivity on specialty medicines could materially impact our business, results of operations, financial condition and prospects*”, while it states on non-GA DMTs that

⁶⁸⁹ ID 815-20, Teva’s reply to Article 18(2) Request of 3 June 2021.

⁶⁹⁰ ID 834-113, Q1 2017 Results – Audit Committee meeting May 8, 2017, Board meeting May 10, 2017, p. 13; see also ID 834-65, Q4&FY 2016 Results – Audit Committee Meeting: Feb. 6, 2016, Board Meeting: Feb. 7-8, 2016; ID 834-21, Q3 2016 Financial Results Audit Committee Meeting, November 7th 2016.

⁶⁹¹ ID 4032, Teva’s Reply to the Statement of Objections, paras. 247-248.

⁶⁹² ID 4032, Teva’s Reply to the Statement of Objections, para. 265; ID 5695, Teva’s Reply to the Letter of Facts I of 9 February 2024, para. 116.

⁶⁹³ ID 5695, Teva’s Reply to the Letter of Facts I of 9 February 2024, para. 120.

“oral treatments for MS, such as Tecfidera, Gilenya and Aubagio, continue to present significant and increasing competition”.⁶⁹⁴

- (514) Third, to support its claim that non-GA first-line DMTs are being consistently raised in TPI and TPE minutes, Teva put forward in its Reply to the Statement of Objections data purportedly showing that *“the frequency with which non-GA first-line treatments were mentioned remained evidently material”*.⁶⁹⁵ The Commission notes that an analysis of this data, broken down by year (see Figure 12), shows that Synthon GA is mentioned overwhelmingly more frequently than non-GA first-line DMTs, both before and after 2015; that this difference in frequency of mentions increases significantly after 2015; and that the proportion of documents mentioning non-GA first-line DMTs more than halved from 2015 onwards compared to the period before 2015. The evidence supports the Commission’s conclusion that the minutes of Teva’s management board meetings show that Teva’s concerns about price competition from Synthon GA were significantly larger than any concerns about competitive constraints through non-price competition from non-GA DMTs. This difference is evident already in the two years prior to the Relevant Period (during 2013 and 2014) and continues to hold true during the entirety of the Relevant Period.
- (515) These observations are perfectly in line with the Commission’s finding that the nature of competition changed drastically once the entry of Synthon GA was imminent. And as discussed, the fact that some lingering competitive interactions may still have existed between Copaxone and non-GA first-line DMTs during the Relevant Period does not mean that non-GA first-line DMTs effectively constrained Copaxone’s market conduct.

Figure 12: Mentions of first-line DMTs as share of all TPI and TPE documents over time, 2010-2021, broken down per year

{...}

Source: Commission Calculations based on “Meeting minutes - rival mentions tracker.xlsx” submitted in “SO Response datapack – 10 February”.

Conclusion

- (516) A comparison between the brief mentions of non-GA DMTs and the extensive discussion of the impending entry of Synthon GA in management board meetings shows that Teva’s concerns about any competitive constraints through non-price competition from non-GA DMTs was significantly smaller than its concerns about price competition from Synthon GA.
- (517) Contrary to Teva’s claims, the impending entry of Synthon GA did not simply introduce price as just one more element of competition for Copaxone. Price in fact became the main element of competition in this market.
- 6.3.3.3.2. Upon generic entry, Teva closely monitored price developments in EEA markets and “GA markets”, and, for the first time, prepared its local Copaxone teams for price competition
- (518) Teva was aware that the entry of Synthon GA would put Copaxone under price pressure in the Relevant Member States and other EEA countries. Teva therefore

⁶⁹⁴ ID 834-69, Annual Report on Form 10-K: 2019 – Reading Materials, Part I, January 10, 2019, pp. 5-6, 22; see also p. 19.

⁶⁹⁵ ID 4032, Teva’s Reply to the Statement of Objections, para. 254 and Figure 4.

closely monitored the launch timeline and price developments of Synthron GA and “GA markets”, and, for the first time, prepared its local Copaxone teams for price competition in dedicated workshops.

- (519) Already in 2014, Teva’s Market Access Team collected information on the potential price impact and on mandatory price decreases in different Member States for Copaxone.⁶⁹⁶ Since October 2016 (at the latest), Teva’s {...} sent monthly “*Updates on FoGA 20/40mg status in Europe*”.⁶⁹⁷ In these emails and the attached documents, the Senior Pricing Manager reports in detail on {...}.
- (520) For example, the “Update on FoGA 20/40mg status in Europe” from December 2018 reports, inter alia, on Italy: “{...}”⁶⁹⁸
- (521) This comprehensive reporting demonstrates how Teva followed every action leading to the launch of Synthron GA and subsequently closely followed the price development of Synthron GA to analyse its impact on Copaxone’s prices.
- (522) Several internal documents show that Teva also started to reference a “GA market” after Synthron GA was launched in Europe. {...}.⁶⁹⁹ {...}.⁷⁰⁰
- (523) But Teva did not only collect information on the potential price impact of generic entry. Teva further actively prepared its local Copaxone teams for the impending price competition through generic entry by organising price competition workshops for the first time. Teva expected Synthron GA to launch in late 2017⁷⁰¹ and therefore organised price competition workshops for its local Copaxone teams in mid-2017 to “{...}”.⁷⁰² For example, the agenda of the price competition workshop for Poland and Czechia included the following points: “{...}”.⁷⁰³ Some of the key messages in these workshops were that “{...}”.⁷⁰⁴ One Teva employee was quoted with the feedback that {their} local team is “{...}” because their country (the document does not specify which country) “{...}”.⁷⁰⁵
- (524) In a presentation prepared for a price competition workshop in Amsterdam in June 2017, Teva notes that “{...}”.⁷⁰⁶ The presentation proceeds to identify, inter alia, {...}. This shows that Teva was aware of the mechanisms in the Relevant Member States that apply to originator drugs after generic entry to increase price pressure and (correctly) assumed that these mechanisms would apply to Copaxone after the entry

⁶⁹⁶ ID 404-487, Input CPX Price.

⁶⁹⁷ See, for example, ID 266-96, Copaxone Litigation Internal Update for week ending 28 October 2016, 31 October 2016; ID 455-2593, Teva internal email dated 10 February 2017 from {...} to {...} and others, pp. 2-3; ID 455-464, Teva internal email dated 15 June 2018 from {...} to {...} and others, pp. 1-10; ID 455-2921, Teva internal email dated 23 January 2019 from {...} to {...} and others. See also Recital (334), referencing meeting minutes for several meetings on “*FoGA/Copaxone MA focus*”: ID 455-461, Teva internal email exchange from 9 December 2016 to 12 May 2017 from {...} to {...} and others, pp. 1-24.

⁶⁹⁸ ID 455-2683, Teva internal email dated 14 December 2018 from {...} to {...} and others, p. 1.

⁶⁹⁹ ID 455-1905, EU FOGA Uptake (Mar 2019 Market Data), 28 May 2019, p. 6. See also ID 263-2828 AOP 2020 – Italy Cluster, 21 October 2019, p. 34.

⁷⁰⁰ ID 262-1317, AOP F2F review Benelux & Nordics, 14 October 2019, p. 17.

⁷⁰¹ ID 262-1695, Price competition workshop – Copaxone & Lonquex, 20-21 June 2017, p. 8.

⁷⁰² ID 262-1600, Teva internal email dated 7 July 2017 from {...} to {...} and others, p. 1.

⁷⁰³ ID 455-2349, Copaxone Price Competition Workshop with PL and CZ Team, Amsterdam, 4 December 2017, p. 2.

⁷⁰⁴ ID 262-1601, Price Competition Workshop Amsterdam, 20-21 June 2017, p. 1.

⁷⁰⁵ ID 262-1601, Price Competition Workshop Amsterdam, 20-21 June 2017, p. 3.

⁷⁰⁶ ID 262-1695, Price competition workshop – Copaxone & Lonquex, 20-21 June 2017, p. 9; see also ID 266-25 Copaxone/FoGA – P&MA outlook, 7 June 2017, p. 3.

of Synthon GA. Under “{...}”, Teva noted, inter alia, “{...}”.⁷⁰⁷ Similar statements are found in a 2017 presentation by the {...}, in which the following “*Rule of thumb*” is established: “{...}”.⁷⁰⁸

- (525) Teva also closely monitored regulatory mechanisms by country (“{...}”⁷⁰⁹). In a Copaxone Brand Plan presentation for the Netherlands from 2014, the prospective entry of Synthon GA was discussed in the form of checklists on “{...}”, “{...}” and “{...}”.⁷¹⁰ The presentation shows that Teva was aware of a possible impact of the “{...}” concerning “{...}”⁷¹¹ and that Teva anticipated the interest of HCPs and authorities in saving on GA expenditure as a “key issue” (“{...}”⁷¹²). Teva’s reporting on and preparation for potential price competition shows that Teva was aware of the shift in the demand structure that generic entry would cause for Copaxone.
- (526) The fact that Teva closely followed price developments and even introduced price competition workshops for its local Copaxone teams in anticipation of entry by Synthon GA shows that Teva perceived price competition from Synthon GA as a significant competitive threat.
- (527) Teva has failed to put forward any evidence that would support the finding that it made comparable monitoring efforts for non-GA DMTs and the Commission has not encountered, during this investigation, any evidence that would suggest that Teva followed the relevant developments of non-GA DMTs or prepared for their entry in a comparable way.

6.3.3.3.3. Teva implemented comprehensive commercial strategies to avoid or mitigate the impact of generic entry

- (528) Teva implemented, or considered, several commercial strategies to avoid or mitigate the impact of generic entry, namely (i) the CCP (Copaxone Continuation Project, see Section 5.2) including a switch from Copaxone 20 mg to Copaxone 40 mg and the launch of a duplicate product and a single dosage device in Germany, (ii) giving priority to defence strategies against competition from Synthon GA over promotional expenditure for differentiation vis-à-vis other (non-GA) DMTs, and (iii) the withdrawal of Copaxone from price-competitive markets to avoid negative impact through external price referencing. No evidence exists on file that Teva employed similar commercial strategies to avoid or mitigate the impact from entry of non-GA first-line DMTs.
- (529) First, Teva had already started in 2012 to develop a “Copaxone defence” strategy, later called the CCP, to overcome the “{...}”.⁷¹³ The main pillars of the CCP were the conversion of patients to 40 mg Copaxone, regulatory litigation against marketing authorisations for Synthon GA and/or against decisions regarding substitution of Copaxone with Synthon GA, commercial litigation to prevent Synthon from marketing its GA (under IP or unfair competition laws) and a comprehensive communication campaign. The two latter pillars of the CCP are the subject-matter of the conduct described in Chapters 8 and 9 below.

⁷⁰⁷ ID 262-1695, Price competition workshop – Copaxone & Lonquex, 20-21 June 2017, p. 9.

⁷⁰⁸ ID 266-25, Copaxone/FoGA – P&MA outlook, 7 June 2017, p. 3.

⁷⁰⁹ ID 404-487, Input CPX Price.

⁷¹⁰ ID 262-1669, Copaxone Brand Plan & LRP 2015-2017 NL, 14 April 2014, pp. 44-46.

⁷¹¹ ID 262-1669, Copaxone Brand Plan & LRP 2015-2017 NL, 14 April 2014, p. 44.

⁷¹² ID 262-1669, Copaxone Brand Plan & LRP 2015-2017 NL, 14 April 2014, p. 45.

⁷¹³ ID 455-9, Global Commercial Strategic Plan, 5 September 2012, p. 17.

- (530) In a 2018 internal presentation, Teva lists the “{...}”.⁷¹⁴ The duplicate strategy, the SDD launch and the Copaxone 40mg launch were part of Teva’s “Copaxone Continuation Project” and aimed at limiting the expansion of Synthron GA (see Section 5.2.3.1, Recital (159)). The update of Copaxone’s SmPC label (“{...}”) and the launch of the patient support programme (“{...}”) and were at least in part motivated by competitive efforts against Synthron GA (see Recitals (471) and (481)).
- (531) The different strategies of the CCP worked together in the regulatory and commercial litigation against Synthron GA 20 mg and stalled the effective launch of the product, which gave Teva additional time to switch its patients from a 20 mg dosage to a 40 mg dosage (see Section 5.2.5). The rationale behind this switch was that Copaxone patients would likely not switch back to a 20 mg dosage only to receive Synthron GA. Thus, there would be little demand in the market for a generic-like 20 mg GA alternative by the time Synthron GA 20 mg was launched. While Teva submits that Copaxone 40 mg was launched as a response to competition from oral DMTs,⁷¹⁵ internal documents show that the main driver of the switch was the impending entry of Synthron GA: “{...}”.⁷¹⁶
- (532) When Teva’s strategy to switch patients from 20 mg to 40 mg became apparent, Synthron started preparations to launch its own 40 mg GA. However, the launch of Synthron GA 40 mg required several preparatory steps, including applying for new marketing authorisations and pricing and reimbursement negotiations. Further, Teva held a secondary patent (plus divisional patents) protecting the 40 mg dosing regimen for Copaxone, which it enforced against Synthron. The secondary patent was challenged by Synthron and withdrawn in 2017⁷¹⁷ but Teva continued to enforce its divisional patents (see Chapter 8).
- (533) As part of the CCP, Teva also considered introducing Copaxone duplicates, i.e. launching its own generic version of Copaxone under a different brand name. In an email, Teva’s {...} explained the rationale behind the launch of a duplicate was to “{...}”,⁷¹⁸ which means that Teva wanted to protect the list price of Copaxone (from the negative effects of external price referencing) by participating in price competition with the duplicate only. In an internal document from 2017, {...}.⁷¹⁹
- (534) Teva was further aware of the potential negative impact of substitution rules for Copaxone. It therefore considered the launch of a slightly modified injection device for Copaxone, namely a single-dose injection pen (internally referred to as the single dosage device – “SDD”) instead of a single-use syringe “{...}”.⁷²⁰ Despite both being single-use injection devices, an injection pen cannot be substituted with a syringe because they are considered to be different pharmaceutical dose forms.⁷²¹ Prescriptions for Copaxone packs with the SDD as injection device can therefore not be substituted with packs of Synthron GA with a syringe as injection device. Teva’s

⁷¹⁴ ID 263-1564, GTMAP EU Copaxone 2018, p. 7.

⁷¹⁵ The Commission has assessed Teva’s claims in detail in Section 6.3.3.2.4.3.1.

⁷¹⁶ ID 455-2523, Germany GGM risk Mgmt AOP 2016, 13 December 2015, p. 2.

⁷¹⁷ See Chapter 8.

⁷¹⁸ ID 404-537, Teva internal email exchange dated 15 June 2018 between {...} and {...}, p. 1.

⁷¹⁹ ID 404-385, internal email dated 12 September 2017 from {...} to {...} and others, p. 1; see also ID 455-2081, internal email dated 23 August 2018 from {...} to {...} and others.

⁷²⁰ ID 263-1255, TPE Multiple Sclerosis: 2018, February 2018, p. 39.

⁷²¹ According to the list of Standard Terms published by the European Directorate for the Quality of Medicines & Health Care (EDQM). See ID 2170, EDQM database definition of “pre-filled syringe”, p. 1; ID 2174, EDQM database definition of “pen”, p. 1; ID 2184, EDQM database definition of “pen for cartridge”, p. 1.

internal documents clearly show that the main rationale for the launch of the “SDD” {...}⁷²² {...}.⁷²³ {...}.⁷²⁴ Teva has failed to provide evidence that would support a finding that it employed comparable commercial strategies in reaction to the entry of new non-GA DMTs (in particular the oral DMTs) or in reaction to competition from any non-GA DMT.⁷²⁵ The Commission has also not encountered, during this investigation, any evidence which would suggest that Teva employed comparable commercial strategies concerning non-GA DMTs or prepared for their entry in a comparable way.

- (535) Second, Teva gave priority to “Copaxone defence” strategies such as the CCP over promotional expenditure for differentiation vis-à-vis other (non-GA) DMTs (see Section 6.3.3.2.). Teva submits that competition in the RRMS segment is not focused on price but on promotion (“{...}”). However, internal documents show that {...}.⁷²⁶ The 2018 Copaxone Brand Plan (see footnote 210) illustrates how {...}.⁷²⁷
- (536) Third, Teva considered withdrawing Copaxone from certain very price-competitive markets to avoid spill over effects of price reductions into other markets. Due to external reference pricing in many Member States (see 6.3.3.2.), a significant reduction of Copaxone’s list price in one market could have a spill over effect into other markets. In several countries, such as Belgium, Czechia and Poland, the entry of a generic (or generic-like) alternative on the market triggers mandatory price decreases for the originator drug. The abovementioned 2017 presentation by Teva’s {...} (see Recital (524)) shows that Teva was prepared to “{...}”.⁷²⁸ In its Copaxone Brand Plans for 2019 and 2020, Teva still considered the “{...}”.⁷²⁹
- (537) A presentation titled “Copaxone in Belgium/Impact in the NL”, prepared by the {...}.⁷³⁰ It follows that Teva was at least considering to give up the reimbursement status for Copaxone in Belgium to avoid the negative price impacts for Teva of generic entry. Considering the high prices of treatment with Copaxone (several hundred Euro per month), giving up the reimbursement status of Copaxone would have left Belgian patients effectively without access to Copaxone and would have *de facto* come close to exiting the Belgian market. Eventually, the threat of a {...}% price decrease dissipated because the launch of Synthon GA in Belgium was delayed. When Synthon GA was eventually launched in Belgium in 2021, the legal framework had been amended and foresaw a significantly lower price decrease for “hybrid drugs” compared to their reference products, such as Copaxone and Synthon GA.
- (538) On the basis of the above, the Commission finds that Teva’s strategies and actions primarily aimed to address the threat of strong price competition from Synthon GA

⁷²² ID 263-1255, TPE Multiple Sclerosis: 2018, February 2018, p. 39; see also: ID 404-537, Teva internal email exchange dated 15 June 2018 between {...} and {...}.

⁷²³ ID 263-1255, TPE Multiple Sclerosis: 2018, February 2018, p. 39.

⁷²⁴ ID 4729-138, Teva internal email dated 13 November 2020 from {...} to {...} and others; ID 4733-66, Teva internal email dated 18 April 2022 from {...} to {...}; ID 4733-14, “Wochenbericht”.

⁷²⁵ See Recitals (469), (471)-(472) and (482).

⁷²⁶ ID 263-2408, Strategic Priorities and Roadmap, June 2016, p. 7.

⁷²⁷ ID 263-1255, TPE Multiple Sclerosis: 2018, February 2018, pp. 39-40; ID 263-780, Budget based on target 2018, 7 December 2017. See also Section 6.3.3.2.2.

⁷²⁸ ID 266-25, Copaxone/FoGA – P&MA outlook, 7 June 2017, p. 4.

⁷²⁹ ID 886-19, 2019 EU Strategic Brand Plan Copaxone, p. 17; ID 886-20, 2020 E.U. Brandplan & High level GTMAP Copaxone, p. 17.

⁷³⁰ ID 404-2469, Copaxone in Belgium/Impact in the NL, 24 April 2018, p. 4.

and were a top priority for Copaxone's commercial strategy (e.g. "{...}").⁷³¹ These commercial strategies went far beyond the commercial actions that Teva was considering vis-a-vis non-GA DMTs. For example, in view of the competitive pressure from Synthon GA, Teva considered withdrawing Copaxone from several EU markets to prevent spill over effects for Copaxone prices elsewhere. Such drastic measures were never considered to respond to competition from other non-GA DMTs. Teva's position recorded in internal documents thus stands in direct contradiction to its claim that the market for Copaxone is driven by non-price competition, even after the entry of Synthon GA. In markets characterised by non-price competition, there would be no rationale for Teva's abovementioned commercial strategies, such as the CCP.

6.3.3.4. A country-specific assessment shows that non-GA first-line DMTs have not been an effective and immediate constraint on Copaxone

(539) In the foregoing, the Commission found, based primarily on qualitative evidence, that Copaxone's (approaching) loss of exclusivity and the (actual or potential)⁷³² entry of Synthon GA introduced (the threat of) intense price pressure and thus led to a change in the nature of competition. Consequently, during the Relevant Period, non-price competition from non-GA first-line DMTs was not an effective and immediate constraint for Copaxone, as also corroborated by Teva's own documents.

(540) Teva claims that, at most, the Commission's analysis could indicate that Synthon GA is a closer (price) rival to Copaxone in a wider, differentiated, product market that includes at least all first-line DMTs.⁷³³ Teva argues that a proper analysis of the relevant product market would require the Commission to conduct a "*hypothetical monopolist test*".⁷³⁴ According to Teva, the only way of carrying out the hypothetical monopolist test is by carrying out the SSNIP test ("*Small but Significant and Non-transitory Increase in Price*" test).⁷³⁵ Teva further claims that, while the SSNIP test refers to price, the same logic applies to reduction in quality, innovation, or promotional activity if these are relevant parameters of competition.⁷³⁶ Teva argues that price is not a key parameter of competition between Copaxone and non-GA first-line DMTs because they compete on R&D investments and seeking to gain prescriptions from each other by differentiating their products, inter alia through promotional efforts.

(541) According to Teva, the appropriate test to determine whether non-GA first-line DMTs compete in the same relevant market as Copaxone is therefore whether a hypothetical monopolist of all GA products could profitably reduce quality, innovation, or promotional activity by an equivalent of a 5-10% reduction in price.⁷³⁷ Teva further claims that the Commission itself, in the draft version of the 2024 Market Definition Notice, emphasises the importance of non-price competition in certain markets, including in "*highly innovative industries*" such as the

⁷³¹ ID 265-277, Copaxone GTMAP UK, 1 November 2017, p. 38.

⁷³² The term "potential entry" refers to Relevant Member States in which Synthon GA could have been launched in a short period of time and with sufficient strength to constitute a serious counterbalance to the originator product. See Recital (198) and Case C-307/18, *Generics (UK) and Others*, paragraph 133.

⁷³³ ID 4032, Teva's Reply to the Statement of Objections, para. 155

⁷³⁴ ID 4032, Teva's Reply to the Statement of Objections, para. 159.

⁷³⁵ ID 4032, Teva's Reply to the Statement of Objections, para. 159. Contrary to Teva's claims, paragraph 15 of the 1997 Market Definition Notice refers to the SSNIP test as "*one way of making this determination [referring to the assessment of demand substitution].*"

⁷³⁶ ID 4032, Teva's Reply to the Statement of Objections, para. 159.

⁷³⁷ ID 4032, Teva's Reply to the Statement of Objections, para. 161.

pharmaceutical sector.⁷³⁸ According to Teva, it follows that, where price is not a key parameter of competition, the relevant market definition should turn on customers' reactions to a small but significant non-transitory decrease in quality.⁷³⁹

- (542) First, and as explained in the foregoing, the Commission's analysis takes into account both price and non-price elements of competition. Moreover, the variation of the hypothetical monopolist test proposed by Teva (referred to as the SSNDQ – "*Small but Significant Non-transitory Decrease in Quality*") is unsuitable and largely uninformative in the present case. This is because of the difference in the nature of competition between Copaxone and Synthon GA on the one hand and Copaxone and non-GA first-line DMTs on the other. Whether a hypothetical monopolist of all GA products (Copaxone and Synthon GA) could profitably reduce quality, innovation or promotional activity by an equivalent of a 5-10% reduction in price is a question entirely separate to the one of whether such a monopolist would be able to profitably increase GA prices by 5-10% (compared to the price level *after* the entry of Synthon GA). For the purposes of this Decision, once it has been established that the GA market can be profitably monopolised in terms of price, it is not necessary to establish the boundaries of the product space that could profitably be monopolised also in terms of quality. Endeavouring to answer the question of whether a monopolist on the market for GA (in this case an entity owning both Copaxone and Synthon GA), having first regained the ability to bring prices back to their (monopoly) level prior to the entry of Synthon GA, would be in a position to exercise **even more** market power, by **also** decreasing the quality of all GA products, would amount to committing the so-called cellophane fallacy⁷⁴⁰. Moreover, Teva's proposal as to the appropriate test could be understood as asking whether a hypothetical monopolist of Copaxone, before the beginning of the Relevant Period, that is to say at a time when the entry of Synthon GA was not imminent and prior to the change in the nature of the competitive landscape that imminent entry brought about, would have the ability to profitably decrease the quality of **just Copaxone**. However, this is not of direct relevance to this Decision, precisely because it does not concern the situation at the time of the Relevant Period, and ignores the presence of the constraint from Synthon GA. In any event, despite Teva's claims, what non-price constraints non-GA DMTs may or may not have exercised on Copaxone, have not been overlooked but have been closely considered in this Decision.
- (543) Second, it has been repeatedly clarified by the Courts that the Commission is not required to carry out a SSNIP test for the definition of the relevant market.⁷⁴¹ Neither the 1997 Market Definition Notice, nor the 2024 Market Definition Notice suggest that the SSNIP test is the only admissible tool to define the relevant market.⁷⁴² Concerning highly innovative markets, the 2024 Market Definition Notice states that

⁷³⁸ ID 4032, Teva's Reply to the Statement of Objections, para. 166. The reply to the Statement of Objections was submitted in February 2023, before the adoption of the Market Definition Notice in February 2024. Therefore, Teva's submission refers to the draft revised Market Definition Notice which was published in November 2022. Teva's argument can likewise be applied to the text of paragraph 30 of the 2024 Market Definition Notice.

⁷³⁹ ID 4032, Teva's Reply to the Statement of Objections, paras. 166, 181.

⁷⁴⁰ Concerning the concept of cellophane fallacy, see footnote 233.

⁷⁴¹ Judgement of the General Court of 11 January 2017, *Topps Europe v Commission*, T-699/14, EU:T:2017:2, paragraph 82; Judgement of the General Court of 22 June 2022, *thyssenkrupp v Commission*, T-584/19, EU:T:2022:386, paragraphs 74-76.

⁷⁴² 2024 Market Definition Notice, para. 31; 1997 Market Definition Notice, paras. 15, 25.

the application of the SSNIP test is difficult when undertakings compete on parameters other than price.⁷⁴³

- (544) Third, although the Commission does not explicitly carry out a SSNIP test, it does carry out an extensive case-specific and country-specific analysis of the relevant market for Copaxone based implicitly on the principles of the hypothetical monopolist test.⁷⁴⁴ Contrary to Teva's claims, the Commission's analysis is not limited to assessing price competition. While price competition has been recognised as a crucial element to assess market definition,⁷⁴⁵ the Commission's analysis also takes into account non-price (natural) events for the analysis, such as the launch of oral first-line DMTs and the entry of Synthon GA and their effect on Copaxone's overall profitability. In this Section, the Commission complements its findings from the foregoing Sections by analysing Copaxone's market data (sourced partly from Teva and partly from IQVIA),⁷⁴⁶ in particular the sales volumes, prices and profitability⁷⁴⁷ of Copaxone in the Relevant Member States, and their development after the entry of new first-line DMTs, on the one hand, and Synthon GA, on the other hand.
- (545) This comparison shows the stark difference between the limited impact the entry of new non-GA first-line DMTs (in particular orals) had on Copaxone prices, sales and profits compared to the strong impact that followed the entry of Synthon GA (in those Member States where entry took place). On this basis, the Commission finds that, during the Relevant Period, Synthon GA was the only product to "*exert effective and immediate competitive constraints*"⁷⁴⁸ on Copaxone in each of the Relevant Member States. The Commission also finds that non-GA first-line DMTs did not constitute an effective and immediate constraint to Copaxone during the Relevant Period. In particular, competition has been driven primarily by price as from the (approaching) entry of Synthon GA in the respective markets. Therefore, for the purpose of the present case, the relevant product market during the Relevant Period is found to be limited to GA products alone.

⁷⁴³ 2024 Market Definition Notice, para. 30.

⁷⁴⁴ It follows from the 2024 Market Definition Notice (para. 29) that the appropriate test is "*whether a hypothetical monopolist in the candidate market could exercise market power*". Further, it follows from paragraph 31 of the 2024 Market Definition Notice that "*in most cases the SSNIP test serves only as a conceptual framework for the interpretation of available evidence*".

⁷⁴⁵ Case C-176/19 P, Commission v Servier, paragraph 388.

⁷⁴⁶ The volume data for Copaxone (as well as for the non-GA first-line DMTs and Synthon GA) is sourced from IQVIA, a multinational company providing health information technology. The volumes for all Relevant Member States except Belgium were recovered from the version of the IQVIA database submitted by Teva on 10.6.2022. The volumes for Belgium were recovered from the version of the IQVIA database available to DG COMP (see file "\$raw/iqvia2021_B_N7A.dta" in the SO data pack). The Teva price and profitability data was submitted by Teva, see ID 1674, Teva's reply to Article 18(2) Request of 25 April 2022. In what follows these two main data sources will be referred to as "IQVIA" and "Teva" respectively. This data has been updated on several occasions during the course of the investigation to include more recent data as that became available.

⁷⁴⁷ These are three important metrics in terms of defining the relevant market for the purposes of Union competition law. The question of which products affect or restrain sufficiently the pricing of the products under consideration is central in examining demand substitution (Market Definition Notice, paragraphs 48-50), whereas evidence of substitution following the launches of new products likewise provides direct evidence of substitutability between products (Market Definition Notice, paragraph 51). Finally, profitability or, put differently, a firm's ability to set prices above marginal cost, is the textbook measure of market power and identifying the set of competitors and products that constrain this power is the main purpose of market definition (Market Definition Notice, paragraph 6).

⁷⁴⁸ Market Definition Notice, paragraph 6 (see Recital (181)).

(546) In the following, the Commission, for each Relevant Member State, sets out how Copaxone’s volumes, prices and profits evolved following the entry of the oral first-line DMTs and Synthon GA. First, the Commission considers the competitive interactions between Copaxone and Synthon GA. Subsequently, the Commission assesses the past competitive interactions (or absence thereof) between Copaxone and the oral first-line DMTs, Tecfidera and Aubagio. In particular, the Commission assesses whether in the absence of Synthon GA, the orals could exercise an effective and immediate competitive constraint on Copaxone, akin to that of Synthon GA. Finally, the Commission does an assessment of past competitive interactions (or absence thereof) between Copaxone and interferons.

6.3.3.4.1. The constraints Synthon GA imposed on Copaxone varied across the Relevant Member States

(547) An analysis of empirical market data concerning the sales volumes of all first-line DMT treatments shows that – despite the fact that all Relevant Member States have similar mechanisms for stimulating generic and generic-like competition – the impact of the (approaching) entry of Synthon GA on Copaxone differed significantly across the Relevant Member States.

(548) The Relevant Member States can be categorised in two groups. In the first group, which includes Italy, Poland, Spain and the Netherlands (the “First Group of Relevant Member States”), Synthon GA’s entry effectively constrained Copaxone and caused an erosion of prices, volumes and/or profits.

– In Italy, Poland and Spain (see Sections 6.3.3.4.2.1, 6.3.3.4.2.3 and 6.3.3.4.2.4), Teva faced strong pricing constraints and contemplated “{...}” and “{...}”,⁷⁴⁹ which would allow it to avoid price discounts in one Member State having a cross-border impact due to international reference pricing. In Italy, Teva was eventually forced to halve the price of Copaxone in order to stay competitive in tenders (see Section 6.3.3.4.2.1 below).

– In the Netherlands (see Section 6.3.3.4.2.2), {...}.⁷⁵⁰ In practice, this meant that sales representatives should “walk away” from a contract and sacrifice sales volumes rather than accept low prices. The price competition from Synthon GA eventually cost Teva {...}% of Copaxone’s volumes (see Section 6.3.3.4.2.2 below).

(549) In this First Group of Relevant Member States, a decline of Copaxone’s profits can be observed, irrespective of whether Teva’s commercial strategy to counter Synthon GA was primarily focused on maintaining a high price level or on lowering prices to defend sales volumes. However, as further explained in Section 6.3.3.4.2 below and in Chapters 8 and 9, even if Synthon constrained Copaxone in this First Group of Relevant Member States, Teva’s actions prevented it from exercising this constraint to the fullest and the constraints were not strong enough to prevent Teva from behaving to an appreciable extent independently in the market (see Chapter 7).

(550) Finally, even though oral DMTs achieved rapid growth in the EEA, their introduction left Copaxone’s volumes, prices and profits virtually untouched in the

⁷⁴⁹ See Teva’s “Pricing and Market Access Strategy” in ID 886-20, 2020 E.U. Brandplan & High level GTMAP Copaxone, p. 15.

⁷⁵⁰ See ID 644-396, 2020 E.U. Brandplan & High level GTMAP Copaxone, p. 15. See also ID 644-401, 2019 EU Strategic Brand Plan Copaxone.

First Group of Relevant Member States. There was no obvious impact by interferons on Copaxone's volumes, prices or profits either.

- (551) In the second group of Relevant Member States, which includes Belgium, Czechia and Germany (the "Second Group of Relevant Member States"), Synthon GA remains to date a marginal or only potential competitive constraint on Copaxone. In this Second Group of Relevant Member States, Teva successfully excluded Synthon GA from the market, at key moments and for significant periods of time, by staggered filings and withdrawal of divisional patents, as explained in Chapter 8 below. In Czechia, for example, Teva successfully prevented Synthon GA from entering the market altogether throughout most of the Relevant Period.
- (552) Apart from staggered filings and strategic withdrawals of divisional patents, contributing to successful interim injunction requests, Teva's "Copaxone defence" strategy in the Second Group of Relevant Member States also included campaigns to disseminate misleading and discrediting information to hinder and/or delay Synthon GA's market entry and uptake (see Chapter 9). As a result, Synthon could not effectively constrain Copaxone's prices and/or volumes. However, in line with the *Generics (UK)*⁷⁵¹ judgment, Synthon GA should be considered to be part of the same delineation of the product market because Synthon was, since the beginning of the Relevant Period, in a position to enter these markets immediately or within a short period, and would have done so in all Relevant Member States if it had not been for Teva's abusive conduct.
- (553) At the same time, similarly as in the First Group of Relevant Member States, the presence of orals DMTs or interferons did not effectively constrain Copaxone during the Relevant Period in the Second Group of Relevant Member States.
- (554) Nonetheless, while the actual pattern of erosion of Teva's prices, volumes and profits has so far only been observed in the First Group of Relevant Member States where Synthon GA managed to effectively compete on the market, the conclusions drawn from observations in the First Group also apply to the Second Group of Relevant Member States, where effective generic-like competition was about to start but has been delayed. As will be described further in Section 6.3.3.4.3 below, this is because the findings from Sections 6.3.3.1 to 6.3.3.3 equally apply to these Member States. Indeed, all the Relevant Member States have highly similar structures of demand, including mechanisms to stimulate price competition after generic or generic-like entry (see Section 6.3.3.2.2), and Teva's actions sought precisely to avoid or delay that competition.

6.3.3.4.2. Relevant Member States where, unlike other (non-GA) first-line DMTs, Synthon GA has effectively and immediately constrained Copaxone

- (555) In Italy, Poland, the Netherlands and Spain, competition from Synthon GA has effectively and immediately constrained Copaxone's prices, volumes and/or profits. Other (non-GA) first-line DMTs have not exercised a significant (and effective) constraint on Copaxone.

6.3.3.4.2.1. Italy

- (556) Italy is the second biggest market for Copaxone in the EEA (after Germany).⁷⁵² Teva's revenue from Copaxone sales in Italy was approximately EUR {...} in 2021,

⁷⁵¹ Case C-307/18, *Generics (UK) and Others*, paragraphs 133-134.

⁷⁵² ID 660, Teva's reply to Article 18(2) Request of 3 June 2020, p. 30; ID 644-178, Teva's reply to Article 18(2) Request of 3 June 2020.

with a sales volume of {...}. The volume of all first-line DMTs in Italy was approximately {...} in 2021. This volume has grown by, on average, approximately {...}% in recent years (between 2015 and 2021 – exhibiting a {...}% dip only between 2020 and 2021).

- (557) In Italy, GA is prescribed in hospitals and only dispensed in hospital pharmacies. Hospital pharmacies can procure drugs via bilateral negotiations with pharmaceutical companies, or, alternatively, they hold tenders. Before the launch of Synthon GA, all Copaxone sales were made through bilateral negotiations at a national price negotiated with the Italian Medicines Agency (*Agenzia Italiana del Farmaco*, or “AIFA”). After the launch of Synthon GA, almost all sales of Copaxone in Italy have been made via tenders.⁷⁵³ Tenders for hospital procurement are organised by regional tender authorities for the hospitals in a region.⁷⁵⁴
- (558) Doctors in Italian hospitals can prescribe GA by brand or by INN. In any event, the hospital pharmacy will dispense the tender-winning product.⁷⁵⁵ For almost all tenders, the company offering the lowest price is the sole winner.⁷⁵⁶
- (559) This section demonstrates that, during the Relevant Period, Synthon GA was the only product capable of exercising an effective and immediate competitive constraint on Teva’s commercial strategy for Copaxone in Italy.
- (560) Figure 13 shows the evolution of volumes in terms of DOT of all first-line DMTs in Italy from 2009 to 2021. It also shows Copaxone’s average net prices (in the shaded area, on the second y-axis). A number of relevant entry events by new first-line DMTs (including Synthon GA in blue) during the Relevant Period are marked in the timeline with differently coloured dotted lines and the name of the respective entrant.
- (561) The figure shows the correlation (or absence thereof) between Copaxone prices and volumes and the entry of oral DMTs and Synthon GA. This allows identifying which products exercise an effective and immediate competitive constraint on Copaxone.

Figure 13: Volumes and Copaxone price in Italy

{...}

Source: Volume data source: IQVIA. Price data source: Teva.

Note: Prices are aggregated at the yearly level.⁷⁵⁷

⁷⁵³ ID 1295-41, Teva’s reply to Article 18(2) Requests of 22 October and 18 November 2021, pp. 2-3.

⁷⁵⁴ ID 1251, Regione Liguria’s Reply to Article 18(2) Request of 15 December 2021, p. 2.

⁷⁵⁵ In exceptional cases that require “therapeutic continuity”, doctors can issue a written request to the hospital and explain their reasons for prescribing a specific brand. Teva submits that doctors exercise this option very rarely. See ID 1295-41, Teva’s reply to Article 18(2) Requests of 22 October and 18 November 2021, p. 1.

⁷⁵⁶ ID 1295-41, Teva’s reply to Article 18(2) Requests of 22 October and 18 November 2021, p. 3.

⁷⁵⁷ While volumes change from one quarter to the next (the data are reported quarterly), prices only change from one year to the other (between Q4 of the previous year and Q1 of the next – in other words, the data are reported annually). This makes prices appear less volatile than volumes, but that is due to the difference in the level of aggregation (quarterly data for volumes and annual data for prices). It should also be noted that the reported prices are, in essence, a weighted average of the prices of Copaxone 20 mg and Copaxone 40 mg. Whereas part of the price decreases observed are due to the switch of the Copaxone customer base from a 20 mg to 40 mg dosage regime (that has a lower average price per DOT), the price evolutions for both dosages are similar if one were to plot the corresponding prices separately. However, since, as discussed in Section 5.2.3.1, the switch to Copaxone 40 mg was part of Teva’s efforts to stave off competition from Synthon GA, the weighted average is a suitable metric for capturing the overall price effect that followed after the entry of Synthon GA.

- (562) Figure 14 shows Teva’s gross profits generated with Copaxone (in EUR) and its evolution, together with indications of a number of entry events by different first-line DMT products, including Synthon GA (referred to as “Synthon_GA_20mg” and “Synthon_GA_40mg”).

Figure 14: Copaxone annual gross profit in Italy

{...}

Source: Commission calculations based on internal data from Teva (ID 1674, Teva’s reply to Article 18(2) Request of 25 April 2022). See folder “[...]/output/Teva profitability” of the SO data pack.

Note: Gross profit refers to total revenues minus costs of goods sold.

- (563) In what follows, the Commission examines and interprets the above graphs, in tandem with qualitative information on the manner in which the specific market functions, to identify indications of competitive constraints exercised, if at all, on Copaxone by (i) Synthon GA, (ii) oral first-line DMTs (Tecfidera and Aubagio) and (iii) interferons first-line DMTs (notably Plegridy).

6.3.3.4.2.1.1. Impact from Synthon GA

- (564) Synthon has entered a licensing agreement with the pharmaceutical company Mylan (now Viatrix) to commercialise Synthon GA in Italy. Mylan launched Synthon GA 20 mg on the Italian market in February 2017 under the brand name “Copemyl”. Figure 13 shows that the sales volumes of Copemyl in 2017 were negligible. This can be attributed to the fact that by April 2017, Teva had already converted {...}% of its patient base from the daily 20 mg administration of Copaxone to the three-times-weekly 40 mg administration of Copaxone.⁷⁵⁸ Teva’s efforts to convert patients to a 40 mg dosing regimen meant that the share of Copaxone patients that could receive Copemyl as a cheaper, generic-like alternative to Copaxone 20 mg was significantly reduced, as neurologists had no incentive to switch prescriptions from 40 mg GA back to 20 mg GA.
- (565) Further, AIFA had initially decided in February 2017 not to include Copaxone 20 mg and Copemyl on the so-called “Transparency List” – a decision made by AIFA after Teva had lobbied intensely (see Section 9.4.4.3.1 below). Products included on AIFA’s Transparency List can be substituted at pharmacy level without intervention from a doctor (regardless of whether a patient has been treated with Copaxone before or is receiving GA for the first time). Inclusion on the Transparency List is a requirement for drugs to be able to compete against each other in tenders, which are organised on the basis of the active ingredient, leading to full-fledged price competition with generic firms.
- (566) In June 2018, Mylan/Viatrix launched the 40 mg dosage of its GA “Copemyltri”. Copemyltri’s list price at launch was 34% below the price of Copaxone 40 mg.⁷⁵⁹ In March 2019, AIFA decided to include Copaxone (20 mg and 40 mg) and Copemyl/Copemyltri on AIFA’s Transparency List (or substitution list), meaning that Copaxone 20 mg and Copemyl on the one hand and Copaxone 40 mg and Copemyltri on the other hand could be substituted by hospital pharmacies and could compete in tenders against each other.⁷⁶⁰ Following this decision, the national prices

⁷⁵⁸ ID 455-3332, Teva internal email dated 19 April 2017 from {...} to {...} and others.

⁷⁵⁹ ID 455-2921, Teva internal email dated 23 January 2019 from {...} to {...} and others.

⁷⁶⁰ Changing its previous conclusion, AIFA had decided to include Copaxone 20 mg and Copemyl in its Transparency List in April 2017 but, following Teva’s action to annul such decision, could only

of Copaxone 20 mg and 40 mg were reduced to the public list prices of Copemyl and Copemyltri, respectively.⁷⁶¹

- (567) The entry of Copemyltri at a 34% lower list price than Copaxone exposed Copaxone to strong price competition on the Italian market. As Teva had anticipated in its “Price Competition Workshops” (see Section 6.3.3.3.2.), the strong generic-like competition from Synthon GA put Teva under pressure to either significantly decrease its prices for Copaxone or compromise its market share on the Italian market.
- (568) First, Teva submitted that generic-like competition from Copemyltri forced Teva to significantly lower the price for Copaxone in Italy.⁷⁶² Not only was Copaxone’s national price aligned with Copemyltri’s price and thereby significantly reduced, Figure 13 shows that Copaxone’s average price per DOT {...} between 2018 and 2021, from around EUR {...} to below EUR {...} per DOT (a {...}% reduction). The main driver of this price development were regional tenders in which both Copaxone and Copemyl/Copemyltri participated.⁷⁶³
- (569) Before Copemyl/Copemyltri’s entry on the Italian market and insertion in the Transparency List, Teva did not compete in tenders against any other DMTs because no other RRMS drugs shared the same active substance as Copaxone and tenders are only organised for products with the same active substance. All sales of Copaxone were made via bilateral negotiations with hospitals, at the maximum sales price negotiated with AIFA.⁷⁶⁴ The development of Copaxone’s prices between 2013 and 2017, (see Figure 13) shows that there was no (or only little) price fluctuation in the price of Copaxone before Synthon GA entered the Italian market (see also Recital (579)). Competition in tenders therefore only took place after therapeutically equivalent and substitutable drugs (generics or hybrid drugs) were made available.⁷⁶⁵ Because these products have the same active substance, the main feature to differentiate these medicines – from a tender authority’s point of view – is their price. For example, one Italian regional tender authority explained that tenders are “*aimed at obtaining the best price for the supply of the types of products concerned, which can be effective if these are not commercialised by only one company due to industrial property rights*” (emphasis added).⁷⁶⁶
- (570) The price decrease that followed the launch of Copemyltri significantly reduced the expenditure of Italian regions on GA drugs. For example, the region of Campania estimates savings due to “*the entry of competing molecules [i.e. active substances]*” at 48% in the first year and 70% in the medium term (3 years).⁷⁶⁷
- (571) Second, Teva incurred a significant loss of volumes after the launch of Copemyltri. Figure 13 shows that the volumes gained by Copemyltri translate into an

ultimately and finally re-include these two products on the Transparency List in March 2019. For further details, see footnote 2521 below.

⁷⁶¹ ID 1295-41, Teva’s reply to Article 18(2) Requests of 22 October and 18 November 2021, p. 6.

⁷⁶² ID 1295-41, Teva’s reply to Article 18(2) Requests of 22 October and 18 November 2021, p. 6-7.

⁷⁶³ ID 1295-41, Teva’s reply to Article 18(2) Requests of 22 October and 18 November 2021, p. 6-7.

⁷⁶⁴ ID 1295-41, Teva’s reply to Article 18(2) Requests of 22 October and 18 November 2021, p. 7.

⁷⁶⁵ See ID 2441, Regione Siciliana’s Reply to Article 18(2) Request of 15 December 2021, p. 2.

⁷⁶⁶ ID 1251, Regione Liguria’s reply to Article 18(2) Request of 15 December 2021, p. 2 (unofficial translation). Original text: “*volte ad ottenere il miglior prezzo per la fornitura delle tipologie di prodotti in questione, che possono essere efficaci a condizione che gli stessi non risultino essere commercializzati in regime di privativa industriale da un’unica Ditta*”.

⁷⁶⁷ ID 1324, Regione Campania’s Reply to Article 18(2) Request of 15 December 2021, p. 3 (unofficial translation). Original text: “*immissione di molecole concorrenti*”.

approximate one-to-one decrease in the volumes of Copaxone in the period between 2018 and 2020. In total, Copaxone's volumes in Italy decreased by approximately {...}% between 2018 and 2021.

- (572) The significant loss of volumes despite Teva's efforts to offer competitive prices can be attributed, at least partly, to the fact that Copaxone lost a number of regional tenders in Italy to Copemyl/Copemyltri. In its Annual Operating Plan 2020 for Italy, Teva estimates the "total market of lost tenders" at {...}% of the volume of 2018.⁷⁶⁸
- (573) Third, the price reduction and loss of volumes significantly impacted Copaxone's gross profit in Italy. Figure 14 shows a decline of approximately {...}% in Copaxone's gross profits after the market entry of Copemyltri in 2018.⁷⁶⁹ A similar impact can be observed in Copaxone's net profits.⁷⁷⁰
- (574) {...}. Teva's gross profit in Italy was circa {...}% below expectations in the Long Range Plan (LRP) for 2020, which Teva attributed to a large part to lost profits in its Italian Copaxone business ("...")⁷⁷¹.

6.3.3.4.2.1.2. Impact from orals

- (575) The oral DMTs Aubagio and Tecfidera, in contrast, have not been capable of constraining Teva's commercial strategy for Copaxone in Italy. The launch of these oral DMTs as new first-line treatments has not been followed by any lasting impact on Copaxone's volumes, prices and/or profits.
- (576) Aubagio and Tecfidera were both launched in Italy in 2014. As is visible from Figure 13, the launch of both drugs was successful and they quickly grew in volume. Especially Tecfidera grew very fast in the first two years after its launch.
- (577) The entry of oral DMTs does not however appear to have had a lasting effect on the volumes of Copaxone in Italy. Figure 13 shows that the volumes of Copaxone had been growing between 2009 and 2014, and then briefly stagnated, and even slightly decreased after the entry of oral DMTs. However, Copaxone's volumes quickly recovered, especially after Teva launched Copaxone 40 mg in 2016. In this regard, the Commission notes that, contrary to Teva's claims, the entry of orals did not lead to a material volume reduction for Copaxone (see Recital (447) and the launch of the 40 mg dosage was not a competitive reaction to oral first-line DMTs (see Recitals (464)-(469)). Instead, the Commission considers it likely that the recovery of

⁷⁶⁸ See ID 263-2828, AOP 2020 – Italian Cluster, 21 October 2019, p. 37.

⁷⁶⁹ It is worth noting that the drop in profitability cannot be attributed to supply-side shocks such as a sudden increase in underlying input costs. On the contrary, Teva's reported average variable costs (COGS) for Copaxone have declined almost every year during the Relevant Period (see for example, "Annex RFI7Q1a - RFI3Q2 follow-up" included in the data-pack of the Commission's Letter of Facts I of 9 February 2024). Moreover, when asked to identify any factors or events that might have affected Copaxone prices, volumes and profits during the Relevant Period (see ID 554, Commission's Request for Information of 3 June 2020, p. 8), Teva did not submit any information besides what is covered and discussed in this Decision. This holds for Italy as well as for all other Relevant Member States.

⁷⁷⁰ See ID 5820 for a side-by-side comparison of Copaxone gross and net profits in all Relevant Member States and the SO data pack for the underlying data and computations (see folder "[...]/output/Teva profitability" of the SO data pack, files: "EUR_net_profit_bar_Belgium.PNG", "EUR_net_profit_bar_Czechia.PNG", "EUR_net_profit_bar_Germany.PNG", "EUR_net_profit_bar_Italy.PNG", "EUR_net_profit_bar_Netherlands.PNG", "EUR_net_profit_bar_Poland.PNG", "EUR_net_profit_bar_Spain.PNG). For the sake of completeness, the Commission notes that the same data pack also included an analysis of Copaxone gross and net profit margins that also exhibit parallel evolution. Further references to ID 5820 in this Decision will not contain the full list of relevant files in the data pack.

⁷⁷¹ See ID 263-2828, AOP 2020 – Italian Cluster, 21 October 2019, p. 18. {...}.

Copaxone's volumes was the result of Teva's promotional campaign surrounding the launch of its 40 mg dosage to incentivise physicians and patients to convert from the 20 mg dosage to the 40 mg dosage (see Sections 5.2.3.1., 6.3.3.2.4.3.1, 6.3.3.3.3). By the time Copemyl entered the Italian market in 2017, Copaxone's volumes had re-started to grow similarly to the period prior to the entry of Tecfidera and Aubagio.

- (578) The volume gains of the oral DMTs can be partly attributed to a steady volume loss from the interferons (market stealing) and partly to the growth of the first-line DMT segment (market expansion).⁷⁷² Certainly, no diversion of demand akin to the one that appears to have taken place from Copaxone to Copemyl/Copemyltri can be observed with respect to Copaxone and the oral DMTs.
- (579) Figure 13 also shows that following the entry of the oral DMTs Copaxone's price remained unaffected and stable between 2013 and 2018. Likewise, and importantly for assessing competitive constraints, Figure 14 shows that the profitability of Copaxone remained largely unaffected by the entry of the oral DMTs. While Figure 14 shows a small decrease in profitability in 2015, the year after oral DMTs were launched, this dip in profitability was not significant and was short-lived. By 2016, Copaxone's profits not only recovered to the level of 2014 but were even rising above the 2014 level of profitability. It was only following the entry of Copemyltri that a lasting and significant decrease of Copaxone's profitability can be observed.
- (580) In summary, despite the small loss in volumes in 2015, none of the oral DMTs have exercised an effective and immediate (and lasting) constraint on Teva and its pricing of Copaxone, for example through price competition in tenders. When asked whether savings to their GA expenses could be achieved without Copemyl/Copemyltri (or any competing GA) on the market, an Italian regional tender authority responded "*if only one drug was available on the market, all economic benefits in terms of cost savings from the market entry of an equivalent pharmaceutical would be lost*".⁷⁷³ This corroborates the Commission's finding.
- (581) In any event, any competitive pressure that might have been exerted by oral DMTs on Copaxone's price or volumes prior to the entry of Synthon GA, still allowed Teva to maintain Copaxone's prices in Italy far above variable costs (as well as to maintain large gross and net profit⁷⁷⁴), which supports the view that this competitive pressure is limited. Despite their leading position in the first-line DMT segment, oral first-line DMTs cannot exercise price competition on Copaxone because they do not have the same active substance and, therefore, they are not able to compete in the same tenders.⁷⁷⁵ Thus, if Synthon GA were not available (as was the market environment following the entry of oral DMTs but before the entry of Synthon GA), none of the oral first-line DMTs would exercise an effective and immediate constraint on Copaxone. Moreover, the first-line oral DMTs are not capable of constraining Copaxone's pricing and/or volumes at the level of the price reductions

⁷⁷² ID 263-2828, AOP 2020 – Italian Cluster, 21 October 2019, p. 34: "*Tecfidera [...] and Aubagio [...] are driving market growth in volumes*".

⁷⁷³ ID 1251, Regione Liguria's reply to Article 18(2) Request of 15 December 2021, p. 3 (unofficial translation). Original text: "*alla presenza in commercio di un unico Farmaco disponibile verrebbero meno tutti i vantaggi economici in termini di risparmi sui costi derivanti dall'avvenuta immisione in commercio di Farmaci equivalenti*".

⁷⁷⁴ Commission calculations based on internal data from Teva (ID 1674, Teva's reply to Article 18(2) Request of 25 April 2022). See ID 5820 for a side-by-side comparison of Copaxone gross and net profits in all Relevant Member States and the SO data pack for the underlying data and computations.

⁷⁷⁵ See ID 2441, Regione Siciliana's Reply to Article 18(2) Request of 15 December 2021, pp. 2-3.

and volume losses that can be observed following the bidding competition with Synthon GA.

6.3.3.4.2.1.3. Impact from interferons

- (582) The interferons (Avonex, Betaferon, Extavia and Rebif) have been available in Italy as first-line DMTs since before 2010. The only new entrant among the interferons was Plegridy in 2015.
- (583) Interferons have not constrained Copaxone's prices, volumes and/or profits in the period under review (2013-2021). As shown in Figure 13, Copaxone's prices were stable until the entry of Copemyltri and Copaxone's volumes do not appear to have been impacted by the presence of interferons in any meaningful way. No obvious correlation in terms of sales volumes is observable between Copaxone and interferons either. Moreover, Figure 14 shows that before the entry of Copemyl/Copemyltri, the gross profit of Copaxone remained stable.
- (584) Just like oral DMTs, interferons cannot compete in the same tenders as Copaxone and Copemyl/Copemyltri in Italy because they have different active substances.
- (585) In summary, the launch of Plegridy, or the commercialisation of other interferons first-line DMTs did not have any impact on Copaxone's profits, which remained relatively stable until the entry of Copemyltri, as shown in Figure 14.

6.3.3.4.2.1.4. Conclusion – the product market in Italy consists only of GA DMTs

- (586) The analysis of market data shows that Copemyl/Copemyltri is the only DMT that has exercised an effective and immediate competitive constraint on Copaxone on a lasting basis in Italy during the Relevant Period (see Section 6.3.2.3 concerning the exclusion of second-line DMTs from the relevant product market). The availability of Copemyl/Copemyltri as a generic-like alternative for Copaxone in Italy exposed Copaxone to effective and immediate (price) competition.
- (587) The entry of Copemyl/Copemyltri in Italy and its eventual inclusion on the Transparency List allowed regional authorities to hold tenders which brought Copaxone in competition with Copemyl/Copemyltri, instead of buying Copaxone at the national price and was followed by a massive erosion of prices, volumes and/or profits for Copaxone. Compared to the level of prices and volumes before the entry of Copemyltri in 2018 and its inclusion on the Transparency List in 2019, Copaxone's prices in 2021 have halved and its volumes have decreased by circa {...}%. Copaxone's gross profits in Italy decreased by circa {...}% since the launch of Copemyltri.
- (588) The strong competition between Copaxone and Copemyl/Copemyltri in tenders significantly reduced the expenditure of Italian regions on GA drugs.
- (589) Following the otherwise successful entry of oral first-line DMTs in Italy there was virtually no impact on Copaxone, in terms of price, and only a small and short-lived decrease of volumes sold and profit generated by Teva. Similarly, the presence of interferons first-line DMTs has not exercised any discernible pressure on Copaxone.
- (590) The Commission therefore finds that the relevant product market in Italy during the Relevant Period is limited to GA, and therefore only includes Copaxone and Synthon GA (Copemyl/Copemyltri).

6.3.3.4.2.2. The Netherlands

- (591) The Netherlands are one of the 20 largest geographic markets in the world for MS treatments (by sales in value).⁷⁷⁶ Teva's revenue with Copaxone in the Netherlands was EUR {...} in 2021, with a sales volume of {...} (in DOT). The volume of all first-line DMTs in the Netherlands was 2.7 million in 2021. This volume has grown by, on average, approximately {...}% in recent years (between 2015 and 2021 - exhibiting a dip only between 2020 and 2021, by {...}%).
- (592) In the Netherlands, GA is not a hospital drug. GA is prescribed by practitioners (prescriptions are usually by INN) and dispensed by pharmacies. Health insurers can set up preference policies for drugs, which means that they can negotiate preferential rates with pharmaceutical companies for one or several drugs of an active substance. If a preference policy exists with a patient's health insurer, pharmacies dispense only the preferred product to the patient, regardless of the doctor's prescription.⁷⁷⁷ Teva did not enter into preference policies with health insurers. After the launch of Synthon GA in the Netherlands, Mylan entered into preference policies with the five major health insurers in the Netherlands, which represent 87% of patients.⁷⁷⁸
- (593) This Section demonstrates that, during the Relevant Period, Synthon GA was the only product capable of exercising an effective and immediate competitive constraint on Teva's commercial strategy for Copaxone in the Netherlands.
- (594) Figure 15 shows the evolution of volumes of all first-line DMTs and Copaxone's average prices in the Netherlands in the period from 2009 to 2021.

Figure 15: Volumes and Copaxone price in the Netherlands

{...}

Source: Volume data source: IQVIA. Price data source: Teva.

Note: Prices are aggregated at the yearly level (see footnote 757).

- (595) Figure 16 shows the evolution of Copaxone's gross profit in the Netherlands from 2014 to 2021.

Figure 16: Copaxone annual gross profit in the Netherlands

{...}

Source: Commission calculations based on internal data from Teva (ID 1674, Teva's reply to Article 18(2) Request of 25 April 2022). See folder "[...]/output/Teva profitability" of the SO data pack.

Note: Gross profit refers to total revenues minus costs of goods sold. The launch of Aubagio in the Netherlands was prior to the time period covered by Figure 16.

- (596) In what follows, the Commission examines and interprets the above graphs, in tandem with qualitative information on the manner in which the specific market functions, to identify indications of competitive constraints exercised, if at all, on Copaxone by (i) Synthon GA, (ii) oral first-line DMTs (Tecfidera and Aubagio) and (iii) interferons first-line DMTs (notably Plegridy) in the Netherlands.

⁷⁷⁶ ID 644-199, Global Customers Insight-Multiple Sclerosis Fact Book, November 2016, p. 35.

⁷⁷⁷ Doctors are allowed to exclude substitution for medical reasons, and pharmacies are allowed to dispense products that are not covered by the preference policy, if it doesn't exceed 10-15% of all prescriptions. See ID 1295-64, Teva's reply to Article 18(2) Requests of 22 October and 18 November 2021, pp. 2, 4.

⁷⁷⁸ ID 2763, {...} reply to Article 18(2) Request of 11 February 2022, p. 19. The main health insurers are Centrale Zorgverzekeraars Groep (CZ), Coöperatie VGZ, Menzis Zorgverzekeraar, ONVZ Ziekttekostenverzekeraar, and Zilveren Kruis Zorgverzekeraar.

6.3.3.4.2.2.1. Impact from Synthon GA

- (597) Synthon entered a licensing agreement with Mylan (now Viatris) to commercialise Synthon GA in the Netherlands. Mylan launched Synthon GA in the Netherlands in January 2018 under the brand name Glatirameeracetaat Mylan. Both strengths of Glatirameeracetaat Mylan (20 mg and 40 mg) were launched around the same time, April 2018 for the 20 mg strength and February 2018 for the 40 mg strength. Figure 15 shows that the sales volumes of Glatirameeracetaat Mylan in 2018 were negligible (28,220 DOT in total). However, the subsequent year, Glatirameeracetaat Mylan drastically increased its sales volume, seemingly at the expense of Copaxone, and ultimately overtook Copaxone's sales by a significant margin.
- (598) The initial slower uptake of Glatirameeracetaat Mylan in the first three quarters of 2018 can be attributed to the procurement system of the main healthcare providers in the Netherlands. After the market entry of Mylan/Viatris's generic-like GA drug, the five main health insurers entered into preference policies with Mylan. For instance, patients insured with the health insurer Zilveren Kruis who were prescribed GA for the first time received Glatirameeracetaat Mylan from November 2018 on. For existing patients, Zilveren Kruis foresaw a 6-month transition period from Copaxone to Glatirameeracetaat Mylan. The other main health insurers followed similar schemes.⁷⁷⁹ Generic suppliers usually enter into preference policies after the loss of exclusivity of an originator drug. The health insurer Zilveren Kruis explains: "*As soon as the patent is expired, we ask generic producers to make an offer. The producer with the lowest offer then becomes the preferred supplier*".⁷⁸⁰ The preferred supplier is usually the exclusive supplier for an active substance.
- (599) Prior to the launch of Glatirameeracetaat Mylan, there were no preference policies pertaining to GA. Because health insurers have to cover at least one drug from an INN group (active substance), they all had to cover Copaxone and Teva had no incentive to enter a preference policy.⁷⁸¹
- (600) The entry of Glatirameeracetaat Mylan, paired with the procurement system in the Netherlands, exposed Copaxone, for the first time ever, to strong generic-like competition.
- (601) First, Teva incurred a significant loss of volumes after the launch of Glatirameeracetaat Mylan 40 mg. Figure 15 shows that Copaxone's volumes dropped by {...}% between 2018 and 2019. After successful implementation of these preference policies between Mylan and the main healthcare providers, the majority of GA patients received Glatirameeracetaat Mylan instead of Copaxone because Mylan/Viatris offered a (therapeutically equivalent) GA drug at a lower price. This is in line with Teva's statement that since the introduction of preference policies in the Netherlands, all Copaxone sales are derived from Copaxone prescriptions with a "medical needs" mention (circa {...}% of prescriptions), or prescriptions for patients

⁷⁷⁹ See ID 3581, {...} Reply to Article 18(2) Request of 15 December 2021. The Commission shows in Recitals (2021)-(2031) how Teva's disparagement campaign could have contributed to a delay in the implementation of preference policies in the Netherlands.

⁷⁸⁰ ID 1235, Zilveren Kruis' Reply to Article 18(2) Request of 15 December 2021, p. 2 (unofficial translation). Original text: "*(...)zodra het patent is verlopen wij generieke fabrikanten vragen een bod uit te brengen. De laagste inschrijver wordt preferent gemaakt.*"

⁷⁸¹ ID 1235, Zilveren Kruis' Reply to Article 18(2) Request of 15 December 2021, p. 3; ID 3625, Menzis' Reply to Article 18(2) Request of 15 December 2021, pp. 3-4.

covered by health insurance companies that do not have a preference policy with Mylan/Viatris (circa {...}% of the patients).⁷⁸²

- (602) The loss of volume had an impact on Copaxone's gross profit, which significantly declined between 2017 and 2021 (see Figure 16). In 2021, Teva's gross profit was around {...}% lower than in 2017, the year before the entry of Glatirameeracetaat Mylan. A similar impact can be observed in Copaxone's net profits.⁷⁸³
- (603) Second, regarding price development, Figure 15 does not show a clear and significant change in the average price for Copaxone after the entry of Synthron GA. In this sense, the price development of Copaxone after generic-like entry in the Netherlands differs from the price development in Italy and Poland under similar circumstances. However, there has been a gradual downward trend of Copaxone's prices after the entry of Glatirameeracetaat Mylan.
- (604) Overall, it appears that Teva decided to sacrifice its volumes (giving up its leading position to Mylan) instead of lowering its prices in the Netherlands. Such a decision would be in line with {...}.⁷⁸⁴ Even so, health insurers in the Netherlands have been able to save on GA expenditure due to the lower price of Glatirameeracetaat Mylan compared to Copaxone's prices.⁷⁸⁵

6.3.3.4.2.2.2. Impact from orals

- (605) The oral DMTs Aubagio and Tecfidera have not been capable of constraining Teva's commercial strategy for Copaxone. The launch of the oral DMTs as new first-line treatments did not have a(n) (lasting) impact on Copaxone's volumes, prices and/or profits.
- (606) The oral drugs Aubagio and Tecfidera were both launched in the Netherlands in 2014. As is visible from Figure 15, the launch of both drugs was successful and their volumes quickly grew in the first-line DMT segment.
- (607) The entry of oral DMTs did not however correlate with any obvious and long-lasting effect on the volumes of Copaxone sold in the Netherlands. As shown in Figure 15, Copaxone's volumes temporarily dropped after the launch of the oral DMTs. However, Copaxone's volumes quickly recovered and remained stable until Glatirameeracetaat Mylan entered the market in the Netherlands. Conversely, the volume gains of Glatirameeracetaat Mylan correlate almost perfectly with a steep and significant decrease in the sales of Copaxone by an approximately equal amount.
- (608) The volume gains of the oral DMTs can be partly attributed to a steady volume loss from interferons (market stealing) and partly attributed to the growth of the first-line DMT segment as such (market expansion).
- (609) Figure 15 shows that the entry of oral DMTs was not followed by any significant effect on Copaxone's prices in the Netherlands either, which remained stable with small fluctuations between the second half of 2014 and 2017. Further, Figure 16 shows that the entry of oral DMTs wasn't followed by any lasting impact on Copaxone's profitability either. Copaxone's volume decline in 2014 led to a small dent in Copaxone's gross profit in 2015, but profits were rising again in 2016 and

⁷⁸² ID 1295-64, Teva's reply to Article 18(2) Requests of 22 October and 18 November 2021, pp. 3-4.

⁷⁸³ See ID 5820 for a side-by-side comparison of Copaxone gross and net profits in all Relevant Member States and the SO data pack for the underlying data and computations.

⁷⁸⁴ ID 262-1695, Price competition workshop – Copaxone & Lonquex, 20-21 June 2017, pp. 11-12, 72.

⁷⁸⁵ ID 1235, Zilveren Kruis' Reply to Article 18(2) Request of 15 December 2021, p. 2; ID 3625, Menzis' Reply to Article 18(2) Request of 15 December 2021, p. 2.

2017 beyond previous levels (until Glatirameeracetaat Mylan entered the market in 2018).

- (610) In any event, any perceived pressure exerted by oral DMTs on Copaxone's price or volumes still allowed Teva to maintain Copaxone's prices in the Netherlands far above variable costs (as well as to maintain large gross and net profit⁷⁸⁶), which supports the view that this competitive pressure is limited.

6.3.3.4.2.2.3. Impact from interferons

- (611) The interferons (Avonex, Betaferon and Rebif) have been available in the Netherlands as first-line DMTs since before 2010. Plegridy was launched in 2014.
- (612) Interferons have not been able to constrain Copaxone's prices, volumes or profits in the Relevant Period. As is visible from Figure 16, until 2017, Copaxone's gross profits remained high despite the presence of interferons in the market. However, these gross (similarly to net) profits dropped significantly after the entry of generic-like competition.

6.3.3.4.2.2.4. Conclusion – the product market in the Netherlands consists only of GA DMTs

- (613) The analysis of the market data shows that Glatirameeracetaat Mylan is the only DMT that has exercised an effective and immediate competitive constraint on Copaxone on a lasting basis in the Netherlands during the Relevant Period (see Section 6.3.2.3 concerning the exclusion of second-line DMTs from the relevant product market). The availability of Glatirameeracetaat Mylan as a generic-like alternative for Copaxone in the Netherlands exposed Copaxone to price competition.
- (614) The entry of Glatirameeracetaat Mylan allowed health insurers in the Netherlands to negotiate preference policies with a generic-like supplier of GA (whereas Teva, as an originator supplier of GA, was not interested in negotiating preference policies) and was followed by a significant erosion of volumes and profits for Copaxone.
- (615) While the prices for Copaxone have remained relatively unaffected by the launch of Glatirameeracetaat Mylan, Copaxone lost {...}% of its volumes within just six months after health insurers in the Netherlands started applying preference policies for GA drugs. As a result of this volume erosion and despite relatively unaffected price levels, Copaxone's gross profits in the Netherlands declined by circa {...}% since the entry of Glatirameeracetaat Mylan in 2018.
- (616) On the contrary, the entry of oral first-line DMTs in the Netherlands had no lasting impact on Copaxone's prices, and only a small and short-lived impact on Copaxone's volumes and profits. Copaxone's volumes and profits continued growing until Glatirameeracetaat Mylan entered the market with significant strength. Similarly, the presence of interferons first-line DMTs has not exercised any discernible pressure on Copaxone. There is no clear relationship between the evolution in sales volumes of Copaxone and non-GA first-line DMTs.
- (617) The Commission therefore finds that the relevant product market in the Netherlands during the Relevant Period is limited to GA, and therefore only includes Copaxone and Synthon GA (Glatirameeracetaat Mylan).

⁷⁸⁶ Commission calculations based on internal data from Teva (ID 1674, Teva's reply to Article 18(2) Request of 25 April 2022). See ID 5820 for a side-by-side comparison of Copaxone gross and net profits in all Relevant Member States and the SO data pack for the underlying data and computations.

6.3.3.4.2.3. Poland

- (618) Poland is the biggest market in Teva’s central and Eastern European cluster, which also includes Czechia, Hungary, Romania, Slovakia, Estonia, Latvia and Lithuania. Teva’s Copaxone revenue in Poland was EUR {...} in 2021, with a sales volume of approximately {...} DOT. In July 2019, {...} patients in Poland were treated with Copaxone.⁷⁸⁷ The volume of all first-line DMTs in Poland was approximately {...} DOT in 2021. This volume has grown constantly by, on average, approximately {...} in recent years (between 2015 and 2021).
- (619) GA is only prescribed in hospitals and dispensed by hospital pharmacies. Doctors have to prescribe the GA medicine that is available in the hospital, which is usually the medicine that won the (national) tender.⁷⁸⁸
- (620) Between 2011 and 2021, more than {...}% of Copaxone’s sales in Poland (in value and volume) were made via hospital tenders.⁷⁸⁹ Tenders are organised on the basis of active substance and dosage (which means separate tenders for GA 20 mg and GA 40 mg).⁷⁹⁰ Before loss of exclusivity, Copaxone was the only product offered in tenders for GA,⁷⁹¹ and as the sole supplier of GA, won all relevant hospital tenders.⁷⁹² In practice, Teva did not bid directly in those tenders, but offered a price to wholesalers who then went on to compete with each other in the tenders. The maximum price at which wholesalers are allowed to sell Copaxone to hospitals is a price negotiated between Teva and the Polish Ministry of Health (so-called “risk-sharing agreement”).⁷⁹³ Hospitals can negotiate lower prices with wholesalers or organise tenders on the basis of the active ingredient.⁷⁹⁴
- (621) From 2022 onwards, Poland introduced a system of national tenders. Under the new system, a single tender organised by the Ministry of Health covers the supply to all hospitals in Poland for a certain period of time.⁷⁹⁵
- (622) This section demonstrates that, during the Relevant Period, Synthon GA was the only product capable of exercising an effective and immediate competitive constraint on Teva’s commercial strategy for Copaxone in Poland.
- (623) Figure 17 shows the evolution of volumes of all first-line DMTs and Copaxone’s average prices in Poland in the period from 2009 to 2021.

⁷⁸⁷ ID 263-797 Business Review – CEE Region – Q3 2019, 2 September 2019, slide 28.

⁷⁸⁸ In exceptional cases that require “therapeutic continuity”, doctors can prescribe a different drug than the tender-winning drug. Teva submits that this rarely happens, see ID 1295-25, Teva’s reply to Article 18(2) Requests of 22 October and 18 November 2021, pp. 1-2.

⁷⁸⁹ The remaining sales were made to hospitals out of tenders, so-called “free-hand sales”. See ID 1295-25, Teva’s reply to Article 18(2) Requests of 22 October and 18 November 2021, p. 3.

⁷⁹⁰ ID 3621, Polish National Health Fund’s Reply to Article 18(2) Request of 15 December 2021, p. 3; ID 1295-25, Teva’s reply to Article 18(2) Requests of 22 October and 18 November 2021, p. 4; ID 1295-42, Teva’s reply to Article 18(2) Requests of 22 October and 18 November 2021.

⁷⁹¹ ID 1295-25, Teva’s reply to Article 18(2) Requests of 22 October and 18 November 2021, p. 3.

⁷⁹² ID 1295-25, Teva’s reply to Article 18(2) Requests of 22 October and 18 November 2021, p. 6.

⁷⁹³ ID 1295-25, Teva’s reply to Article 18(2) Requests of 22 October and 18 November 2021, p. 6.

⁷⁹⁴ ID 1295-25, Teva’s reply to Article 18(2) Requests of 22 October and 18 November 2021, pp. 1, 4, 6.

⁷⁹⁵ Both Alvogen and Teva submitted bids in the national tender, with Teva winning the tender. Alvogen has the option to match the winning price offered by Teva to continue to also supply hospitals in Poland. See ID 1295-25, Teva’s reply to Article 18(2) Requests of 22 October and 18 November 2021, p. 4.

Figure 17: Volumes and Copaxone price in Poland

{...}

Source: Volume data source: IQVIA. Price data source: Teva.

Note: Prices are aggregated at the yearly level (see footnote 757).

(624) Figure 18 shows the evolution of Copaxone's gross profits in Poland over 2014-2021.

Figure 18: Copaxone annual gross profit in Poland

{...}

Source: Commission calculations based on internal data from Teva (ID 1674, Teva's reply to Article 18 (2) Request of 25 April 2022). See folder "[...]/output/Teva profitability" of the SO data pack.

Note: Gross profit refers to total revenues minus costs of goods sold.

(625) In what follows, the Commission examines and interprets the above graphs, in tandem with qualitative information on the manner in which the specific market functions, to identify indications of competitive constraints exercised, if at all, on Copaxone by (i) Synthon GA, (ii) oral first-line DMTs (Tecfidera and Aubagio), and (iii) interferons first-line DMTs (notably Plegridy).

6.3.3.4.2.3.1. Impact from Synthon GA

(626) Synthon has entered a licensing agreement with Alvogen to commercialise Synthon GA in Poland.⁷⁹⁶ Alvogen launched Synthon GA in January 2017 under the brand name Remurel. At launch, Remurel was offered in a 20 mg dosage at a price that was 25% lower than Copaxone's net price for the 20 mg dosage.⁷⁹⁷ Figure 17 shows that the sales volumes of Remurel 20 mg in 2017 and the first half of 2018 were negligible.

(627) The slow uptake of Remurel 20 mg can be explained by the fact that by January 2017, Teva had converted {...}% of its patient base in Poland from Copaxone 20 mg to Copaxone 40 mg.⁷⁹⁸ Indeed, this conversion was an important element of the CCP and Teva put great effort into switching Copaxone 20 mg patients to Copaxone 40 mg before the entry of Synthon GA 20 mg in all the Relevant Member States in order to protect Copaxone from generic-like competition (see Sections 5.2.3.1 and Section 6.3.3.2.4.3.1). As shown by Teva's internal documents, the conversion of patients in Poland had the aim of hindering a successful launch of Remurel 20 mg. In a presentation called "Copaxone Update Poland", a graph tracking conversion rates between January 2016 and August 2017 is described as follows: "{...}" (emphasis added).⁷⁹⁹

(628) Further, Alvogen was not able to participate with Remurel in a number of tenders in Poland because suppliers were required to provide both dosage strengths of GA (20 mg and 40 mg).⁸⁰⁰ The 40 mg strength of Remurel was launched only in July 2018.

⁷⁹⁶ In April 2020, the Czech generic company Zentiva acquired the right to license Synthon GA in Poland from Alvogen {...}.

⁷⁹⁷ ID 455-2610, internal email dated 28 September 2018 from {...} to {...} and others.

⁷⁹⁸ ID 455-2027, Copaxone Poland Update 21/09/2017, 21 September 2017, p. 5.

⁷⁹⁹ ID 455-2027, Copaxone Poland Update 21/09/2017, 21 September 2017, p. 5.

⁸⁰⁰ ID 1664, {...} Reply to Article 18(2) Request of 11 February 2022, p. 5.

- (629) The entry of Remurel 40 mg exposed Copaxone, for the first time, to strong generic-like competition on the Polish market.
- (630) First, the entry of Remurel led to a significant decrease of Copaxone’s price. Upon Remurel’s entry on the Polish market in 2017, Copaxone’s net price was subject to a mandatory 25% price decrease.⁸⁰¹ A significant reduction in Copaxone’s price is visible on Figure 17 between 2016 and 2017. However, the price drop visible in Figure 17 can also be attributed, at least partly, to the introduction of Copaxone 40 mg at a lower price per mg than Copaxone 20 mg, paired with the fact that the vast majority of Copaxone patients had been switched to the 40 mg strength. A 1-month pack of Copaxone 40 mg is considerably cheaper than a one-month pack of Copaxone 20 mg.⁸⁰² In any event, as discussed in Section 5.2.3.1 and Section 6.3.3.2.4.3.1, the introduction of Copaxone 40 mg must be seen primarily as a competitive reaction by Teva to the imminent entry of Synthon GA.
- (631) Before Remurel’s entry on the Polish market, Teva did not compete against any other DMTs in tenders because no other RRMS drugs shared the same active substance as Copaxone. After Remurel’s launch and subsequent participation in tenders, Teva had to align its prices to those of Remurel in tender biddings in order to stay competitive and win tenders.⁸⁰³ Figure 17 shows that Teva’s prices continued to decrease in pace with the uptake of Remurel. Teva had anticipated this price impact, as can be seen from a presentation prepared for a meeting of the Copaxone Continuation Project in 2017: “{...}”.⁸⁰⁴ Between 2018 and 2021, Copaxone’s prices further declined by almost {...}%.
- (632) Overall, the entry of generic-like competition was followed by a {...}% reduction in Copaxone’s prices in Poland.⁸⁰⁵ These reduced prices significantly decreased the expenditure of the Polish National Health Fund on these drugs.⁸⁰⁶
- (633) Second, Figure 17 shows that Copaxone appears to have continuously lost volumes to Remurel (an approximate one-to-one decrease) between 2018 and beginning of 2020. Internal evidence from a Teva presentation titled {...}.⁸⁰⁷ As is visible from Figure 17, Copaxone only regained volumes after its prices decreased further. In 2020 and 2021, the volume trend for Copaxone and Remurel is reversed, with a one-to-one increase of Copaxone’s volumes, at the expense of Remurel. This is likely due to the fact that Copaxone successfully competed against Remurel in tenders after significantly decreasing its prices in 2020.
- (634) Third, the price reduction and loss of volumes significantly impacted Copaxone’s gross profit in Poland. Figure 18 shows a decline of circa {...}% in Copaxone’s

⁸⁰¹ In Poland, originator medicines are subject to a 25% price decrease upon market entry of a generic. This rule applied to Copaxone when Remurel entered the Polish market, see ID 1295-25, Teva’s reply to Article 18(2) Requests of 22 October and 18 November 2021, p. 7.

⁸⁰² A 1-month pack of Copaxone 20 mg includes 28 pre-filled syringes à 20 mg, which equals 140 mg per week. A 1-month pack of Copaxone 40 mg includes 12 pre-filled syringes à 40 mg, which equals 120 mg per week. Price per mg is the same for both products. See ID 3612, Polish Ministry of Health’s Reply to Article 18(2) Request of 16 December 2021, p. 3; see also ID 906, Teva’s reply to Article 18(2) Request of 3 June 2021 p. 25.

⁸⁰³ See ID 1295-25, Teva’s reply to Article 18(2) Requests of 22 October and 18 November 2021, p. 5: Teva significantly lowered its prices in reaction to the entry of Synthon GA on the Polish market.

⁸⁰⁴ ID 455-1444, COPAXONE vs FoGA deep dive 2nd session, 7 June 2017, p. 10.

⁸⁰⁵ ID 1295-25, Teva’s reply to Article 18(2) Requests of 22 October and 18 November 2021, p. 5.

⁸⁰⁶ ID 3621, Polish National Health Fund’s Reply to Article 18(2) Request of 15 December 2021, p. 4.

⁸⁰⁷ ID 263-797, Business Review – CEE Region – Q3 2019, 2 September 2019, p. 29.

gross profit between the market entry of Remurel 40 mg in 2018 and 2021. A similar impact can be observed in Copaxone's net profits.⁸⁰⁸

6.3.3.4.2.3.2. Impact from orals

- (635) The oral first-line DMTs, Aubagio and Tecfidera, have not been capable of constraining Teva's commercial strategy for Copaxone in Poland, since their launch as new first-line treatments in 2014 and 2015 has not had a lasting impact on either Copaxone's volumes, prices or profits.
- (636) As noted above, more than {...}% of Copaxone's sales in Poland (in value and volume) at the time of the investigated practices were made via hospital and (as of 2022) national tenders. In Poland, hospital tenders are based on the active substance of the medicines. In practice, this means that for {...}% of its sales, Copaxone did not face any competition on price until the entry of Remurel on the Polish market. Only Remurel has been capable of exercising an effective and immediate competitive constraint on Copaxone in tenders organised by hospitals (and since 2022, by the Ministry of Health). That alone is sufficient to draw the conclusion that orals have not been able to exercise an effective and immediate competitive constraint on Teva's commercial strategy for Copaxone in Poland.
- (637) Figure 17 shows that Tecfidera has experienced rapid growth in the market since 2016 while Aubagio has been growing its volumes since 2018, albeit not as rapidly as Tecfidera. These volume gains appear to be partly attributable to a steady volume loss from the interferons (market stealing), and partly to growth of the first-line DMT segment (market expansion).
- (638) The uptake of orals did not have a material impact on Copaxone's sales volumes. The entry of the oral DMTs did not have an effect on Copaxone's prices, either. As explained above, the price decreases visible in Figure 17 can more credibly be attributed to (i) the switch from 20 mg to 40 mg, (ii) the mandatory 25% price decrease due to the entry of Remurel, and (iii) the price competition between Copaxone and Remurel in tenders.
- (639) Finally, Figure 18 shows that the profitability of Copaxone remained seemingly unaffected by the entry of the oral DMTs. In comparison, the entry of Remurel 40 mg was followed by a lasting and significant decrease of Copaxone's profits, which had remained stable until then.
- (640) In any event, any observed pressure exerted by oral DMTs on Copaxone's price or volumes, still allowed Teva to maintain Copaxone's prices in Poland far above variable costs (as well as to maintain large gross and net profit⁸⁰⁹), which supports the view that this competitive pressure is limited.

6.3.3.4.2.3.3. Impact from interferons

- (641) Interferons cannot compete in the same tenders as Copaxone and Remurel in Poland because of the different active substances of the medicines. In practice, this means that since the entry of Remurel on the Polish market, only Remurel has been capable of exercising a competitive constraint on Copaxone in tenders organised by hospitals (and since 2022, by the Ministry of Health). That alone is sufficient to show that

⁸⁰⁸ See ID 5820 for a side-by-side comparison of Copaxone gross and net profits in all Relevant Member States and the SO data pack for the underlying data and computations.

⁸⁰⁹ Commission calculations based on internal data from Teva (ID 1674, Teva's reply to Article 18(2) Request of 25 April 2022).

interferons have not been able to exercise an effective and immediate competitive constraint on Teva's commercial strategy for Copaxone in Poland.

- (642) The interferons (Avonex, Betaferon, Extavia and Rebif) have been available in Poland as first-line DMTs since before 2010. The only new entrant among the interferons was Plegridy in 2015. The launch of Plegridy does not appear to have any impact on Copaxone's gross profits, which continued to grow after its launch on the market, as shown in Figure 18.
- (643) Interferons have not been able to constrain Copaxone's prices or volumes in the period under review (2013-2021). As shown in Figure 17, Copaxone's prices were stable until the entry of Copaxone 40 mg and Remurel and Copaxone's volumes have not been impacted either by the presence of interferons in the first-line DMT segment. There is no obvious relationship between the changes in sales volumes of Copaxone and interferons.

6.3.3.4.2.3.4. Conclusion – the product market in Poland consists only of GA DMTs

- (644) The analysis of market data shows that Remurel is the only DMT that has exercised an effective and immediate competitive constraint on Copaxone on a lasting basis in Poland during the Relevant Period (see Section 6.3.2.3 concerning the exclusion of second-line DMTs from the relevant product market). The availability of Remurel as a generic-like alternative for Copaxone in Poland exposed Copaxone to price competition.
- (645) The entry of Remurel 40 mg was followed by a significant decrease of prices, volumes and profits for Copaxone. This can be attributed to the fact that the vast majority of Copaxone's sales (in value and in volume) are made through tenders organised by hospitals, and since 2022, the Ministry of Health, that are based on the active substance of the medicines. Synthron GA/Remurel is the only medicine that can compete with Copaxone in these tenders and is therefore capable of exercising an effective competitive constraint on Teva's commercial strategy for Copaxone. The only reason why this decrease of prices, volumes and profits cannot be observed already after the entry of Remurel 20 mg is that Teva had already switched the vast majority of its Copaxone patients to the 40 mg dosage before the entry of Remurel 20 mg.
- (646) Compared to the level of prices and volumes before the entry of Remurel 40 mg in 2018, Copaxone's prices in 2021 decreased by {...}%. Furthermore, Copaxone seemingly lost significant volumes to Remurel between 2018 and the beginning of 2020, and then regained volumes from Remurel since 2020. Despite the regained volumes, Copaxone's gross profits decreased by circa {...}% since the launch of Remurel.
- (647) On the contrary, the uptake of oral first-line DMTs in Poland has not had a material impact on Copaxone's prices, volumes or profits, which continued growing until the entry of Remurel (in particular Remurel 40 mg). Similarly, the presence of interferons as first-line DMTs has not exercised any discernible pressure on Copaxone.
- (648) The Commission therefore finds that the relevant product market in Poland during the Relevant Period is limited to GA, and therefore only includes Copaxone and Synthron GA (Remurel).

6.3.3.4.2.4. Spain

- (649) Spain is the fourth biggest market for Copaxone in the EEA.⁸¹⁰ Teva's Copaxone revenue in Spain was EUR {...} in 2021, with a sales volume of {...} DOT. The volume of all first-line DMTs in Spain was 7.9 million in 2021. This volume has grown by, on average, approximately 5% in recent years (between 2015 and 2021 - exhibiting a dip between 2017 and 2018, by 8%, and between 2020 and 2021, by 0.3%).
- (650) In Spain, GA is prescribed in hospitals and only dispensed in hospital pharmacies. During exclusivity, drugs are purchased through negotiated procedures or direct purchase. After loss of exclusivity, drugs can be purchased through tenders. Tenders are organised on the basis of active substance and dosage (i.e. separate tenders for GA 20 mg and GA 40 mg),⁸¹¹ and held by regional tender authorities for the hospitals in the region. Doctors have to prescribe the GA drug that is available in the hospital, i.e. the tender-winning drug.⁸¹²
- (651) This section demonstrates that, during the Relevant Period, Synthon GA was the only product capable of exercising an effective and immediate competitive constraint on Teva's commercial strategy for Copaxone in Spain.
- (652) Figure 19 shows the evolution of volumes of all first-line DMTs and Copaxone's average prices in Spain in the period from 2009 to 2021.

Figure 19: Volumes and Copaxone price in Spain

{...}

Source: Volume data source: IQVIA. Price data source: Teva.

Note: Prices are aggregated at the yearly level (see footnote 757).

- (653) Figure 20 shows the evolution of Copaxone's gross profit in Spain from 2014 to 2021.

Figure 20: Copaxone annual gross profit in Spain

{...}

Source: Commission calculations based on internal data from Teva (ID 1674, Teva's reply to Article 18(2) Request of 25 April 2022). See folder "[...]/output/Teva profitability" of the SO data pack.

Note: Gross profit refers to total revenues minus costs of goods sold.

- (654) In what follows, the Commission examines and interprets the above graphs, in tandem with qualitative information on the manner in which the specific market functions, to identify indications of competitive constraints exercised, if at all, on Copaxone by (i) Synthon GA, (ii) oral first-line DMTs (Tecfidera and Aubagio), and (iii) interferons first-line DMTs (notably Plegridy).

⁸¹⁰ ID 660, Teva's reply to Article 18(2) Request of 3 June 2020, p. 30; ID 644-178, Teva's reply to Article 18(2) Request of 3 June 2020.

⁸¹¹ ID 1133, Consorci Catalunya's Reply to Article 18(2) Request of 15 December 2021, p. 6; ID 1295-9, Teva's reply to Article 18(2) Requests of 22 October and 18 November 2021, p. 3; ID 1295-48, Teva's reply to Article 18(2) Requests of 22 October and 18 November 2021.

⁸¹² Prescriptions of non-tender winning products must be approved by the hospital pharmacy. Teva submits that prescription of non-tender winning products is very uncommon. See ID 1295-9, Teva's reply to Article 18(2) Requests of 22 October and 18 November 2021, p. 1-2.

6.3.3.4.2.4.1. Impact from Synthon GA

- (655) Synthon has entered a licensing agreement with Mylan (now Viartis) to commercialise Synthon GA in Spain. Mylan launched Synthon GA in February 2017 under the brand name Glatiramero Mylan. At launch, Glatiramero Mylan was offered in a 20 mg dosage. Figure 19 shows that the sales volumes of Glatiramero Mylan 20 mg in 2017 and 2018 were negligible. This can be explained by the fact that Teva had converted {...}% of its patient base in Spain from the 20 mg dosage to the 40 mg dosage by the time Glatiramero Mylan 20 mg was launched.⁸¹³
- (656) The uptake of Glatiramero Mylan 20 mg was further slowed down because of Teva's interaction with tender authorities. By way of example, when Glatiramero Mylan 20 mg was awarded a tender in the region of Valencia in May 2017, Teva challenged the tender. Teva's challenge was ultimately rejected, but as a result the tender contract was only signed in November 2017. Teva also lobbied for tender criteria that would exclude Glatiramero Mylan from tenders, for example the requirement to include a QR code on the syringe (Copaxone was the only GA product with such a QR code).⁸¹⁴
- (657) Teva was aware that these actions would delay generic-like competition and employed them at least partly for this purpose. In a presentation from May 2018, Teva noted "{...}"⁸¹⁵
- (658) In June 2018, Mylan launched the 40 mg dosage of Glatiramero Mylan⁸¹⁶, at parity with Copaxone's 40 mg list price (actual prices were however only established in tenders).
- (659) The entry of Glatiramero Mylan exposed Copaxone, for the first time, to generic-like competition on the Spanish market.
- (660) First, the launch of generic-like competition from Glatiramero Mylan in 2017 was followed by a gradual but significant price decrease for Copaxone in Spain. Before Glatiramero Mylan was launched, the price typically paid by hospitals and regions was the national price minus a rebate (in the form of a clawback⁸¹⁷) of 7.5%. Following Glatiramero Mylan's launch, Copaxone's price was determined by price negotiations with individual customers or through tenders.⁸¹⁸ Since then, circa {...}% of annual Copaxone revenue and {...}% of annual Copaxone volumes in Spain have been generated via tenders.⁸¹⁹ Teva submits that the price development for tenders broadly represents the prices currently paid for Copaxone.⁸²⁰ Hospitals and regions therefore no longer paid the national price for Copaxone.
- (661) Figure 19 shows that the price of Copaxone started to decrease in 2015, before the entry of Glatiramero Mylan. Between 2015 and 2016, the price of Copaxone dropped by around {...}% from EUR {...} per DOT to EUR {...} per DOT. This can most likely be attributed to the fact that, following Copaxone's loss of exclusivity in May

⁸¹³ ID 2763, {...} Reply to Article 18(2) Request of 11 February 2022, p. 23. By July 2017, {...}% of Copaxone patients were converted to the 40 mg dosage.

⁸¹⁴ ID 2763, {...} Reply to Article 18(2) Request of 11 February 2022, p. 24.

⁸¹⁵ ID 263-2954, European Legal Meeting, 22-23 May 2018, p. 5.

⁸¹⁶ ID 455-2610, Teva internal email dated 28 September 2018 from {...} to {...} and others.

⁸¹⁷ A clawback is a form of repayment in which purchaser first pays the full price of the product and later receives a refund for part of the payment.

⁸¹⁸ ID 1295-9, Teva's reply to Article 18(2) Requests of 22 October and 18 November 2021, p. 5.

⁸¹⁹ ID 1295-9, Teva's reply to Article 18(2) Requests of 22 October and 18 November 2021, p. 2.

⁸²⁰ ID 1295-9, Teva's reply to Article 18(2) Requests of 22 October and 18 November 2021, p. 5.

2015, there was an increase in the applicable clawbacks (15% instead of 7.5%).⁸²¹ Further, Copaxone 40 mg was launched in September 2015 at a lower price per DOT than Copaxone 20 mg and Teva actively converted patients from 20 mg to 40 mg Copaxone.⁸²²

- (662) Figure 19 further shows a significant price decrease in the price of Copaxone of around {...}% (from EUR {...} to EUR {...} per DOT) between 2017 and 2021. This price decrease can be explained by the introduction of a reference group for Copaxone and Glatiramero Mylan when the latter was launched, which led to a mandatory decrease of Copaxone’s national price by 20% for Copaxone 20 mg and 24% for Copaxone 40 mg.⁸²³ Therefore, in spite of the negligible sales of Glatiramero Mylan 20mg, its entry had a direct impact on Copaxone’s national price in Spain. However, the main reason for Copaxone’s price decrease was the entry of Glatiramero Mylan 40 mg in June 2018, which exposed Teva to price competition via tenders for GA drugs, because the competition in tenders further decreased prices below the (already decreased) national price.
- (663) The region of Asturias, a Spanish regional tender authority, explains: “*where market exclusivity for medicines is concerned, the administration’s margin for ‘negotiation’ is more or less non-existent*”.⁸²⁴ The region of Navarre reports “*the price improves as a result of the competition that is created when the patent for a substance is lost*”.⁸²⁵
- (664) Teva submits that its strategy in tenders was to primarily compete on price along with some other minor technical improvements.⁸²⁶ Tender prices for Copaxone 40 mg in 2020 were EUR {...} per pack,⁸²⁷ which is {...}% lower than Copaxone’s price before market entry by Glatiramero Mylan and translates to approx. EUR {...} per DOT.⁸²⁸ The price decrease that followed the launch of Glatiramero Mylan also significantly reduced the expenditure of Spanish regions on GA.⁸²⁹
- (665) Thus, following the entry of Glatiramero Mylan, Copaxone has seen an overall decrease of average prices from around EUR {...} per DOT in 2017 to around EUR {...} per DOT in 2022.
- (666) Second, Teva incurred a significant loss of volumes after the launch of Glatiramero Mylan, especially the 40 mg dosage. Figure 19 shows that the volumes gained by Glatiramero Mylan appear to translate into an almost one-to-one decrease in the volumes of Copaxone. In total, Copaxone’s volumes in Spain have decreased by around {...}% between 2018 and 2021. This development can be attributed to tender procedures in which Copaxone competed with Glatiramero Mylan. In Spain, Copaxone is a hospital drug and tenders are organised by the regions for the hospitals

⁸²¹ ID 455-1003, LRP and Brand plan Copaxone review Spain, 25 April 2014, p. 1.

⁸²² ID 455-1003, LRP and Brand plan Copaxone review Spain, 25 April 2014, p. 1.

⁸²³ ID 1295-9, Teva’s reply to Article 18(2) Requests of 22 October and 18 November 2021, p. 5.

⁸²⁴ ID 3624, Region of Asturias’ Reply to Article 18(2) Request of 15 December 2021, p. 4 (unofficial translation, see footnote 483 for original text).

⁸²⁵ ID 1113, Servicio Navarro de Salud’s reply to Article 18(2) Request of 15 December 2021, p. 3 (unofficial translation). Original text: “*la mejora de precio se consigue gracias a la competencia que se crea cuando se pierde la patente de un principio*”.

⁸²⁶ ID 1295-9, Teva’s reply to Article 18(2) Requests of 22 October and 18 November 2021, p. 4.

⁸²⁷ ID 1295-9, Teva’s reply to Article 18(2) Requests of 22 October and 18 November 2021, p. 6.

⁸²⁸ Based on the assumption that one pack of Copaxone 40 mg including 12 syringes lasts for 28 DOT.

⁸²⁹ ID 3624, Region of Asturias’ Reply to Article 18(2) Request of 15 December 2021, p. 4; ID 1133, Consorci Catalunya’s Reply to Article 18(2) Request of 15 December 2021, p. 7; ID 1340, Servicio Extremeño de Salud’s Reply to Article 18(2) Request of 15 December 2021, p. 6; ID 1113, Servicio Navarro de Salud’s Reply to Article 18(2) Request of 15 December 2021, pp. 2-3.

in their territory. The tender-winning product is dispensed to all GA patients in the region, regardless of whether they are naïve patients or existing patients that have received a different treatment before.⁸³⁰ For Teva, losing a tender therefore results in a loss of all the sales in the territory covered by the tender.⁸³¹ Contrary to Teva's claims,⁸³² Synthon GA could therefore contest Copaxone's entire patient base in Spain (see also Recitals (353)-(354)).

- (667) Third, the price reduction and loss of volumes significantly impacted Copaxone's gross profit in Spain. Figure 20 shows a decline of around {...}% in Copaxone's gross profit between 2017 and 2021. A similar impact can be observed in Copaxone's net profits.⁸³³
- (668) Teva had expected that the launch of a generic-like GA product would lead to these effects. In a Brand Plan for Spain, Teva notes "{...}"⁸³⁴ {...}.⁸³⁵

6.3.3.4.2.4.2. Impact from orals

- (669) The oral first-line DMTs, Aubagio and Tecfidera, have not been capable of constraining Teva's commercial strategy for Copaxone in Spain. The launch of the oral DMTs as new first-line treatments did not have a lasting and significant impact on Copaxone's volumes (especially compared to the strong impact that followed the entry of Glatiramero Mylan) and similarly, did not have any impact on Copaxone's prices.
- (670) Aubagio was launched in Spain in (late) 2014 and Tecfidera in the beginning of 2015. As is visible from Figure 19, the launch of both drugs was successful and they quickly grew their volumes in the first-line DMT segment.
- (671) The volume gains of the oral DMTs can be attributed partly to a steady volume loss from the interferons and partly to growth of the first-line DMT segment.⁸³⁶
- (672) The entry of orals did not have a significant effect on Copaxone's volumes in Spain. Figure 19 shows a stagnation in Copaxone's growth shortly before and after the entry of the oral DMTs. However, Copaxone's volumes remained stable even though both oral first-line DMTs rapidly gained volumes. Conversely, when Glatiramero Mylan started to gain significant volumes, this coincided with a similarly sharp volume decrease for Copaxone (see above).
- (673) In the abovementioned Brand Plan for Spain, Teva projected a {...}% decrease in Copaxone patients for 2015 {...}.⁸³⁷ In the same document, Teva projected Copaxone to lose more than {...}% of its patients to generic-like GA by 2020. This in itself shows that, in Teva's perception, competition from all oral products combined could not compare with competition from Synthon GA.
- (674) Figure 19 shows, first, that contrary to Teva's projections, the entry of the oral first-line DMTs had no significant effect on Copaxone's patient basis. Second, the introduction of oral first-line DMTs had no obvious impact on Copaxone prices. As

⁸³⁰ ID 1295-9, Teva's reply to Article 18(2) Requests of 22 October and 18 November 2021, p. 4.

⁸³¹ ID 1295-9, Teva's reply to Article 18(2) Requests of 22 October and 18 November 2021, p. 4.

⁸³² ID 4032, Teva's Reply to the Statement of Objections, para. 326.

⁸³³ See ID 5820 for a side-by-side comparison of Copaxone gross and net profits in all Relevant Member States and the SO data pack for the underlying data and computations.

⁸³⁴ ID 455-1003, LRP and Brand plan Copaxone review Spain, 25 April 2014, p. 3.

⁸³⁵ ID 455-1003, LRP and Brand plan Copaxone review Spain, 25 April 2014, p. 8.

⁸³⁶ ID 906, Teva's reply to Article 18(2) Request of 3 June 2021, pp. 1-3.

⁸³⁷ ID 455-1003, LRP and Brand plan Copaxone review Spain, 25 April 2014, p. 1.

explained above, the price decrease in 2015 can more credibly be attributed to Copaxone's loss of exclusivity (mandatory clawback) and the launch of Copaxone 40 mg at a lower price than Copaxone 20 mg. Finally, while a slight decline of Copaxone's gross profits can be observed in Figure 19 following the entry of the oral first-line DMTs in 2014 and 2015, this decline is trivial when compared to the steep and lasting impact on Copaxone's gross profits observed after the launch of Glatiramero Mylan in 2017 (20 mg) and 2018 (40 mg).

- (675) In any event, any observed pressure exerted by oral DMTs on Copaxone's price or volumes, still allowed Teva to maintain Copaxone's prices in Spain far above variable costs (as well as to maintain large gross and net profit⁸³⁸), which supports the view that this competitive pressure is limited.

6.3.3.4.2.4.3. Impact from interferons

- (676) The interferons (Avonex, Betaferon, Extavia, and Rebif) are established first-line treatments in Spain. The only new entrant among the interferons was Plegridy in 2015. The launch of Plegridy does not appear to have had any impact on Copaxone's gross profits, which remained stable after its launch on the market, as shown in Figure 19.

- (677) Interferons have not been able to effectively and immediately constrain Copaxone's prices, volumes or profits in the period under review. As appears from Figure 19, Copaxone's prices were stable until its loss of exclusivity and Copaxone's volumes do not appear to have been impacted by the presence of interferons in the first-line DMT segment. There is no obvious relationship between the changes in sales volumes between Copaxone and interferons.

6.3.3.4.2.4.4. Conclusion – the product market in Spain consists only of GA DMTs

- (678) The analysis of the market data shows that Glatiramero Mylan is the only DMT that has exercised an effective and immediate competitive constraint on Copaxone on a lasting basis in Spain during the Relevant Period (see Section 6.3.2.3 concerning the exclusion of second-line DMTs from the relevant product market). The availability of Glatiramero Mylan as a generic-like alternative for Copaxone in Spain exposes Copaxone to price competition.
- (679) The entry of Synthon GA led to a mandatory decrease of Copaxone's national price and allowed regional authorities to hold tenders in which Copaxone was exposed to price competition and was followed by a massive erosion of prices, volumes and profits for Copaxone. Compared to the level of prices and volumes before entry of Glatiramero Mylan, Copaxone's prices have decreased by around {...}% and its volumes have decreased by around {...}%. Copaxone's gross profits in Spain decreased by around {...}% since the launch of Glatiramero Mylan.
- (680) The otherwise successful entry of oral first-line DMTs in Spain has not had a significant impact on Copaxone's sales, which remained relatively stable until Glatiramero Mylan entered the market. Similarly, the presence of interferons first-line DMTs has not exercised any discernible pressure on Copaxone.
- (681) The Commission therefore finds that the relevant product market in Spain during the Relevant Period is limited to GA, and therefore only includes Copaxone and Synthon GA (Glatiramero Mylan).

⁸³⁸ Commission calculations based on internal data from Teva (ID 1674, Teva's reply to Article 18(2) Request of 25 April 2022).

- 6.3.3.4.3. Relevant Member States where, unlike other (non-GA) first-line DMTs, Synthon GA was capable of effectively and immediately constraining Copaxone but, due to Teva's conduct, this has not happened
- (682) In Belgium, Czechia and Germany, Teva's conduct, comprising several practices, including those described in Chapter 5 and those assessed in Chapters 8 and 9, was successful in delaying Synthon GA from effectively and immediately constraining Copaxone's volumes, prices and profits. At the same time, non-GA first-line DMTs have not been able to exercise a competitive constraint on Copaxone's commercial strategy.
- (683) Teva's conduct aimed precisely at preventing or hindering the entry of Synthon GA in order to avoid or delay price competition to Copaxone, by Synthon's generic-like product. The fact that this strategy was especially successful in Belgium, Czechia and Germany and that, to date, market data has not shown a significant impact on Copaxone cannot justify a different product market definition than in markets where, despite Teva's conduct, Synthon GA's entry already significantly eroded Copaxone's prices, volumes and/or profits. This is consistent with the findings of the Court in the *Generics (UK)* case, according to which generic versions of a medicine may be taken into account for the definition of the relevant product market even before their market entry.⁸³⁹ Indeed, this is borne out by the following elements.
- (684) First, the examples of market evolution in the First Group of Relevant Member States (see Section 6.3.3.4.2) show that markets have been profoundly transformed following Synthon GA's entry resulting in an effective and immediate constraint on Copaxone volumes, prices and profits. This shows that Synthon GA had the capacity to exert effective and immediate constraints on Copaxone in the Second Group of Relevant Member States.
- (685) Second, the threat of generic or generic-like entry can already in itself change the nature of competition in the market, towards one driven by price competition and commoditisation (see Sections 6.3.3.1 and 6.3.3.2). For instance, the entry of Synthon GA in Germany and in Belgium – even if it could not exert the same level of competitive constraint as it did in Italy or the Netherlands – has nonetheless caused a significant decrease of Copaxone's prices and profits due to the price rules in place in these Member States (see Sections 6.3.3.4.3.1 and 6.3.3.4.3.3).
- (686) Third, Synthon and its licensees (Mylan/Viatriis and Alvogen/Zentiva) made advanced preparations (patent challenges against asserted Teva patents) to enter Belgium, Czechia and Germany after obtaining a marketing authorisation.⁸⁴⁰ Still, Synthon GA was only launched in Belgium in 2021 and in Czechia in 2023 (and only in the 20 mg dosage). In Germany, Synthon GA was actually launched in 2016 but was subsequently blocked by Teva's preliminary injunctions. Teva's disparagement campaign was also capable of further hindering Synthon GA's uptake as described in Chapter 9. For example, following the introduction of Synthon GA 40 mg in Germany in January 2018, its sales started to rise significantly in January 2019 (seemingly to the detriment of Copaxone), until a preliminary injunction was granted to Teva in mid-2019. Consequently, Synthon GA 40 mg was withdrawn from the market until the preliminary injunction was lifted in autumn 2020 and struggled to regain the momentum that was interrupted by the injunction (see Section 6.3.3.4.3.3 and Figure 25).

⁸³⁹ Case C-307/18, *Generics (UK) and Others*, paragraphs 133-134.

⁸⁴⁰ On challenges to Teva's patents see Table 13 and Table 14 and Recitals (1349)-(1350).

- (687) Fourth, Teva’s own documents testify that Teva’s focus was on confronting generic-like competition from Synthon GA as the only real competitive threat at the relevant time. This focus preceded the entry by Synthon GA by months and even years (see Section 6.3.3.2.4). There is abundant evidence of such focus for Belgium, Czechia and Germany, Teva’s largest Copaxone market in the EEA.
- (688) Fifth, there are no significant structural differences in how the structure of demand and supply for patented medicines in, on the one hand, Italy, Poland, the Netherlands, and Spain, and on the other hand, Belgium, Czechia and Germany changes in reaction to generic-like entry. In all these markets, there were significant incentives put in place by the competent authorities to favour generic-like price competition to Copaxone. In Belgium, originator medicines are subject to a significant mandatory rebate (in Copaxone’s case 23%) upon market entry of a therapeutically equivalent medicine. Belgian regulation further foresees a “dispense of the cheapest drug rule” which incentivises pharmacists to dispense the cheaper of several automatically substitutable medicines.⁸⁴¹ In Czechia, the market entry of Synthon GA would have led to a likely decrease in the price for Copaxone because both medicines would have competed against each other in tenders.⁸⁴² In Germany, too, the two medicines would have competed against each other in more tenders absent Teva’s conduct (such as the enforcement of the 40 mg dosage patents against Viartis and the introduction of the SDD).⁸⁴³
- (689) Sixth, market data consistently shows no significant or lasting impact on Copaxone of first-line oral DMTs (Aubagio and Tecfidera) or interferon-based first-line DMTs (notably Plegridy) despite their very successful entry across the EU. There is no evidence suggesting that the presence of oral DMTs has been capable of exercising an effective and immediate constraint on the prices, volumes and profits of Copaxone, especially not to the same or at least a similar extent as Synthon GA. For example, evidence from Belgium suggests that Teva was considering that the degree of competition from Synthon GA may lead Teva to take extreme measures and withdraw Copaxone from the Belgian market to prevent increased price competition from spilling over into other markets using the external reference pricing system.⁸⁴⁴ Another example is Germany, where Teva made elaborate financial projections building on the preliminary injunction barring Synthon GA from the market (see Recital (501)). These financial projections show that the very significant financial gains from the injunctions solely resulted from the absence of Synthon GA from the market. In contrast, the financial projections do not mention non-GA first-line DMTs at all, which suggests that Teva did not consider them as an effective competitive threat to discuss in relation to Copaxone’s financial development (see also Section 6.3.3.3.1).⁸⁴⁵

⁸⁴¹ The cheapest drug rule does not apply to Copaxone and Synthon GA because they are not deemed to be automatically substitutable in Belgium (see Section 6.3.3.4.3.1.1).

⁸⁴² ID 1295-45, Teva’s reply to Article 18(2) Requests of 22 October and 18 November 2021, p. 4.

⁸⁴³ Copaxone and Synthon GA did compete against each other in tenders in Germany (see ID 1295-7, Teva’s reply to Article 18(2) Requests of 22 October and 18 November 2021, p. 5-6) but Viartis was unable to sell the 40 mg dosage of Synthon GA in Germany for circa 1 year due to a preliminary injunction. Further, Teva introduced a revised injection device for Copaxone (the single-dosage device, SDD) that was sold via separate tenders without competition from Synthon GA (see Section 6.3.3.4.3.3 below).

⁸⁴⁴ ID 404-2469, Copaxone in Belgium/Impact in the NL, 24 April 2018, p. 4.

⁸⁴⁵ ID 806-36, TPE Board Meeting – Finance – Q3 2020, 5 October 2020, p. 6.

6.3.3.4.3.1. Belgium

- (690) This Section discusses how, during the Relevant Period, neither orals nor interferon-based first-line DMTs exercised an effective and immediate constraint on Copaxone. Synthon GA (sold under the brand “Glatiramyl”) was the only product capable of exercising an effective and immediate competitive constraint on Teva’s commercial strategy for Copaxone in Belgium, even though, due to Teva’s conduct, the full potential of competition between Glatiramyl and Copaxone in Belgium has yet to develop.
- (691) Belgium is one of the 20 largest geographic markets for MS treatments (by sales) world-wide.⁸⁴⁶ Teva’s revenue with Copaxone in Belgium was EUR {...} in 2021, with a sales volume of {...} (in DOT). The volume of all first-line DMTs in Belgium was 1.61 million DOTs in 2021. This volume has been decreasing by, on average, approximately 2% between 2015 and 2021.
- (692) In Belgium, GA is not a hospital drug. GA is primarily prescribed by practitioners and dispensed by pharmacies. Doctors are encouraged to prescribe by INN or prescribe drugs that are categorised as “cheap” drugs by brand.⁸⁴⁷ If presented with an INN prescription, pharmacists are obliged to dispense a “cheap” drug within the INN group (the “cheapest drug rule”).⁸⁴⁸ However, the Belgian Federal Agency for Medicines and Health Products (FAMHP) has not recommended prescription by INN for GA drugs and therefore GA is included on the “no-INN” list. Teva submits that doctors are likely warned by the electronic prescribing system that GA is included on the “no-INN” list and will not prescribe GA by INN. GA has been on the no-INN list since 2018.⁸⁴⁹
- (693) The “cheapest drug” rule, therefore, does not apply to Glatiramyl and there is thus no regulatory mechanism that would encourage doctors in Belgium to prescribe GA by INN or to prescribe Glatiramyl as the “cheapest drug” by brand. Both Copaxone and Synthon GA are reimbursed at the same level. There are no incentives for Belgian doctors to prescribe Synthon GA instead of Copaxone and, as explained above, a prescription by INN is discouraged.⁸⁵⁰
- (694) Figure 21 shows the evolution of volumes of all first-line DMTs and Copaxone’s average prices in Belgium from 2009 to 2021.

Figure 21: Volumes and Copaxone price in Belgium

{...}

Source: Volume data source: IQVIA data from DG COMP (because the IQVIA data provided by Teva does not include Belgium). Price data source: Teva.

Note: Prices are aggregated at the yearly level (see footnote 757). Synthon GA 20 mg and Synthon GA 40 mg both entered in August 2021. The blue line therefore depicts the entry of both dosages.

⁸⁴⁶ ID 644-199, Global Customers Insight-Multiple Sclerosis Fact Book, November 2016, p. 35.

⁸⁴⁷ ID 1288, Teva’s reply to Article 18(2) Requests of 22 October and 18 November 2021, pp. 1-2; A drug is considered “cheap” if it is the cheapest drug in the relevant cluster, or if its price is within a range of 5% of the cheapest drug.

⁸⁴⁸ ID 2508, Brochure by the Belgian Royal institute for sickness and invalidity insurance (RIZIV-INAMI), <https://www.riziv.fgov.be/SiteCollectionDocuments/goedkoopste-geneesmiddel-stofnaam-antibiotica-antimycotica-brochure.pdf>, accessed on 1 October 2022, p. 4.

⁸⁴⁹ ID 1288, Teva’s reply to Article 18(2) Requests of 22 October and 18 November 2021, p. 3.

⁸⁵⁰ ID 1288, Teva’s reply to Article 18(2) Requests of 22 October and 18 November 2021, p. 2.

(695) Figure 22 shows the evolution of Copaxone’s gross profit in Belgium over 2014-2021.

Figure 22: Copaxone annual gross profit in Belgium

{...}

Source: Commission calculations based on internal data from Teva (ID 1674, Teva’s reply to Article 18(2) Request of 25 April 2022). See folder “[...]output/Teva profitability” of the SO data pack.

Note: Gross profit refers to total revenues minus costs of goods sold. Synthon GA 20 mg and Synthon GA 40 mg both entered in August 2021. The blue line therefore depicts the entry of both dosages.

(696) In what follows, the Commission examines and interprets the above graphs, in tandem with qualitative information on the manner in which the specific market functions, to identify indications of competitive constraints exercised, if at all, on Copaxone by (i) Synthon GA, (ii) oral first-line DMTs (Tecfidera and Aubagio) and (iii) from interferons first-line DMTs (notably Plegridy).

6.3.3.4.3.1.1. Impact from Synthon GA

(697) Viartis launched Synthon GA on the Belgian market in August 2021 under the brand name Glatiramyl in a 20 mg and a 40 mg dosage.

(698) In the following, the Commission analyses both the indications of Glatiramyl’s impact on Copaxone’s volumes, prices, and profits, as well as the potential for further impact that Glatiramyl could have had on Copaxone absent Teva’s conduct.

Observations concerning Copaxone’s volumes, prices and profits in Belgium

(699) An analysis of main commercial indicators of Copaxone in Belgium shows that Glatiramyl is the only product capable of exercising an effective and immediate constraint.

(700) First, the analysis of Copaxone’s volume development in the Relevant Period suggests that Glatiramyl is the sole product that could have effectively constrained Copaxone’s volumes.

(701) Copaxone’s volumes were stable between 2013 and 2017 and have only slowly and gradually decreased after that. Figure 21 does not show a sudden and significant drop in volumes as seen in the First Group of Relevant Member States (such as Italy, the Netherlands and Poland). Considering the impact Synthon GA had on Copaxone in those Relevant Member States, the fact that volumes in Belgium are relatively stable can be attributed to the absence of Synthon GA from the Belgian market until 2021 (as explained below in Sections 6.3.3.4.3.1.2 and 6.3.3.4.3.1.3, non-GA first-line DMTs did not exert an effective and immediate competitive constraint on Copaxone in Belgium). After 2021, Copaxone’s volumes did not decrease because automatic substitution between Copaxone and Synthon GA is not authorised to this day, Synthon GA having been placed on a “no INN” list which effectively excludes automatic substitution. While the Commission does not take issue with Teva’s aim of lobbying against automatic substitution, Chapter 9 finds that Teva used disparaging messages when communicating on automatic substitution.⁸⁵¹

(702) Second, the analysis of Copaxone’s price development in the Relevant Period shows that the entry of Glatiramyl in August 2021 was followed by a significant impact on Copaxone’s prices, just like as in the First Group of Relevant Member States.

⁸⁵¹ For Teva’s conduct concerning automatic substitution in Belgium, see Section 9.4.4.2.1, including Recital (1843).

- (703) The mere entry of Synthron GA in 2021 (at negligible realised sales volumes) triggered a significant statutory price decrease for Copaxone in Belgium – not yet visible in the available price data of Figure 21. Following the entry of the therapeutically equivalent drug Glatiramyl on the Belgian market, both Copaxone and Glatiramyl were subject to a price cap of 23% below the then prevalent price of Copaxone. According to Teva, there were no other significant price changes in Belgium in the 10 years before the launch of Glatiramyl (2010-2020).⁸⁵² The mandatory 23% rebate was lower than Teva had expected. Initially, a mandatory rebate of 44% for both Copaxone and Glatiramyl against the prevalent price of Copaxone was to be imposed upon the launch of the latter.⁸⁵³ When Glatiramyl entered the Belgian market in August 2021, Belgium had introduced a new regulatory framework specifically for “complex” active substances launched as generics, which foresees a lower mandatory rebate of 23% for certain medicines. Copaxone and Glatiramyl were subject to this law and therefore to a rebate of 23% against the prevalent price of Copaxone (instead of 44%). The application of the mandatory rebate was triggered by Glatiramyl’s market entry and independent of the medicine’s uptake. Copaxone, too, had to set its price at least 23% below the prevalent price of Copaxone.
- (704) The effect of the mandatory rebate on Copaxone’s prices is not reflected in the price data in Figure 21 because the mandatory rebate only came into effect from January 2022 onwards.⁸⁵⁴ The figure shows a significant price decrease in 2015, which the Commission understands to be the result of a statutory price decrease for medicines that have been marketed in Belgium for longer than 12 years and was therefore not related to either Synthron GA or non-GA first-line DMTs.⁸⁵⁵
- (705) Third, the analysis of Teva’s gross profits from Copaxone during the Relevant Period shows that no event caused a profit decrease comparable to the one that is observed in the First Group of Relevant Member States following the entry of Synthron GA. Copaxone’s net profits exhibit a similar picture.⁸⁵⁶ Therefore, Glatiramyl is the sole product that could constrain Copaxone’s profits.
- (706) Figure 22 shows that the profits of Copaxone were stable between 2015 and 2018 (after a profit decline in 2015 compared to 2014, which is likely related to the statutory price decrease in 2015). In line with the slow and gradual volume decline of Copaxone since 2018, profits have slowly declined as well. This development is markedly different in the First Group of Relevant Member States. There, the entry of Synthron GA was followed by a lasting and significant profit decline, which cannot be observed in Belgium. The fact that profits in Belgium were relatively stable can be attributed to the absence of Synthron GA from the Belgian market until 2021, amongst others, due to an interim injunction. After 2021, this can be attributed to the fact that automatic substitution between Copaxone and Synthron GA is not authorised to this day, Synthron GA having been placed on a “no INN” list which effectively excludes automatic substitution, in line with the objective of Teva’s exclusionary behaviour.⁸⁵⁷

⁸⁵² ID 906, Teva’s reply to Article 18(2) Request of 3 June 2021, p. 15.

⁸⁵³ ID 404-2469, Copaxone in Belgium/Impact in the NL, 24 April 2018, p. 2.

⁸⁵⁴ ID 2228, Teva’s reply to Article 18(2) Request of 13 July 2022, p. 29.

⁸⁵⁵ See Recital (719).

⁸⁵⁶ See ID 5820 for a side-by-side comparison of Copaxone gross and net profits in all Relevant Member States and the SO data pack for the underlying data and computations.

⁸⁵⁷ See footnote 851.

(707) It follows from analysing the development of Copaxone’s volumes, prices, and profits in the Relevant Period in Belgium that Glatiramyl’s launch was followed by a significant decrease in Copaxone’s prices. Glatiramyl has not (yet) had a noticeable impact on Copaxone’s volumes or profits. The Commission considers that the lack of volume impact is due to the fact that Glatiramyl could not exert effective and immediate constraints on Copaxone (as Synthon GA did in Italy or the Netherlands) due to Teva’s conduct, as will be explained in the following.

The observable impact following Synthon GA’s entry would have likely been stronger in the absence of Teva’s actions, including the abusive conduct

(708) The Commission finds that the impact on Copaxone prices and profitability following the effective entry of Glatiramyl would have likely occurred earlier, and been stronger, in the absence of Teva’s conduct aimed at prolonging the exclusivity of Copaxone.

(709) First, the sales volumes of Glatiramyl in the first 6 months after launch were negligible with only {...} DOT sold.⁸⁵⁸ By comparison, in the same period Teva sold {...} DOT of Copaxone. This is in stark contrast to Synthon GA’s successful volume developments in Relevant Member States such as Italy and the Netherlands in the first six months after launch. In these countries, Teva’s conduct, notably Teva’s actions in the context of the CCP (Section 5.2), including the conduct that the Commission assesses in Chapters 8 and 9 did not ultimately entirely eliminate competition from Synthon GA. An examination of the evidence concerning the expected effects of unfettered competition from Glatiramyl in Belgium will illustrate the potential strength of the constraint that Glatiramyl could exercise on Copaxone⁸⁵⁹.

(710) Second, Teva’s CCP activities likely influenced the degree of competition from Glatiramyl.

(711) In the first place, Teva obtained a preliminary injunction that hindered Mylan from entering the Belgian market. The preliminary injunction was in place from May 2018 to May 2020.⁸⁶⁰ The preliminary injunction concerned only Glatiramyl 40 mg and did not affect Glatiramyl 20 mg. However, as also experienced in other markets such as Germany, the launch of Glatiramyl 20 mg was no longer commercially attractive, and possibly not even viable, for Mylan because Teva had already switched the majority of its patients to Copaxone 40 mg.⁸⁶¹

(712) In the second place, in line with Teva’s endeavours, Glatiramyl was not recommended for automatic substitution in Belgium. The entry of Glatiramyl on the Belgian market was capable of exposing Copaxone to additional price competition under the “dispense the cheapest drug” rule. These rules were introduced to encourage price competition between pharmaceutical companies supplying drugs with the same INN (i.e. between originators and generics, or between different generics).⁸⁶²

⁸⁵⁸ See Figure 21. {...}, see ID 2763, {...} Reply to Article 18(2) Request of 11 February 2022, p. 6.

⁸⁵⁹ See Recital (715).

⁸⁶⁰ ID 2162, Teva’s Reply to Article 18(2) Request of 13 July 2022.

⁸⁶¹ ID 2763, {...} Reply to Article 18(2) Request of 11 February 2022, p. 5.

⁸⁶² ID 2508, Brochure by the Belgian Royal institute for sickness and invalidity insurance (RIZIV-INAMI), <https://www.riziv.fgov.be/SiteCollectionDocuments/goedkoopste-geneesmiddel-stofnaam-antibiotica-antimycotica-brochure.pdf>, accessed on 1 October 2022, p. 4.

- (713) However, these rules do not apply to Copaxone and Glatiramyil as they were included in the “no INN” list which effectively excludes automatic substitution. The inclusion of Copaxone and Synthon GA on the “no INN” list was in keeping with Teva’s objectives to avoid substitutability between Copaxone and Synthon GA. While the Commission does not take issue with the fact that Teva lobbied against automatic substitution, Chapter 9 finds that Teva’s messages when communicating on automatic substitution were disparaging towards Synthon GA. In a presentation prepared by the multiple sclerosis brand team in January 2017, Teva notes regarding Belgium “{...}”.⁸⁶³ The “no INN” list is a list of drugs for which prescription by INN and therefore substitution at pharmacy level is not recommended (albeit not forbidden). Of the Relevant Member States, Belgium is the only one in which automatic substitution between Copaxone and Synthon GA is not authorised to this day. In effect, this means that doctors have no incentives to prescribe the cheaper medicine, and are even actively discouraged from prescribing by INN (see Recital (692)). Considering that prescription by INN and automatic substitution are regulatory mechanisms aimed at increasing the uptake of generic or generic-like medicines, the lack of such incentivizing mechanisms made it difficult for Glatiramyil to gain volumes in Belgium. This was exactly what Teva had aimed at in their CCP strategy, as can be shown from an internal document entitled {...}.⁸⁶⁴
- (714) Third, absent Teva’s actions, constraints from Glatiramyil would likely have been stronger.
- (715) Teva’s own analysis expected the impact from effective competition by Synthon GA to be so strong that Teva even considered withdrawing Copaxone from Belgium to prevent knock-on price reductions in other EEA countries due to external reference pricing. In a presentation titled “Copaxone in Belgium/Impact in the NL”, prepared by Teva’s {...} in April 2018, the impact of a price decrease in Belgium on prices in the Netherlands is discussed: “{...}”.⁸⁶⁵ {...}.⁸⁶⁶ Already in 2015, Teva’s {...} noted in an email that “{...}” (emphasis added).⁸⁶⁷ In the end, Teva did not have to resort to such extreme measures as it successfully attained the objective of avoiding automatic substitution thus avoiding strong competition from Synthon GA and the resulting price erosion.
- (716) As explained in Chapter 9, Teva disseminated messages to Belgian authorities that were capable of misleading them as to the safety, efficacy and tolerability of Glatiramyil as well as to its therapeutic equivalence with Copaxone. In the absence of such conduct, it is likely that, Copaxone and Glatiramyil would have been substitutable at pharmacy level (as is the case in all other Relevant Member States). Price competition from Synthon would have led Teva to either drop its prices to preserve volumes or to lose volumes in order to avoid price decreases, like in the First Group of Relevant Member States.

6.3.3.4.3.1.2. Impact from orals

- (717) The oral DMTs Aubagio and Tecfidera were launched in Belgium in September 2014 and August 2015, respectively. Neither launch had a significant and lasting impact on Teva’s commercial strategy for Copaxone.

⁸⁶³ ID 455-223, MS BT Jan 2017, 18 January 2017, p. 17.

⁸⁶⁴ ID 455-2743, Scenarios FoGA launch in Belgium & Impact on Copaxone, 10 December 2018, p. 3.

⁸⁶⁵ ID 404-2469, Copaxone in Belgium/Impact in the NL, 24 April 2018, p. 4.

⁸⁶⁶ ID 404-2469, Copaxone in Belgium/Impact in the NL, 24 April 2018, p. 4.

⁸⁶⁷ ID 266-109, Teva internal email dated 17 November 2015 from {...} to {...} and others, p. 1.

- (718) The entry of oral DMTs possibly had some transitory effect on the volumes of Copaxone in Belgium. It appears from Figure 21 that the volumes of Copaxone grew until 2013, then decreased slightly after the entry of Aubagio. Then they increased again after the launch of Copaxone 40 mg and started a slow continuous decline from 2017 onwards.
- (719) Figure 21 also shows a significant decrease in the price of Copaxone in 2015. While the price decrease coincides with the entry of Aubagio on the Belgian market, Teva has not reported that the entry of Aubagio impacted Copaxone's prices in any way. Conversely, Teva submits that the pricing of non-GA first-line DMTs has not impacted the price of Copaxone following its launch.⁸⁶⁸
- (720) Rather, the Commission understands that Copaxone was subject to a mandatory price decrease starting from July 2015 because the drug had been reimbursed in Belgium for 12 years.⁸⁶⁹ This decrease was therefore unrelated to competition with other DMTs, including orals.
- (721) Since 2015, the price of Copaxone in Belgium has been stable. Teva submits that a few mandatory price decreases dictated by the Belgian authorities have applied to Copaxone. These price decreases did not target Copaxone individually and were not driven by comparisons with other DMTs, but were instead the result of general savings measures mandated by the law and applicable to all medicines across the board.⁸⁷⁰
- (722) Therefore, overall, oral DMTs potentially had some limited transitory impact on Copaxone's volumes in the Relevant Period, but no impact on Copaxone's prices. Therefore, even if the entirety of Copaxone's observed volume decrease were to be attributed to the entry of Aubagio and Tecfidera, this effect is far from being sufficient to show that orals imposed an effective and immediate competitive constraint on Copaxone, especially not when compared to the effects generic or generic-like competition can have (that is, either a significant drop in price – like in Italy and Poland – or a significant loss of volumes to a cheaper comparable drug – like in the Netherlands).
- (723) Figure 22 further shows that the gross profit of Copaxone in Belgium has been stable between 2015 and 2018 despite the successful entry of oral DMTs in this period.
- (724) In any event, any observed pressure exerted by oral DMTs on Copaxone's price or volumes, still allowed Teva to maintain Copaxone's prices in Belgium far above variable costs (as well as to maintain large gross and net profits⁸⁷¹), which supports the view that this competitive pressure is limited.

⁸⁶⁸ ID 1288, Teva's reply to Article 18(2) Requests of 22 October and 18 November 2021, p. 8. Teva submits that the prices of existing MS treatments (the interferons) may have been used as a benchmark in the price negotiations for Copaxone 20 mg when it was first launched in Belgium.

⁸⁶⁹ A mandatory price decrease of 17% was applied to Copaxone as of 1 July 2015, see ID 2228, Teva's reply to Article 18(2) Request of 13 July 2022, p. 29. The Commission attributes the significant price decrease of Copaxone that is visible in Figure 21 to this mandatory price decrease. The fact that the price decrease appears in the graph already in the first quarter of 2015, while the price decrease only took effect in the third quarter of 2015, does not change this assessment, as it can be caused by small inaccuracies in Teva's reporting for the year 2015.

⁸⁷⁰ ID 1288, Teva's reply to Article 18(2) Requests of 22 October and 18 November 2021, p. 7.

⁸⁷¹ Commission calculations based on internal data from Teva (ID 1674, Teva's reply to Article 18(2) Request of 25 April 2022).

6.3.3.4.3.1.3. Impact from interferons

- (725) The interferons Extavia, Avonex, Betaferon and Rebif are established first-line DMTs in Belgium.⁸⁷² Plegridy entered the Belgian market in 2015.
- (726) Interferons have not been able to constrain Copaxone's prices, volumes and/or profits. It is impossible to study the effect of entry by interferons on Copaxone's volumes, prices and profits because all interferons (except Plegridy) have been in the market for a longer time than Copaxone. However, the Commission notes that (i) interferons overall have been declining steadily and fast since at least 2010 and (ii) as mentioned above in Recital (719), Teva submits that the pricing of non-GA first-line DMTs has not impacted the price of Copaxone following its launch.

6.3.3.4.3.1.4. Teva claims that the Commission misrepresents the competitive dynamic in Belgium

- (727) Teva claims that the Commission misrepresents the competitive dynamics between Copaxone and Synthon GA in Belgium.⁸⁷³ The Commission rejects this claim.
- (728) According to Teva, the Commission's analysis does not properly consider the Belgian regulatory framework, in particular the fact that GA is not automatically substitutable in Belgium and that it is not sold via tenders.⁸⁷⁴ These particularities of the Belgian market are not disputed (see Recitals (692)-(693)). Teva argues that there can be no shift from competition on promotion to price competition (which the Commission has found in Section 6.3.3.2.2) in Belgium in the absence of automatic substitution rules and tenders.⁸⁷⁵
- (729) However, the Commission's assessment of the relevant market for Copaxone in Belgium does not rest on a finding of tender markets and automatic substitutability. Instead, the Commission's analysis is based on the findings that (i) the entry of Synthon GA on the Belgian market led to a significant price decrease for Copaxone (see Recitals (703) and (707)), (ii) the impact on Copaxone prices and profitability following the entry of Glatiramyil would have likely occurred earlier, and been stronger, in the absence of Teva's conduct (Recital (708)); and (iii) the entry of orals (and the interferon Plegridy) on the Belgian market has not impacted Teva's profits with Copaxone (Recital (722)).

6.3.3.4.3.1.5. Conclusion: the product market in Belgium consists only of GA products

- (730) The analysis of market data for Belgium suggests that Synthon GA (Glatiramyil) is the only DMT that could have effectively exercised competitive constraints on Copaxone in Belgium during the Relevant Period (see Section 6.3.2.3 concerning the exclusion of second-line DMTs from the relevant product market).
- (731) The analysis of the market data shows that, while the entry of Synthon GA was followed by a significant {...}% reduction in prices, and – absent Teva's conduct – further price decreases might have materialised (if the "cheapest drug rule" had applied), the otherwise successful entry of oral first-line DMTs in Belgium had no

⁸⁷² While the information provided by Teva on market entry of first-line DMTs suggests that the only first-line interferon-based treatments available in Belgium are Extavia and Plegridy (see ID 2222, Teva's reply to Article 18(2) Request of 13 July 2022), volume data for Belgium sourced from IQVIA (see source information for Figure 21) suggests that Avonex, Betaferon and Rebif are also available in Belgium.

⁸⁷³ ID 4032, Teva's Reply to the Statement of Objections, para. 331.

⁸⁷⁴ ID 4032, Teva's Reply to the Statement of Objections, paras. 328-329.

⁸⁷⁵ ID 5695, Teva's Reply to the Letter of Facts I of 9 February 2024, paras. 140-142.

impact on Copaxone's prices and was only followed by a limited and transitory impact on Copaxone's volumes. Similarly, the presence of interferon-based first-line DMTs has not exercised any discernible pressure on Copaxone.

- (732) Moreover, there are no indications that, apart from the delayed entry of Synthon GA, the competitive constraints on Copaxone in Belgium are fundamentally different from those in Italy, the Netherlands, Poland and Spain and therefore there is no reason to believe that, absent Teva's behaviour, the competitive constraints posed by Synthon to Copaxone would not have developed at least like in the First Group of Relevant Member States as far as Copaxone's prices, volumes and profits are concerned.
- (733) The Commission therefore finds that the relevant product market in Belgium during the Relevant Period is limited to GA, and therefore only includes Copaxone and Synthon GA (Glatiramy).

6.3.3.4.3.2. Czechia

- (734) This section discusses how, during the Relevant Period, neither orals nor interferon-based first-line DMTs exercised an effective and immediate constraint on Copaxone. Synthon GA would have been the only product capable of exercising an effective and immediate competitive constraint on Teva's commercial strategy for Copaxone in Czechia, even though, due to Teva's conduct, while Synthon GA has entered the Czech market with its 20 mg dosage in 2023, it did not enter the Czech market with its 40 mg dosage during the Relevant Period, and therefore effective competition between Remurel and Copaxone in Czechia has yet to develop.
- (735) Teva's Copaxone revenue in Czechia was approximately EUR {...} in 2021, with a sales volume of approximately {...} DOT and approximately {...} patients.⁸⁷⁶ The volume of all first-line DMTs in Czechia was 3.06 million DOT in 2021. This volume has grown by, on average, 3% between 2016 and 2021.
- (736) In Czechia, GA medicines are prescribed in specialised MS health centres ("MS centres"). MS centres usually source medicines via tenders. Any supplier of a medicines that meets the medical requirements can submit a bid and the lowest-priced bid wins. Teva submitted in 2021 that {...}% of these tenders were based on the active substance for GA medicine and the other {...}% are on a brand-basis for Copaxone.⁸⁷⁷ Teva's bids in tenders are constrained by the reimbursement price for Copaxone and are, absent other GA products in Czechia, equal to this price. Teva estimates that at least {...}% of its sales value and volume in Czechia between 2011 and 2021 was earned via tenders.⁸⁷⁸
- (737) Doctors in MS centres can prescribe treatments either by INN or by brand but will usually prescribe the brand that the MS centre has sourced via a tender.⁸⁷⁹
- (738) Figure 23 shows the evolution of volumes of all first-line DMTs and Copaxone's average prices in Czechia from 2009 to 2021.

⁸⁷⁶ ID 1151-12, 2022 GTMAP Czech Republic Copaxone, p. 9.

⁸⁷⁷ ID 1295-45, Teva's reply to Article 18(2) Requests of 22 October and 18 November 2021, p. 4. Because Synthon GA has – to date – not been launched in Czechia, Copaxone is the only drug that competes in both tender formats, molecule-basis and brand-basis.

⁸⁷⁸ The other {...}% was earned from hospitals that were not legally required to hold tenders. ID 1295-45, Teva's reply to Article 18(2) Requests of 22 October and 18 November 2021, p. 3-4.

⁸⁷⁹ ID 1295-45, Teva's reply to Article 18(2) Requests of 22 October and 18 November 2021, p. 2.

Figure 23: Volumes and Copaxone price in Czechia

{...}

Source: Volume data source: IQVIA data provided by Teva. For Copaxone in Czechia, the Commission used data provided directly by Teva from its internal accounts, as more quarters of data were available compared to IQVIA. Price data source: Teva.

Note: Prices are aggregated at the yearly level (see footnote 757).

(739) Figure 24 shows the evolution of Copaxone’s gross profit in Czechia over 2014-2021.

Figure 24: Copaxone annual gross profit in Czechia

{...}

Source: Commission calculations based on internal data from Teva (ID 1674, Teva’s reply to Article 18(2) Request of 25 April 2022). See folder “[...]output/Teva profitability” of the SO data pack.

Note: Gross profit refers to total revenues minus costs of goods sold.

(740) In what follows, the Commission examines and interprets the above graphs, in tandem with qualitative information on how the specific market functions, to identify indications of competitive constraints exercised, if at all, on Copaxone by (i) Synthon GA, (ii) oral first-line DMTs (Tecfidera and Aubagio) and (iii) interferons first-line DMTs (notably Plegridy).

6.3.3.4.3.2.1. Impact from Synthon GA

(741) Due to preliminary injunctions requested by Teva, the entry of Synthon GA in Czechia has been severely delayed.⁸⁸⁰ Zentiva, who holds the rights to market Synthon GA in Czechia, has been ready to launch Synthon GA on the Czech market under the brand name “Remurel” for a considerable amount of time. In September 2021, Zentiva obtained a pricing and reimbursement decision from the Czech authorities in preparation for the future launch of Remurel.⁸⁸¹ Zentiva was prevented from launching Synthon GA 40 mg due to a preliminary injunction obtained by Teva on 16 May 2019 (see Recital (1395)). Unable to launch the 40 mg dosage, Zentiva {...} {...} {...}.⁸⁸² Since 2023, Zentiva has sold Synthon GA 20 mg in Czechia, albeit in very low volumes.⁸⁸³ Synthon GA 40 mg did not enter in Czechia during the Relevant Period.⁸⁸⁴

(742) With only marginal competition from Remurel, Teva’s commercial strategy for Copaxone was not subject to effective and immediate competitive constraints on the Czech market. Had Remurel been able to enter the Czech market, unhindered by Teva’s preliminary injunction, as well as not only with its 20 mg dosage but also with its 40 mg dosage (a dosage to which most of Copaxone’s patients had been converted, see Recital (741) above), it would likely have been capable of constraining Teva’s commercial strategy for Copaxone in Czechia during the Relevant Period.

⁸⁸⁰ ID 1664, {...} Reply to Article 18(2) Request of 11 February 2022, p. 3; ID 2161, Teva’s Reply to Article 18(2) Request of 13 July 2022.

⁸⁸¹ ID 1664, {...} Reply to Article 18(2) Request of 11 February 2022, p. 4.

⁸⁸² ID 1664, {...} reply to Article 18(2) Request of 11 February 2022, p. 3.

⁸⁸³ ID 5737, RLoF data pack, data file “EU_MIDAS_quarterly_with_DOT_CLEAN - including 2022-Q22023.dta”.

⁸⁸⁴ ID 5673, Teva’s Reply to Article 18(2) Request of 15 February 2024, pp. 1-2.

- (743) In Czechia, doctors will usually source the prescribed DMT from their MS centre’s pharmacy and dispense it directly to their patients.⁸⁸⁵ For this reason, doctors will usually prescribe the product that the relevant MS centre (or the hospital to which the MS centre belongs) has sourced via a tender.⁸⁸⁶
- (744) In these tenders, any supplier with a product that meets the medical requirements can submit a bid and the lowest-priced bid wins.⁸⁸⁷ Tenders are mostly held on the basis of the active substance of the products, and less frequently on a brand basis. Non-GA DMTs therefore do not participate in the same tenders as Copaxone. Consequently, Teva did not face any competition in hospital tenders for the majority of the Relevant Period, until Remurel 20 mg entered in 2023, and only faces marginal competition since Remurel 20 mg’s entry since the majority of GA patients receive the 40 mg dosage.
- (745) Teva submits that its bids in tenders are constrained by the reimbursement price (and would correspond to the reimbursement price).⁸⁸⁸ Copaxone is included in a reimbursement group with the interferons. Normally, the cheapest drug in the reimbursement group sets the reimbursement price for all products in the group. In Copaxone’s case, the Czech regulator exceptionally accepted that Copaxone’s price was not to be aligned with that of the cheapest product in the reimbursement group for several years because Copaxone was, at the time, the only GA treatment available in the market (see Section 6.3.3.4.3.2.3 below).
- (746) If Remurel 40 mg had been available in the Czech market during the Relevant Period, Teva’s commercial strategy for Copaxone would have been constrained by price competition in tenders due to Remurel 40 mg competing in the same tenders as Copaxone 40 mg. Considering that the majority of Copaxone’s sales in Czechia are done through tenders, it is to be expected that competition for Copaxone in tenders would lead to similar results as in the First Group of Relevant Member States, which is either significant price decreases (as in Italy and Poland), significant volumes decreases (as in the Netherlands), or a mix of both (as in Spain).
- (747) Teva’s internal documents show that {...}. In the 2021 and 2022 Brand Plans for Copaxone in Czechia, Teva lists “{...}” and “{...}” as potential threats to Copaxone’s business.⁸⁸⁹ The 2022 Brand Plan goes into further detail, stating “{...}” and “{...}”.⁸⁹⁰ A loss of {...} patients corresponds to circa {...}% of Teva’s patient base in Czechia. In an email from January 2019, the {...} reports that Alvogen (now Zentiva) had submitted the pricing and reimbursement application for Remurel with a proposed price reduction of {...}% versus the pricing and reimbursement level of Copaxone, and concludes, “{...}”.⁸⁹¹
- (748) Czech health insurers report that due to “*obstructive behaviour of Teva*” and the absence of Remurel from the Czech market, their expenditure on GA is “*higher than it should be in other circumstances*”.⁸⁹² They estimate that “*potential competition*

⁸⁸⁵ ID 1295-45, Teva’s Reply to Article 18(2) Requests of 22 October and 18 November 2021, p. 2.

⁸⁸⁶ ID 1295-45, Teva’s Reply to Article 18(2) Requests of 22 October and 18 November 2021, p. 2.

⁸⁸⁷ ID 1295-45, Teva’s reply to Article 18(2) Requests of 22 October and 18 November 2021, p. 3.

⁸⁸⁸ ID 1295-45, Teva’s reply to Article 18(2) Requests of 22 October and 18 November 2021, p. 4.

⁸⁸⁹ ID 1151-69, 2021 GTMAP Czech republic Copaxone, p. 9; ID 1151-12, 2022 GTMAP Czech Republic Copaxone, p. 8.

⁸⁹⁰ ID 1151-12, 2022 GTMAP Czech Republic Copaxone, p. 9.

⁸⁹¹ ID 455-2921, Teva internal email dated 23 January 2019 from {...} to {...} and others, p. 5.

⁸⁹² ID 1276, VOZP’s Reply to Article 18(2) Request of 15 December 2021, p. 1-2.

*could save to health insurance companies approx. 20 % of expenditure of glatiramer acetate”.*⁸⁹³

6.3.3.4.3.2.2. Impact from orals

- (749) The oral DMTs Aubagio and Tecfidera have not been capable of constraining Teva’s commercial strategy for Copaxone. The launch of the oral DMTs as new first-line treatments does not appear to have had a significant and lasting impact on Copaxone’s volumes, prices and/or profits.
- (750) Aubagio was launched in Czechia in (late) 2014 and Tecfidera in the beginning of 2015. As Figure 23 shows, the launch of both drugs was successful, and they quickly grew their volumes in the first-line DMT segment. Copaxone’s volumes have similarly grown since 2016, despite the entry and continued growth of the oral treatments. In the data presented in Figure 23, no material diversion of demand from Copaxone to the oral DMTs can be detected.
- (751) The price of Copaxone has been unaffected by the entry of orals. Figure 23 shows that Copaxone’s prices even increased between 2014 and 2018, i.e. in the period during which the oral treatments entered the Czech market. Copaxone is not in the same price-referencing group as Aubagio and Tecfidera. As explained above, Copaxone does not compete with either Aubagio or Tecfidera in tenders in Czechia.
- (752) In any event, any observed pressure exerted by oral DMTs on Copaxone’s price or volumes, still allowed Teva to maintain Copaxone’s price far above variable costs (as well as to maintain large gross and net profits⁸⁹⁴), which suggests that any competitive pressure would have been limited. Figure 24 shows that Copaxone’s profitability increased between 2014 and 2018, i.e. during the period of the market entry and uptake of orals. This indicates that the presence and even the rapid growth of orals exercised no effective and immediate constraint on Teva’s volumes, prices or profits (neither gross nor net profits).⁸⁹⁵ This is a very different outcome compared to the evolution of gross profits in the First Group of Relevant Member States.

6.3.3.4.3.2.3. Impact from interferons

- (753) The interferons (Avonex, Betaferon, Extavia and Rebif) are established first-line DMTs in Czechia. Plegridy entered the Czech market in 2016.
- (754) The interferons have not been able to effectively constrain Copaxone’s prices and volumes in the period under review (2014-2021). Copaxone’s volumes grew steadily up until 2021 and only started declining in 2022. The strong fluctuations in the volumes of interferons, visible on Figure 23 for the years 2014-2016, do not appear to correlate in any meaningful way with Copaxone’s volume development.
- (755) The interferons have not affected Copaxone’s prices either. Teva submits that the price of the interferons has directly constrained the price of Copaxone (or vice versa) since Copaxone was launched.⁸⁹⁶ This statement, however, is neither supported by the development of Copaxone’s prices between 2014 and 2021 (as shown in Figure 24), nor by the pricing and reimbursement rules applicable to Copaxone in Czechia.

⁸⁹³ ID 1155, OZP’s Reply to Article 18(2) Request of 15 December 2021, p. 3.

⁸⁹⁴ Commission calculations based on internal data from Teva (ID 1674, Teva’s reply to Article 18(2) Request of 25 April 2022).

⁸⁹⁵ See ID 5820 for a side-by-side comparison of Copaxone gross and net profits in all Relevant Member States and the SO data pack for the underlying data and computations.

⁸⁹⁶ ID 1295-45, Teva’s reply to Article 18(2) Requests of 22 October and 18 November 2021, p. 12; ID 4032, Teva’s Reply to the Statement of Objections, para. 243.

- (756) Copaxone’s prices slowly increased between 2014 and 2016, even after the market entry of a new interferon, Plegridy. Copaxone’s prices did not exhibit any change in 2014/2015 in reaction to the significant volume losses and gains of interferons.
- (757) As described above, Copaxone is in a reimbursement group with the interferons. Between 2010 and 2018, the price of Copaxone set the reimbursement price because Copaxone’s price was the cheapest drug in the reimbursement group. During this period, Copaxone’s price may have influenced the prices of the interferons but not the other way around. Proceedings by SUKL (the Czech institute for Drug Control) to change the reference product started in 2014.⁸⁹⁷ The decision to change the reference product came into effect in 2018.⁸⁹⁸
- (758) Therefore, under normal circumstances, Teva would have had to adjust the price of Copaxone to the (lower) price of the new reference product in 2018. However, Teva successfully applied for an exemption from such a mandatory price adjustment. In response to the Commission’s Article 18(2) Request of 22 October 2021, Teva submitted the following:
- “Teva argued that the changes to the reimbursement conditions would mean access to Copaxone (the only GA available in the market) would be jeopardised for certain patients who, due to specific conditions and contraindications, could not be treated with interferons. This was for instance the case for patients who were pregnant or planning to be pregnant, since at the time interferons were contraindicated in such circumstances.*
- Teva submitted that GA treatments should have a higher (increased) amount of reimbursement for these specific patients to ensure full access”* (emphasis added).⁸⁹⁹
- (759) Teva requested the annulment of SUKL’s decision, and the decision was fully annulled by the Czech Ministry of Health and sent back to SUKL for reconsideration.⁹⁰⁰ In essence, Teva successfully argued that Copaxone was not therapeutically substitutable with any of the interferons, and that limited access to Copaxone as a result of a price decrease would be detrimental for patients. This clearly shows that Copaxone’s prices were not effectively constrained by the interferons.
- (760) Consequently, and contrary to Teva’s claims,⁹⁰¹ the exception from the price reduction did not only apply to patients with *“specific conditions and contraindications”*.
- (761) As of 2020, Betaferon set the reimbursement price as the new reference product.⁹⁰² Since then, the SUKL issued several pricing decisions concerning different packs of Copaxone (for the different dosages, as well as different pack sizes such as 1-month packs and 3-month packs),⁹⁰³ which were partly annulled by the Ministry of Health.

⁸⁹⁷ ID 1295-45, Teva’s reply to Article 18(2) Requests of 22 October and 18 November 2021, pp. 12-13.

⁸⁹⁸ ID 1295-45, Teva’s reply to Article 18(2) Requests of 22 October and 18 November 2021, pp. 12-13.

⁸⁹⁹ ID 1295-45, Teva’s reply to Article 18(2) Requests of 22 October and 18 November 2021, p. 13.

⁹⁰⁰ ID 910-33, Decision no. MZDR 21811/2018-3/CAU of 18 December 2019 by the Czech Ministry of Health, submitted as Annex Q11b CR 4-3 to Teva’s reply to the Article 18(2) Request of 3 June 2021, pp. 3, 13.

⁹⁰¹ ID 4032, Teva’s Reply to the Statement of Objections, para. 243.

⁹⁰² ID 1295-45, Teva’s reply to Article 18(2) Requests of 22 October and 18 November 2021, p. 12.

⁹⁰³ There are 1-month pack sizes of Copaxone 20 mg and Copaxone 40 mg, and Teva has launched at least two different 3-month packs of Copaxone 40 mg. While all of these products fall under the umbrella

Despite these decisions, actual reductions (through price reduction decisions by SUKL that were not annulled) of the reimbursement price of Copaxone only took effect as of October 2021 and did not affect all Copaxone sales but only selected packs.⁹⁰⁴ This is because Teva regularly launched new packs of Copaxone in Czechia to which pricing reductions did not apply immediately. While price reductions were applied to some packs of Copaxone, these reductions did not significantly affect the prices of the Copaxone packs which generated the most sales at least until 2022.⁹⁰⁵ Therefore, the price of Copaxone was not significantly impacted by the reference price of the reimbursement group until, at the earliest, January 2022. Czech Payers have referred to this practice as “*obstructive behaviour of Teva*” to keep the expenditure on Copaxone “*higher than it should be*”.⁹⁰⁶

- (762) Teva claims that due to the inclusion in the same reference group as interferons, Copaxone’s net price decreased in 2021 and 2023 for purportedly an estimated overall {...}% decrease (between 2018 and 2023). According to Teva, this is evidence of Copaxone’s price being directly constrained by interferons and vice versa during the Relevant Period.⁹⁰⁷
- (763) The Commission notes that any impact on Copaxone prices that may have arisen due to the inclusion in the same reference group as interferons, was neither as immediate nor as significant as Teva contends, and cannot, in any event, be attributed to a competitive interaction stemming from a significant threat of substitution between Copaxone and interferons since Copaxone and interferons are at most imperfect therapeutic substitutes (see Section 6.3.2.2) and as evidenced by the lack of impact on Copaxone volumes to the benefit of interferons (or vice versa) in the period under review (see Figure 23). Importantly, the Commission observes no comparable impact on Copaxone volumes or profit margins (market power) that can be attributed to a constraint exercised by interferons.
- (764) First, despite these pricing and reimbursement rules, the price of Copaxone was not immediately and significantly impacted by the prices of cheaper interferons in the reimbursement group until at least January 2022. As discussed, Teva successfully applied for exemptions to the Czech pricing and reimbursement rules (see Recital (758)), on the ground that access to GA products (i.e., Copaxone, the only GA product available in the market) should not be jeopardised for patients who cannot be treated with interferons. By 2018 Teva had successfully migrated almost the entirety of its patient base in Czechia from the 20 mg to the 40 mg dosage of Copaxone, making any pricing rules that related to the 20 mg compound outdated and ineffective. As explained above, Teva frequently launched new packs to avoid the effect of price reductions that had been applied to the existing packs.
- (765) Second, just as oral DMTs, interferons cannot compete in the same tenders as Copaxone in Czechia because tenders are held on the basis of the active substance of products. It follows that by default, during the Relevant Period, no substitutability of volumes between the two can take place, contrary to between Copaxone and Synthron GA. In any event, there is no obvious correlation between the volume trends of

term “Copaxone” and therefore automatically belong to the same reference group, the price reductions do not apply automatically but have to be issued in a separate pricing decision per product.

⁹⁰⁴ ID 4896, Teva’s reply to Article 18(2) Request of 20 July 2023 (question 3), pp. 5-6.

⁹⁰⁵ ID 4805, Teva’s reply to Article 18(2) Request of 20 July 2023 – Czechia (question 1b).

⁹⁰⁶ ID 1276, VOZP’s Reply to Article 18(2) Request of 15 December 2021, p. 1-2.

⁹⁰⁷ ID 4032, Teva’s Reply to the Statement of Objections, para. 243; ID 5695, Teva’s Reply to the Letter of Facts I of 9 February 2024, paras. 112, 114.

Copaxone and interferons during the Relevant Period that would indicate significant substitution between the two with respect to physicians' prescribing practices.

- (766) Third, despite a {...}% decrease of average Copaxone prices in Czechia (net revenues over volume in DOTs) between 2018 and 2023, the corresponding net margins remained mostly stable (decreased only by {...}%),⁹⁰⁸ suggesting that Teva's price setting (market) power with respect to Copaxone remained constant.⁹⁰⁹
- (767) In summary, despite the inclusion of Copaxone and interferons in the same pricing reference group, interferons have not exercised a meaningful competitive constraint on Copaxone of the type that would lead to the conclusion that in Czechia interferons would be included in the same relevant product market as Copaxone. This still holds true after the effective inclusion of Copaxone in the price reference group, after which interferons may have had a measurable impact on Copaxone's prices. What marginal pricing interaction may be argued to have taken place between Copaxone and interferons in Czechia is not comparable to the significant and non-transitory effect that the entry of Synthon GA had on Copaxone prices, volumes and profits in Italy, Spain, Poland and the Netherlands.

6.3.3.4.3.2.4. Conclusion: the product market in Czechia consists only of GA products

- (768) The analysis of market data suggests that Remurel is the only DMT that could have – after its launch – exercised competitive constraints on Copaxone in Czechia during the Relevant Period (see Section 6.3.2.3 concerning the exclusion of second-line DMTs from the relevant product market).
- (769) In Czechia, the vast majority of Copaxone's sales (in value and in volume) are made through hospital tenders based on the active substance of the medicines. Thus, absent the entry of Synthon GA on the Czech market, Copaxone did not face any effective competition from orals and interferon-based first-line DMTs when participating in tenders. It follows that Remurel is the only medicine capable of exercising competitive constraints on Copaxone and was likely to have exerted an effective and immediate constraint on Teva, as well as an earlier one, if it had not been for Teva's conduct.
- (770) Moreover, the analysis of the market data shows that the entry of oral first-line DMTs in Czechia has not had a material impact on Copaxone's prices, volumes or profits. Similarly, the presence of interferon-based first-line DMTs has not exercised an effective competitive pressure on Copaxone either. Overall, the fact that Remurel 20 mg only entered in 2023 and Remurel 40 mg did not enter at all during the

⁹⁰⁸ Commission calculations based on ID 5710, Teva's Reply to the Letter of Facts I of 9 February 2024, data pack, file "Annex RFI9Q7 - RFI3Q2 follow-up.xlsx". See also Table 12.

⁹⁰⁹ In ID 5909, Teva's Reply to the Letter of Facts II of 17 May 2024, para. 40, Teva argues that its ability to set prices above marginal costs is not indicative of sustained market power because both prices and costs fell due to price pressure from interferons, and one should consider absolute net profit margins (in EUR per DoT) instead. According to Teva the decrease in absolute net profits between 2018 and 2023 is evidence of price competition from interferons. The Commission notes that it does not dispute that Copaxone prices in Czechia have decreased during the Relevant Period and Teva's analysis of absolute net profits (that ignore cost shifts) capture the same effect. The Commission however notes, as discussed in this sub-section of the Decision, that this decrease is not indicative of a meaningful competitive constraint exercised by interferons that could lead to the conclusion that Copaxone and interferons together comprise a distinct relevant product market. Relatedly see also footnote 1135 for a discussion about Teva's argumentation with respect to the use of absolute net profit margins (in EUR per DoT) as opposed to net profit margins (p-c/p).

Relevant Period led to a very different outcome compared to the evolution of gross profits in the First Group of Relevant Member States.

- (771) Finally, apart from the delayed entry of Synthon GA, there are no indications that the competitive constraints on Copaxone in Czechia are fundamentally different from those in Italy, the Netherlands, Poland or Spain and therefore there is no reason to believe that, absent Teva's behaviour, the competitive constraints posed by Synthon to Copaxone would have developed at least as in the First Group of Relevant Member States as far as Copaxone's prices, volumes and profits are concerned.
- (772) The Commission therefore finds that the relevant product market in Czechia during the Relevant Period is limited to GA, and therefore only includes Copaxone and Synthon GA (Remurel).

6.3.3.4.3.3. Germany

- (773) This Section discusses how, during the Relevant Period, neither oral first-line DMTs nor interferon first-line DMTs exercised an effective and immediate constraint on Copaxone in Germany. Synthon GA (sold under the brand "Clift") was the only product capable of exercising an effective and immediate competitive constraint on Teva's commercial strategy for Copaxone in Germany even though, due to Teva's conduct, the full potential of competition between Clift and Copaxone has yet to develop.
- (774) Germany is the biggest market for Teva in the EEA.⁹¹⁰ Teva's Copaxone revenue in Germany was approximately EUR {...} in 2021, with a sales volume of {...} DOTs. The volume of all first-line DMTs in Germany was 27.95 million DOTs in 2021. This volume has grown, on average, by 1% between 2015 and 2021.
- (775) In Germany, GA is not a hospital drug. GA is prescribed by practitioners (either by INN or by brand) and dispensed by pharmacies. Regardless of whether the prescription is by INN or by brand, as of Clift's market entry, automatic substitution between Copaxone and Clift can (depending on a patient's health insurance) take place at the pharmacy level. Pharmacists are legally obliged to prioritise dispensing products which are covered by a tender concluded with the patient's health insurer.⁹¹¹ All tenders are held on the basis of the active substance.⁹¹² Before the entry of Synthon GA, pharmacists could only substitute Copaxone prescriptions with parallel imports of Copaxone from other countries where the drug is cheaper.
- (776) Tenders for MS drugs are held by health insurers and can be either exclusive or open house. In exclusive tenders, only the winning bidder becomes the qualified supplier for an active substance with a particular health insurer. In open house tenders, the tendering health insurer specifies the criteria that suppliers must meet in order to qualify, including a price and a rebate that must be matched. There is no bidding process. All suppliers that meet the specified criteria (and agree to the price and rebate) can join an open house tender and supply the drug for patients of the tendering health insurer.⁹¹³

⁹¹⁰ ID 660, Teva's reply to Article 18(2) Request of 3 June 2020, p. 30; ID 644-178, Teva's reply to Article 18(2) Request of 3 June 2020.

⁹¹¹ If the drug is not covered by a health insurer tender, the pharmacist must dispense one of the four cheapest products for that INN. See ID 1295-7, Teva's reply to Article 18(2) Requests of 22 October and 18 November 2021, p. 2.

⁹¹² ID 1295-7, Teva's reply to Article 18(2) Requests of 22 October and 18 November 2021, p. 5.

⁹¹³ ID 1295-7, Teva's reply to Article 18(2) Requests of 22 October and 18 November 2021, p. 4.

- (777) Approximately {...}% of Copaxone’s annual revenue and volume in Germany was earned from open house contracts in the Relevant Period.⁹¹⁴ Before the entry of Synthon GA on the German market, the participants in tenders were Teva and parallel importers of Copaxone.
- (778) Doctors can exclude any type of substitution by prescribing a drug by brand and ticking the box “aut-idem”⁹¹⁵ on the prescription form. The quota of aut-idem prescriptions increased from {...}% of Copaxone sales in 2016 to {...}% by 2019 (see Recital (355)). Teva submitted to the Commission in 2021 that aut-idem sales represent approximately {...}% of prescriptions on average.⁹¹⁶
- (779) Figure 25 shows the evolution of volumes of all first-line DMTs and Copaxone’s average prices in Germany from 2009 to 2021.

Figure 25: Volumes and Copaxone price in Germany

{...}

Source: Volume data source: IQVIA. Price data source: Teva.

Note: Prices are aggregated at the yearly level (see footnote 757). Copaxone’s volumes include sales of Teva’s duplicate product AbZ. Based on IQVIA data provided by Teva, AbZ was sold in Germany only from 2019 Q2 to date. Its volumes have remained negligible and have never been above {...} DOTs per quarter.

- (780) Figure 26 shows the evolution of Copaxone’s gross profit in Germany over 2014-2021.

Figure 26: Copaxone annual gross profit in Germany

{...}

Source: Commission calculations based on internal data from Teva (ID 1674, Teva’s reply to Article 18(2) Request of 25 April 2022). See folder “[...]/output/Teva profitability” of the SO data pack.

Note: Gross profit refers to total revenues minus costs of goods sold.

- (781) In what follows, the Commission examines and interprets the above graphs, in tandem with qualitative information on the manner in which the specific market functions, to identify indications of competitive constraints exercised, if at all, on Copaxone by (i) Synthon GA, (ii) oral first-line DMTs (Tecfidera and Aubagio), and (iii) from interferons first-line DMTs (notably Plegridy).

6.3.3.4.3.3.1. Impact from Synthon GA

- (782) Synthon GA entered the German market in October 2016 under the brand name “Clift”, marketed by Mylan (now Viatri). At launch, Clift was offered in a 20 mg dose. In January 2018, Clift 40 mg entered the German market.
- (783) In the following, the Commission analyses both the actual developments following the entry of Synthon GA in Germany based on observations concerning Copaxone’s

⁹¹⁴ Around {...}% were earned via contracts with private health insurance companies, less than {...}% were earned from exclusive tenders and the remaining {...}% were earned through other sales, e.g. aut-idem prescriptions. See ID 1295-7, Teva’s reply to Article 18(2) Requests of 22 October and 18 November 2021, p. 5.

⁹¹⁵ The term “aut idem” translates to “or a similar alternative” and is used to refer to a mechanism in German pharmaceutical law where the pharmacists doesn’t dispense the prescribed drug but a different drug of the same active ingredient, i.e. automatic substitution of one drug with a (cheaper) alternative. By ticking the aut-idem box on the prescription, the doctor can exclude this substitution. See ID 4955, Glossary article “Aut-idem-Regelung” by the German Federal Ministry of Health, <https://www.bundesgesundheitsministerium.de/aut-idem-regelung.html>, accessed on 9 October 2023.

⁹¹⁶ ID 1295-7, Teva’s reply to Article 18(2) Requests of 22 October and 18 November 2021, p. 3.

volumes, prices and profits, as well as the potential for further impact that Synthon GA could have had on Copaxone absent Teva's conduct.

Observations concerning Copaxone's volumes, prices and profits in Germany

- (784) An analysis of main commercial indicators of Copaxone in Germany shows that Clift is the only product capable of exercising an effective and immediate constraint.
- (785) First, the development of Copaxone volumes during the Relevant Period suggests that Clift is the only product that has been capable of effectively constraining Copaxone's volumes.
- (786) Figure 25 represents the sales volumes of Clift and Copaxone, amongst others. Copaxone's annual sales volumes have remained at a stable level between 2009 and 2021, the entire period shown in the graphs, and, unlike in Member States like Italy or the Netherlands, have not seen a significant and lasting drop in sales volumes. At the same time, the uptake of Clift to date has been very limited. After an initial period of limited sales of Clift 20 mg, the sales growth accelerated only from mid-2018 onwards with the launch of Clift 40 mg, a much more attractive product considering that most of Copaxone prescriptions at that time had been converted to the 40 mg dosage in Germany.⁹¹⁷ The volume peak for Mylan observed in Figure 25 coincides with the time when Mylan won an exclusive tender awarded by the German health insurer {...}.⁹¹⁸ This tender took effect in April 2019. Figure 25 also shows that the (limited) increase in sales by Mylan corresponds to practically a one-to-one decrease in volumes for Copaxone.
- (787) However, after the divisional patent that Teva enforced against the marketing of Clift in Germany was found valid in a first instance EPO opposition decision and a preliminary injunction against Clift 40 mg was issued by a German court in June 2019, the overall sales of Clift plummeted. Viatri (formerly Mylan) was no longer able to participate in (open house) tenders in Germany until the relevant patent was later annulled in September 2020 and the preliminary injunction against Clift 40 mg was lifted. To date, the sales volumes of Clift remain minimal which is likely due to Teva's conduct in the context of the CCP (Copaxone Continuation Project) described below (see Recitals (797) to (818)). As a result, throughout the period following the entry of Clift, the sales volume of Copaxone has remained rather stable.
- (788) Second, although it appears that Clift has not had a meaningful impact on Copaxone's volumes in the period under review in Figure 25, its (marginal) entry was followed by a significant impact on Copaxone's prices. As Figure 25 shows, prices of Copaxone were stable until the conversion of patients to Copaxone 40 mg, which implied a decrease of price per day of treatment of around {...}% due to a decreased daily dosage.⁹¹⁹
- (789) Copaxone was then subject to an additional price decrease of around 10% which was triggered by the launch of Clift. Following the entry of Clift on the German market, the prices of Copaxone 20 mg and Copaxone 40 mg were subject to a mandatory 10% rebate because Clift is a therapeutically equivalent drug.⁹²⁰ Teva initially

⁹¹⁷ ID 2763, {...} Reply to Article 18(2) Request of 11 February 2022, p. 15.

⁹¹⁸ ID {...}.

⁹¹⁹ ID 264-82, Clift 40mg (Mylan) DE market exit, July 2019, p. 15.

⁹²⁰ Teva initially decided to implement a 10% price decrease instead of applying the 10% rebate. See ID 1295-7, Teva's reply to Article 18(2) Requests of 22 October and 18 November 2021, p. 8.

contested the rebate⁹²¹ but reached an agreement with the German authorities for a 10% price decrease of Copaxone's list price, which was applied from July 2018 on. The rebate could be applied retroactively as well, from as early as October 2016 (when Clift was launched in Germany). {...}.⁹²²

- (790) Moreover, Copaxone 40 mg competed with Clift 40 mg in health insurer tenders. Teva estimates that the competition with Clift in open house tenders led to an additional net price decrease of Copaxone of approximately {...}%. Overall, the entry of Clift therefore led to a {...}% price decrease for Copaxone whenever it is sold through open house tenders (c. {...}% of Copaxone's sales in Germany).⁹²³
- (791) Figure 25 shows the cumulative effect of the price decrease and the rebates to health insurers as a significant decrease of Copaxone's average prices in January 2018. The entry of Clift 20 mg does not appear to have had a similar effect because Teva had switched the majority of Copaxone patients from the 20 mg dosage to 40 mg before Clift 20 mg entered the German market.⁹²⁴
- (792) The market exit of Clift 40 mg due to the preliminary injunction issued in June 2019 does not appear to have had an impact on Copaxone's prices. The 10% mandatory rebate caused by the launch of Clift as a therapeutically equivalent drug remained in place because Teva had launched its own therapeutically equivalent GA duplicate shortly before the preliminary injunction was issued (see Recital (807) below).⁹²⁵ Further, the open house contracts which Teva entered for Copaxone while Clift 40 mg was on the German market were still in place and, for the majority of these contracts, the market exit of Clift did not influence the conditions of the contract, i.e. Teva could not lower the rebate it had agreed to when entering the contract.⁹²⁶
- (793) However, as explained further below in Recital (802) and following, Teva benefitted from the preliminary injunction since it had the effect of avoiding further price erosion for Copaxone in Germany at a key point in time, i.e. when the sales of Clift 40 mg started to gain significant momentum, and of maintaining doubts as to the security of supply of Clift, even after the preliminary injunction was lifted.
- (794) Third, the price decrease following Clift's entry also significantly impacted Teva's Copaxone gross profits. A similar impact can be observed in Copaxone's net profits.⁹²⁷
- (795) Figure 26 shows the impact that even the limited uptake of Clift appears to have had on Copaxone's profits in Germany. Copaxone's annual gross profits in Germany grew from 2015 onwards and peaked around 2017 at a level of EUR {...}. They then decreased by around {...}% in the course of 2018, mainly driven by the price decreases associated with the launch of Clift. While the decrease was temporarily halted in 2019 with Teva's injunction against Clift 40 mg, since the re-entry of Clift, Teva's overall annual gross profits in Germany decreased to a level of around EUR {...} in 2021 (approximately EUR {...} less than in 2017).

⁹²¹ ID 455-464, Teva internal email of 15 June 2018 from {...} to {...} and others.

⁹²² See ID 2483, email correspondence between DG COMP and GKV-SV, 20 September 2022. See also ID 263-2710, GKV price reduction, 24 March 2017.

⁹²³ ID 1295-7, Teva's reply to Article 18(2) Requests of 22 October and 18 November 2021, pp. 5-6.

⁹²⁴ ID 2763, {...} Reply to Article 18(2) Request of 11 February 2022, p. 15.

⁹²⁵ ID 264-82, Clift 40mg (Mylan) DE market exit, July 2019, p. 20.

⁹²⁶ ID 264-82, Clift 40mg (Mylan) DE market exit, July 2019, pp. 12-13.

⁹²⁷ See ID 5820 for a side-by-side comparison of Copaxone gross and net profits in all Relevant Member States and the SO data pack for the underlying data and computations.

(796) It follows from analysing the development of Copaxone's volumes, prices and profits in the Relevant Period that even if Clift could not exert its competitive constraint to the fullest due to Teva's conduct, it nonetheless appears to have caused a significant decrease in Copaxone's prices and profits.

The observable impact following Synthon GA's entry would have likely been stronger in the absence of Teva's actions

(797) Teva's conduct in the context of the CCP focused on hindering generic-like competition from Synthon GA and was not geared towards defending Copaxone from alleged non-GA competitors. The Commission finds that the observable impact on Copaxone following Clift's entry would have likely been stronger in the absence of Teva's conduct in Germany as (i) the impact following Clift's entry has been lower than what is normally observed after generic or generic-like entry in Germany, (ii) Teva's actions explicitly aimed at limiting competitive pressure from Clift; and (iii) evidence suggests that absent Teva's practices, competition from Clift was expected to significantly impact Copaxone.

(798) First, the impact following Synthon GA's entry has been lower than what can normally be observed after generic or generic-like entry in Germany. The Commission understands that, in Germany, the (unhindered and effective) entry of generic or generic-like competition usually leads to significant price decreases of – on average – more than 35% compared to the initial price of the originator drug.⁹²⁸

(799) Second, the impact following Synthon GA's entry is also lower than those observed in the First Group of Relevant Member States despite Teva's CCP activities (for example Italy and the Netherlands where, amongst other factors, Synthon GA was not subject to a preliminary injunction). In Italy, following Synthon GA's entry Copaxone prices decreased by approximately {...}%, volumes by {...}%, and gross profits by {...}%. In the Netherlands, the entry of Synthon GA did not significantly affect Copaxone's prices but was followed by a {...}% decrease in volumes and an {...}% decrease in gross profits. Considering the similarities in the regulatory systems in Germany, Italy and the Netherlands (medicines of the same active substance compete in tenders), there is no reason to believe that the situation in Germany absent Teva's CCP activities would have been significantly different than in Italy or the Netherlands.

(800) Third, Teva's CCP involved comprehensive activities to defend Copaxone and limit the uptake of Synthon GA in Germany.

(801) In the context of the CCP, Teva deployed several mechanisms to confront Clift's effective entry in Germany, including, (i) the switch of patients to the Copaxone 40 mg dosage, which Teva sought to protect with a secondary patent and several divisional patents, (ii) the launch of a duplicate drug for Copaxone to shield the brand Copaxone from the effects of price competition, and (iii) the launch of a single-dosage device (SDD, also referred to as single-dose injection pen) to avoid substitution. Teva also engaged in other conduct, discussed in Chapters 8 and 9 below, namely (iv) enforcing divisional patents which were shielded from timely and effective legal review, and (v) the campaign to disparage Synthon GA in the eyes of various health bodies and health care professionals. These actions aimed to limit competition from Synthon GA in different yet complementary ways, notably by:

⁹²⁸ ID 1281, AOK Bundesverband's Reply to Article 18(2) Request of 15 December 2021, p. 4.

- Outright exclusion of Synthron GA from the market, notably by preliminary injunctions based on divisional patents;
 - Deterring German health insurers from organising exclusive tenders that would have introduced head-to-head price competition between Copaxone and Clift;
 - Mitigating price competition in tenders with the launch of Copaxone’s own generic product (duplicate);
 - Limiting substitution between Copaxone and Clift, for example by convincing doctors to prevent substitution from Copaxone to Clift in individual patients (aut-idem campaign), or the launch of the SDD.
- (802) In the first place, Teva sought to exclude Clift from the German market by requesting preliminary injunctions based on its divisional patents. In fact, Teva did obtain a preliminary injunction that barred Clift 40 mg from the German market from June 2019 until September 2020, at a crucial time when the sales of Clift started gaining momentum (see Figure 25) and when Mylan won some exclusive tenders in direct price bidding against Teva. Throughout the injunction period, competition from Clift was virtually non-existent, as the vast majority of prescriptions were for the 40 mg GA which Mylan could not sell. Once the injunction was lifted (because the EPO revoked the underlying divisional patent), the sales of Clift 40 mg had to start from zero.
- (803) In the second place, the injunction and Teva’s disparagement of Synthron GA (see Chapter 9) deterred German insurers from organising exclusive tenders based on price bidding from Copaxone and Clift. Instead, they opted for open house contracts which avoid head-to-head competition between the two therapeutically equivalent products.
- (804) Teva had an interest in convincing health insurance funds to organise open house tenders instead of exclusive tenders because prices in open house tenders are significantly higher than in exclusive tenders.⁹²⁹ For example, Teva considered that {...}.⁹³⁰ Also, under an open house contract, the risk of Copaxone losing volumes because of substitution with Clift was lower because all products covered by an open house contract cost the insurer the same price and the pharmacist can therefore dispense either drug to a patient. Considering that both would be reimbursed, there was little incentive for doctors or pharmacists to switch patients from Copaxone to Synthron GA.
- (805) Teva’s strategic use of divisional patents created uncertainty for Synthron, its licensees, and other market participants, in particular health insurers, about the continued availability of Clift on the German market. Teva used this uncertainty to delay exclusive tenders that it expected Clift to participate in (“{...}”)⁹³¹ or deter insurers from organising exclusive tenders altogether. It appears that most health insurers opted out of exclusive tenders and issued open house tenders only, despite

⁹²⁹ ID 262-1695, Price competition workshop – Copaxone & Lonquex, 20-21 June 2017, p. 104.

⁹³⁰ ID 404-86, Teva internal email dated 22 August 2018 from {...} to {...}.

⁹³¹ ID 404-727, Teva internal email dated 19 April 2017 from {...} to {themselves}, p. 2; See also ID 455-460, Teva internal email dated 18 April 2017 from {...} to {...} and others, p. 1: “{...}”.

the fact that in exclusive tenders, health insurers can usually negotiate higher rebates than in open house tenders.⁹³²

- (806) While a few health insurers awarded exclusive tenders to Clift in 2019⁹³³, they faced supply problems after Teva obtained a preliminary injunction against Mylan in June 2019 and Mylan was unable to market Clift 40 mg in Germany. The association of statutory health insurers in Germany, GKV-SV, reports that health insurers considered uncertainty about whether Copaxone was still patent protected (despite expiry of the main patent EP ‘888) as a hindrance to awarding exclusive tenders or open-house contracts to Clift.⁹³⁴ {...} the preliminary injunction still had a negative impact on Clift’s sales even after it was lifted because of uncertainties regarding the availability of Clift 40 mg in the future.⁹³⁵
- (807) In the third place, Teva further mitigated the impact from tenders by launching its own generic of Copaxone (a so-called duplicate). This allowed Teva to enter in price competition in certain important tenders with the duplicate drug only (under the brand name “AbZ”), without compromising the price levels of Copaxone: “{...}”.⁹³⁶
- (808) This was seen as an opportunity to “{...}”.⁹³⁷ However, this instrument was subsidiary to Teva’s attempts to promote open house contracts. The {...} explained in an email from 2017 that the “{...}”.⁹³⁸
- (809) In the fourth place, also as part of the CCP, Teva tried to further limit substitution between Copaxone and Clift, notably by influencing health care professionals (e.g. via the aut-idem campaign) or by switching Copaxone patients to SDD, an injection device for Copaxone, which would de facto disable automatic substitution.
- (810) As described below in Chapter 9, Teva carried out a campaign to discourage doctors and pharmacists from switching Copaxone patients to Clift. For example, Teva advised doctors to use the aut-idem box on prescriptions, which would prevent pharmacists from automatically substituting Copaxone with the cheaper Clift.
- (811) Moreover, Teva also sought to limit switching to Clift by switching patients to a new injection device, SDD, for Copaxone. The rationale behind the launch of the SDD was to further differentiate Copaxone from Clift, to circumvent substitution rules and competition by Clift in tenders (non-substitutable products, such as a pre-filled injection syringe and an injection device, cannot compete in the same tenders), and was not driven by patient benefits “{...}”.⁹³⁹ Teva’s sales representatives in Germany made sure to inform doctors that the SDD cannot be substituted for Synthon GA⁹⁴⁰ and that therefore “{...}”.⁹⁴¹

⁹³² See ID 2203, Barmer’s Reply to Article 18(2) Request of 15 December 2021, p. 2; ID 1143, IKK’s Reply to Article 18(2) Request of 15 December 2021, p. 4; ID 264-991, GA 2nd brand CNS – Germany, 2 May 2017, p. 8.

⁹³³ Those were {...}, which at the time represented c. 16% of the GA market (see ID 264-857, Rabattvertragsupdate Glatirameracetat, 1 April 2019, p. 6 and {...}).

⁹³⁴ ID 1258, GKV-Spitzenverband’s reply to Article 18(2) Request of 15 December 2021, p. 3.

⁹³⁵ ID 2763, {...} Reply to Article 18(2) Request of 11 February 2022, p. 16.

⁹³⁶ ID 404-86, Teva internal email dated 22 August 2018 from {...} to {...}, p. 1.

⁹³⁷ ID 404-385, Teva internal email dated 12 September 2017 from {...} to {...} and others, p. 1; see also ID 455-2081, Teva internal email dated 23 August 2018 from {...} to {...} and others.

⁹³⁸ ID 455-460, Teva internal email dated 18 April 2017 from {...} to {...}, p. 1.

⁹³⁹ ID 263-2936, GCC Update and Recommendation: COPAXONE Single Dose Disposable (SDD), 6 March 2017, p. 2.

⁹⁴⁰ ID 4729-138, Teva internal email dated {...} to {...} and others; ID 4733-14, “Wochenbericht”.

- (812) While Teva claims that the launch of the SDD was investment in non-price competition with non-GA DMTs by improving the treatment experience for patients,⁹⁴² evidence from internal documents clearly shows that Teva’s rationale for the launch of the SDD in Germany was not to increase patient benefit but to avoid substitution between Copaxone and Synthon GA. {...}.⁹⁴³ An internal document prepared to update and make recommendations to the Global Commercial Committee (GCC) of Teva, notes that {...}.⁹⁴⁴ {...}.⁹⁴⁵
- (813) Teva carried out these varied tactics, from patent enforcement to launch of differentiated products, to defend against Synthon GA. Such tactics were not used with respect to non-GA first-line DMTs, highlighting how important and central the activities to confront generic-like competition were for Teva.
- (814) Fourth, while it is difficult to estimate the developments that would have occurred absent the preliminary injunction and the uncertainty around the availability of Clift, it is likely that prices and/or volumes for GA would have further decreased significantly, following the pattern observed in Italy and the Netherlands.
- (815) Importantly, this is confirmed by Teva’s own assessment. Teva’s German team was aware of the fact that the entry of a generic-like alternative would exert significant price pressure on Copaxone. In a risk assessment analysis from 2015, the risk “Competition Copaxone” was described as follows: “{...}”.⁹⁴⁶ {...}.⁹⁴⁷
- (816) Similarly, the federal association of all regional AOK health insurers (AOK Bundesverband) submits that the entry of generic competition usually leads to price decreases of – on average – more than 35% compared to the initial price of the originator drug.⁹⁴⁸
- (817) Teva considered that the organisation of exclusive tenders would require a price cut of {...}% to win the tender⁹⁴⁹, and associated (exclusive) tenders with a negative impact on profits: “{...}”.⁹⁵⁰ This said, the organisation of such tenders was stopped in its tracks with the injunction that was granted to Teva in June 2019 and has not (fully) resumed after the injunction was lifted in September 2020.
- (818) Based on the above, the Commission finds that the constraints Synthon GA/Clift imposed on Copaxone’s volumes, prices and profits would have likely been stronger in the absence of Teva’s conduct.

⁹⁴¹ ID 4733-66, Teva internal email dated 18 April 2022 from {...} to {...} (unofficial translation). Original text: “{...}”

⁹⁴² ID 4032, Teva’s Reply to the Statement of Objections, para. 213.

⁹⁴³ ID 455-3114, Copaxone EU AOP2018, p. 5. See also ID 404-537, Teva internal email exchange dated 15 June 2018 between {...} and {...}; ID 263-1564, GTMAP EU Copaxone 2018, p. 7 (see Recital (530)).

⁹⁴⁴ ID 263-2936, GCC Update and Recommendation: COPAXONE Single Dose Disposable (SDD), 6 March 2017, p. 1.

⁹⁴⁵ ID 263-2936, GCC Update and Recommendation: COPAXONE Single Dose Disposable (SDD), 6 March 2017, p. 2.

⁹⁴⁶ ID 455-2521, Risk Management Germany Commercial, 15 September 2015, p. 6; see also ID 404-487, Input CPX Price.

⁹⁴⁷ ID 455-2521, Risk Management Germany Commercial, 15 September 2015, pp. 4, 6.

⁹⁴⁸ ID 1281, AOK Bundesverband’s Reply to Article 18(2) Request of 15 December 2021, p. 4.

⁹⁴⁹ ID 404-86, Teva internal email dated 22 August 2018 from {...} to {...}.

⁹⁵⁰ ID 455-2081, Teva internal email dated 22 August 2018 from {...} to {...} and others, p. 2; see also 404-1859, Teva internal email dated 24 January 2018 from {...} to {...} and {...}.

6.3.3.4.3.3.2. Impact from orals

- (819) The oral DMTs Aubagio and Tecfidera has not been capable of constraining Teva's commercial strategy for Copaxone. The launch of the oral DMTs as new first-line treatments has not had a lasting impact on Copaxone's volumes, prices and/or profits.
- (820) Aubagio was launched in Germany in 2013 and Tecfidera in 2014. As is visible from Figure 25, the launch of both drugs was successful and they quickly grew their volumes in the first-line DMT segment. However, Copaxone's volumes have continued to grow since 2016, despite the entry and uptake of these oral treatments.
- (821) The entry of oral DMTs did not have a lasting effect on the volumes of Copaxone in Germany. Figure 25 shows that the volumes of Copaxone only had a small and temporary dip in sales after the entry of oral DMTs. However, Copaxone's volumes quickly recovered, especially after Teva launched Copaxone 40 mg in 2015, continuing the earlier growth trend.
- (822) The volume gains of the oral DMTs can be attributed to a steady volume loss from the interferons and also to overall growth of the market size for first-line DMT segment.
- (823) Figure 25 shows that following the entry of the oral DMTs no observable effect on Copaxone's prices can be detected (which even show a small price increase in 2014) either. The small price decreases for Copaxone in 2015 and 2016 are likely connected to the introduction of Copaxone 40 mg at a lower price per pack than Copaxone 20 mg. Teva was not able to charge the same price for, e.g., a one month pack of Copaxone 40 mg as for a one month pack of Copaxone 20 mg because the former dosage implies fewer milligrams of the active substance, GA, per week of treatment ($120 \text{ mg} = 40 \text{ mg} \times 3 \text{ times/week}$, compared to $140 \text{ mg} = 20 \text{ mg} \times 7 \text{ times/week}$).⁹⁵¹ German rules do not permit manufacturers to charge a higher price per milligram when launching a new dosing regimen.⁹⁵²
- (824) Teva claims to have implemented a {...}% price reduction in July 2018 in reaction to competition from oral DMTs and that oral DMTs therefore had direct impact on Copaxone's list price in Germany.⁹⁵³ However, this claim is inconsistent with Teva's own statements in its reply to the Article 18(2) Requests of 22 October 2021 and 18 November 2021 that the price decrease of {...}% was implemented to avoid a mandatory price decrease due to the launch of Synthron GA/Clift (see also Recital (491)).⁹⁵⁴ Internal documents confirm that the reason for the price decrease in Germany was linked to the launch of Synthron GA and not the price decrease for Tecfidera and Aubagio.⁹⁵⁵

⁹⁵¹ A monthly (28 day) pack of Copaxone 20 mg includes 560 mg of GA. As Copaxone 40 mg is only administered three times weekly, a monthly (28 day) pack includes only 480 mg of GA.

⁹⁵² ID 1295-7, Teva's reply to Article 18(2) Requests of 22 October and 18 November 2021, p. 11.

⁹⁵³ ID 4032, Teva's Reply to the Statement of Objections, para. 244; see also ID 906, Teva's reply to the Article 18(2) Request of 3 June 2021, p. 20, and ID 1295-7, Teva's reply to the Article 18(2) Requests of 22 October 2021 and 18 November 2021, p. 9.

⁹⁵⁴ ID 1295-7, Teva's Reply to Article 18(2) Requests of 22 October 2021 and 18 November 2021, p. 8, see Recital (789) Notably, the Commission informed Teva of its view of the facts in the Statement of Objections. In its Reply to the Statement of Objections, Teva claims that the Commission misunderstood or even disregarded the facts but it does not attempt to explain or reconcile its own contradicting statements.

⁹⁵⁵ Internal documents suggest that Teva implemented the voluntary price decrease to avoid that the relevant German authority (GKV-Spitzenverband), would issue a decision that Synthron GA is to be

- (825) Copaxone’s price stability is all the more remarkable considering the very significant price reduction incurred by the newly launched orals. While between 2014 and 2020, the treatment costs for Tecfidera more than halved and the treatment cost of Aubagio was reduced by nearly 40%, Copaxone’s prices remained largely stable⁹⁵⁶ and were reduced by around {...}% only once Clift was launched. This is demonstrated in Figure 27 which presents the evolution of net costs of Copaxone, Clift and the oral first-line treatments Aubagio and Tecfidera in Germany from 2014 to 2020.

Figure 27: Net cost per defined daily dose in Germany

{...}

Source: Scientific Institute of the AOK (WIdO), available at <https://arzneimittel.wido.de/PharMaAnalyst/?0>, see also excel document with WIdO price data provided by the German Ministry of Health (ID 1145).

Note: Net costs refer to gross sales (the cost of a drug in relation to the pharmacy sales price) minus statutory manufacturer and pharmacy discounts before deducting the effects of confidential discount agreements.

- (826) Likewise, Figure 26 shows that the profitability of Copaxone remained largely unaffected by the entry of the oral DMTs. Instead, it was only the entry of Clift 40 mg in 2018 that was followed by a noticeable decrease of Copaxone’s profitability.
- (827) This confirms that, contrary to Synthon GA, none of the oral DMTs have exercised an effective and immediate constraint on Teva and its pricing of Copaxone, for example through price competition in tenders. In particular, oral first-line DMTs have not been able to exercise meaningful price competition on Copaxone because they are not able to compete in the same tenders.⁹⁵⁷ To confirm this conclusion, the Commission asked German health insurers whether the entry of Synthon GA allowed them to reduce their GA-related expenditure, and if it would be possible to achieve comparable savings without Clift (or any competing GA) on the market. Several health insurers replied that comparable savings are not possible with drugs that are not substitutable with Copaxone and that direct competition can only be exercised by generic drugs and not by drugs of different active substances.⁹⁵⁸
- (828) Internal documents show that the focus of Teva’s competitive efforts in Germany was on Clift and not on oral DMTs. {...}⁹⁵⁹ {...}.⁹⁶⁰

treated as a generic version of Copaxone, see ID 404-1631, Teva internal email exchange dated 29-30 May 2018 between {...} and others; ID 404-93, Copaxone® EU Litigation Internal Update, 31 August 2018, pp. 1-2.

⁹⁵⁶ The drastic price reductions for Tecfidera and Aubagio in 2015 were mandatory because both drugs are price referenced against the price of GA drugs. They first had to adapt their price to that of Copaxone, and later to the price of Clift. This price referencing system does not apply to Copaxone because it was introduced in the German market before 2011, and the price referencing system was introduced only in 2011. See also ID 1847, Minutes of call between the Commission, the German Ministry of Health and GKV-Spitzenverband, p. 3.

⁹⁵⁷ ID 1309, Techniker Krankenkasse’s Reply to Article 18(2) Request of 15 December 2021, p. 2; ID 1178, DAK’s Reply to Article 18(2) Request of 15 December 2021, p. 1; ID 1261, AOK Bayern’s Reply to Article 18(2) Request of 15 December 2021, p. 4.

⁹⁵⁸ ID 1178, DAK’s Reply to Article 18(2) Request of 15 December 2021, p. 2, ID 2203, Barmer’s Reply to Article 18(2) Request of 15 December 2021, p. 2; ID 1270 Knappschaft’s Reply to Article 18(2) Request of 15 December 2021, p. 2; ID 1364, AOK Baden-Württemberg’s Reply to Article 18(2) Request of 15 December 2021, p. 7; ID 1555, AOK Hessen’s Reply to Article 18(2) Request of 15 December 2021, p. 4; ID 1243, AOK Niedersachsen’s Reply to Article 18(2) Request of 15 December 2021, p. 6; ID 1312, AOK Plus’s Reply to Article 18(2) Request of 15 December 2021, p. 6.

⁹⁵⁹ ID 264-726, Fragen Jahresendtagung 2017 (unofficial translation). Original text: „{...}“.

⁹⁶⁰ ID 264-726, Fragen Jahresendtagung 2017 (unofficial translation). Original text: „{...}“.

(829) In any event, any observed pressure exerted by oral DMTs on Copaxone's price or volumes, still allowed Teva to maintain Copaxone's price far above variable costs (as well as to maintain large gross and net profits⁹⁶¹), which supports the view that any such competitive pressure would have been limited.

6.3.3.4.3.3.3. Impact from interferons

(830) The interferon-based first-line DMTs Avonex, Betaferon, Extavia and Rebif have been available in Germany since before 2010. The only new entrant among the interferon-based first-line DMTS was Plegridy in 2014.

(831) Interferons have not been able to constrain Copaxone's prices, volumes or profits in the period under review (2013-2021). As is visible from Figure 25, Copaxone's prices only decreased after the entry of Copaxone 40 mg and Clift, and Copaxone's volumes were not impacted by the presence of interferons in the first-line DMT segment.

(832) Similarly to oral DMTs, interferons cannot compete in the same tenders as Copaxone and Clift in Germany because they are based on different active substances.

6.3.3.4.3.3.4. Conclusion: the product market in Germany consists only of GA products

(833) Clift is the only DMT that was capable of exercising an effective competitive constraint on Copaxone in Germany during the Relevant Period (see Section 6.3.2.3 concerning the exclusion of second-line DMTs from the relevant product market). The availability of Clift as a generic-like version of Copaxone in Germany has exposed Copaxone to some price competition, and would have likely been capable – absent Teva's conduct described in Chapter 8 and Chapter 9 – of exposing Copaxone to further significant price competition as was the case, for example, in Italy or the Netherlands. There are no indications that, apart from the delayed entry of Synthon GA, the competitive landscape for Copaxone in Germany is fundamentally different from those in Italy, the Netherlands, Poland and Spain and therefore there is no reason to believe that, absent Teva's behaviour, the competitive constraints posed by Synthon to Copaxone would not have developed like in the First Group of Relevant Member States as far as Copaxone's prices, volumes and profits are concerned.

(834) The entry of Clift was followed by a significant reduction in prices, and – absent Teva's conduct – would likely have been followed by an even stronger price erosion or a decrease in volumes. Teva's conduct aimed at both excluding Clift from the market altogether, as well as preventing exclusive tenders from large health insurers, and curbing automatic substitution between Copaxone and Clift.

(835) The entry of oral first-line DMTs in Germany has not had any impact on Copaxone's prices and only some limited and transitory impact on Copaxone's volumes, which recovered quickly and have remained stable since. Similarly, the presence of interferons first-line DMTs has not exercised any discernible pressure on Copaxone.

(836) The Commission therefore finds that the relevant product market in Germany during the Relevant Period is limited to GA, and therefore only includes Copaxone and Synthon GA (Clift).

⁹⁶¹ Commission calculations based on internal data from Teva (ID 1674, Teva's reply to Article 18(2) Request of 25 April 2022).

6.3.3.5. Conclusion: Synthon GA is the only first-line DMT that is capable of effectively and immediately constraining Copaxone

- (837) As a result of the second step in the analysis of the relevant product market for Copaxone, the Commission concludes that, following the change in conditions in competition, during the Relevant Period, Synthon GA is the only first-line DMT that is capable of effectively and immediately constraining Copaxone.
- (838) Synthon GA is therefore in the same relevant product market as Copaxone. Not only are Synthon GA and Copaxone therapeutically substitutable terms, and even therapeutically equivalent, as concluded in the first step to the analysis, but Synthon GA was also apt to exert sufficient competitive pressure on Copaxone to effectively and immediately constrain Teva's pricing, volumes and profits in relation to Copaxone. Moreover, it was the only product capable of contesting the entire patient base for Copaxone.
- (839) Conversely, the second step of the analysis has shown that non-GA first-line DMTs have not been, during the Relevant Period, an effective and immediate competitive constraint on Copaxone. With the (approaching) loss of exclusivity for Copaxone, the national markets for Copaxone became driven by price competition with Synthon GA that was stimulated by a wide array of regulatory measures, such as statutory price decreases, automatic substitution rules and tenders. With this change in the dynamics of the markets, non-GA first-line DMTs, did not exert any effective and immediate competitive constraint on Copaxone's volumes, prices or profits. Those non-GA first line DMTs cannot, therefore, be considered to be in the same relevant product market with Copaxone.
- (840) The country-specific assessment of Copaxone market data shows that non-GA first-line DMTs have not been an effective and immediate competitive constraint for Copaxone. This became evident from analysing the constraints posed by Synthon GA in the First Group of Relevant Member States, in which entry of Synthon GA led to the generic-like erosion of Copaxone's prices, volumes and/or profits. In contrast, the otherwise successful entry of oral first-line DMTs in the Relevant Member States had no significant impact on Copaxone's prices, volumes and profitability. Similarly, the presence of interferon-based DMTs has not exercised any discernible pressure on Copaxone. In the Second Group of Relevant Member States (Belgium, Czechia, Germany), Synthon GA has not exercised effective and immediate constraints on Copaxone, as it had no significant impact on Copaxone's prices, volumes and profits. However, since all Relevant Member States have similar structures of demand, and in light of the significant and effective constraint Synthon was able to exert on Copaxone in the First Group of Member States, it can be concluded that Synthon was also able to exercise such a constraint on the Second Group of Member States, had it not been prevented by Teva's conduct to enter sooner or to effectively compete.
- (841) Moreover, Teva's reporting, actions and plans show that Teva itself perceived generic-like competition as the real competitive threat for Copaxone and that non-price competition from non-GA first-line DMTs was not an effective and immediate competitive constraint for Copaxone during the Relevant Period. An analysis of Teva's management meetings shows that concerns over Synthon GA dwarfed constraints from other (non-GA) first-line DMTs. Teva also closely monitored price developments for Synthon GA in European markets and prepared price competition workshops for local Copaxone teams. Further, Teva implemented comprehensive commercial strategies, e.g. from the Copaxone Continuation Project, to avoid or

mitigate the impact of generic-like entry, whereas no comparable strategy was developed to prepare for the entry of non-GA first-line DMTs.

- (842) Thus, during the Relevant Period, Synthron GA is the only first-line DMT that effectively and immediately constrained (or had the capability to effectively and immediately constrain) Copaxone whereas other non-GA first-line DMTs, could not.
- (843) Teva claims that the entry of Synthron GA did not lead to a shift in market dynamics that would justify finding a market for GA only.
- (844) Teva claims that the entry of Synthron GA did not introduce any significant changes to the relevant market in which Copaxone is active, and, more specifically, that Synthron GA's entry did not lead to a narrowing of the relevant market for Copaxone to a market that comprises only the molecule (i.e., GA). According to Teva, the Commission's evidence can only support the finding that Synthron GA is a closer price competitor to Copaxone than non-GA first-line DMTs have been.⁹⁶²
- (845) In support of its claim, Teva argues, first, that product markets often include rivals of varying strength. Therefore, even if one were to accept that Synthron GA is a closer, or even the closest, (price) competitor to Copaxone, that does not necessarily mean that non-GA first-line DMTs do not also compete with Copaxone in the same market.⁹⁶³
- (846) Second, Teva argues that the Commission's analysis overstates the competitive constraints that Synthron GA exercises on Copaxone by (i) unduly focusing only on price competition; (ii) omitting to acknowledge that Synthron GA, similarly to non-GA first-line DMTs, is unable to compete for the entirety of Copaxone demand; and (iii) failing to identify the specific situation in Belgium, where no automatic substitution or tender processes take place.⁹⁶⁴
- (847) The Commission rejects Teva's claim for the reasons set out below.

6.3.3.5.1. Teva's argument on closeness of competition

- (848) Teva argues that the Commission's analysis can only show that Synthron GA is a closer competitor to Copaxone than non-GA first-line DMTs. According to Teva, Synthron GA "*being Copaxone's closest rival does not in any way suggest that other first-line DMTs do not still exert a material constraint on, or are not competing in the same market as, Copaxone*".⁹⁶⁵
- (849) On this point, Teva first reiterates the claim that the analysis of the Commission unduly focuses on price competition alone, which has already been addressed above (see Section 6.3.3.2.4.1). Teva then makes two further claims, first, that the mere fact that one competitor might, hypothetically, exert a stronger competitive constraint than another, in no way implies that the former is in the relevant market and the latter is not, and second, that this is especially so where certain rivals focus on different parameters of competition, in a market such as for first-line DMTs where competition takes place not only across price but also on a variety of non-price parameters.⁹⁶⁶ Teva contends that the Merger Guidelines and Commission merger

⁹⁶² ID 4032, Teva's Reply to the Statement of Objections, para. 304.

⁹⁶³ ID 4032, Teva's Reply to the Statement of Objections, para. 306.

⁹⁶⁴ ID 4032, Teva's Reply to the Statement of Objections, para. 310.

⁹⁶⁵ ID 5695, Teva's Reply to the Letter of Facts I of 9 February 2024, para. 49.

⁹⁶⁶ ID 4032, Teva's Reply to the Statement of Objections, para. 307.

decisions (such as *Mylan/Meda*, *Ryanair/Aer Lingus III*⁹⁶⁷ and *Siemens/Alstom*⁹⁶⁸) support its claims.⁹⁶⁹

- (850) These claims are not convincing. The Commission notes, first, that Synthon GA is a medicine with the same active ingredient as Copaxone, while the non-GA first-line DMTs have different active ingredients. Synthon GA is therefore not just “closer” to Copaxone, it is the only medicine in the first-line DMTs segment that is fully interchangeable with Copaxone from a therapeutic point of view (as shown in the first step of the Commission’s analysis, see Recital (313)). Synthon GA is also the only medicine that is economically substitutable with Copaxone and therefore capable of effectively and immediately constraining it (as shown in the second step of the Commission’s analysis, see Recital (842)). This entails a fundamental change in the nature of competition that Copaxone faces, commonly referred to as the “commoditisation” of a market following generic entry, and not simply the addition to the same market of a closer but still differentiated competitor. The non-GA DMTs, which include very successful blockbuster medicines Tecfidera and Aubagio, did not exercise even remotely similar constraints on Copaxone as the constraint exercised by Synthon GA.
- (851) Second, Teva’s claims are not supported by the Commission’s Merger Guidelines or by standard practice in merger decisions. While the Horizontal Merger Guidelines state that markets may contain rivals of varying strength,⁹⁷⁰ also more remote competitors – in this case non-GA first-line DMTs – would still need to sufficiently constrain the product in question to constitute an effective and immediate constraint.⁹⁷¹ As explained above in Recitals (218) and (424), the Commission already concluded in *Teva/Allergan* that Copaxone did not face any competition before the entry of Synthon GA. Similarly, the Commission concluded in *Takeda/Shire* – regarding other products than Copaxone – that, while “*the Commission nonetheless recognises that competitive pressure could theoretically be exerted on [the relevant product] by products in neighbouring markets [...], that competitive pressure from these neighbouring markets is limited*” and therefore “*insufficient*”.⁹⁷² In *Takeda/Shire*, competitive pressure from products in neighbouring markets was found to be limited and therefore insufficient mainly because the more remote competitor products had different safety profiles and did not constitute suitable alternatives in many situations. The same holds true for Copaxone and non-GA first-line DMTs (see Recitals (276) and (284)).

⁹⁶⁷ Commission Decision of 27 February 2013, *Ryanair/Aer Lingus III*, Case M.6663.

⁹⁶⁸ Commission Decision of 6 February 2019, *Siemens/Alstom*, Case M.8677.

⁹⁶⁹ ID 4032, Teva’s Reply to the Statement of Objections, para. 308.

⁹⁷⁰ Commission Guidelines on the assessment of horizontal mergers under the Council Regulation on the control of concentrations between undertakings (OJ C 31, 5.2.2004, p. 5–18), paragraph 28. Teva further points to the 2009 Final Report of the Commission’s Pharmaceutical Sector Inquiry to support its argument, which states in the introduction to chapter C.2 “Competition Between Originator and Generic Companies – The Issues” that “*Originator companies compete with other originator companies (see Chapter C.3.) as well as with generic companies.*” (paragraph 464). The following chapter C.3 is dedicated to “Competition between Originator Companies – The Issues”. The context of the statement shows that it does not mean to say that originator companies generally compete with other originators and generic companies in the same market (which would support Teva’s argument) but that it merely states that there are different situations of competition for originator companies – competition with other originators and competition with generics.

⁹⁷¹ See 2024 Market Definition Notice, paras. 25-26.

⁹⁷² Case M.8955, *Takeda/Shire*, paragraphs. 78-79. Notably, competitive pressure was limited because of the differences in the safety profiles of the medicines in question.

- (852) Conversely, the Commission found in the *Mylan/Meda* decision that in “*certain circumstances*” medicines “*with an equivalent therapeutic profile*” can be considered to be part of the same relevant market. However, in the case of Copaxone, the Commission has already come to the conclusion that non-GA first-line DMTs do not have equivalent therapeutic profiles (and are, in any event, not therapeutically equivalent). As explained above in Recital (217), the Commission has regularly defined the relevant product market for genericised products like Copaxone at the level of the active substance. Finally, as explained in point 30 and footnote 55 of the Market Definition Notice, where a market is already subject to existing dominance or monopoly power (for example, where generic competition is excluded from a single molecule market), the prevailing market price cannot be assumed to be that of a competitive equilibrium, as would normally be the case in merger control. A monopolist that raises (quality adjusted) prices above the monopoly level would still lose some customers to products outside the market, but this does not mean that those other products, that were not close enough competitors to prevent the monopoly price from arising in the first place, should, as a result, be characterised as still close enough competitors to be included in the narrow (already monopolised) market. As discussed elsewhere, this is the so-called cellophane fallacy.
- (853) Third, Teva’s argument that the Commission’s analysis has solely focused on price competition is a mischaracterisation of the exercise that was carried out in Section 6.3.3.4. Non-GA first-line treatments were not only found to be incapable of disciplining Copaxone’s pricing to the same degree as Synthon GA, they also had no appreciably and non-transitory effect on either Copaxone sales or profitability, especially when compared to the sizeable and non-transitory effects that followed the entry of Synthon GA (see Section 6.3.3.2.4). As confirmed by the Court of Justice in *Servier*, “*price and quantity sold of a product are not the expression of a distinct type of competition, which could be contrasted with competition which depends on the quality of that product or the efforts made to ensure its commercial promotion*”.⁹⁷³ Finally, the Teva’s claims of significant competition between Copaxone and non-GA first-line DMTs, should be dismissed for the reasons set out in Section 6.3.3.2.4.

6.3.3.5.2. Teva argues that the Commission overstates the constraint of Synthon GA on Copaxone

- (854) Teva claims that the Commission’s analysis overstates the constraint of Synthon GA on Copaxone vis-à-vis constraints from non-GA first-line DMTs.⁹⁷⁴ In particular, Teva claims that the Commission’s quantitative analysis understates the competitive constraint of non-GA first-line DMTs by design.⁹⁷⁵ The Commission rejects this claim.
- (855) Teva claims that the Commission's analysis of prices and gross margins does not, capture non-price competition to any significant degree because the Commission’s quantitative analysis focused on the evolution of Copaxone’s price and gross margins and therefore only took into account price competition faced by Copaxone failing to

⁹⁷³ Case C-176/19 P, *Commission v Servier*, paragraph 387.

⁹⁷⁴ ID 4032, Teva’s Reply to the Statement of Objections, para. 312.

⁹⁷⁵ ID 4032, Teva’s Reply to the Statement of Objections, para. 316. Teva further supports its claim by submitting that the Commission does not take into account that Synthon GA is differentiated from Copaxone and cannot compete for all Copaxone demand and that the Commission misrepresents the competitive dynamics between Copaxone and Synthon GA in Belgium. The Commission addresses these claims in Recitals (351) to (358) and Section 6.3.3.4.3.1.4 respectively.

take into consideration non-price competition.⁹⁷⁶ Teva further submits that short term changes in price levels are primarily affected by price (rather than non-price) competition, while the same is also true for gross margins.⁹⁷⁷ This is because gross margins represent revenue earned minus the costs of goods sold, and hence do not take into account any R&D costs, sales costs, marketing costs, or patient support costs, i.e., costs that are incurred at least in substantial part due to non-price competition.⁹⁷⁸

- (856) The Commission notes that Teva's characterisation of the Commission's analysis as exclusively focusing on price competition is wrong for the reasons set out in Section 6.3.3.2.4.1. Moreover, while the Commission's analysis focussed on figures of the evolution Copaxone's gross margins, the Commission did also analyse Copaxone's net margins. Net margins include all available costs that could be attributed to the type of non-price competition that Teva refers to (including variable costs such as sales and marketing activities), exhibit similar patterns and support the same conclusions.⁹⁷⁹ Teva's argument that the Commission failed to consider non-price competition by focusing only on gross margins is therefore misguided because it ignores that the Commission also analysed Copaxone net margins.⁹⁸⁰
- (857) Teva further claims that, even if one were to consider all costs recorded in the data analysed by the Commission, that would still not fully capture non-price competition since (i) some costs associated with non-price competition are incurred at EEA-level and are not reflected in the country-level data (for example sponsorships for large conferences), (ii) some costs are incurred at global level and are not reflected in the dataset at all (for example key medical studies), and (iii) R&D costs, such as the costs associated with the development and launch of Copaxone 40 mg, are not included in this data.⁹⁸¹ Teva also claims to have engaged in significant investments in non-price competition (referring to sales, marketing and medical costs), including during the Relevant Period.⁹⁸²
- (858) The Commission rejects Teva's claim because Teva overstates the significance of such additional costs.
- (859) First, Teva claims that some costs associated with non-price competition are not reflected in the country-level data used by the Commission for its analysis because they are incurred at the EEA-level.⁹⁸³ The Commission finds that taking into account costs incurred at EEA-level would not considerably change the outcome of the Commission's analysis.
- (860) Teva has failed to provide any evidence in support of the claim that EEA-level costs, above and beyond the sum of the costs incurred at the national level, directly relevant to Copaxone competitiveness, have been incurred. Teva has not provided any data on

⁹⁷⁶ ID 4032, Teva's Reply to the Statement of Objections, para. 316.

⁹⁷⁷ ID 4032, Teva's Reply to the Statement of Objections, para. 315.

⁹⁷⁸ ID 4032, Teva's Reply to the Statement of Objections, para. 315.

⁹⁷⁹ See ID 5820 for a side-by-side comparison of Copaxone gross and net profits in all Relevant Member States and the SO data pack for the underlying data and computations.

⁹⁸⁰ As discussed elsewhere, see Recital (474), Teva's assertion that all promotional activity necessarily corresponds to non-price competition against exclusively first-line DMTs other than Synthon GA is erroneous and directly refuted by available evidence.

⁹⁸¹ ID 4032, Teva's Reply to the Statement of Objections, para. 317; ID 5909, Teva's Reply to the Letter of Facts II of 17 May 2024, para. 11.

⁹⁸² ID 4032, Teva's Reply to the Statement of Objections, paras. 228-237.

⁹⁸³ ID 4032, Teva's Reply to the Statement of Objections, para. 317a).

the size of such costs, despite the fact that it ought to have the relevant information available in at least some accounting records. In fact, Teva submitted in its reply to the Commission’s Article 18(2) Request of 3 June 2020 that country-level data is representative for Teva’s expenses on promotional activities: “{...}”.⁹⁸⁴ Teva further submitted data on the development of the total budget for promotional activities for Copaxone in the EU (by year), which shows a continuous and significant decrease in expenditure in the time around loss of exclusivity and around the (anticipated) entry of Synthon GA.⁹⁸⁵ Teva submitted that “*the decline in expenditure should be considered in the context of both Copaxone’s current position in its product life cycle and the general cuts made by Teva across the board due to financial difficulties*” (emphasis added).⁹⁸⁶ Teva further submitted two board presentations from 2019 and 2020 stating that EU expenses on sales and marketing for Copaxone were at a “{...}”⁹⁸⁷ in 2019/2020 and planned “{...}”⁹⁸⁸ for the coming years. An internal document prepared by Teva’s management in the Netherlands makes a clear connection between the reduction of expenses on sales and marketing and the entry of Synthon GA: “{...}”.⁹⁸⁹ Teva’s Brand Plan for Copaxone for the year 2024 shows that {...}.⁹⁹⁰

- (861) Second, Teva claims that some costs were not reflected in the data that the Commission used for its analysis because they are incurred at global level.⁹⁹¹ The Commission finds that taking into account costs incurred at global level would not considerably change the outcome of the Commission’s analysis either.
- (862) As mentioned above, Teva has not provided any evidence to support its claim that it has incurred significant costs at global level that are directly relevant to Copaxone’s competitiveness. Instead, Teva’s statements in earnings calls suggest that Teva’s percentage of expenses on Copaxone “{...}”⁹⁹² and that Teva even reduced its expenses on Copaxone.⁹⁹³ At a conference in May 2014, Teva’s {...} and {...} referred to Copaxone as a product “{...}” that was {...}.⁹⁹⁴
- (863) In relation to both EEA-level and global level costs, the Commission notes that Teva’s Copaxone gross margins were {...}% and the corresponding net margins {...}% (and most often {...}%) in all Relevant Member States for the most part of the Relevant Period. Both of those figures are very high, indicative of prices significantly above costs. It is highly unlikely that any costs at EEA or global level that Teva claims to have incurred, but fails to either quantify or substantiate, would be of a magnitude capable of explaining a substantial part of the significant gap between prices and costs at the national level and in turn undermine the

⁹⁸⁴ ID 660, Teva’s reply to Article 18(2) Request of 3 June 2020, p. 46.

⁹⁸⁵ ID 660, Teva’s reply to Article 18(2) Request of 3 June 2020, p. 45.

⁹⁸⁶ ID 660, Teva’s reply to Article 18(2) Request of 3 June 2020, p. 45.

⁹⁸⁷ ID 834-8, “Europe AOP 2020”, 12 December 2019, p. 7. “AOP” stands for “annual operating plan”.

⁹⁸⁸ ID 834-56, “EU LRP 2021-25”, May 2020, p. 12. “LRP” stands for “long range plan”.

⁹⁸⁹ ID 262-1284, Memo from Teva NL’s management to the Works Council, 23 January 2018, p. 11 (unofficial translation). Original text: “{...}”

⁹⁹⁰ ID 4733-390, COPAXONE® EU Strategic Plan-2024, June 2023, pp. 13, 16. The European Committee for Treatment and Research in Multiple Sclerosis (ECTRIMS) is Europe’s and the world’s largest professional organisation dedicated to the understanding and treatment of MS.

⁹⁹¹ ID 4032, Teva’s Reply to the Statement of Objections, para. 317b).

⁹⁹² ID 4964, Teva Earnings Call Q1 2015, 30 April 2015, pp. 80-81.

⁹⁹³ ID 4964, Teva Earnings Call Q2 2015, 30 July 2015, p. 26 (referring to a reduction of sales and marketing expenses); ID 5199, Teva Earnings Call Q3 2017, 2 November 2017, pp. 27, 29 (referring to investment in and expenses on Copaxone in general).

⁹⁹⁴ ID 5205, Teva’s presentation at UBS Global Healthcare Conference (transcript), 19 May 2014, pp. 3-4.

Commission's analysis and conclusions that Teva was not effectively and immediately constrained by non-GA DMTs during the Relevant Period. Moreover, Teva reduced spendings in the time around loss of exclusivity and around the (anticipated) entry of Synthon GA on the EEA level and globally as well.

- (864) Third, Teva's claim that R&D costs such as costs associated with the development and launch of Copaxone 40 mg were not included in the dataset⁹⁹⁵ has already been addressed in Section 6.3.3.2.4.3.1 above. Evidence shows that the development and launch of Copaxone 40 mg was not a key instance of non-price competition against non-GA first-line DMTs but was aimed to protect Copaxone from Synthon GA by switching the patients from the 20 mg dosage to the then still patent protected 40 mg dosage, thus avoiding the diversion of Copaxone 20 mg sales to Synthon GA 20 mg. In regard to R&D costs besides the launch of Copaxone 40 mg, the Commission has shown above that Teva's EEA and global expenses on Copaxone throughout the Relevant Period, including on R&D, were not significant (“[v]ery little R&D invested”).
- (865) Considering the above, Teva's claim that the Commission's analysis fails to capture non-price competition to any significant degree must be rejected. Teva's claim that the country-level data that the Commission relies on for its analysis is not representative of Teva's expenses on non-price competition is also unfounded. The Commission therefore maintains its findings set out in Section 6.3.3.5 above that Synthon GA is the only first-line DMT that effectively and immediately constrained, or was capable of effectively and immediately constraining Copaxone during the Relevant Period.

6.3.4. *Conclusion: the relevant product market is the market for glatiramer acetate*

- (866) In view of the above, the Commission concludes that the relevant product market during the Relevant Period was the market for glatiramer acetate.
- (867) In line with the Court of Justice's judgment in *Generics (UK)*, and on the basis of the detailed two-step analysis set out in Sections 6.3.2 (therapeutic substitutability) and 6.3.3 (assessment of effective and immediate constraints), the Commission finds that due to the changes in the conditions of competition, the (approaching) market entry of Synthon GA has led to a situation in which Copaxone can be considered to be effectively and immediately constrained only by GA medicines – i.e. by Synthon GA, currently the only generic-like GA drug authorised in the Relevant Member States.

6.4. **Relevant geographic market**

- (868) According to the Market Definition Notice and established case law, the relevant geographic market comprises an area in which the undertakings concerned are involved in the supply and demand of the relevant products and where the conditions of competition are sufficiently homogeneous for the effects of the conduct under investigation to be able to be assessed, and which can be distinguished from other geographic areas, in particular because conditions of competition are appreciably different in those areas.⁹⁹⁶

⁹⁹⁵ ID 4032, Teva's Reply to the Statement of Objections, para. 317c).

⁹⁹⁶ See Market Definition Notice, para. 12; see also Judgment of the Court of Justice of 14 February 1978, *United Brands v Commission*, C-27/76, EU:C:1978:22, paragraph 44; Judgment of 30 September 2003, *Cableuropa and Others v Commission*, T-346/02 and T-347/02, EU:T:2003:256, paragraph 115.

- (869) In the case at hand, the relevant geographic market is defined as national. This is because the conditions of supply and demand are likely to vary across Member States due to several factors. As laid out above in Sections 4.3 and 6.3.3.4, Member States have different rules and practices regarding the granting of marketing authorisations, the pricing and reimbursement of medicines and automatic substitution between medicines, as the organisation of their health systems is a matter of national policy. The nature and scope of barriers related to patents and other intellectual property rights may vary significantly from one Member State to another. Further, the prescribing practices of doctors and the dispensing behaviour of pharmacists may vary across Member States. Accordingly, the conditions of competition in each Member State are likely to be different from other Member States. Consequently, previous Commission decisions regarding marketed pharmaceutical products have defined the geographic market as national.⁹⁹⁷
- (870) In view of the above, and taking into account that Teva did not contest this finding, the Commission takes the view that the geographic market for GA is national in scope.

7. DOMINANCE

7.1. Principles

- (871) According to settled case law, dominance is “*a position of economic strength enjoyed by an undertaking, which enables it to prevent effective competition being maintained on the relevant market by affording it the power to behave to an appreciable extent independently of its competitors, its customers and ultimately of consumers*”.⁹⁹⁸
- (872) For dominance to exist, the undertaking concerned must have substantial market power that allows it to have an appreciable influence on the conditions under which competition will develop.⁹⁹⁹ However, dominance does not imply that an undertaking has eliminated all opportunity for competition or that it does not face any competitive constraint.¹⁰⁰⁰
- (873) The existence of a dominant position derives from a combination of several factors which, taken separately, are not necessarily determinative.¹⁰⁰¹ One important factor is the existence of very large market shares. In *AstraZeneca*, the Court of Justice held that “*although the importance of the market shares may vary from one market to another, the possession, over a long period, of a very large market share constitutes in itself, save in exceptional circumstances, proof of the existence of a dominant position [...]*” and that “*market shares of more than 50% constitute very large market shares.*”¹⁰⁰² A share of between 70% and 80% is, in itself, a clear indication of the

⁹⁹⁷ See for example Commission Decision of 30 November 2006, *AstraZeneca*, Case COMP/A 37.507/F3, paragraph 503; Case COMP/M.5865, *Teva/Ratiopharm*, paragraph 83; Commission Decision of 5 October 2012, *Watson/Actavis*, Case COMP/M.6613, paragraph 34; Case COMP/M.7379, *Mylan/Abbott*, paragraph 26.

⁹⁹⁸ Case C-27/76, *United Brands v Commission*, paragraph 65; Case C-85/76 *Hoffmann-La Roche v Commission*, paragraph 38; Judgment of the Court of First Instance of 17 September 2007, *Microsoft v Commission*, T-201/04, EU:T:2007:289, paragraph 229.

⁹⁹⁹ Case C-85/76, *Hoffmann-La Roche v Commission*, paragraph 39.

¹⁰⁰⁰ Case C-27/76, *United Brands v Commission*, paragraph 113.

¹⁰⁰¹ Case C-27/76, *United Brands v Commission*, paragraph 66; Case C-85/76, *Hoffmann-La Roche v Commission*, paragraph 39.

¹⁰⁰² Case C-457/10 P, *AstraZeneca*, paragraph 176.

existence of a dominant position in a relevant market.¹⁰⁰³ Further, a decline in market shares, which still remain very large, cannot in itself constitute proof of the absence of a dominant position.¹⁰⁰⁴

- (874) Other important factors when assessing dominance are the existence (or lack thereof) of countervailing buyer power as well as barriers to entry or expansion, preventing potential competitors from having access to the market and actual competitors from expanding their activities in the market.

7.2. Assessment

- (875) In order to assess whether Teva held a dominant position in the GA market in the Relevant Member States, the Commission first assesses Teva's market shares and profit margins (7.1.2.1.). Second, the Commission evaluates the existence and extent of possible barriers to entry (7.1.2.2.). In the third place, the role of countervailing buyer power is examined (7.1.2.3.). Finally, the Commission demonstrates that Teva itself acknowledges its dominant position (7.1.2.4.). On the basis of these considerations, the Commission concludes that Teva held a dominant position on the GA markets in Belgium, Czechia, Germany and Spain for the entire Relevant Period ((i.e. from 3 February 2015 to 7 February 2024). The Commission concludes that Teva held a dominant position on the GA market in Italy from February 2015 until 31 December 2021, in the Netherlands from February 2015 until 31 December 2018 and in Poland from February 2015 until 31 December 2022.
- (876) The Commission notes that Teva's primary claim is that the relevant product market includes all first-line DMTs and that Copaxone has never been dominant on such a market.¹⁰⁰⁵ The Commission has explained in Chapter 6 why the relevant product market for Copaxone is limited to medicines containing the active ingredient GA.
- (877) Moreover, according to Teva, "*even based on the SO's overly narrow market definition, the Relevant Period is overstated*".¹⁰⁰⁶ Teva claims that the earliest possible start date for the Relevant Period is May/June 2016, the date of Synthon GA's MA approvals in the Relevant Member States (January 2017 for Italy).¹⁰⁰⁷ The Commission addresses Teva's claims on the start of the Relevant Period, which pertain primarily to the definition of the relevant product market, in Sections 6.3.3.1.2 and 6.3.3.2.2 and Chapter 12. Teva further claims that the latest possible end date of dominance, and therefore the Relevant Period, in Germany, Italy, the Netherlands, Poland and Spain is end of 2018.¹⁰⁰⁸ In support of this claim, Teva argues that market shares are not reliable indicators of dominance in the context of tender markets and that tender and price evidence indicate that Synthon GA was an effective competitive constraint on Copaxone shortly after its entry.¹⁰⁰⁹ The

¹⁰⁰³ Judgment of the Court of First Instance of 12 December 1991, *Hilti v Commission*, T-30/89, EU:T:1991:70, paragraph 92; Judgment of the Court of First Instance of 30 September 2003, *Atlantic Container Line and Others v Commission*, T-191/98 and T-212/98 to T-214/98, EU:T:2003:245, paragraph 907; Judgment of the General Court of 25 June 2010, *Imperial Chemical Industries v Commission*, T-66/01, EU:T:2010:255, paragraph 257; Judgment of the General Court of 29 March 2012, *Telefónica and Telefónica de España v European Commission*, T-336/07, EU:T:2012:172, paragraph 150.

¹⁰⁰⁴ Judgment of the Court of First Instance of 30 January 2007, *France Télécom v Commission*, T-340/03, EU:T:2007:22, paragraph 104.

¹⁰⁰⁵ ID 4032, Teva's Reply to the Statement of Objections, para. 337.

¹⁰⁰⁶ ID 4032, Teva's Reply to the Statement of Objections, para. 340.

¹⁰⁰⁷ ID 4032, Teva's Reply to the Statement of Objections, para. 354 and Table 5.

¹⁰⁰⁸ ID 4032, Teva's Reply to the Statement of Objections, Table 6 and footnotes 422-426.

¹⁰⁰⁹ ID 4032, Teva's Reply to the Statement of Objections, para. 368(a).

Commission addresses Teva's claims on the end date of the Relevant Period, including on the evidential value of market shares in the present case, in the corresponding country-chapters of Section 7.2.1 below and in Section 7.2.1.8.

- (878) Teva's claims concerning the Commission's findings on barriers to entry and expansion and on Teva's acknowledgement of its own dominant position are addressed in Sections 7.2.1.9 and 7.2.4 below.

7.2.1. *Market shares and profit margins*

- (879) The Commission considers, first and foremost, that market shares in the GA market in the Relevant Member States provide a good indication of Teva's competitive strength. The market shares presented below are based on volume data (in DOT) from IQVIA for all Relevant Member States.¹⁰¹⁰ The Commission considers that where market shares based on volume indicate market power, this is sufficient for the purpose of its assessment (instead of also analysing market shares by value) given that market shares by volume are the more conservative method to assess the market power of a pharmaceutical company in relation to its originator product. That is so because value-based market shares for originators tend to be higher than market shares based on volume (due to – on average – higher prices for originator products than for its generic competitors). Still, the Commission extends its analysis to include market shares by value where the market shares by volume do not enable the Commission to form a conclusive view (in particular, as regards Italy). Including market shares by value may reflect even more accurately the actual market power the originator enjoys because they reflect both its prices and sales volumes in the relevant market.
- (880) In its analysis of market shares, the Commission takes into account the trend, or development, of market shares over time. Trends such as a steep erosion of market shares or a continuous progressive reduction of market shares can indicate that a company is not capable of operating to an appreciable extent independently of its competitors. In contrast, if, after an initial trend of decrease in market share, the market shares stabilise and the market finds a new equilibrium at still very high market shares, this can indicate that a company is still dominant despite the initial market share decrease.
- (881) The Commission supplements this analysis of Teva's market power in the GA market based on its market position by also considering Copaxone's net profit margins. Copaxone's net profit margins directly measure Teva's pricing (market) power, meaning Teva's ability to set prices above marginal cost.
- (882) The degree of Teva's market power in each of the seven Relevant Member States is assessed on a country-by-country basis.
- (883) Teva claims that market shares are not a reliable indicator for Copaxone's market power¹⁰¹¹ (see Section 7.2.1.8 below). Teva further claims that Copaxone should no longer be regarded as dominant "*soon after*" the entry of Synthon GA in Germany, Italy, Poland, the Netherlands and Spain because "*the price of Copaxone began to fall materially and [Synthon GA] won a material proportion of tenders*"¹⁰¹² and because "*Copaxone's absolute profit margins were significantly eroded as a result of*

¹⁰¹⁰ For all Relevant Member States except Belgium, the IQVIA data was provided by Teva. For Belgium, the Commission used data from its own IQVIA subscription. See footnote 746.

¹⁰¹¹ ID 4032, Teva's Reply to the Statement of Objections, para. 372.

¹⁰¹² ID 4032, Teva's Reply to the Statement of Objections, para. 423(b).

competition with [Synthon GA]”¹⁰¹³. Teva claims that the latest end date of the Relevant Period for Germany, Italy, the Netherlands, Poland and Spain is end of 2018.¹⁰¹⁴ These claims are addressed in Sections 7.2.1.3, 7.2.1.4, 7.2.1.5, 7.2.1.6 and 7.2.1.7 respectively.

7.2.1.1. Copaxone’s market shares and profit margins in Belgium

(884) Table 3 shows the market shares of Teva and Mylan/Viatris (the licensee of Synthon GA) in Belgium in the period from 2015 to 2022.

Table 3: Market shares (in DOTs) for GA in Belgium

Year	Copaxone	Synthon GA
2015	{...}	{...}
2016	{...}	{...}
2017	{...}	{...}
2018	{...}	{...}
2019	{...}	{...}
2020	{...}	{...}
2021	{...}	{...}
2022	{...}	{...}

Source: IQVIA, see footnote 746.

(885) Teva enjoyed an absolute monopoly (market shares of 100%) on the GA market in Belgium since 2015 and until 2020. The market entry of Synthon GA in August 2021 under the brand name Glatiramyl did not noticeably change Teva’s monopolistic market position, as its market shares remained very high at {...}% in 2022.

(886) Copaxone’s very high market shares may be attributable to the actions Teva took to defend Copaxone’s exclusivity in Belgium, some of which the Commission considers abusive within the meaning of Article 102 TFEU (see Chapters 8 and 9). As a result of a preliminary injunction obtained by Teva on 15 May 2018, Glatiramyl 40 mg (brand name for Synthon GA 40 mg in Belgium) was prevented from entering the Belgian market from May 2018 to May 2020. This preliminary injunction was based on a divisional patent that had been shielded from timely and effective legal review by Teva’s conduct (see Chapter 8). When Glatiramyl (both 20 mg and 40 mg)

¹⁰¹³ ID 5695, Teva’s Reply to the Letter of Facts I of 9 February 2024 paras. 151, 163. Teva does not include the Netherlands in this claim.

¹⁰¹⁴ ID 4032, Teva’s Reply to the Statement of Objections, Table 6 and footnotes 422-426. Teva has not submitted any claims on the end of the Relevant Period in Belgium and Czechia because it claims that the Relevant Period “could not have started before at least when [Synthon GA] obtained MA approval in that country” or while a PI is in place.

was finally launched in August 2021, Teva, aiming to discourage automatic substitution, disseminated misleading messages on Synthon GA to the Belgian Payer(s) (see Recitals (708) to (716)). This conduct was capable of slowing down Synthon’s uptake and likely did.

- (887) Copaxone’s net profit margins remained relatively stable and significant over the Relevant Period (between {...}% and {...}%), with a small overall margin decrease at {...}% between 2015 and 2023.¹⁰¹⁵ This indicates that Teva retained significant market (pricing) power throughout the Relevant Period.¹⁰¹⁶
- (888) As explained in Recital (877), Teva claims that for several Member States the latest possible end date of dominance is the end of 2018. Teva makes no such claim for Belgium and concedes that, in Belgium, “*the constraint Copaxone has faced from [Synthon GA] is less close competition vis-à-vis other Relevant Member States*”.¹⁰¹⁷ However, Teva upholds its claim that Copaxone was not dominant in Belgium on a product market that includes all first-line DMTs.¹⁰¹⁸
- (889) The Commission concludes that Teva’s very large market shares on the GA market in Belgium are such as to create a strong presumption of dominance on the Belgian GA market for the entirety of the Relevant Period, meaning from 3 February 2015 to 7 February 2024. This presumption is further supported by Copaxone’s significant net profit margins.

7.2.1.2. Copaxone’s market shares and profit margins in Czechia

- (890) Table 4 shows the market shares of Teva and Alvogen/Zentiva (the licensee of Synthon GA) in Czechia in the period from 2015 to the first half of 2023.

Table 4: Market shares (in DOTs) for GA in Czechia

Year	Copaxone	Synthon GA
2015	{...}	{...}
2016	{...}	{...}
2017	{...}	{...}
2018 ¹⁰¹⁹	{...}	{...}
2019	{...}	{...}
2020	{...}	{...}

¹⁰¹⁵ Commission calculations based on ID 5710, Teva’s Reply to the Letter of Facts I of 9 February 2024, data pack, file “Annex RFI9Q7 - RFI3Q2 follow-up.xlsx”. See also Table 12.

¹⁰¹⁶ In theory, competition should drive variable profit margins down to zero, but this rarely occurs in practice. As reference, the Commission notes that in Italy Copaxone net profit margins were eventually reduced to just {...}% in 2023 once Synthon GA gained a significant foothold in that market.

¹⁰¹⁷ ID 4032, Teva’s Reply to the Statement of Objections, para. 383.

¹⁰¹⁸ ID 4032, Teva’s Reply to the Statement of Objections, para. 383.

¹⁰¹⁹ In 2018, one pack of Synthon GA 40 mg was sold in Czechia. Therefore, Teva’s market share was {...}% and Synthon’s market share was {...}% in 2018.

2021	{...}	{...}
2022	{...}	{...}
{...}	{...}	{...}

Source: IQVIA (see footnote 746) and Teva’s internal data (for the year 2015).

- (891) Teva has held a monopoly for GA in Czechia from 2015 to 2022. Since 2023, Synthon GA 20 mg has been sold in Czechia (albeit in very low volumes).¹⁰²⁰ By the end of February 2024, Synthon GA 40 mg had not yet entered the Czech market.¹⁰²¹ Preliminary injunctions, obtained by Teva on 1 June 2015 and 16 May 2019, for the 20 mg and 40 mg dosage respectively, have prevented the effective uptake of Synthon GA during the Relevant Period. These preliminary injunctions were based on divisional patents that had been shielded from timely and effective legal review by Teva’s conduct (see Chapter 8). Copaxone’s net profit margins in Czechia remained relatively stable and significant over the Relevant Period (between {...}% and {...}%) and even increased still for several years after 2015.¹⁰²² This indicates that Teva retained significant market (pricing) power throughout the Relevant Period.
- (892) Teva claims that the Relevant Period “cannot yet have started in Czechia” because Synthon GA “can at most be considered future potential competition to Copaxone”.¹⁰²³ Teva’s claims on the start of the Relevant Period are addressed in Sections 6.3.3.1.2 and 6.3.3.2.2.
- (893) Given that Teva’s Copaxone was effectively the only product on the Czech GA market during the Relevant Period, the Commission finds that Teva held a dominant position in the Czech GA market for the entirety of the Relevant Period, meaning from 3 February 2015 to 7 February 2024.

7.2.1.3. Copaxone’s market shares and profit margins in Germany

- (894) Table 5 shows the market shares of Teva and Mylan/Viatris (the licensee of Synthon GA) in Germany in the period from 2015 to the first half of 2023. The market shares for Copaxone include direct sales by Teva as well as sales of parallel imports of Copaxone.¹⁰²⁴

¹⁰²⁰ ID 5737, RLoF data pack, data file “EU_MIDAS_quarterly_with_DOT_CLEAN - including 2022-Q22023.dta”.

¹⁰²¹ ID 5673, Teva’s Reply to Article 18(2) Request of 15 February 2024, pp. 1-2.

¹⁰²² Commission calculations based on ID 5710, Teva’s Reply to the Letter of Facts I of 9 February 2024, data pack, file “Annex RFI9Q7 - RFI3Q2 follow-up.xlsx”. See also Table 12.

¹⁰²³ ID 4032, Teva’s Reply to the Statement of Objections, para. 382.

¹⁰²⁴ For the purpose of this Decision, it is not necessary to break down the Copaxone market shares by distributor in view of the following (i) the aggregate market shares fairly represent the share of GA prescriptions filled by Copaxone, (ii) Teva was the ultimate supplier of all Copaxone sold in Germany and (iii) even if parallel imports were not taken into account in Teva’s market share, this would not materially change the assessment of Teva’s market shares, which would still remain above {...}.

Table 5: Market shares (in DOTs) for GA in Germany

Year	Copaxone	Synthon GA
2015	{...}	{...}
2016	{...}	{...}
2017	{...}	{...}
2018	{...}	{...}
2019	{...}	{...}
2020	{...}	{...}
2021	{...}	{...}
2022	{...}	{...}
2023H1	{...}	{...}

Source: IQVIA, see footnote 746.

- (895) Until Synthon GA 20 mg entered the German market in October 2016 under the brand name Clift, the only market participants besides Teva were parallel traders for Copaxone. Even after the entry of Synthon GA on the German market in 2016, Teva’s market shares remained above {...}% (including sales of its product via parallel importers).¹⁰²⁵ The low uptake of Synthon GA can be attributed to Teva’s conduct on the German GA market. Teva’s conduct led to a preliminary injunction, obtained on 14 June 2019, preventing Mylan/Viatis from selling Clift 40 mg on the German market between June 2019 and September 2020. This preliminary injunction concerned a divisional patent that, due to Teva’s conduct, had been shielded from timely and effective legal review (see Chapter 8). Moreover, Teva’s disparagement campaign (see Section 9.4.4.4), aimed at hindering substitution and switching between Copaxone and Clift, was equally capable of protecting Teva’s very large market shares.
- (896) Copaxone’s net profit margins remained relatively stable and significant over the Relevant Period (between {...}% and {...}%) and increased still for several years after 2015. Copaxone’s net profit margins increased even after the entry of Synthon GA 20 mg in 2016 and again after the entry of Synthon GA 40 mg in 2018. Copaxone’s highest net profit margins across the observed period are in 2019, one year after the entry of Synthon GA 40 mg, and also the year Teva obtained a

¹⁰²⁵ Regarding the role of parallel traders, the Commission observes that parallel traders are not engaged in the marketing of products different from the original reference product. After repackaging and re-labelling as the case may be, parallel traders in fact sell the originator product which they have obtained, directly or indirectly, from the same originator in another Member State.

preliminary injunction against Synthron GA 40 mg.¹⁰²⁶ This indicates that Teva retained significant market (pricing) power throughout the Relevant Period.

- (897) Teva claims that, if Copaxone was to be considered dominant in Germany, then Copaxone’s dominance would have ended by the end of 2017 because the price of Copaxone began to fall materially and Synthron GA won a material proportion of tenders.¹⁰²⁷ According to Teva, the latest end date for dominance in Germany is the end of 2018 because the price of Copaxone in Germany had fallen by nearly {...}% by then.¹⁰²⁸ The Commission notes that the fact that the entry of Synthron GA led to significant price decreases in Germany is not disputed. As explained above, Copaxone’s price decreased by {...}% by 2018 (see Figure 25 and Recital (788)). However, it appears that Teva claims that Copaxone ceased to be dominant as of the entry of a competitor who is capable of eliciting some form of competitive reaction from Copaxone. Teva essentially equates dominance with monopoly power and therefore claims that dominance ends the moment that Copaxone is no longer a monopolist.
- (898) Teva does not dispute that Copaxone’s market shares in Germany in 2017 and 2018 were above {...}%¹⁰²⁹ but claims that market shares are not a reliable indicator to find that Copaxone is dominant in Germany (or any Relevant Member State) because tender and price evidence indicates that Synthron GA was an effective competitive constraint on Teva shortly after its entry.¹⁰³⁰ The claim that market shares are not a reliable indicator for market power in the present case is an overarching claim that Teva makes for Germany, Italy, the Netherlands, Poland and Spain. The Commission therefore addresses this claim in Section 7.2.1.8 below.
- (899) However, it is appropriate to discuss certain of Teva’s submissions on dominance in Germany already in this Section. Teva claims that Synthron GA has been able to compete effectively with Copaxone shortly after its entry in October 2016.¹⁰³¹ In support of this claim, Teva argues, first, that Synthron GA won four out of the eight exclusive tenders that were opened in Germany since the entry of Synthron GA.¹⁰³² With this, Teva suggests that Synthron GA was a significant competitor to Copaxone in exclusive tenders.
- (900) This suggestion is misleading. According to Teva, “*any assessment as to the effectiveness of the EU FoGA as a competitor at a given point in time should focus on the outcome of those tenders*”.¹⁰³³ However, the relevant question is not whether Synthron GA won tenders. The question is whether Synthron GA won over a significant part of the demand for GA. This was not the case because the tenders that Synthron GA won only represent a very small part of the GA demand (hence the consistently low market shares of Synthron GA) Three of the four exclusive tenders won by Synthron GA were tenders for the 20 mg dosage of GA. By the time Synthron GA 20 mg was launched and competed with Copaxone 20 mg in tenders, Teva was

¹⁰²⁶ Commission calculations based on ID 5710, Teva’s Reply to the Letter of Facts I of 9 February 2024, data pack, file “Annex RFI9Q7 - RFI3Q2 follow-up.xlsx”. See also Table 12.

¹⁰²⁷ ID 4032, Teva’s Reply to the Statement of Objections, para. 423(b) and Table 6.

¹⁰²⁸ ID 4032, Teva’s Reply to the Statement of Objections, para. 386(b), Table 6 and footnote 422.

¹⁰²⁹ ID 4032, Teva’s Reply to the Statement of Objections, para. 371(b).

¹⁰³⁰ ID 4032, Teva’s Reply to the Statement of Objections, para. 423(b).

¹⁰³¹ ID 4032, Teva’s Reply to the Statement of Objections, para. 391 and Table 5.

¹⁰³² ID 4032, Teva’s Reply to the Statement of Objections, para. 401; ID 5909, Teva’s Reply to the Letter of Facts II of 17 May 2024, para. 78(a).

¹⁰³³ ID 5909, Teva’s Reply to the Letter of Facts II of 17 May 2024, para. 78(a).

successful in converting most GA prescriptions in Germany to the 40 mg dosage (see Recital (786)). The fact that Mylan/Viatriis won exclusive tenders for GA 20 mg does therefore not indicate that Synthon GA exercised sufficient competitive constraints to no longer allow Teva to behave to an appreciable extent independently of participants in the GA market.

- (901) Synthon GA also won one tender for the 40 mg dosage, which was issued by German health insurer {...} and took effect in April 2019 (see Recital (786)). Only two months after the tender took effect – in June 2019 – a preliminary injunction was issued against Synthon GA that prevented Mylan/Viatriis from selling the 40 mg dosage in Germany.¹⁰³⁴ The preliminary injunction was only lifted in September 2020. That means that, while it is correct that Synthon GA won the 40 mg tender of {...}, the tender was only effective for a few months before Synthon GA was prevented from selling the 40 mg dosage in Germany due to the preliminary injunction. {...} then had to enter an open house contract with Teva to secure its supply with GA 40 mg.¹⁰³⁵ As explained in Recital (804), prices in open house tenders are significantly higher than prices in exclusive tenders. It follows that Synthon GA’s participation in exclusive tenders has not put appreciable competitive pressure on Copaxone. This is also corroborated by the very high market share that Teva maintained in Germany throughout the Relevant Period.
- (902) Second, Teva argues in the Reply to the Statement of Objections that Copaxone's prices in Germany decreased by around {...}% after Synthon GA started to participate in open house tenders.¹⁰³⁶ It follows from Teva’s reply to the Article 18(2) Requests of 22 October and 18 November 2021 that the {...}% price decrease of Copaxone was caused by a {...}% mandatory rebate after the entry of Synthon GA in Germany (which is unrelated to Synthon GA’s participation in tenders, be they open house or exclusive tenders) and that competition of Synthon GA in open house tenders only led to a {...}% rebate on Copaxone’s prices.¹⁰³⁷ A {...}% price decrease, which allows Teva to not only maintain significant net profit margins but to even increase them (see Recital (896)), is not an indication of competitive pressure that negates market power (see also Recital (999)).¹⁰³⁸
- (903) The Commission therefore concludes that Teva’s very large market shares on the GA market in Germany are such as to create a strong presumption of dominance for the entirety of the Relevant Period, meaning from 3 February 2015 to 7 February 2024. This presumption is supported by Copaxone’s significant net profit margins.

7.2.1.4. Copaxone’s market shares and profit margins in Italy

- (904) Table 6 shows the market shares of Teva and Mylan (the licensee of Synthon GA) in Italy in the period from 2015 to the first half of 2023.

¹⁰³⁴ Teva claims that the preliminary injunction was valid and that it did not impact the bidding process, see ID 5909, Teva’s Reply to the Letter of Facts II of 17 May 2024, para. 78(b). However, this only shows that Synthon GA had the potential to be an effective competitor for Teva. Due to Teva’s multi-faceted strategies to hinder its market entry and uptake, Synthon GA could not realise this potential.

¹⁰³⁵ ID {...}.

¹⁰³⁶ ID 4032, Teva’s Reply to the Statement of Objections, para. 404.

¹⁰³⁷ ID 1295-7, Teva’s Reply to Article 18(2) Requests of 22 October and 18 November 2021, pp. 5-6, see Recitals (789) and (790).

¹⁰³⁸ See also the Commission’s finding in Recital (797) that the impact of Sython GA’s entry would have likely been stronger absent Teva’s anticompetitive conduct.

Table 6: Market shares (in DOTs) for GA in Italy

Year	Copaxone	Synthon GA
2015	{...}	{...}
2016	{...}	{...}
2017	{...}	{...}
2018	{...}	{...}
2019	{...}	{...}
2020	{...}	{...}
2021	{...}	{...}
2022	{...}	{...}
2023H1	{...}	{...}

Source: IQVIA, see footnote 746.

- (905) Teva was the only undertaking active on the Italian GA market prior to 2017. From 2017 and onwards, Teva’s market shares progressively decreased and Teva held a {...}% market shares in the first half of 2023.
- (906) Teva’s market shares significantly decreased since Synthon GA entered the Italian market in 2017 under the brand name Copemyl (20 mg) and in 2018 under the brand name Copemyltri (40 mg). The launch of the 40 mg product Copemyltri in June 2018 introduced a competitive pressure on Teva and Copaxone. Teva incurred an increasingly significant loss of volumes following competition between Copaxone and Copemyl/Copemyltri in regional tenders in Italy.
- (907) Until 2019, Teva’s volume market shares on the GA market in Italy remained very high (more {...}), and were significantly higher than Synthon’s market shares (which were below {...}% in 2017/2018 and below {...}% in 2019). In 2020 and 2021, Synthon reached significantly higher volume market shares of {...}% and {...}%, while Teva’s market shares dropped to {...}% and {...}%. It follows that, for 2020 and 2021, the market shares in DOT, i.e. by volume, of Teva and Synthon are moving closer to each other (even if there is still a significant gap). The Commission therefore extends its analysis to include market shares by value, which allow to capture the fact that the average prices of Copaxone are higher than the average prices of Copemyl/Copemyltri.
- (908) Table 7 below shows Teva’s and Mylan’s respective market shares based on their revenue with GA products.¹⁰³⁹

¹⁰³⁹ The Commission notes that the revenue data used in Table 7 were recovered from the IQVIA database (see footnote 746). The revenue data reported therein are based on average observed package prices that do not take into consideration rebates and discounts applied on these list prices. Volume data (DOT) remain the most appropriate metric for comparing sales of different products, and in particular different

Table 7: Market shares (in revenues) for GA in Italy

Year	Copaxone	Synthon GA
2015	{...}	{...}
2016	{...}	{...}
2017	{...}	{...}
2018	{...}	{...}
2019	{...}	{...}
2020	{...}	{...}
2021	{...}	{...}
2022	{...}	{...}
2023H1	{...}	{...}

Source: IQVIA, see footnote 746.

- (909) Although Copaxone’s value-based market shares indeed dropped in the period from 2018-2019, one can observe that Teva’s shares stabilised as of 2020 at the level of {...}% of the value of the GA market in Italy. Further, the analysis of both volume- and value-based market shares shows that Teva’s market shares stabilized on a still very high level in 2020 and 2021 after an initial steep decrease of Copaxone’s market shares between 2018 and 2020. Copaxone’s net profit margins remained relatively stable and significant between 2015 and 2021 (between {...}% and {...}%). A noticeable dip in net profit margins can first be detected only in 2022 (down to {...}%) and 2023 (down to {...}%). Copaxone’s highest net profit margins across the observed period ({...}%) are in 2018, in the year of Synthon GA’s entry.¹⁰⁴⁰ Copaxone’s very high market shares (in volume, and even more so in value) and the significant net profit margins indicate that Teva was still capable of operating, to an appreciable degree, independently of its competitors after the entry of Synthon GA 40 mg in 2018, as it continued to command almost two thirds of the overall market for GA in Italy and maintained net profit margins of at least {...}% until 2021.
- (910) Teva claims that, if Copaxone was dominant in Italy, then Copaxone’s dominance would have ended “during 2018” because the price of Copaxone began to fall materially and Synthon GA won a material proportion of tenders.¹⁰⁴¹ According to

originator products, but a comparison between Table 6 and Table 7 offers sufficient support to the qualitative argument that DOT data underestimate Copaxone’s market position compared its generic-like rival Synthon GA. The Commission further underlines that the pricing and profitability figures reported in this Decision that are based on the Teva data (see footnote 746), as indicated by the corresponding references whenever such data is presented, and do not suffer from this drawback.

¹⁰⁴⁰ Commission calculations based on ID 5710, Teva’s Reply to the Letter of Facts I of 9 February 2024, data pack, file “Annex RFI9Q7 - RFI3Q2 follow-up.xlsx”. See also Table 12.

¹⁰⁴¹ ID 4032, Teva’s Reply to the Statement of Objections, para. 423(b) and Table 6.

Teva, the latest end date for dominance in Italy is end of 2018.¹⁰⁴² The Commission does not dispute that the entry of Synthon GA led to significant price decreases in Italy and that Synthon GA competed against Copaxone in tenders (see Figure 13 and Recitals (567) and (568)). However, it appears that Teva claims that Copaxone ceased to be dominant as of the entry of a competitor who is capable of constraining Copaxone. Teva essentially equates dominance with monopoly power and therefore claims that dominance ends in the moment that Copaxone is not a monopolist anymore.

(911) From the above, the Commission concludes that, despite a decrease of market shares between 2018 and 2020, Teva’s very large market shares in Italy are such as to create a strong presumption of dominance on the Italian GA market from February 2015 until 31 December 2021. This presumption is also supported by Copaxone’s significant net profit margins during this period.

7.2.1.5. Copaxone’s market shares and profit margins in the Netherlands

(912) Table 8 shows the market shares of Teva and Mylan (the licensee of Synthon GA) in the Netherlands in the period from 2013 to the first half of 2023. The market shares for Copaxone include direct sales by Teva as well as sales of parallel imports of Copaxone.

Table 8: Market shares (in DOTs) for GA in the Netherlands

Year	Copaxone	Synthon GA
2015	{...}	{...}
2016	{...}	{...}
2017	{...}	{...}
2018	{...}	{...}
2019	{...}	{...}
2020	{...}	{...}
2021	{...}	{...}
2022	{...}	{...}
2023H1	{...}	{...}

Source: IQVIA

(913) In the Netherlands, Teva was the market leader from 2015 to 2018 with market shares of more than {...}%. Before 2018, Teva was virtually the only company offering GA in the Netherlands. Only a very limited amount of sales (between {...}% and {...}%) was made by parallel importers.

¹⁰⁴² ID 4032, Teva’s Reply to the Statement of Objections, footnote 423.

- (914) Synthon GA entered the market in the Netherlands in February 2018 under the brand name Glatirameeracetaat Mylan and, as a result, Teva’s market shares significantly decreased from 2019. The launch of Glatirameeracetaat Mylan exercised significant competitive pressure on Teva. Teva incurred a significant loss of market shares from {...}% in 2018 to {...}% in 2019 because it chose to sacrifice its volume of sales instead of lowering its prices in the Netherlands (see Recital (604)). As a result of preference policies agreed between Mylan and the five main health insurers in the Netherlands (which ultimately rejected Teva’s position that Copaxone should not be substituted to Synthon GA, see Section 6.3.3.4.2.2.), most GA patients received Glatirameeracetaat Mylan instead of Copaxone from 2019 onwards. Copaxone’s net profit margins in the Netherlands remained relatively stable and significant despite the loss in volumes and even increased still for several years after 2015 (between {...}% and {...}%). This can be attributed to the fact that Teva maintained a high price level for Copaxone in the Netherlands (see Figure 15).
- (915) Teva claims that, if Copaxone was dominant in the Netherlands, then Copaxone’s dominance would have ended end of 2017 because of Synthon GA’s success in tenders.¹⁰⁴³ Teva does not dispute that Copaxone’s market shares in the Netherlands in 2018 were above {...}% but claims that market shares are not a reliable indicator to find that Copaxone is dominant in the Netherlands. As stated above (Recital (898)), this is an overarching claim which is addressed in Section 7.2.1.8 below.
- (916) Teva states in its Reply to the Statement of Objections that Synthon GA has “*won all tenders*” in the Netherlands since 2018.¹⁰⁴⁴ However, Teva omits to mention that Copaxone did not compete with and lose against Synthon GA in these tenders because Teva in fact chose not to participate in them. When health insurers started to implement preference policies (essentially exclusive tenders) in the Netherlands, Teva decided to only sell Copaxone outside of tenders (see Recitals (601) and (604)). This allowed Teva to maintain significant prices and profit margins, while keeping circa one third of the market shares. Therefore, Teva’s claim that Copaxone was not dominant in the Netherlands in 2018 despite a market share above {...}% does not convince.
- (917) However, the steep erosion of Copaxone’s market shares as well as the loss of its position as a leading supplier of GA in the Netherlands, indicate that Teva has not been capable of operating independently of its competitors in the market for GA in the Netherlands after 2018.¹⁰⁴⁵ From this, the Commission concludes that Teva’s very large market shares in the Netherlands are such as to create a strong presumption of dominance on the GA market in the Netherlands since February 2015 until 31 December 2018. This presumption is supported also by Copaxone’s significant net profit margins during this period. While Teva was able to maintain these profit margins also for the following years, this was only possible at the cost of allowing Synthon GA to take over the position of the clear market leader.

7.2.1.6. Copaxone’s market shares and profit margins in Poland

- (918) Table 9 shows the market shares of Teva and Alvogen/Zentiva (the licensee of Synthon GA) in Poland in the period from 2015 to the first half of 2023.

¹⁰⁴³ ID 4032, Teva’s Reply to the Statement of Objections, paras. 398, 423(b) and Table 6.

¹⁰⁴⁴ ID 4032, Teva’s Reply to the Statement of Objections, para. 398.

¹⁰⁴⁵ The Commission’s finding on the end of Teva’s dominance in the GA market in the Netherlands aligns with Teva’s claim that “*the latest end date for dominance in the Netherlands is end of 2018*”, see ID 4032, Teva’s Reply to the Statement of Objections, footnote 424.

Table 9: Market shares (in DOTs) for GA in Poland

Year	Copaxone	Synthon GA
2015	{...}	{...}
2016	{...}	{...}
2017	{...}	{...}
2018	{...}	{...}
2019	{...}	{...}
2020	{...}	{...}
2021	{...}	{...}
2022	{...}	{...}
2023H1	{...}	{...}

Source: IQVIA

- (919) Until 2017, Teva was the only undertaking active on the Polish GA market, with market shares of {...}% in 2015 and 2016.
- (920) Synthon GA entered the Polish GA market with a 20 mg dosage in January 2017 and with a 40 mg dosage in July 2018 under the brand name Remurel. Between 2017 and 2019, Teva's market shares dropped from {...}% to {...}%, while Remurel gained significant market shares (c. {...}% in 2019). Still, despite such a significant increase in Synthon's shares, Teva remained well ahead with an approximately {...} percentage points higher share. After Teva lowered its tender bids for Copaxone, it regained market shares in 2020 (c. {...}%) and 2021 (c. {...}%).
- (921) In October 2021, the Ministry of Health announced a single national tender, applicable as of January 2022, to cover the GA supply to all hospitals in Poland.¹⁰⁴⁶ Contracts signed with hospitals under the national tender were valid for one year but could be extended.¹⁰⁴⁷ Teva won the tender but the licensee for Synthon GA in Poland could also sign contracts with hospitals, provided that they matched the winning price offered by Teva in their tender bid.¹⁰⁴⁸ It follows from the market share data in Table 9 that Copaxone was virtually the only GA medicine sold in Poland in 2022. In the first half of 2023, Teva's market shares decreased but were still at a very high level.
- (922) Copaxone's net profit margins in Poland remained relatively stable and significant between 2015 and 2021 (between {...}% and {...}%). A noticeable dip in net profit margins can first be detected in 2022 (down to {...}%) and 2023 (down to {...}%).

¹⁰⁴⁶ ID 4896, Teva's Reply to Article 18(2) Request of 20 July 2023 (question 3), p. 7.

¹⁰⁴⁷ ID 4896, Teva's Reply to Article 18(2) Request of 20 July 2023 (question 3), p. 7. As of 20 September 2023, no follow-up national tender had been announced, see also Recital (621).

¹⁰⁴⁸ See footnote 795.

Copaxone's highest net profit margins across the observed period ({...}%) are in 2018, in the year of Synthon GA's entry. In 2023, Copaxone's net profit margins in Poland are no longer at a level that can support a strong conclusion that Teva holds a dominant position in the GA market in Poland after 2022.

- (923) Teva claims that, if Copaxone was dominant in Poland, then Copaxone's dominance would have ended "*during 2018*" because the price of Copaxone began to fall materially and Synthon GA won a material proportion of tenders.¹⁰⁴⁹ According to Teva, the latest end date for dominance in Poland is end of 2018 because the price of Copaxone was {...}% lower by then.¹⁰⁵⁰ The Commission does not dispute that the entry of Synthon GA led to significant price decreases in Poland and that Synthon GA competed against Copaxone in tenders (see Figure 17 and Recitals (630) and (631)). However, it appears that Teva claims that Copaxone ceased to be dominant as of the entry of a competitor who is capable of constraining Copaxone. Teva essentially equates dominance with monopoly power and therefore claims that dominance ends the moment that Copaxone is no longer a monopolist.
- (924) According to Teva, the fact that Copaxone's price fell by {...}% by 2018 shows the extent of the competitive pressure that Synthon GA put on Copaxone (and due to which dominance allegedly ended). Teva omits to mention that Copaxone was subject to a mandatory 25% price decrease upon Synthon GA's entry on the Polish market. This means that the price decrease by 2018 was not the result of Synthon GA's competition in tenders, but a government measure to reduce the health systems expenses on GA (which takes effect regardless of whether Synthon GA has a successful uptake on the Polish market or not).
- (925) The Commission concludes that Teva's very large market shares on the GA market and its significant net profit margins with Copaxone in Poland are such as to create a strong presumption of dominance on the Polish GA market from February 2015 and until 31 December 2022. While Teva was able to maintain very high market shares even in 2023, this came at the cost of sacrificing almost the entirety of Teva's profits (its ability to set prices above marginal costs).

7.2.1.7. Copaxone's market shares and profit margins in Spain

- (926) Table 10 shows the market shares of Teva and Mylan (the licensee of Synthon GA) in Spain in the period from 2015 to the first half of 2023.

¹⁰⁴⁹ ID 4032, Teva's Reply to the Statement of Objections, para. 423(b) and Table 6.

¹⁰⁵⁰ ID 4032, Teva's Reply to the Statement of Objections, footnote 425.

Table 10: Market shares (in DOTs) for GA in Spain

Year	Copaxone	Synthon GA
2015	{...}	{...}
2016	{...}	{...}
2017	{...}	{...}
2018	{...}	{...}
2019	{...}	{...}
2020	{...}	{...}
2021	{...}	{...}
2022	{...}	{...}
2023H1	{...}	{...}

Source: IQVIA

- (927) Until 2017, Teva was the only undertaking active on the Spanish GA market, with market shares of 100% in 2015 and 2016. Since 2017, Teva’s market shares have been steadily decreasing. However, Teva still held almost {...}% of the GA market in Spain in 2021 and even increased its market shares both in 2022 and again in the first half of 2023 ({...}%).
- (928) Synthon GA entered the Spanish GA market with a 20 mg dosage in 2017 and with a 40 mg dosage in 2018 under the brand name Glatiramero Mylan. The launch of Glatiramero Mylan 40 mg exercised noticeable competitive pressure on Teva as of 2019. Between 2017 and 2019, Teva’s market shares dropped from {...}% to {...}% and further to {...}% in 2021, to the benefit of Glatiramero Mylan. This decrease in Teva’s market shares is due to competition between Copaxone and Glatiramero Mylan in regional tenders, since losing a regional tender means losing most, if not all sales to hospitals in the relevant region. Nonetheless, in 2021, Teva still had a market share that was almost {...} of Synthon GA’s market share and Teva’s shares stabilised as of 2021, and even increased again in 2022 (up to {...}%) as well as in the first half of 2023 (up to {...}%).
- (929) Copaxone’s net profit margins in Spain remained relatively stable and significant over the Relevant Period (between {...}% and {...}%) and increased still for several years after 2015. Copaxone’s highest net profit margins across the observed period are in 2018 ({...}%), 2019 ({...}%) and 2020 ({...}%), meaning in the years following the entry of Synthon GA 40 mg in June 2018.
- (930) Teva claims that, if Copaxone was dominant in Spain, then Copaxone’s dominance would have ended “during 2018” because the price of Copaxone began to fall materially and Synthon GA won a material proportion of tenders.¹⁰⁵¹ According to

¹⁰⁵¹ ID 4032, Teva’s Reply to the Statement of Objections, para. 423(b) and Table 6.

Teva, the latest end date for dominance in the Netherlands is end of 2018 because Synthon GA “won around {...}% of tenders” in 2019.¹⁰⁵² The Commission does not dispute that the entry of Synthon GA led to tangible price decreases in Spain and that Synthon GA competed against Copaxone in tenders (see Figure 19 and Recitals (665) and (666)). However, it appears that Teva claims that Copaxone ceased to be dominant as of the entry of a competitor who is capable of constraining Copaxone. Teva essentially equates dominance with monopoly power and therefore claims that dominance ends the moment that Copaxone is no longer a monopolist.

(931) However, it is appropriate to discuss certain of Teva’s submissions on dominance in Spain already in this Section. Teva claims that Synthon GA “won almost {...}% of all tendered volumes in the year following [its] entry (i.e., in 2018), almost {...}% two years after [2019], and over {...}% three years after [2020]”.¹⁰⁵³ The Commission notes that only {...}% of Copaxone volumes in Spain are generated via tenders (see Recital (660)). Accordingly, Table 10 shows that Copaxone’s market share in Spain was at or above {...}%, despite Synthon GA winning {...}% of “all tendered volumes”. Moreover, Teva states that Copaxone lost tenders to Synthon GA “despite the fact that Copaxone reduced its price by over {...}% across this same period [2018-2020]”.¹⁰⁵⁴ The Commission notes that Copaxone’s price was subject to a 24% mandatory price decrease upon entry of Synthon GA. The price decrease of “over {...}%” was therefore to a large extent caused by a government measure to reduce the health systems expenses on GA and not only by Teva’s price reaction to Synthon GA’s competition in tenders.

(932) The Commission concludes that Teva’s very large market shares and its significant net profit margins with Copaxone in Spain are such as to create a strong presumption of dominance on the Spanish GA market for the entirety of the Relevant Period, meaning from 3 February 2015 to 7 February 2024.

7.2.1.8. Teva’s claims that market share evidence is not a reliable indicator for dominance in view of tenders

(933) Teva claims that market shares are not a reliable indicator of market power in the present case. That is because, according to Teva, first, market shares in most Relevant Member States have, since the entry of Synthon GA, been significantly driven by tenders and one should therefore assess whether rivals can effectively contest tenders against the allegedly dominant firm;¹⁰⁵⁵ second, few tenders generally account for a relatively large portion of the total volume tendered each year and it is generally accepted that in tender markets, where demand is lumpy, market shares at any given point in time will often not serve as a reliable indicator of competitive strength at that point in time;¹⁰⁵⁶ and third, tenders are sometimes longer than one year and therefore market shares at any given point in time will be, at least in part, an outcome of historic competition (including in some cases before the entry of Synthon GA), and not reflect current competition (meaning, the actual competitive constraint faced by Copaxone)¹⁰⁵⁷.

¹⁰⁵² ID 4032, Teva’s Reply to the Statement of Objections, footnote 426.

¹⁰⁵³ ID 4032, Teva’s Reply to the Statement of Objections, para. 393.

¹⁰⁵⁴ ID 4032, Teva’s Reply to the Statement of Objections, para. 393.

¹⁰⁵⁵ ID 4032, Teva’s Reply to the Statement of Objections, paras. 372, 378.

¹⁰⁵⁶ ID 4032, Teva’s Reply to the Statement of Objections, paras. 373-374.

¹⁰⁵⁷ ID 4032, Teva’s Reply to the Statement of Objections, para. 376.

- (934) The Commission notes, first and foremost, that the use of tenders is not in and by itself a sufficient condition for concluding that high market shares do not necessarily indicate the existence of significant market power. The design of the tenders (that also determines whether the incumbent will benefit from any advantages in future tenders), the frequency and relative size of tenders and the share of total demand they represent all matter in ascertaining the informative value of market shares as a proxy for market power. Rather than it being “*generally accepted that in tender markets, where demand is lumpy, market shares at any given point in time will often not serve as a reliable indicator of competitive strength at that point in time*” (emphasis added)¹⁰⁵⁸, a case-by-case assessment is necessary.
- (935) It is correct that, in the context of bidding markets, especially when all (or most) of the market demand is assigned to a single successful bidder, high market shares at a specific point in time may not necessarily be a reliable indication of significant market power. That is because contemporary market share figures might not necessarily indicate how competition will unfold when a new tender comes up, absent significant incumbency advantages and/or barriers to entry.¹⁰⁵⁹ For example, that would be the case when 100% of the market is assigned to a single winner each time a new tender is decided and each time all market participants have, *ex ante*, the same chances of winning the whole market. However, it is not a foregone conclusion that market shares fail to capture the existence of entrenched market power, in particular where they are measured over longer periods of time as in this Decision.
- (936) First, the Commission notes that, in the Relevant Member States, it is not the entire demand in that market that is tendered in a single procedure¹⁰⁶⁰. It is important to clarify that “lumpy demand” is not a binary concept. On the one extreme the entire market demand could be awarded to a single supplier for an extended period of time, whereas on the other extreme, demand could be extremely fragmented with many small tenders, each representing only a marginal fraction of total demand. The national markets for GA, like most markets, lie in between these two extremes, and certainly fall far below the extreme where the entire demand is tendered to a single supplier for an extended period of time. Table 11 presents summary statistics on the number of tenders and their relative size (the percentage of total annual demand that the tender data submitted by Teva covers– and that each individual tender represents on average) that took place in Italy, Poland and Spain between 2017 and 2021.¹⁰⁶¹
- (937) The data shows that the part of demand for GA that was assigned through a tender process was always broken down among several procurement processes, ranging from as many as 126 in Poland in 2020 to just four in Spain in 2020. On average, each individual auction represented less than 10% of the annual auctioned demand,

¹⁰⁵⁸ ID 4032, Teva’s Reply to the Statement of Objections, para. 374.

¹⁰⁵⁹ In the past, the Commission has found that, in such a case, the number of credible competitors may be a better metric of market power than market shares. See e.g. Commission decision of 17 August 2020, *Mastercard/Nets*, Case M.9744, paragraphs 61ff.; Commission Decision 19 April 2017, *Advent/International Morpho*, Case M.8258, paragraphs 161-162, and Commission Decision of 25 January 2005, *BT/Infonet*, Case M.3641, paragraph 16.

¹⁰⁶⁰ An exception to this is Poland, where a national tender for GA was awarded to Teva in 2022. However, the tender specifications gave Alvogen/Zentiva the option to match the winning price offered by Teva to continue to also supply hospitals in Poland (see footnote 795).

¹⁰⁶¹ The Commission’s analysis relies on data submitted by Teva in its Reply to the Statement of Objections. The geographic and temporal scope of the data was determined by Teva and not by the Commission. The data does not cover tenders in the Netherlands, even though tenders did take place. See also footnote 1062 for a discussion of Germany and the corresponding data. Further, the data does not cover the period in Poland in which GA was procured through a national tender (2022).

over the period under observation. Some noticeable outliers are a few sizeable tenders in Italy as well as the year 2020 in Spain where, according to the data submitted by Teva, only four tenders took place, two of which represented approximately half of the demand captured by this data for that year each. However, the Commission notes that the particular year in Spain appears in itself to be an outlier with the total demand of those four tenders representing only approximately 15% of total demand tendered in just the previous year (2019) and only approximately 13% of the Spanish GA market in the same year (2020). In short, this evidence shows that demand for GA was relatively fragmented during the period under observation.

Table 11: Summary statistics of relative size of tenders in Poland, Spain and Italy for the period 2017-2021

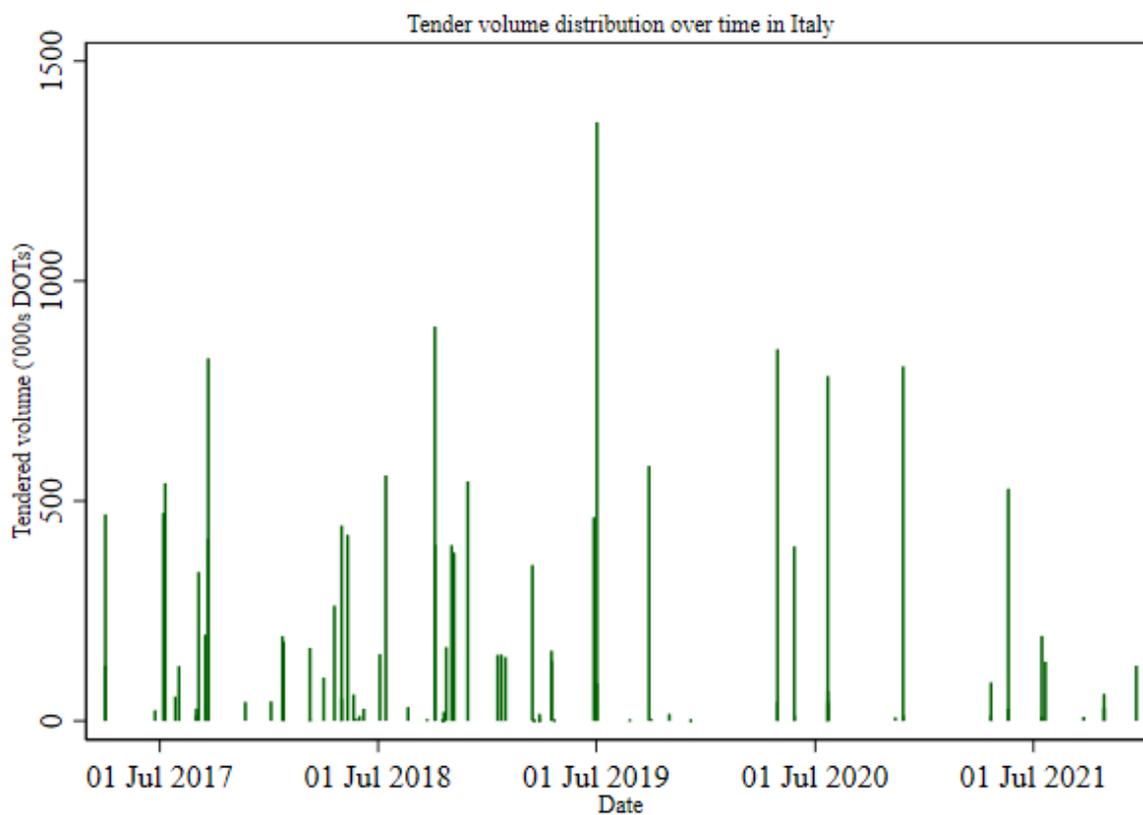
Country	Year	Count	Mean	Median	Min	Max
<i>Italy</i>	<i>2017</i>	14	7.1%	4.4%	0.3%	22.5%
<i>Italy</i>	<i>2018</i>	28	3.6%	2.2%	0.0%	16.0%
<i>Italy</i>	<i>2019</i>	18	5.6%	3.1%	0.0%	37.5%
<i>Italy</i>	<i>2020</i>	11	9.1%	1.5%	0.2%	27.6%
<i>Italy</i>	<i>2021</i>	13	9.1%	5.0%	0.8%	43.3%
<i>Poland</i>	<i>2018</i>	42	2.4%	1.3%	0.1%	10.7%
<i>Poland</i>	<i>2019</i>	114	0.9%	0.4%	0.0%	5.9%
<i>Poland</i>	<i>2020</i>	126	0.8%	0.4%	0.0%	6.1%
<i>Poland</i>	<i>2021</i>	84	1.2%	0.5%	0.0%	6.7%
<i>Spain</i>	<i>2017</i>	21	4.8%	2.4%	0.1%	28.8%
<i>Spain</i>	<i>2018</i>	13	7.7%	2.4%	0.0%	28.5%
<i>Spain</i>	<i>2019</i>	10	10.0%	7.7%	0.2%	28.0%
<i>Spain</i>	<i>2020</i>	4	25.0%	24.2%	0.5%	51.2%

Source: data included in the folder “Tender data” submitted in SO Response datapack – 10 February.

- (938) Second, concerning Teva’s argument that market shares can reflect the outcome of historic rather than current competition because tendered contracts are sometimes longer than one year, the Commission notes that market shares are by definition a measure of market outcomes. As such, market shares are by construction a summary of competitive interactions that have already taken place irrespective of whether tenders are involved or not.
- (939) In the present case, demand of GA is relatively fragmented and spread out relatively continuously across time, as shown in Figure 28, Figure 29 and Figure 30. These Figures present the distribution of tendered volumes (DOT) across time in Spain, Italy and Poland, based on the data submitted by Teva.¹⁰⁶² Even though some tenders

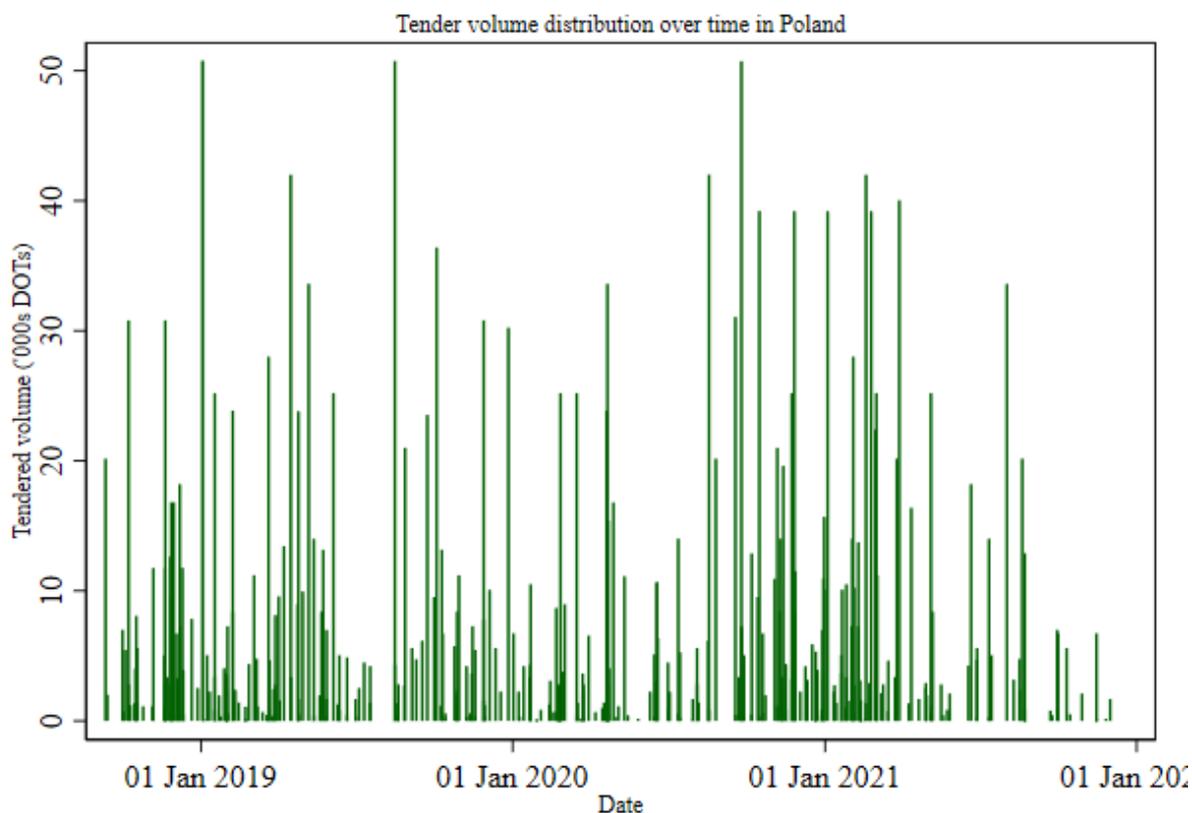
¹⁰⁶² The discussion here focuses on the three countries for which Teva submitted tender data to make the argument that Synthon GA won material share of those (see ID 4032, Teva’s Reply to the Statement of Objections, para. 390). Teva also submitted data for and discussed the German market in its Reply to the Statement of Objections (see paras. 399-405), but in that case Teva’s analysis focuses only on open-house tenders for which Synthon GA could legally compete for (meaning only for the 20 mg dosage, seeing how a preliminary injunction against Synthon GA 40 mg was in place during a significant share of the time period considered). The Commission notes that this analysis that shows that Synthon GA

Figure 29: Distribution of tendered volumes across time in Italy for the period 2017-2021



Source: data included in the folder "Tender data" submitted in SO Response datapack – 10 February.

Figure 30: Distribution of tendered volumes across time in Poland for the period 2017-2021



Source: data included in the folder “Tender data” submitted in SO Response datapack – 10 February.

- (940) Finally, the Commission notes that even if one were to conclude that market shares do not capture prevailing competition dynamics and one should instead consider the total number of credible bidders available to participate in and potentially win a forthcoming tender, the fact remains that Copaxone’s only challenger in the markets for GA is Synthon GA. The fact that Copaxone may not act as a monopolist but has to decide how to adapt its market conduct to the existence of a singular competitor, a competitor that has been targeted aggressively by the conducts discussed in this Decision, is not sufficient ground to conclude that its dominant position disappears the moment Synthon GA enters a market. Teva is still capable of behaving independently to an appreciable extent, as evidenced by its ability to maintain high market shares and very high profit margin despite the participation of Synthon GA in numerous tenders.
- (941) Teva counters that the Commission has no sound basis to ignore the evidence from tender outcomes¹⁰⁶³. According to Teva, irrespective of the “lumpiness” of demand, in a market where competition primarily takes place via tenders, tender outcomes still shed light on the competitive constraint of the Synthon GA on Copaxone at that time;¹⁰⁶⁴ and, the average proportion of demand accounted for by each tender is a

¹⁰⁶³ ID 5695, Teva’s Reply to the Letter of Facts I of 9 February 2024, para. 150, second bullet.

¹⁰⁶⁴ ID 5695, Teva’s Reply to the Letter of Facts I of 9 February 2024, para. 177.

misleading metric of the extent to which demand is concentrated across a relatively small number of tenders in this case.¹⁰⁶⁵

- (942) Neither of these arguments undermines the Commission’s analysis or conclusions. First, the Commission notes that it does not ignore the evidence on tender outcomes, as Teva claims, but rather the Commission shows that the tender processes for which data has been submitted by Teva are both relatively fragmented in terms of relative size as well as continuously distributed across time and that the sales that Synthon GA captures via these processes are, as a result, adequately represented in the market share data, as is the case in Italy. Similarly, where increased competition due to the introduction of tender processes led to an erosion of Copaxone profit margins, as in the case of Poland where Teva managed to retain its market leadership position only via a significant profit sacrifice, this was promptly reflected in the market share and profit margin data assessed (Section 7.2.1). The Commission recalls that it is Teva that claims that market share data should be ignored in favour of only considering tender data, while the Commission simply shows that such an approach is not warranted.
- (943) Second, Teva’s argument that the average proportion of demand accounted for by each tender is a misleading metric of the extent to which demand is concentrated across a relatively small number of tenders is itself misguided. In support of its thesis, Teva uses the example of a market where demand is split between two tenders, one representing 5% of the market and the other representing 95% of the market. While it is true that in that particular example the proportion of demand accounted for on average by each tender would not be representative of the sample, in none of the Relevant Member States concerned is the distribution of tenders that skewed. This is evident by the rest of the descriptive statistics listed in Table 11 and the distribution of tendered volumes across time presented in Figure 28 and Figure 30. The fact that several of the biggest tenders in each Relevant Member State **together** account for a significant portion of demand tendered,¹⁰⁶⁶ does not alter the facts that no single tender process appears to have an overbearing effect on market share outcomes and that the only competitor that Teva faces in all of those tenders is Synthon GA.
- (944) Teva further claims that it was not able to “*act to an appreciable extent independently of its rivals*” because Teva reacted to competition from Synthon GA by lowering the price for Copaxone, and because Synthon GA was able to compete effectively in tenders.¹⁰⁶⁷
- (945) This claim does not convince. First, Teva’s subjective perception of its market position in Europe – as stated in earnings calls from 2017 to 2020 – matches its situation as indicated by its market shares. Teva continuously described the market situation in Europe as “stable” and the volume decline as “modest”.¹⁰⁶⁸ For example, in its Q2 2019 earnings call Teva states that it has a “*relatively stable situation in*

¹⁰⁶⁵ ID 5695, Teva’s Reply to the Letter of Facts I of 9 February 2024, para. 178.

¹⁰⁶⁶ ID 5695, Teva’s Reply to the Letter of Facts I of 9 February 2024, para. 180.

¹⁰⁶⁷ ID 4032, Teva’s Reply to the Statement of Objections, para. 380.

¹⁰⁶⁸ ID 5199, Teva Earnings Call Q2 2017, 3 August 2017, p. 56; ID 5200, Teva Earnings Call Q4 2018, 13 February 2019, pp. 3-4; ID 5198, Teva Earnings Call Q2 2019, 7 August 2019, p. 4; ID 5198, Teva Earnings Call Q3 2019, 7 November 2019, pp. 21, 35; ID 5198, Teva Earnings Call Q4 2019, 12 February 2020, p. 39; ID 5201, Teva Earnings Call Q1 2020, 7 May 2020, p. 26; ID 5201, Teva Earnings Call Q2 2020, 5 August 2020, p. 7.

*Europe with a moderate decline*¹⁰⁶⁹ and in the Q3 2019 earnings call Teva states: “We see a very stable development in Europe. [...] If there is no new competitor coming in, then there's a high likelihood that the pricing environment will stay relatively stable. [...] In terms of share development, it looks pretty steady”.¹⁰⁷⁰

(946) Second, Teva was not a competitor among equals in tenders. As the incumbent on the GA market, Teva had a special position on the market and a special relationship with the relevant tender authorities. Evidence from internal documents indicates that Teva is likely to have influenced tenders for GA, in particular in Italy, Germany, Poland and Spain. {...}.¹⁰⁷¹ {...}. As long as Synthon or its licensees could only offer Synthon GA 20 mg – because Synthon GA 40 mg either had not been launched yet or there was a preliminary injunction in place against Synthon GA 40 mg – they could not participate in tenders with combined 20 mg and 40 ng lots.

(947) {...}.¹⁰⁷² {...}.¹⁰⁷³ {...}.¹⁰⁷⁴

(948) {...}.¹⁰⁷⁵ {...}.¹⁰⁷⁶

(949) {...} that Teva’s interference with a tender process in Spain, while ultimately not successful, caused a delay of several months before the tender contract could be executed.¹⁰⁷⁷

7.2.1.9. Teva’s claim that the Commission considers market shares and pricing evidence in isolation

(950) Teva takes issue with the Commission’s assessment of market shares and profit margins as indicators of market power by claiming that the Commission erroneously assesses the evidence in relation to price reductions (in conjunction with percentage profit margins) and market share losses over time in isolation from one another. According to Teva, the Commission finds that Teva was not dominant in (a) the Netherlands in 2018 “*due to the steep erosion of Copaxone market shares*” despite a “*relatively stable and significant*” percentage net profit margin; and (b) Poland in 2022 due to “*Teva’s profit margins decreas[ing] significantly*” despite the fact that “*Copaxone’s market shares in Poland were still at {...}% (in volume) and {...}% (in value) in the first half of 2023*”.¹⁰⁷⁸ Teva argues that it is more correct to consider the combination of price reductions and volume losses in a consolidated manner by focusing the analysis on the impact of competition on the amount of revenue lost to competition by Synthon GA.¹⁰⁷⁹ Teva proposes a methodology of comparing Copaxone revenue developments in Italy, the Netherlands, Poland and Spain against an assumed counterfactual in which Synthon GA has not entered. By assuming Copaxone pricing would remain fixed at the level prior to generic-like entry and that Copaxone would capture the entire GA demand, Teva constructs what it refers to as the share of “revenue retained” which is Teva’s real Copaxone revenues as a share of

¹⁰⁶⁹ ID 5198, Teva Earnings Call Q2 2019, 7 August 2019, p. 4.

¹⁰⁷⁰ ID 5198, Teva Earnings Call Q3 2019, 7 November 2019, p. 35.

¹⁰⁷¹ ID 404-727, Teva internal email dated 19 April 2017 from {...} to {themselves}.

¹⁰⁷² ID 455-3184, Copaxone / GA tenders, 5 April 2017, pp. 4-16, 22-24.

¹⁰⁷³ ID 455-3184, Copaxone / GA tenders, 5 April 2017, pp. 8-9.

¹⁰⁷⁴ ID 455-1967, Copaxone® - Price Competition workshop in Italy, 5 September 2017, p. 1.

¹⁰⁷⁵ ID 404-1756, Teva internal email exchange dated 15 and 29 May 2017 between {...} and others, p. 3.

¹⁰⁷⁶ ID 404-1756, Teva internal email exchange dated 15 and 29 May 2017 between {...} and others, p. 1.

¹⁰⁷⁷ ID 2763, {...} Reply to Article 18(2) Request of 11 February 2022, p. 24 (including footnote 78).

¹⁰⁷⁸ ID 5909, Teva’s Reply to the Letter of Facts II of 17 May 2024, para. 81. The quotes Teva refers to are extracts from paras. 18 and 19 of the Commission’s Letter of Facts II of 17 May 2024.

¹⁰⁷⁹ ID 5909, Teva’s Reply to the Letter of Facts II of 17 May 2024, para. 84.

this hypothetical counterfactual.¹⁰⁸⁰ According to Teva this analysis shows that the entry of Synthon GA had a significant impact on Copaxone revenues and that Teva cannot be presumed to have a dominant position by Q2 2019 in Italy, Q3 2019 in Poland and Q3 2020 in Spain.¹⁰⁸¹

- (951) For the reasons explained below, Teva’s claim that the Commission assesses market shares and profit margins in isolation from one another is incorrect. Rather, it is Teva’s analysis of “revenue retained” that blurs the lines between market shares and profit margins (pricing power) and presents a skewed picture of Teva’s market power in the GA markets, based also on an arbitrary benchmark that determines what conclusion can be drawn from the analysis.
- (952) First, the Commission does not assess market shares and profit margins in isolation from one another. If that were the case, the Commission would need to maintain a strong presumption that Teva retained its dominant position in the Netherlands and Poland during the entire Relevant Period (meaning until 7 February 2024), based on the facts that Teva maintained respectively very high prices and profit margins in the Netherlands and very high market shares in Poland. It is only by assessing market shares and profit margins together and in relation to one another that it is possible to observe that Teva’s price maintenance strategy in the Netherlands (see Recital (604)) came at the cost of a significant erosion of Copaxone market shares and that Teva was only capable of maintaining a very high market share in Poland by sacrificing almost all profits. It is under these conditions and **only** by considering market shares and profit margins **together** that the Commission cannot maintain a presumption of dominance in those two GA markets past a certain point in time. In all other Relevant Member States (with the exception of Italy from the beginning of 2022 onwards), Teva was capable of maintaining both a significant market position (market shares) and significant pricing (market) power for the entirety of the Relevant Period despite the competition it faced from Synthon GA.
- (953) Second, and with respect to the so-called analysis of “revenue retained” carried out by Teva, the Commission notes the following.
- (954) In the first place, the Commission does not contest the fact that the entry of Synthon GA had a material constraining impact on Copaxone profitability and that Teva could not behave as a monopolist in the GA market wherever Synthon GA’s entry was successful. This has been discussed in great length and detail in Section 6.3.3.4.2 (and not, as Teva suggests, only with respect to the calculation of fines¹⁰⁸²). The “revenue retained” analysis largely captures the same effect on Copaxone gross and net profits discussed in the assessment of the relevant market definition, where the Commission assesses how the entry of Synthon GA had a meaningful impact on Copaxone profitability, while the presence of other first-line DMTs did not.¹⁰⁸³ The fact remains that despite the decrease in Copaxone profits that followed the entry of Synthon GA, and the fact that Teva could no longer act as a monopolist in the GA markets, Teva still retained significant market shares and significant market power for several years after Synthon GA’s entry in all Relevant Member States, which is particularly evident when comparing to the market outcomes once a post-generic(-

¹⁰⁸⁰ For the full analysis see, ID 5909, Teva’s Reply to the Letter of Facts II of 17 May 2024, paras. 81-93.

¹⁰⁸¹ ID 5909, Teva’s Reply to the Letter of Facts II of 17 May 2024, para. 90.

¹⁰⁸² ID 5909, Teva’s Reply to the Letter of Facts II of 17 May 2024, footnote. 89.

¹⁰⁸³ See for example, Section 6.3.3.4.2.1.1, on the impact of the entry of Synthon GA on Copaxone profitability in Italy, and Sections 6.3.3.4.2.1.2 and 6.3.3.4.2.1.3, on the absence of a significant and lasting impact on Copaxone profitability from oral DMTs and Interferons, respectively.

like) entry competitive equilibrium was finally achieved (e.g. in Poland in 2023 and in Italy in 2022).

- (955) In the second place, the Commission notes that Teva’s analysis and conclusions are premised on the construction of an arbitrary benchmark value of “retained revenue” share, below which, according to Teva it cannot be presumed to have a dominant position. Teva constructs this benchmark based on Copaxone revenue developments in the Netherlands where the Commission finds that no presumption of dominance can be sustained beyond the end of 2018. According to Teva this benchmark “retained revenue” is {...}% of the total hypothetical revenue Teva would have realised in the case Synthon GA had not entered the market.¹⁰⁸⁴ According to Teva, dominance cannot be maintained in any Relevant Member State beyond the point in time when this hypothetical “retained revenue” drops below this threshold.¹⁰⁸⁵ However, the Commission notes that, first, its finding that Teva’s dominance in the Netherlands cannot be presumed to persist beyond 2018 is based on the steep erosion of Copaxone market shares that Teva experienced between 2018 and 2019 (due to its choice to pursue a price and margin maintenance strategy) and not on how Copaxone revenues developed. Teva cannot claim that the Commission’s findings in that regard offer legitimacy to the construction of a “retained revenue” benchmark at {...}% (this is the value that the “retained revenue” hypothetical line that Teva constructed for the Netherlands takes in the first quarter of 2019). Second, the choice of the Netherlands as the Member State to base the construction of a benchmark on is completely arbitrary and largely determines the outcome of Teva’s analysis. If Teva were to instead base the construction of this “retained revenue” benchmark on the Commission’s finding that Teva’s dominance in the GA market cannot be maintained beyond the end of 2021 in Italy, the corresponding threshold, based on the methodology employed by Teva, would be {...}% instead of {...}%. Based on a “retained revenue” benchmark of {...}%, and based on the methodology employed by Teva, Teva never lost its dominant position in any Relevant Member State other than Italy with the sole exception of Poland in 2022Q3 and 2022Q4.
- (956) In summary, Teva’s “retained revenue” analysis does not properly assess how Teva’s market power developed in each Relevant Member State and depends crucially on an arbitrary benchmark that lacks validity. As a result, this analysis is incapable of undermining the Commission’s correct assessment of Teva’s dominance that considers the development of Copaxone market shares and profit margins as well as the relationship between the two.

7.2.2. *Barriers to entry and expansion*

- (957) When assessing Teva’s position of dominance, the Commission also considers the existence and extent of barriers to entry and expansion on the relevant GA markets.
- (958) In that respect, the Commission considers whether the market is characterised by factors that may affect timely and sufficient entry. On a preliminary note and in view of Teva’s claims that Synthon GA did not face significant barriers to entry or expansion (see also (963))¹⁰⁸⁶, it is first necessary to clarify the following: easy

¹⁰⁸⁴ As discussed in Recital (950), Teva constructs this hypothetical counterfactual by assuming that Copaxone prices remain constant at their level before the entry of Synthon GA and that Copaxone volumes take up the entire GA market, as that developed during the period (in other words, the sum of Copaxone and Synthon GA sales).

¹⁰⁸⁵ ID 5909, Teva’s Reply to the Letter of Facts II of 17 May 2024, para. 89.

¹⁰⁸⁶ ID 4032, Teva’s Reply to the Statement of Objections, paras. 410-411.

expansion and entry in a market limits the ability of an undertaking in that market to behave independently, as applying prices or other conditions above the competitive level would attract expansion or new entry by rivals. Barriers to entry do not have to be absolute, or insurmountable, for dominance to exist.

- (959) The Commission finds that the market for GA in all Relevant Member States is characterised by high barriers to entry and expansion.
- (960) First, any potential entrant has to overcome regulatory barriers, such as obtaining a marketing authorisation and negotiating pricing and reimbursement conditions with national authorities. These regulatory barriers exist in all Relevant Member States. The barriers to obtaining a marketing authorisation are especially high for products which are not authorised as a generic medicine, but through a special procedure for hybrid medicines. As explained in Sections 4.2.2 and 6.3.2.1, the marketing authorisation for Synthon GA was assessed in a procedure for hybrid drugs with Copaxone as the reference product because of the difficulty to produce compositionally 100% identical GA.
- (961) The relevant hybrid authorisation procedure (see Section 4.2.2) requires potential entrants to a GA market to produce additional studies (pre-clinical or clinical) to prove therapeutic equivalence to the originator drug in terms of efficacy and safety (Art.10(3) Directive 2001/83/EC). In addition to the uncertainty surrounding the success in obtaining a market authorisation, the hybrid authorisation procedure is both costly and long. For example, in the case of Synthon GA, the study that ultimately showed equivalence to Copaxone (GATE study) consisted in a nine-month double-blind efficacy comparison followed by a 15-month open-label extension and was conducted with RRMS patients in Europe, Mexico, South Africa and the United States.
- (962) As such, entering the GA market entails overcoming much higher regulatory barriers than entering a market for a conventional generic medicine and much higher costs. {...} acknowledged that the development of Synthon GA cost around EUR {...},¹⁰⁸⁷ which shows that the high regulatory barriers also translate into high upfront investments. This is supported by the fact that, to date, Synthon has been the only company in the EEA to initiate (and conclude) the hybrid authorisation procedure for GA.
- (963) Teva claims that barriers to entering a market are not relevant for the assessment of dominance because Synthon GA has already entered in the Relevant Member States, or – in the case of Czechia – has at least an MA.¹⁰⁸⁸ This claim does not convince. The Commission does not consider barriers to entry (only) to assess whether Synthon GA can compete with Copaxone in the national GA markets. The Commission considers barriers to entry to assess the likelihood of new, additional entrants on the GA market. The “*likely, timely and sufficient*” entry of additional competition could deter Copaxone from exercising its market power.¹⁰⁸⁹ However, as stated above, there are significant barriers for potential competitors to enter the national GA markets.

¹⁰⁸⁷ ID 455-2158, internal chat conversation of 16 July 2019 between {...} and {...}, p. 7.

¹⁰⁸⁸ ID 4032, Teva’s Reply to the Statement of Objections, para. 407; ID 5695, Teva’s Reply to the Letter of Facts I of 9 February 2024, para. 190.

¹⁰⁸⁹ Communication from the Commission — Guidance on the Commission’s enforcement priorities in applying Article 82 of the EC Treaty to abusive exclusionary conduct by dominant undertakings (OJ C 45, 24.2.2009, p. 7-20), para. 16.

- (964) In addition to the already significant barriers to entry described above, a competitor wishing to enter the market would also have to overcome Teva's attempts to intervene in regulatory procedures for the grant of marketing authorisations. As set out in Section 5.2.3.3, Teva in particular contacted national agencies in the Netherlands, the RMS (reference Member State) in the Decentralised Procedure, to convince them of Teva's position concerning the requirements for authorising a GA.¹⁰⁹⁰
- (965) Teva also launched a number of legal actions against the grant of the MA to Synthon GA. Teva internally reported that its actions delayed launches of Synthon GA.¹⁰⁹¹ Furthermore, Teva contacted the EMA and advocated for the strictest possible requirements for the authorisation of generic-like alternatives to Copaxone.¹⁰⁹²
- (966) Therefore, any competitor willing to enter the GA market would not only have to take part in time-consuming and costly procedures, but would also risk facing repeated interferences from Teva in the process.
- (967) Second, Teva held (or was the exclusive licensee to) a number of (divisional) patents claiming exclusivity rights on the manufacturing process for GA and is still the exclusive licensee to two (divisional) patents covering the 40 mg GA dosing regimen. These patents were enforceable in all Relevant Member States. As explained by the General Court, "[t]he mere possession by an undertaking of an exclusive right normally results in keeping competitors away, since public regulations require them to respect that exclusive right".¹⁰⁹³ The General Court added in *AstraZeneca* that "Although the mere possession of intellectual property rights cannot be considered to confer such a [dominant] position, their possession is none the less capable, in certain circumstances, of creating [such] a dominant position, in particular by enabling an undertaking to prevent effective competition on the market".¹⁰⁹⁴
- (968) While EP '888 expired on 23 May 2015, the Commission finds that Teva's secondary patents, including divisional patents, significantly extended the legal uncertainty concerning the validity of patents protecting Copaxone for the duration of the Relevant Period. They were thus capable of prolonging Teva's exclusivity on the GA market, and, where preliminary injunctions were granted, actually prolonged Teva's exclusivity for the GA product concerned. Moreover, Teva's conduct obstructed effective legal review of the asserted patents as described in Chapter 9 and further protracted the legal and commercial uncertainty surrounding those patents.
- (969) Third, Copaxone's brand position confers competitive advantages on Teva that competitors cannot easily match and thus constitutes a further barrier to entry and expansion. At the time it lost patent exclusivity in 2015, Copaxone had been prescribed for over 10 years and had thus been, and still is, an established player in

¹⁰⁹⁰ ID 455-1181, Teva internal email dated 1 May 2015 from {...} to {...} and others.

¹⁰⁹¹ See Section 5.2.5 and Recital (408).

¹⁰⁹² ID 404-946, Dutch intervention, 15 October 2014; ID 455-2735, final draft letter to EMA, 20 October 2014.

¹⁰⁹³ Case T-321/05, *AstraZeneca v Commission*, paragraph 362.

¹⁰⁹⁴ Case T-321/05, *AstraZeneca v Commission*, paragraph 270; Judgment of the General Court of 12 December 2018, *Krka Tovarna Zdravil d.d.*, T-684/14, EU:T:2018:918, paragraph 128.

the treatment of MS in the Relevant Member States. As pointed out in Teva's internal training materials, "{...}"¹⁰⁹⁵

- (970) In the same vein, Copaxone's longstanding market presence allowed Teva to leverage its brand position so as to be the leader on the GA market. As described in Section 9.4.3, Teva invested significant efforts in both committing to MS and promoting the Copaxone franchise. Thanks to its investment and the success of Copaxone, during the Relevant Period, Teva enjoyed an unquestionable authority amongst professionals in the MS field and Teva even described itself as "{...}"¹⁰⁹⁶
- (971) Furthermore and as pointed out in Section 9.4.2, the pharmaceutical sector is characterised by strong inertia on the part of the prescribers, i.e. they have a "*natural' tendency to prescribe to new patients medicinal products which have proven to be successful for their previous patients*".¹⁰⁹⁷ The General Court noted in this regard that "*inertia' is a factor which is liable to reinforce the market position of an incumbent product by creating barriers to entry or expansion for competing products newly introduced on the market*".¹⁰⁹⁸ As such, prescribing doctors are unlikely to switch to a different medicine than the one they have been treating patients with in the absence of a pressing medical need and tend to prescribe the incumbent originator product.
- (972) This played in favour of Copaxone, from which prescribers would generally be unlikely to switch in the absence of medical need. In this regard, {...} (a leading KOL in Germany) explained in 2016 that one of Copaxone's major advantages lied in it being administered to MS patients for more than 20 years. Despite the availability of the GATE study, {...} concluded that at "*this point in time, I would still be reluctant to make the switch*".¹⁰⁹⁹ Similarly, a Teva sales representative from Germany reported in an internal "monthly report" from January 2017 that "{...}"¹¹⁰⁰ Physicians also report that there is a "*psychological component*" to the disease MS and that a switch in medication can unsettle patients and even trigger a relapse.¹¹⁰¹
- (973) Copaxone's brand position, in combination with inertia from prescribers, can be a significant barrier to expansion of competing GA in markets such as Germany, where doctors were free to prescribe either Copaxone or Synthon GA because both medicines were covered by open tenders under the same conditions (in particular, with the same price for the health insurer who issued the open tender, see Recital

¹⁰⁹⁵ ID 404-1677, Talking Points Clift, 24 November 2016, p. 8 (unofficial translation). Original text: "{...}".

¹⁰⁹⁶ ID 263-1255, TPE Multiple Sclerosis: 2018, February 2018, p. 14; see also ID 1135-23, Poland GTMAP for 2016, p. 10 and ID 1135-36, Poland GTMAP for 2017, p. 3, listing "{...}" as one of the critical success factors for maintaining market access. Similarly, ID 1151-5, Spain GTMAP for 2017, p. 12: "{...}".

¹⁰⁹⁷ Case T-691/14, *Servier v European Commission*, paragraph 1486.

¹⁰⁹⁸ Case T-321/05, *AstraZeneca v Commission*, paragraph 105; see also Case C-457/10 P, *AstraZeneca v Commission*, paragraph 50 where the Court concluded that "*enjoying a solid brand image and reputation, was further supported by the fact that doctors generally require time in order to learn about a new medicinal product and thus that they will hesitate to prescribe PPIs of other producers entering that market*".

¹⁰⁹⁹ ID 455-502, extract of DMSG article dated April 2016 (unofficial translation), p. 1. Original text: "*Zum jetzigen Zeitpunkt wäre ich mit einer Umstellung noch zurückhaltend*".

¹¹⁰⁰ ID 5161-265, Monatsbericht Januar: Region Süd, January 2017 (unofficial translation), p. 3. Original text: "{...}".

¹¹⁰¹ ID 455-1371, "Will the substitution exclusion list be expanded? Round Table in Frankfurt am Main", DAP Dialogue, p. 1.

(776)). In such situations, Copaxone’s brand position and prescribers’ inertia gives Copaxone a strong competitive advantage that competitors cannot easily match.

- (974) Teva claims that physicians’ inertia cannot materially impact Synthon GA because prescriptions are made at the molecule level and demand for GA is awarded via tenders.¹¹⁰² The effects of doctors’ inertia and branding are indeed stronger in Member States in which doctors are free to prescribe either Copaxone or Synthon GA, as the Commission states above. The Commission considers that the Relevant Member States in which doctors’ inertia can convey particularly strong advantages on Copaxone are Belgium and Germany.
- (975) In Belgium, physicians prescribe either Copaxone or Synthon GA by brand (as opposed to prescribing GA, by simply referencing the molecule) because the medicines are not considered automatically substitutable. In Germany, the medicines are automatically substitutable. However, due to the particularities of the German system (in particular aut-idem prescriptions and open tenders), the effects of automatic substitution are mitigated and physicians can influence which medicine their patient receives at the pharmacy. Contrary to Teva’s claims,¹¹⁰³ the Commission shows in Recital (778) that doctors frequently prevent automatic substitution in Germany.
- (976) Moreover, a strong brand position and physician’s inertia can convey advantages also in tenders. As explained above in Recitals (947) and (948), Teva had a “tender strategy” to influence tender specifications and tender outcomes. The strong brand position of the originator company, together with the fact that physicians may prefer to prescribe the established medicine due to inertia, could make tender authorities more receptive to such a strategy.
- (977) The existence of significant barriers to entry and expansion is also visible from the difficulties Synthon and other potential entrants¹¹⁰⁴ faced (and are still facing in certain Relevant Member States) when they entered or attempted to enter the GA market in the Relevant Member States.
- (978) First, Synthon (and the licensees of Synthon GA) is to date Copaxone’s sole competitor on the Relevant Member State GA markets, and in fact in the entire EEA, despite other pharmaceutical companies, such as Momenta/Sandoz having received approval and having launched a GA product in the US.
- (979) Second, the existing barriers have also contributed to preventing Synthon GA from entering or expanding in some national markets. Preliminary injunctions based on Teva’s divisional patents¹¹⁰⁵ prevented Synthon GA 40 mg from entering the Czech market during the Relevant Period and seriously delayed its entry in other markets, such as Germany and Belgium. In addition, and as explained in Section 6.3.3.4.3.1, Synthon GA and Copaxone are still not considered substitutable at pharmacy level in Belgium.

¹¹⁰² ID 4032, Teva’s Reply to the Statement of Objections, para. 409; ID 5695, Teva’s Reply to the Letter of Facts I of 9 February 2024, para. 190.

¹¹⁰³ ID 5695, Teva’s Reply to the Letter of Facts I of 9 February 2024, para. 194.

¹¹⁰⁴ Teva’s GA patents were also challenged before the EPO by two other generic manufacturers, namely the Novartis subsidiary Hexal AG and Actavis which shows their interest in removing obstacles to market entry for competing GA in the EU, see Table 13.

¹¹⁰⁵ ID 1664, {...} reply to Article 18(2) Request of 11 February 2022, p. 3; ID 2162, Teva’s reply to Article 18(2) Request of 13 July 2022.

(980) Therefore, the GA markets in the Relevant Member States are characterised by high barriers to entry and expansion. The obstacles Synthon and its licensees faced to commercialise Synthon GA, and the observation that no other competitors have to date been able to enter the market, confirm the significance of those barriers.

7.2.3. *Payers did not exercise sufficient countervailing buyer power during the Relevant Period*

(981) As laid out in Section 6.2.1 above, pharmaceutical markets are characterised by a complex demand structure. Doctors and patients are drivers of demand but are not responsible for covering the costs of (MS) treatments. The responsibility for the costs lies with the Payers (Member State authorities, procurement bodies and health insurers, see Section 4.3). Therefore, the assessment of countervailing buyer power focuses on whether Payers can limit Teva's ability to act to an appreciable extent independently in the Relevant Member States' GA markets.

(982) An originator company is usually shielded from countervailing buyer power while its drug is on-patent as it enjoys legally protected market exclusivity. Due to the regulatory mechanisms put in place by health systems in the Relevant Member States, an originator medicine such as Copaxone may be exposed to strong competition from generics upon their entry. Against the backdrop of high originator prices and margins, the change in the demand structure due to mandatory price reductions and automatic substitution rules provides strong incentives for generic or generic-like entry and may endow Payers with some degree of countervailing buyer power. Under automatic substitution rules, pharmacies and hospitals may be legally obliged to dispense the cheaper alternative of two or more substitutable drugs, even if the treating physician has prescribed the branded product. This means that producers of generic or generic-like medicines can expect their product to be dispensed in pharmacies without having to invest in costly marketing campaigns.

(983) This said, Payers depended on the existing structure of supply and were notably not able to influence the number of sources of supply of GA to counter Teva's exercise of market power. This allowed Teva to keep Copaxone prices and profit margins way above competitive levels. Therefore, Teva's market shares and profit margins, as assessed in Section 7.2.1, continue to represent reliable indicators of Teva's market power.

(984) Until Synthon GA was launched in the different Relevant Member States, Teva enjoyed full exclusivity for GA since no alternative to Copaxone existed for Payers to switch to. Moreover, because of the conduct, which the Commission considers abusive in the meaning of Article 102 TFEU (misuse of the divisional patents and dissemination of misleading information), Payers may not have been able to fully benefit in a timely manner from the competitive pressure Synthon GA would have been capable of exercising on Teva. For example, in view of the preliminary injunction prohibiting the marketing of Clift 40 mg in Germany, Payers had no choice but to continue reimbursing the much more costly Copaxone 40 mg. As to its dissemination of misleading information, Teva was targeting Synthon GA's characteristics which were a condition to the successful conclusion of its Decentralised Procedure (see Section 9.2.3.5). These characteristics were also a necessary precondition for automatic substitution, so that questioning them also questioned the basis for automatic substitution between Synthon GA and Copaxone. If the Payers were misled with respect to these characteristics, this was also likely to affect their decision to authorise automatic substitution. Therefore, Teva's messages were capable of producing exclusionary effects (see Section 9.4).

- (985) Statements from health insurers and procurement bodies confirm that they can only exercise price pressure upon entry of a generic or generic-like drug on the market. For example, according to the Health Service of the Principality of Asturias, “*where market exclusivity for medicines is concerned, the administration’s margin for ‘negotiation’ is more or less non-existent*”.¹¹⁰⁶ This is confirmed by the Dutch insurer Menzis, which states that suppliers of on-patent drugs “*have no incentive at all in our system to lower prices for a health insurance. They are directing their efforts to prescribers through visits, advertising etc. Only when a generic became available was there price pressure*”.¹¹⁰⁷ This also shows that the buyers, especially the Payers, were dependent on the existence of competitive pressure from Synthon GA and did not consider they were able to exercise any countervailing buyer power on Teva, for example by sponsoring another GA entrant.
- (986) The absence of Payers’ countervailing buyer power is also evident from Teva’s internal documents. {...}.¹¹⁰⁸ This suggests that Teva knew health insurers lacked countervailing buyer power in tender negotiations because (i) they could not afford not to procure Copaxone, which was thus a “must have” product, and (ii) they therefore had to enter open house tenders with Teva, even though health insurances would have saved on GA expenditure if they had been able to enter exclusive tenders with Synthon GA.

Assessment in the Relevant Member States

- (987) The Commission has also concluded, for each of the Relevant Member States, that the Payers did not exercise sufficient countervailing buyer power during the periods where Teva’s high market shares and profit margins created a strong presumption of dominance as determined in Section 7.2.1.
- (988) In Belgium, Copaxone was the only GA medicine on the Belgian market until August 2021. Before the entry of Synthon GA on the Belgian market, Payers could not achieve relevant savings on GA medicines.¹¹⁰⁹ When Synthon GA entered the market, Synthon GA and Copaxone were not subject to the usual mandatory 44% rebate. The Belgian authorities had introduced a new regulatory framework specifically for “complex” active substances launched as generics (meaning specifically for GA and similar drugs) that foresaw a lower mandatory rebate of 23% (see Recital (703)). Moreover, Teva influenced the decision of the Belgian medicines agency to put GA on the no-INN list (meaning that doctors are discouraged from prescribing GA by INN and automatic substitution is excluded) (see Recital (713)). Based on this, the Commission finds that, despite price control mechanisms, Payers in Belgium did not have sufficient countervailing buyer power to challenge, or offset, Teva’s market power.
- (989) In Czechia, Payers can usually exercise price pressure on medicines by changes to the authorised maximum selling price, the reimbursement price and through tenders (see Recital (744)). But Teva’s price has not significantly decreased throughout the Relevant Period, or at least not until 2022. There was no price pressure on Copaxone through tenders because Copaxone was the only GA medicine on the Czech market

¹¹⁰⁶ ID 3624, Region of Asturias’ Reply to Article 18(2) Request of 15 December 2021, p. 4 (unofficial translation, see footnote 483 for original text).

¹¹⁰⁷ ID 3625, Menzis’ Reply to Article 18(2) Request of 15 December 2021, pp. 3-4 (unofficial translation, see footnote 482 for original text).

¹¹⁰⁸ ID 262-1695, Price competition workshop – Copaxone & Lonquex, 20-21 June 2017, p. 104.

¹¹⁰⁹ ID 1529, Solidaritis’ reply to Article 18(2) Request of 15 December 2021, pp. 3-4 (questions 6 and 8).

throughout the Relevant Period. The price for Copaxone in tenders is therefore only constrained by the (high) reimbursement price for Copaxone.¹¹¹⁰ Teva also successfully avoided a price impact from the price-reference group until at least 2022 (see Recitals (758)-(761)). Czech health insurers report that due to “*obstructive behaviour of Teva*” and the absence of Remurel from the Czech market, their expenditure on GA is “*higher than it should be in other circumstances*”.¹¹¹¹ They estimate that “*potential competition could save to health insurance companies approx. 20% of expenditure of glatiramer acetate*”.¹¹¹² From this, the Commission finds that, despite the existence of price-control mechanisms, Payers in Czechia did not have sufficient countervailing buyer power to challenge, or offset, Teva’s market power.

- (990) In Germany, health insurers had no influence on the price development of Copaxone as long as there was no other GA drug on the market.¹¹¹³ Competition on the GA market only started when Synthon GA 40 mg was launched in January 2018.¹¹¹⁴ However, between June 2019 and September 2020 Copaxone was again *de facto* the only supplier on the GA market because a preliminary injunction (based on a Teva divisional patent) barred Mylan/Viatrix from selling Synthon GA (Clift) 40 mg in Germany (see Recital (787)). Teva’s strategic use of divisional patents (to achieve preliminary injunctions) created uncertainty for health insurers about the continued availability of Synthon GA on the German market. Teva used this uncertainty to delay exclusive tenders¹¹¹⁵ that it expected Synthon GA to participate in (“{...}”¹¹¹⁶) or deter insurers from organising exclusive tenders altogether and opt for open tenders instead (which generally result in lower price reductions compared to exclusive tenders). {...}.¹¹¹⁷ Teva also launched the aut-idem campaign and the promotion of the Copaxone SDD/PEN to further limit substitution between Synthon GA and Copaxone, and thereby limited the negotiating power of the health insurers on Teva (see Recitals (809) to (812)).
- (991) Similarly, even government authorities in Germany had difficulties to enforce their pricing decisions against Teva. As of October 2016, a mandatory 10% rebate should have applied to Copaxone due to the entry of Synthon GA 20 mg. Teva engaged in discussions with the relevant German authority, GKV-SV, and challenged the finding that Synthon GA had the same active ingredient as Copaxone. In the end, the rebate was only applied as of July 2018 (in the form of a voluntary price decrease of Copaxone by {...}%).¹¹¹⁸ The entry of generic or generic-like competition in Germany usually leads to significant price decreases of – on average – more than

¹¹¹⁰ ID 1295-45, Teva’s reply to Article 18(2) Requests of 22 October and 18 November 2021, p. 4 (question 5e).

¹¹¹¹ ID 1276, VOZP’s Reply to Article 18(2) Request of 15 December 2021, pp. 1-2. See also Recital (748).

¹¹¹² ID 1155, OZP’s to Article 18(2) Request of 15 December 2021, p. 3. See also Recital (748).

¹¹¹³ ID 1258, GKV-Spitzenverband’s reply to Article 18(2) Request of 15 December 2021, p. 1.

¹¹¹⁴ Synthon GA 20 mg was launched in October 2016 but its uptake was limited because Teva had already converted patients to the 40 mg version of Copaxone. See ID 2763, {...} reply to Article 18(2) Request of 11 February 2022, p. 15 (paragraph 53).

¹¹¹⁵ Exclusive tenders usually achieve higher price reductions than open tenders. But they also make a health insurer dependent on only one supplier.

¹¹¹⁶ ID 404-727, Teva internal email dated 19 April 2017 from {...} to {themselves}, p. 2; see also ID 455-460, Teva internal email dated 18 April 2017 from {...} to {...} and others, p. 1: “{...}”, see footnote 931.

¹¹¹⁷ ID 404-86, Teva internal email dated 22 August 2018 from {...} to {...}, see Recital (804).

¹¹¹⁸ ID 404-1631, Teva internal email exchange dated 29-30 May 2018 from {...} to {...} and others; ID 404-93, Copaxone® EU Litigation Internal Update, 31 August 2018, pp. 1-2: see also Recital (789).

35% compared to the initial price of the originator drug.¹¹¹⁹ Overall, the entry of Synthon GA led to a {...}% price decrease for Copaxone where it is sold in open house tenders (see Recital (790)). Copaxone’s price decrease in Germany thus stayed well below the usual price decrease after Synthon GA’s entry. From this, and the fact that Teva was able to maintain relatively stable profit margins throughout most of the Relevant Period, the Commission finds that, despite the existence of price-control mechanisms, Payers in Germany did not have sufficient countervailing buyer power to challenge, or offset, Teva’s market power.

- (992) In Italy, Copaxone only faced price pressure after Synthon GA 40 mg (Copemyltri) was launched and included on the so-called transparency list.¹¹²⁰ It was only then that Copaxone started facing competition in tenders.¹¹²¹ Initially, the Italian authority (AIFA) had decided not to include Copaxone and Synthon GA on the transparency list. Before that decision, Teva had interactions with the relevant authority, in which it argued that Copaxone and Synthon GA were similar but not identical, and that they should therefore be treated analogously to biosimilars which were not automatically substitutable (instead of being treated like generics).¹¹²² Copaxone and Synthon GA (both strengths) were only included on the transparency list in March 2019.¹¹²³
- (993) Even when Copaxone competed against Synthon GA in tenders in Italy, Teva’s strategy was to protect its price. In a 2017 presentation titled “Copaxone Tender Update”, Teva makes the following statement on competition between Copaxone 20 mg and Synthon GA 20 mg: “{...}” (emphasis added).¹¹²⁴ Moreover, the Commission has already shown in Recital (946) that Teva is likely to have influenced tender specifications for GA in Italy with the aim of excluding Synthon GA from tenders. Based on this, the Commission finds that, despite the existence of price-control mechanisms, Payers did not have sufficient countervailing buyer power to challenge, or offset, Teva’s market power for a large part of the Relevant Period in Italy. While Payers’ buyer power may have increased towards the end of the Relevant Period in 2021 (when tenders and automatic substitution rules started to show an effect in Synthon GA’s market shares), this does not suggest that the end of the Relevant Period in Italy is earlier than 31 December 2021. The key indicators for dominance remain market shares combined with profits. As the Commission concludes in Recital (911), Teva’s very large market shares and significant net profit margins create a strong presumption of dominance on the Italian GA market until the end of the calendar year 2021.
- (994) In the Netherlands, health insurers could only exert competitive pressure on Teva once their preference policies for Synthon GA (comparable to exclusive tenders) took effect. After the market entry of Synthon GA 40 mg in January 2018, the main health insurers in the Netherlands entered into preference policies with Mylan/Viatrix for Synthon GA. Throughout 2018, Teva sought to influence the health insurers’ preference policy, requesting initially not to apply the preference policy to the existing patients and later, requesting to terminate the preference policy for GA

¹¹¹⁹ ID 1281, AOK Bundesverband’s Reply to Article 18(2) Request of 15 December 2021, p. 4.

¹¹²⁰ Shortly after the entry of Synthon GA 20 mg, Teva had converted {...} of patients to the 40 mg version of Copaxone. ID 455-3332, email dated 19 April 2017 from {...} to {...} and others.

¹¹²¹ ID 1295-41, Teva’s reply to Article 18(2) Requests of 22 October and 18 November 2021, p. 7. See also Recital (569).

¹¹²² ID 655, Teva’s reply to Article 18(2) Request of 3 June 2021 (Annex Q39), p. 11.

¹¹²³ ID 906, Teva’s reply to Article 18(2) Request of 3 June 2021, p. 19.

¹¹²⁴ ID 455-2214, Copaxone Tender Update, 5 September 2017, p. 9.

medicines altogether.¹¹²⁵ Health insurers in the Netherlands submitted in their replies to the Commission’s Article 18(2) Requests that Teva’s interventions delayed the implementation of preference policies by six to nine months.¹¹²⁶ {...} further stated that Teva’s patient support programme was contracted to a third-party company called “Eurocept”. Eurocept requested neurologists to supply them with Teva’s products instead of the product agreed on in the preference policy of a patient (which was Synthon GA). This issue persisted until 2019, when Mylan’s patient support programme was more established and prescriptions to Eurocept became less frequent.¹¹²⁷ From this, the Commission finds that, despite the existence of price-control mechanisms, Payers in Netherlands did not have sufficient countervailing buyer power to challenge, or offset, Teva’s market power until the end of the calendar year 2018 (the end of the Relevant Period in the Netherlands).

- (995) In Poland, Copaxone only faced price pressure in tenders after Synthon GA 40 mg was launched in July 2018. Not only had Teva converted {...}% of its patients in Poland to Copaxone 40 mg by the time that Synthon GA 20 mg was launched in 2017,¹¹²⁸ but Synthon GA was also barred from participating in a number of tenders for the 20 mg strength because the tender requirements stated that suppliers had to be able to provide both dosage strength.¹¹²⁹ Moreover, the Commission has already shown in Recital (946) that Teva is likely to have influenced tender specifications for GA in Poland with the aim of excluding Synthon GA from tenders. From this, the Commission finds that, despite the existence of price-control mechanisms, Payers in Poland did not have sufficient countervailing buyer power to challenge, or offset, Teva’s market power for a large part of the Relevant Period in Poland. While Payers’ buyer power may have increased towards the end of the Relevant Period in 2022 (when competition in the national tender started to show an effect in Copaxone’s decreased profit margins), this does not suggest an earlier end of the Relevant Period in Poland. Teva’s very large market shares and significant net profit margins create a strong presumption of dominance on the GA market in Poland until the end of the calendar year 2022 (see Recital (925)).
- (996) In Spain, Copaxone only faced price pressure in tenders after Synthon GA 40 mg was launched in June 2018. By the time Synthon GA 20 mg was launched in Spain in 2017, Teva had converted {...}% of its patient base in Spain from the 20 mg dosage to the 40 mg dosage, and by July 2017, {...}% of Copaxone patients were converted to the 40 mg dosage.¹¹³⁰ Moreover, the Commission has already shown in Recital (946) that Teva is likely to have influenced tender specifications for GA in Spain with the aim of excluding Synthon GA from tenders. From this, the Commission finds that, despite the existence of price-control mechanisms, Payers in Spain did not have sufficient countervailing buyer power to challenge, or offset, Teva’s market power.

¹¹²⁵ ID 3584, email dated 27 February 2019 from {...} to {...}: see also ID 404-1637, Teva internal email dated 21 February 2018 from {...} to {...} (see footnote 1610 of the SO).

¹¹²⁶ ID 1235, {...} reply to Article 18(2) Request of 15 December 2021, p. 3 (question 10); ID {...}, email dated 10 December 2018 by {...} to {...} (both {...}). Submitted as part of {...} reply to Article 18(2) Request of 15 December 2021.

¹¹²⁷ ID {...}.

¹¹²⁸ ID 455-2027, Copaxone Poland Update 21/09/2017, 21 September 2017, p. 5.

¹¹²⁹ ID 1664, {...} reply to Article 18(2) Request of 11 February 2022, p 5.

¹¹³⁰ ID 2763, {...} reply to Article 18(2) Request of 11 February 2022, p. 23.

- (997) Teva claims that it engaged in competitive pricing responses in Spain, Italy, Poland and Germany after the entry of Synthon GA.¹¹³¹ According to Teva, if Copaxone were able to “*act to an appreciable extent independently of its rivals*” the evidence should show that, after Synthon GA’s entry, (i) Copaxone did not react by materially lowering its prices, and (ii) Synthon GA was unable to compete effectively for tenders.¹¹³²
- (998) Teva’s line of argumentation essentially amounts to equating the concept of dominance to that of an outright monopoly. According to Teva, as long as the entry of Synthon GA elicits a material price decrease by Copaxone – previously unrivalled in the market for GA - and as long as Synthon GA manages to win some tenders, no finding of dominance can stand.
- (999) With respect to prices, Teva argues that Copaxone engaged in competitive pricing responses in Spain, Italy, Poland, and Germany after the entry of Synthon GA which, according to Teva, indicates that Synthon GA exerted an effective competitive constraint on Teva shortly after entry.¹¹³³ The Commission notes that a price decrease does not necessarily entail a significant loss of market power (the ability to set prices above marginal costs). Figure 31 shows the corresponding net profit margins for Copaxone. This figure shows that the price decreases in these four Relevant Member States in the first four years following the entry of Synthon GA are not necessarily indicative of a significant decrease in market (pricing) power. In fact, Copaxone’s variable costs also decreased significantly and (net) profit margins remained mostly unchanged.¹¹³⁴ The margins in Germany and Spain even increased. The decrease in Italy was negligible at just {...}%. In Poland, margins decreased noticeably but only by {...}%. It is only in the fifth and sixth year after Synthon GA’s entry in Italy and Poland (years 2022 and 2023) that a noticeable dip in profit margins can be detected. Profit margins in Germany and Spain remain relatively

¹¹³¹ ID 4032, Teva’s Reply to the Statement of Objections, paras. 385-387.

¹¹³² ID 4032, Teva’s Reply to the Statement of Objections, para. 379.

¹¹³³ ID 4032, Teva’s Reply to the Statement of Objections, paras. 385-387 and Figure 6.

¹¹³⁴ In the Letter of Facts I of 9 February 2024 the Commission observed that “*the price decreases in these four Relevant Member States in the first four years following the entry of Synthon GA are not necessarily indicative of a significant decrease in market (pricing) power since they appear to be driven by corresponding decreases in costs, leaving profit margins unchanged*” (emphasis added). Teva correctly noted in its Reply to the Letter of Facts I of 9 February 2024 (ID 5695, paras. 160-169) that the price decreases cannot be fully attributable to the decreases in variable costs since there is no one-to-one correspondence between the two which would in turn entail unrealistically high cost pass-on rates. Teva further submitted that whilst it is correct to observe that Teva’s costs fell over the period that it was reducing its prices, the inference that an exogenous reduction in costs caused the reduction in prices is incorrect and that a material portion of the cost reduction was due to royalty payments falling over time because of the (expected) entry of Synthon GA. According to Teva this means that the reduction in prices and at least part of the reduction in costs observed were a reaction to the entry of Synthon GA (ID 5695, Teva’s Reply to the Letter of Facts I of 9 February 2024, paras. 157-159; ID 5909, Teva’s Reply to the Letter of Facts II of 17 May 2024, paras. 60-71). The Commission notes that it never claimed or assumed, as Teva implies, that the observed cost reductions were exogenous. On the contrary, it has been discussed in some detail how Copaxone’s cost structure has changed materially in relation to the commoditisation of the GA market (see Section 6.3.3.2.4.3.3). Similarly, the fact that Teva had an agreement to gradually decrease royalty payments as the impending loss of Copaxone exclusivity drew nearer can more accurately be considered as a (planned) consequence of the anticipated shift in the nature of competition faced by Copaxone rather than, as Teva suggests, as a competitive reaction to the entry of Synthon GA. In any event, the fact remains that variable costs decreased as the nature of competition in the GA market(s) shifted and Teva’s ability to set prices above variable costs (a direct measure of market power) remained relatively constant during this time, despite the observed decrease in average prices.

constant during the entire period under observation. For the sake of completeness, the Commission presents also the evolution of absolute net profit margins (as opposed to the change compared to 2016 values) for all Relevant Member States (as opposed to only Germany, Italy, Poland and Spain) in Figure 32 and Table 12. These figures have been discussed in some detail already in Section 7.2.1 above. The evidence shows that Teva was able to profitably maintain prices above the competitive level for a significant period, thereby providing further support to the conclusion that during the Relevant Period the competitive pressure that Copaxone faced from Synthon GA was not (yet) capable of materially limiting its market power.¹¹³⁵ In summary, while the competitive constraints that Synthon GA exercised on Copaxone were material, leading to meaningful price reductions in those Relevant Member State where Teva chose to engage in price competition, Teva still maintained significant market power for the periods laid out in Recital (1011).

Figure 31: Net profit margin* of Copaxone following Synthon GA entry in the tendering Relevant Member States

{...}

Source: Annex RFI7Q1a - RFI3Q2 follow-up.xlsx; * Operating profits before R&D and G&A over Net Revenues

Figure 32: Copaxone net profit margins

{...}

Source: Commission calculations based on ID 5710, Teva's Reply to the Letter of Facts I of 9 February 2024, data pack, file "Annex RFI9Q7 - RFI3Q2 follow-up.xlsx".

Table 12: Copaxone net profit margins

	Year										
	2013	2014	2015	2016	2017	2018	2019	2020	2021	2022	2023
Belgium	{...}	{...}	{...}	{...}	{...}	{...}	{...}	{...}	{...}	{...}	{...}
{...}	{...}	{...}	{...}	{...}	{...}	{...}	{...}	{...}	{...}	{...}	{...}
{...}	{...}	{...}	{...}	{...}	{...}	{...}	{...}	{...}	{...}	{...}	{...}
{...}	{...}	{...}	{...}	{...}	{...}	{...}	{...}	{...}	{...}	{...}	{...}
{...}	{...}	{...}	{...}	{...}	{...}	{...}	{...}	{...}	{...}	{...}	{...}
{...}	{...}	{...}	{...}	{...}	{...}	{...}	{...}	{...}	{...}	{...}	{...}
{...}	{...}	{...}	{...}	{...}	{...}	{...}	{...}	{...}	{...}	{...}	{...}

¹¹³⁵ In the its Reply to the Letter of Facts I of 9 February 2024 (ID 5695, Figure 2 and paras. 162-163), Teva adds that Copaxone **absolute** net profit margins per DOT ($p - c$, measured in EUR/DOT terms), as opposed to net profit margins ($p - c/p$), also dropped during the same period. Teva repeats its argument that one needs to consider absolute net profit margins instead of net profit margins also in its Reply to the Letter of Facts II of 17 May 2024 (ID 5909, paras. 60-75). The Commission does not contest that the entry of Synthon GA had some negative impact on Copaxone profitability. This has been discussed in detail in Section 6.3.3.4. Figure 2 of the Reply to the Letter of Facts I of 9 February 2024 (reproduced as Figure 3 in the Reply to the Letter of Facts II of 17 May 2024) captures the same effect as that presented in Figure 14, Figure 16, Figure 18, Figure 20, Figure 22 and Figure 26 of this Decision. Figure 6 of Teva's Reply to the Statement of Objections (ID 4032) similarly captures part of the same effect. The fact that Copaxone profitability, in absolute terms, was diminished following the commoditisation of GA products (mainly due to partly a price effect and partly a volume effect) is undisputed. However, this absolute measure of profitability does not capture or contradict the fact that Teva maintained the ability to set prices significantly above variable costs, still exercising significant market power under the new market conditions that prevailed following the generic-like entry of Synthon GA.

Source: Commission calculations based on ID 5710, Teva's Reply to the Letter of Facts I of 9 February 2024, data pack, file "Annex RFI9Q7 - RFI3Q2 follow-up.xlsx"; in shaded background the period after the (first) entry of Synthon GA in respective country.

(1000) Under these circumstances, the Commission concludes that there is no sufficient countervailing buyer power to challenge, or offset, Teva's market power in any of the Relevant Member States during the respective periods that the Commission finds a strong presumption of dominance. In other words, the countervailing buyer power is not sufficient to disqualify Teva's market shares and net profit margins (see Section 7.2.1) as a relevant and reliable indicator of Teva's market power. The buying position of Payers and other drivers of demand depends on the prevailing market conditions, which they have not been able to influence in order to counter Teva's market power.

7.2.4. Teva's acknowledgement of its own dominant position

(1001) The findings concerning Teva's dominance in the GA markets in the Relevant Member States are further corroborated by the fact that Teva itself acknowledges its dominant position and is aware of the special responsibility of an undertaking in such a position.

(1002) In an internal Teva email exchange of 16 March 2016, which contains the minutes of a meeting, a Teva employee noted that the {...} stated that: "{...}" (emphasis added).¹¹³⁶

(1003) An internal Teva document containing the minutes of a meeting that took place on 12 May 2016 further paraphrased statements from "Legal" (meaning Teva's legal team) as follows: "{...}" (emphasis added).¹¹³⁷

(1004) {...}.¹¹³⁸

(1005) An email from {...} in the Netherlands from January 2018 is another example of internal acknowledgement that Teva had a dominant position on the GA market. {...}.¹¹³⁹ {...}.¹¹⁴⁰

(1006) Teva claims that the Commission fails to rely on documents with "any real evidential value" to demonstrate that Teva acknowledged a dominant position.¹¹⁴¹ First, Teva argues that the Commission "makes no assessment of the origin, authors, and recipients of each document" and does not take into account the context in which the documents were drafted.¹¹⁴² Second, Teva argues that the Commission "does not refer to a single document setting out even the beginning of an assessment, by Teva or a third party of whether Teva holds a dominant position."¹¹⁴³

(1007) Teva's claim does not convince. First, the Commission has assessed the authors and recipients of the above-mentioned documents and has taken into account their

¹¹³⁶ ID 404-2555, Teva internal email dated 16 March 2016 from {...} to {...} and others, p. 1.

¹¹³⁷ ID 404-1260, Notulen Sales Team meeting CNS 12 mei 2016, 4 May 16, p. 1 (unofficial translation). Original text: "{...}".

¹¹³⁸ ID 262-1695, Price competition workshop – Copaxone & Lonquex, 20-21 June 2017, p. 104.

¹¹³⁹ ID 404-1796, Teva internal email dated 30 January 2018 from {...} to {...} and others, p. 1 (unofficial translation). Original text: "{...}".

¹¹⁴⁰ ID 264-825, Copaxone Continuation Plan – Projekt Charter, 9 August 2016, p. 42 (unofficial translation). Original text: "{...}".

¹¹⁴¹ ID 4032, Teva's Reply to the Statement of Objections, para. 420.

¹¹⁴² ID 4032, Teva's Reply to the Statement of Objections, para. 413.

¹¹⁴³ ID 4032, Teva's Reply to the Statement of Objections, para. 414.

context. In particular, the Commission carries out an assessment of each document concerning “*the origin of the document, the circumstances in which it was drawn up, the person to whom it was addressed and its content, and whether, according to those aspects, the information it contains appears sound and reliable*” (as required by case-law¹¹⁴⁴) before relying on it as evidence. The Commission has verified the positions and areas of expertise of the relevant Teva employees before relying on their statements. All of the above-mentioned statements originate from Teva’s internal documents, which means that Teva in any event knows (or can easily determine) the positions and area of expertise of the relevant Teva employees.

- (1008) For example, with regard to the document cited in Recital (1002), the Commission has relied on an email sent by the {...}. {...} are Teva employees whose area of expertise is to assess Teva’s position on the market. The context of the document is therefore such that “*the information it contains appears sound and reliable*”.
- (1009) Second, Teva sets unreasonably high standards for documents to have “*any real evidential value*” for the finding of dominance by requiring evidence that shows a full legal assessment of dominance “*by Teva or a third party*”. Such an assessment – if carried out by a third party – would likely be legally privileged and not accessible to the Commission. Regarding assessments carried out by Teva itself, Teva explains that “*it is common practice for large companies to assume a position of dominance on a conservative basis*”¹¹⁴⁵, that it is “*legitimate for a legal team to envisage that the company might hold a dominant position*” (original emphasis)¹¹⁴⁶ which the legal team may then disseminate as “*overly conservative guidance*”¹¹⁴⁷ and that “*to be practical, both concepts [dominance and abuse] are often simplified to a level that can be easily understood by non-specialists*”¹¹⁴⁸. With these arguments, Teva paints the picture that statements on dominance within Teva cannot be assumed to be the result of a full legal assessment of dominance by Teva’s legal team. This would mean that the Commission cannot rely on any internal statements from Teva on dominance because they are allegedly “*overly conservative*” and “*simplified*” nor can the Commission rely on third-party legal assessments because these documents likely fall under legal privilege. It follows that Teva has set the standard for evidential value of internal documents to corroborate the finding of dominance so high that it cannot be met.
- (1010) The Commission does therefore not follow Teva in this standard. The documents presented in this Section have been carefully analysed for their evidential value. The evidence shows that Teva consistently referenced its special position in the GA market in several documents stemming from different internal Teva teams. The Commission relies on statements from Teva’s higher management ({...}) and from the legal teams (including the local legal teams). Therefore, Teva’s argument that the statements are made by “*a small number of employees*”¹¹⁴⁹ does not convince. Moreover, this evidence of Teva’s subjective view on its market position, while in itself not sufficient for the finding of a dominant position in the GA market,

¹¹⁴⁴ Judgment of the Court of First Instance of 13 December 2018, *Iran Insurance Company v Council*, T-558/15, EU:T:2018:945, paragraph 154 and the case-law cited.

¹¹⁴⁵ ID 4032, Teva’s Reply to the Statement of Objections, para. 415.

¹¹⁴⁶ ID 4032, Teva’s Reply to the Statement of Objections, para. 416.

¹¹⁴⁷ ID 4032, Teva’s Reply to the Statement of Objections, para. 417.

¹¹⁴⁸ ID 4032, Teva’s Reply to the Statement of Objections, para. 418.

¹¹⁴⁹ ID 4032, Teva’s Reply to the Statement of Objections, para. 419.

corroborates the Commission's above findings based on the assessment of objective evidence.

7.3. Conclusions on dominance

(1011) In view of (i) Copaxone's consistently very large market shares and significant net profits in Belgium, Czechia, Germany and Spain for the entirety of the Relevant Period, i.e. from 3 February 2015 to 7 February 2024, as well as in the Netherlands from 3 February 2015 to 31 December 2018, in Italy from 3 February 2015 to 31 December 2021 and in Poland from 3 February 2015 to 31 December 2022, (ii) the high barriers to entry and expansion characterising the GA markets, (iii) the lack of sufficient countervailing buyer power and (iv) Teva's internal documents referring to its dominance and corroborating the Commission's analysis, the Commission concludes that:

- Teva has held a dominant position within the meaning of Article 102 of the Treaty on the GA market in Belgium, Czechia, Germany and Spain for the entirety of the Relevant Period.
- Teva held a dominant position on the GA market from 3 February 2015 until 31 December 2018 in the Netherlands.
- Teva held a dominant position on the GA market from 3 February 2015 until 31 December 2021 in Italy.
- Teva held a dominant position on the GA market from 3 February 2015 until 31 December 2022 in Poland.

8. FIRST ABUSE: MISUSE OF DIVISIONAL PATENTS

(1012) In this chapter, the Commission sets out the reasons supporting the conclusion that Teva has committed an abuse of its dominant position in breach of Article 102 TFEU in the markets for GA in the Relevant Member States by misusing the patent system and gaming patent procedures. Teva's abusive conduct consisted in filing multiple, staggered divisional patents with overlapping content and then strategically withdrawing challenged patents before a reasoned decision on their validity could be issued. This recurrent conduct, by avoiding the precedents that such reasoned decisions would establish, artificially prolonged legal uncertainty about the validity of Teva's exclusive rights flowing from its remaining divisional patents. In turn, this conduct enabled Teva to assert its remaining divisional patents against its competitors, Synthon and its licensees in particular.¹¹⁵⁰ This conduct cannot be considered as competition on the merits and is capable of hindering and/or delaying the market entry and expansion of competing GAs on the relevant markets, thereby eliminating price competition.

(1013) First, in Section 8.1, the Commission provides an overview of Teva's strategy and conduct regarding its divisional patents (Teva's "divisionals game"). Second, in Section 8.2, the Commission describes the legal and economic context within which Teva's first abuse has been taking place. Third, in Section 8.3, the Commission establishes that Teva's conduct, considered as a whole and comprising recurrent and staggered patent filings and strategic withdrawals, which aimed at hindering and/or

¹¹⁵⁰ Synthon GA is the only generic-like GA drug authorised in the Relevant Member States and the only GA product competing with Copaxone in the EU in the Relevant Period (see in particular Section 7.2.1).

delaying market entry and expansion of competing GAs, falls outside the scope of competition on the merits. More specifically, Teva multiplied divisional patents with that shared essential features by filing them in a staggered manner and obstructed their legal review by strategically withdrawing the challenged patents before such review had been concluded (i.e. withdrawing immediately before a reasoned decision by the TBA and while another patent with overlapping claims was still in place). Teva's conduct has been carefully timed to maximize delays in the legal reviews of its patents (and, thereby, hindering competition). In addition, since Teva has put forward arguments in that regard, the Commission will rebut Teva's claims as regards the existence of an alleged plausible explanation for its conduct. Fourth, in Section 8.4, the Commission demonstrates that Teva's conduct is capable of having anticompetitive effects and finally, in Section 8.5 the Commission explains that there are no objective justifications for Teva's conduct and that it does not generate efficiencies. Section 8.6 concludes this chapter.

8.1. Overview of Teva's divisionals game

- (1014) In 1987, Yeda Research & Development Co. Ltd. ("Yeda") concluded a licensing agreement with Teva according to which Yeda granted Teva an exclusive license to develop, manufacture and market drugs for the treatment of MS based on the compound known as GA.
- (1015) The main patent protecting the composition of GA within a specific molecular weight range – EP 0 762 888 ("EP '888") – was filed by Yeda on 23 May 1995, was granted by EPO on 6 February 2002 and expired on 23 May 2015.
- (1016) In 2005, Teva filed a secondary patent relating to claimed improvements in the manufacturing process, i.e. the process parent patent EP 1 799 703 (the "Original Process Patent" or "EP '703"), before the EPO. The Original Process Patent was granted by the EPO on 6 January 2010. On 5 January 2010, five years before the expiry of EP '888 and just one day *before* the grant of the Original Process Patent, Teva started filing divisional process patents. The Original Process Patent together with the divisional patents filed on its basis form the "process patent family".
- (1017) In 2010, Teva¹¹⁵¹ also filed a secondary patent relating to a new dosing regimen (40 mg instead of 20 mg) of GA, i.e. the dosage parent patent EP 2 405 749 (the "Original Dosage Patent" or "EP '749") before the EPO. The Original Dosage Patent was granted by the EPO on 8 May 2013. On 30 April 2013, just eight days before the grant of the Original Process Patent, Teva started filing divisional dosage patents. The Original Dosage Patent, together with the divisionals filed on its basis, form the "dosage patent family".
- (1018) The divisional patents forming the process and dosage divisional patent families were filed over the course of eight years – between 2010 and 2018.¹¹⁵² The intervals between the filings were not driven by any ongoing research. Facts relevant for the filings of the divisional process and dosage patents had been known already since the date of the filing of the Original Process Patent (i.e. in 2005) and the Original Dosage Patent (i.e. in 2010), respectively.¹¹⁵³ In addition, the differences between the divisional patents filed in the respective patent families were marginal. Key Teva

¹¹⁵¹ Yeda is the ultimate holder of five dosage patents but the right to decide on the filing of the patent applications as well as on the enforcement and withdrawal of these patents is reserved to Teva. ID 656, Teva's reply to Article 18(2) Request of 3 June 2020, question 23, p. 86: {...} {...}.

¹¹⁵² See Figure 35 and Figure 36.

¹¹⁵³ See Section 8.3.6.2.

employees had doubts about the validity of the two original parent patents (i.e. the Original Process Patent and the Original Dosage Patent) and did not believe that they would survive challenges before the EPO (see Section 8.3.3.3). Moreover, since the divisional patents shared essential features and their ingrained weaknesses with their respective parent patents, key Teva employees did not believe that the divisional patents would survive challenges before the EPO either.¹¹⁵⁴

- (1019) Teva's strategy and conduct as regards patents in the process and dosage families was aimed at blocking or delaying market entry by potential GA entrants and by Synthon GA in particular.¹¹⁵⁵ Thus, by staggering the filing of divisional patents Teva obtained staggered grant dates, which in turn resulted in staggered opposition and appeal procedures, since potential GA entrants had to overcome Teva's patents in order to enter the market. Accordingly, potential GA entrants had to repeatedly challenge each single patent in the respective patent family. In addition to these staggered patent filings, Teva strategically withdrew the challenged patents before the adoption of a reasoned revocation decision of those challenged patents by the TBA, while making sure that another patent with overlapping claims remained in place in the respective patent family.¹¹⁵⁶
- (1020) A reasoned revocation decision would have had a strong precedent effect on the remaining divisional patents of the same patent family and could have been relied on at least as persuasive evidence by potential GA entrants in proceedings before EPO bodies and national courts concerning those remaining divisional patent(s).¹¹⁵⁷ Indeed, all patents within the same patent family of the challenged patent would be affected by the same weaknesses as regards their shared essential features and would as likely be revoked on that basis.¹¹⁵⁸
- (1021) By staggering its patent filings¹¹⁵⁹ and withdrawing the challenged patents at strategic moments, Teva extended the overall duration of uncertainty regarding the validity of its patent rights and thus uncertainty about the possibility for potential GA entrants to enter the market. Teva's conduct forced potential GA entrants to challenge patents one by one during a protracted period of time, effectively making it impossible for those GA entrants to achieve a timely revocation of these patents and to remove legal uncertainty. In the meantime, while Teva still had process and dosage patents in force, GA entrants could be (and actually were in certain Relevant Member States) subject to preliminary injunctions, granted on the basis of those patents, delaying the launch of their generic-like version of GA.

¹¹⁵⁴ See Section 8.3.3.

¹¹⁵⁵ Teva's patents in the process and dosage families were not targeting Synthon GA specifically but aimed at blocking entry of any potential entrant with a competing GA product (see Section 5.2 describing the CCP, its components and its aims). However, since Synthon and its licensees are to date Teva's only competitors on the Relevant Member State GA markets, and in fact in the entire EEA (see Section 7.2), Synthon GA was a natural, immediate target of Teva's divisionals game.

¹¹⁵⁶ Teva would withdraw its approval of the text of the challenged patent. It was then no longer possible for the TBA to adopt a reasoned decision on the validity of the challenged patent. Teva's withdrawals equally affected invalidity challenges against the very same – withdrawn – patent at national level, which were thus rendered moot.

¹¹⁵⁷ See Section 8.3.3.1 and 8.3.3.5.

¹¹⁵⁸ See Section 8.3.2.1.

¹¹⁵⁹ In 2010, EP '528 was filed the day before the grant of its parent EP '703; in 2013, EP '962 was filed one week before the grant of its parent EP '749; in 2018, EP '286 was filed one week before the grant of its parent EP '962.

- (1022) In particular, Teva’s staggered patent filings and strategic withdrawals allowed it to artificially extend the legal uncertainty with respect to its process patent family until September 2017 when its last remaining divisional process patent was invalidated by reasoned decision of the TB, almost 7 years after the first opposition notice against the Original Process Patent had been filed in October 2010 by Synthon. During this time, Teva delayed the market entry and the uptake of Synthron GA’s 20 mg by sending warning letters and requesting preliminary injunctions before national courts based on the patents forming part of the process patent family.
- (1023) Expecting the revocation of its process patents, Teva also pursued a large-scale pre-emptive conversion of its patients from the daily 20 mg dose to a three-times-a-week 40 mg dose of Copaxone¹¹⁶⁰ which was protected by the patents from the dosage patent family.¹¹⁶¹ By the time Synthron GA’s 20 mg was ready to be launched on the market in 2017 (after the last process divisional patent barriers had been cleared), most patients had already been moved from Teva’s 20 mg Copaxone to 40 mg Copaxone. These patients were unlikely to switch to competing 20 mg GA, as this would require an inconvenient switch back to their previous dosing regimen.¹¹⁶²
- (1024) Thus, in order to compete effectively in the market for GA, Synthron and its licensees also had to enter the market with a 40 mg GA.¹¹⁶³ However, this market entry was also hindered by Teva’s staggered filings of dosage patents and the withdrawal of the Original Dosage Patent successfully protracting legal uncertainty regarding their validity. In the meantime, Teva continued to enforce these dosage patents by sending warning letters to Synthron and requesting preliminary injunctions before national courts.
- (1025) In addition to the validity review before the EPO, Synthron also brought validity review proceedings at national level in numerous Member States.¹¹⁶⁴ The majority of these actions (with the exception of those in Belgium and the Netherlands)¹¹⁶⁵ were stayed pending the respective proceedings before the TBA or, in the case of the proceedings concerning preliminary injunctions, were influenced by EPO decisions.¹¹⁶⁶ Thus, judicial review at national level was also not an effective remedy for Synthron (or any other potential GA entrants) in view of Teva’s divisionals strategy before the EPO. For the same reasons, there was (except for the Netherlands)¹¹⁶⁷ no need for Teva to also withdraw patents in national validity review proceedings.

¹¹⁶⁰ See e.g. ID 404-1946, Teva internal email dated 24 June 2016 from {...} to {...} and others, concerning “Copaxone defence europe”; ID 404-1922, Teva internal email dated 16 April 2016 from {...}. On launch of 40 mg dosage of Copaxone see above Section 5.2.3.1.

¹¹⁶¹ Indeed, the challenges with respect to the validity of the patents forming part of the dosage patent family were less advanced, given that Teva’s dosage patents were filed and granted later than the process patents.

¹¹⁶² See Recital (127).

¹¹⁶³ In March 2017, a Teva employee stated that {...}, ID 455-556, Teva internal email dated 24 March 2017 from {...} to the distribution list Copaxonegbl and others, p. 1.

¹¹⁶⁴ Teva’s GA patents were also challenged before the EPO by two other generic manufacturers, namely the Novartis subsidiary Hexal AG, which challenged the process patents EP ‘528 and EP ‘924 as well as the dosage patents EP ‘335, EP ‘172 and EP ‘962 and Actavis, which challenged the process patent EP ‘924 and dosage patent EP ‘749. Actavis (which became Allergan in 2015) was acquired by Teva in 2016. However, Synthron GA was the only GA product competing with Copaxone in the Relevant Member States (see in particular Section 7.2.1).

¹¹⁶⁵ And the United Kingdom.

¹¹⁶⁶ See for example, Recital(1395) for Czechia or Recital (1399) for Germany.

¹¹⁶⁷ See Section 8.3.3.6.2.

- (1026) Teva’s comprehensive divisionals game was part of its Copaxone Continuation Project¹¹⁶⁸ which had the aim to artificially prolong the patent protection of its blockbuster drug Copaxone. Teva’s strategy and its aim to hinder and/or delay the market entry and expansion of generic-like versions of GA is apparent from numerous internal Teva documents. For example, in an email sent to several of Teva’s employees, including {...}, {...} explained {...} by expressly linking the plurality of Teva’s patents (i.e. parallel existence of several patents capable of being enforced) and the withdrawal of a challenged one (to avoid far-reaching negative consequences of a finding of invalidity): {...} (emphasis added).¹¹⁶⁹ A follow up correspondence illustrates in rather unambiguous terms that {...} (emphasis added).¹¹⁷⁰
- (1027) Other examples include documents describing Teva’s strategy to {...}¹¹⁷¹ and being a part of Teva’s {...}¹¹⁷² for Copaxone. The strategy was designed to compensate for the {...}¹¹⁷³ (in other words, for the fact that Teva’s patents were deemed as insufficient to prevent competitors’ entry) and to artificially prolong the exclusivity rights concerning Copaxone to keep competitors out or to delay their entry. Teva achieved this by combining the multiplication of its secondary patents (by filing divisional patents)¹¹⁷⁴ with strategic patent withdrawals.¹¹⁷⁵ Teva feared a {...}¹¹⁷⁶ and expected the legal review of its patents to result in their revocation, which would both accelerate the revocation of its remaining patents and reduce Teva’s chances to obtain preliminary injunctions.¹¹⁷⁷ There was a broad acceptance of this strategy within Teva. Employees learned about the importance of Teva “{...} (emphasis added)¹¹⁷⁸ in order {...}¹¹⁷⁹ that {...} (emphasis added).¹¹⁸⁰
- (1028) Teva’s conduct consisting of staggered filings and subsequent strategic withdrawals was motivated by anticompetitive considerations. It artificially prolonged legal uncertainty concerning the validity of Teva’s patents and caused significant costs and increased commercial uncertainty for all potential GA entrants, and Synthron in particular. It was therefore capable of hindering and/or delaying market entry and expansion of any potential or actual GA competitors, Synthron and its licensees in particular.¹¹⁸¹ It did in fact delay the market entry of Synthron’s licensees in at least some of the Relevant Member States.¹¹⁸²

¹¹⁶⁸ See Section 5.2 above. See also ID 266-296, email dated 9 February 2014 from {...} to {...} and {...} proposing that {...} responsible for patent filings {...}.

¹¹⁶⁹ ID 404-1647, Teva internal email dated 2 February 2015 from {...} to {...} and others.

¹¹⁷⁰ ID 404-1647, Teva internal email dated 2 February 2015 from {...} to {...} and others.

¹¹⁷¹ ID 455-1784, Teva internal email dated 24 June 2012 from {...} to {...} and others.

¹¹⁷² ID 455-2502, Teva internal email dated 14 April 2016 from {...} to {...}.

¹¹⁷³ ID 455-9, Commercial Strategic Plan, 5 September 2012, p. 17.

¹¹⁷⁴ See Section 8.3.1.

¹¹⁷⁵ See Section 8.3.3.

¹¹⁷⁶ In May 2015, Teva’s {...} expressed concerns about a (negative) patent decision in the Netherlands {...}. ID 404-2207, Teva internal email exchange dated 4 May 2015 between {...} and {...}.

¹¹⁷⁷ See Section 8.3.3.4.

¹¹⁷⁸ ID 404-2555, Teva internal email dated 16 March 2016 from {...} to {...} and others.

¹¹⁷⁹ ID 404-1647, Teva internal email dated 2 February 2015 from {...} to {...} and others.

¹¹⁸⁰ ID 404-1705, Teva internal email dated 27 September 2016 from {...} (to {...}) summarizing internal presentation/discussions on various CCP items.

¹¹⁸¹ Synthron GA was the only GA product competing with Copaxone in the Relevant Member States (see in particular Section 7.2.1).

¹¹⁸² See Section 8.4.3.

(1029) While Teva’s conduct, consisting of the combination of recurrent and staggered divisional patent filings and strategic patent withdrawals, concerned procedures before the EPO and were thus pan-European in scope, this Decision assesses Teva’s conduct in the Relevant Member States, namely in Belgium, Czechia, Germany, Italy, the Netherlands, Poland and Spain.

8.2. The legal and economic context of Teva’s divisionals game

8.2.1. General principles

(1030) Article 102 TFEU prohibits as incompatible with the internal market “[a]ny abuse by one or more undertakings of a dominant position within the internal market or in a substantial part of it [...] in so far as it may affect trade between Member States”.

(1031) It is well-established case law of the Union Courts that Article 102 TFEU does not prohibit an undertaking from acquiring, on its own merits, a dominant position on a market.¹¹⁸³ Furthermore, competition on the merits may, by definition, lead to the departure from the market or the marginalisation of competitors that are less efficient.¹¹⁸⁴

(1032) According to the Union Courts, the concept of abuse under Article 102 TFEU is an objective concept referring to “*the behaviour of an undertaking in a dominant position which is such as to influence the structure of a market where, as a result of the very presence of the undertaking in question, the degree of competition is [already] weakened and which, through recourse to methods different from those which condition normal competition [...] has the effect of hindering the maintenance of the degree of competition still existing in the market or the growth of that competition*”.¹¹⁸⁵

(1033) While “*there is no requirement to establish that the dominant undertaking has an anticompetitive intent, evidence of such an intent [...] constitutes a fact that may be taken into account in order to determine that a dominant position has been abused*”.^{1186 1187} Whether the dominant undertaking has such intent can be concluded from internal documents demonstrating intent or the finding that such conduct made no economic sense but for excluding a competitor. Conversely, as the EU Courts have held, “*the existence of an intention to compete on the merits, even if it were established, could not prove the absence of abuse*”.¹¹⁸⁸

¹¹⁸³ Judgment of 19 January 2023, *Unilever Italia Mkt Operations*, C-680/20, EU:C:2023:33, paragraph 37; Judgment of 12 May 2022, *Servizio Elettrico Nazionale and Others*, C-377/20, EU:C:2022:379, paragraph 73.

¹¹⁸⁴ Judgment of the Court of Justice of 27 March 2012, *Post Danmark*, C-209/10, EU:C:2012:172, paragraphs 21-22; Case C-377/20, *Servizio Elettrico Nazionale and Others*, paragraph 73.

¹¹⁸⁵ Judgment of the Court of Justice of 9 September 2010, *Tomra Systems and Others v Commission*, T-155/06, EU:T:2010:370, paragraph 206 and the case law cited.

¹¹⁸⁶ Case C-307/18, *Generics (UK) and Others*, paragraph 162; Case C-549/10 P, *Tomra and Others v Commission*, paragraphs 20, 21 and 24.

¹¹⁸⁷ Teva asserts that “[t]he Commission noted in its Final Report regarding its inquiry into the pharmaceutical sector from July 2009, that the originator’s “intention” may be key to determine an abuse” (ID 4032, Teva’s Reply to the Statement of Objections, para. 527). This is incorrect as the Final report never describes the intention as a “key” to determine an abuse, but rather, in line with the established jurisprudence, it acknowledges that “[t]he intention can also be taken into account in competition law assessments.” (Pharmaceutical Sector Inquiry, Final report, Commission Staff Working Document, Part 1, 8 July 2009, footnote 375).

¹¹⁸⁸ Case T-612/17, *Google and Alphabet v Commission (Google Shopping)*, paragraph 256.

- (1034) It follows that, in specific circumstances, Article 102 TFEU may deprive undertakings in a dominant position of the right to adopt a course of conduct or take measures which would be unobjectionable if adopted or taken by non-dominant undertakings.¹¹⁸⁹ Indeed, Article 102 TFEU imposes a special responsibility on dominant undertakings not to allow their conduct to impair genuine undistorted competition on the internal market.¹¹⁹⁰
- (1035) As regards exclusionary practices, the Court of Justice has held that a dominant undertaking's conduct can only be characterised as abusive if two cumulative conditions are met: (i) the practice must be based on the use of means other than those which come within the scope of competition on the merits; and (ii) the practice must be capable of producing an exclusionary effect. Where those two conditions are fulfilled, the undertaking in a dominant position can nevertheless escape the prohibition laid down in Article 102 TFEU if it shows that the practice at issue was either objectively justified and proportionate to that justification, or counterbalanced or even outweighed by advantages in terms of efficiency that also benefit consumers.¹¹⁹¹
- (1036) In the first place, Article 102 TFEU prohibits a dominant undertaking from eliminating or marginalising a competitor¹¹⁹² and thereby strengthening its position by using methods other than those which come within the scope of competition on the merits.¹¹⁹³
- (1037) Thus, the Court of Justice has held that “*the preparation by an undertaking, even in a dominant position, of a strategy whose object it is to minimise the erosion of its sales and to enable it to deal with competition from generic products is legitimate and is part of the normal competitive process, provided that the conduct envisaged does not depart from practices coming within the scope of competition on the merits [...]*”.¹¹⁹⁴
- (1038) Concerning, in the second place, the effects of the dominant undertaking's conduct, Article 102 TFEU prohibits behaviour that tends to restrict competition or is capable of having that effect,¹¹⁹⁵ regardless of its success.¹¹⁹⁶ The Court of Justice has held that “*conduct is capable of constituting an abuse of a dominant position if it is demonstrated that it has – at least potential – anticompetitive effects that hinder the maintenance of the degree of competition existing on the market as a whole or the*

¹¹⁸⁹ Judgment of the Court of Justice of 9 November 1983, *Michelin v Commission*, C-322/81, EU:C:1983:313, paragraph 57; Judgment of the Court of First Instance of 9 September 2009, *Clearstream v Commission*, T-301/04, EU:T:2009:317, paragraph 133.

¹¹⁹⁰ Case C-322/81, *Michelin v Commission*, paragraph 57; Case C-209/10, *Post Danmark*, paragraph 23; Case T-301/04, *Clearstream v Commission*, paragraph 132; Judgment of 6 September 2017, *Intel v Commission*, C-413/14 P, EU:C:2017:632, paragraph 135.

¹¹⁹¹ Case C-377/20, *Servizio Elettrico Nazionale and Others*, C-377/20, paragraph 103.

¹¹⁹² See reference to the elimination and marginalisation of competitors in Case C-209/10, *Post Danmark*, paragraph 22.

¹¹⁹³ Judgement of the Court of 3 July 1991, *AKZO v Commission*, C-62/86, EU:C:1991:286, paragraph 70; Judgment of the Court of Justice of 2 April 2009, *France Télécom v Commission*, C-202/07 P, EU:C:2009:214, paragraph 106; Case C-457/10 P, *AstraZeneca v Commission*, paragraph 75; Case C-377/20, *Servizio Elettrico Nazionale and Others*, paragraph 76.

¹¹⁹⁴ Case C-457/10 P, *AstraZeneca v Commission*, paragraph 129.

¹¹⁹⁵ Judgment of the Court of Justice of 25 March 2021, *Slovak Telekom v Commission*, C-165/19 P, EU:C:2021:239, paragraph 109; Case C-549/10 P, *Tomra and Others v Commission*, paragraph 68.

¹¹⁹⁶ Case T-321/05, *AstraZeneca v Commission*, paragraph 347, confirmed on appeal in Case C-457/10 P, *AstraZeneca*, paragraphs 109 and 111; see also judgment of the Court of First Instance of 17 December 2003, *British Airways*, T-219/99, EU:T:2003:343, paragraphs 297 and 298.

growth of that competition".¹¹⁹⁷ That assessment must be undertaken having regard to all the relevant facts surrounding that conduct.¹¹⁹⁸

- (1039) Furthermore, Article 102 TFEU is aimed not only at practices which may cause prejudice to consumers directly, but also at those which are detrimental to them through their impact on the structure of competition.¹¹⁹⁹ The Court has held that "*competition rules laid down in the Treaty (...) aim to protect not only the interests of competitors or of consumers, but also the structure of the market and, in so doing, competition as such*".¹²⁰⁰ Moreover, the Court has found that the Commission is not required to "*demonstrate that possible consequences of the elimination or restriction of competition actually manifested themselves, for example in the form of less innovation or price increases that could only be explained by the lack of competition*" and that "[i]t is accepted in that regard that the weakening of competition is highly likely to have such consequences".¹²⁰¹
- (1040) Moreover, customers should have the opportunity to benefit from whatever degree of competition is possible on the market and competitors should be able to compete on the merits for the entire market and not just for a part of it.¹²⁰² An undertaking in a dominant position may not therefore justify abusive conduct in a certain segment of a market by the fact that its competitors remain free to compete in other segments.¹²⁰³ The Court of Justice made clear that "*it is not the place of a dominant undertaking to dictate how many viable competitors are to be allowed to compete with it*".¹²⁰⁴
- (1041) Finally, it is open to the dominant undertaking to provide a justification that its conduct was objectively necessary or that the exclusionary effect produced could be counterbalanced by advantages in terms of efficiency gains that also benefited customers. It is for the undertaking relying on such justifications to put them forward convincingly.¹²⁰⁵ In that respect, "*the onus is on the dominant undertakings to behave in a way which is proportionate to the objectives they seek to achieve*".¹²⁰⁶
- 8.2.2. *Specific principles concerning the investigated conduct in the context of intellectual property rights*
- (1042) It is well-established case-law of the Court of Justice that "*whilst the Treaty does not affect the existence of rights recognized by the legislation of a Member State in matters of industrial and commercial property, yet the exercise of these rights may*

¹¹⁹⁷ Case C-549/10 P, *Tomra and Others v Commission*, paragraphs 41 to 45; Judgment of the Court of First Instance of 10 November 2021, *Google and Alphabet v Commission (Google Shopping)*, T-612/17, EU:T:2021:763, paragraph 504.

¹¹⁹⁸ Case C-307/18, *Generics (UK) and Others*, paragraph 154.

¹¹⁹⁹ Judgment of the Court of First Instance of 13 December 2018, *Slovak Telekom*, T-851/14, EU:T:2018:929, paragraph 110; Judgment of the Court of Justice of 15 March 2017, *British Airways C-95/04*, EU:C:2007:166, paragraphs 106-107; Case 6/72, *Europemballage and Continental Can*, paragraph 26.

¹²⁰⁰ Judgment of the Court of Justice of 6 October 2009, *GlaxoSmithKline Services Unlimited v Commission*, joined cases C-501/06 P, C-513/06 P, C-515/06 P and C-519/06 P, EU:C:2009:610, paragraph 63; see also judgment of the Court of Justice of 4 June 2009, *T-Mobile Netherlands and Others*, C-8/08, EU:C:2009:343, paragraphs 38 and 39.

¹²⁰¹ Case T-612/17, *Google and Alphabet v Commission (Google Shopping)*, paragraph 443.

¹²⁰² Case C-549/10 P, *Tomra and Others v Commission*, paragraph 42.

¹²⁰³ Case T-286/09, *Intel v Commission*, paragraph 132.

¹²⁰⁴ Case C 549/10 P *Tomra and Others v Commission*, paragraph 42; Case C-307/18, *Generics (UK) and Others*, paragraph 161.

¹²⁰⁵ Case T-612/17, *Google and Alphabet v Commission (Google Shopping)*, paragraphs 552 and 577.

¹²⁰⁶ Joined Cases T-191/98 and T-212/98 to T-214/98, *Atlantic Container Line and Others v Commission*, paragraph 1120.

nevertheless [...] be affected by the prohibitions in the Treaty".¹²⁰⁷ Thus, the exercise of an exclusive right linked to an intellectual-property right may, in exceptional circumstances, amount to abusive conduct within the meaning of Article 102 TFEU.¹²⁰⁸

- (1043) The protection afforded by a patent does not include a protection against challenges to the patent's validity. As the Court of Justice held in *Centrafarm*, "*the specific subject matter of the industrial property is the guarantee that the patentee, to reward the creative effort of the inventor, has the exclusive right to use an invention [...] as well as the right to oppose infringements*".¹²⁰⁹ The Court of Justice further clarified in *Windsurfing* that a patent's subject-matter is not to afford "*protection against actions brought in order to challenge the patent's validity, in view of the fact that it is in the public interest to eliminate any obstacle to economic activity which may arise where a patent was granted in error*".¹²¹⁰ and that the patent holder cannot substitute "*its discretion for the decisions of national courts, which were the proper forum for actions*".¹²¹¹ In *Lundbeck*, the Court of Justice restated "*that a patent does not guarantee protection against actions seeking to contest its validity; and that such actions, and, in particular, the 'at risk' launch of a generic medicinal product, and the consequent court proceedings, commonly take place in the period before or immediately after the market entry of such a generic medicinal product*".¹²¹²
- (1044) More specifically, the Court of Justice recently held in *Generics (UK)* that patent related conduct can be abusive if "*its purpose is precisely to strengthen the dominant position of the party engaging in it and to abuse that position [...] as when such conduct is intended to deprive [...] potential competitors of effective access to a market*".¹²¹³ These legal principles also apply to unilateral actions seeking to hinder generic competition by delaying the legal review of a patent's validity and prolonging legal uncertainty in this respect.
- (1045) In *AstraZeneca*, the Court of Justice found that a "*deregistration, without objective justification and after the expiry of the exclusive right [...] to hinder the introduction of generic products and parallel imports – does not come within the scope of competition on the merits*".¹²¹⁴ The Court referred to this as conduct whose sole purpose is to render a procedure, which is necessary for normal market entry unavailable for generic competitors, thereby excluding them from the market for as long as possible, and qualified the conduct as abusive.¹²¹⁵

¹²⁰⁷ Judgment of the Court of Justice of 31 October 1974, *Centrafarm BV and Adriaan de Peijper v Sterling Drug Inc*, C-15/74, EU:C:1974:114, paragraphs 7-9.

¹²⁰⁸ Judgment of the Court of Justice of 29 April 2004, *IMS Health*, C-418/01, EU:C:2004:257, paragraph 35; C-170-13, *Huawei Technologies*, paragraph 47.

¹²⁰⁹ Judgement of the Court of 31 October 1974, *Centrafarm BV and Others*, C-15/74, EU:C:1974:114, paragraphs 7-9.

¹²¹⁰ Judgment of the Court of Justice of 25 February 1986, *Windsurfing International*, C-193/83, EU:C:1986:75, paragraph 92.

¹²¹¹ Case C-193/83, *Windsurfing International v Commission*, paragraph 52.

¹²¹² Judgment of the Court of Justice of 25 March 2021, *H. Lundbeck A/S and Lundbeck Ltd v European Commission*, C-591/16 P, EU:C:2021:243, paragraph 60.

¹²¹³ Case C-307/18, *Generics (UK) and Others*, paragraph 151.

¹²¹⁴ Case C-457/10 P, *AstraZeneca*, paragraph 130.

¹²¹⁵ Case C-457/10 P, *AstraZeneca*, paragraph 154.

8.2.3. Particular features of divisional patents and their susceptibility to misuse

- (1046) The ability of generic entrants to effectively challenge the validity of patents is an essential part of the competitive process in the pharmaceutical sector.¹²¹⁶ The Court of Justice specifically held that “*challenges to the validity and scope of a patent are part of normal competition in the sectors where there exist exclusive rights in relation to technology*”.¹²¹⁷ Pursuing litigation to challenge these patents is the only mechanism available to generic companies to clear their way to the market and they are indeed a usual feature of competition in these markets.¹²¹⁸
- (1047) On the other hand, a patent holder can effectively use patent claims, even if it internally considers them as weak, to create very significant obstacles for generic competitors since the grant of a preliminary injunction generally only requires the originator to establish a *prima facie* basis for its claim. Originators can bring numerous patent infringement actions against the same generic company in several Member States, based on one or more putatively infringed patent(s), even in cases where they do not expect this litigation to be ultimately successful on the merits of the patent(s).¹²¹⁹ In fact, the Commission's 2009 Pharmaceutical Sector Inquiry found that generic companies won 62% of all patent litigation cases that resulted in a “final judgment”.¹²²⁰
- (1048) Divisional patents are particularly susceptible to create legal uncertainty for generic companies seeking to launch a competing product, resulting in such launches being delayed. Already in 2007, the EPO noted that “[i]t appears that what applicants consider a legitimate exploitation of the procedural possibilities afforded by the EPC, others consider an abuse in relation to the law as they think it ought to be rather than as it is. The [EPO] finds it unsatisfactory that sequences of divisional applications each containing the same broad disclosures of the original patent application, by means of at least an unamended description, should be pending for up to twenty years. If administrative measures, such as giving priority to the examination of divisional applications and bundling and speedily deciding co-pending divisional applications so as to minimise the possibility for applicants to keep alive subject-matter on which the Examining Division had already given a negative opinion in one application by means of refiling the same subject-matter again and again, are not adequate, it would be for the legislator to consider where there are abuses and what the remedy could be”.¹²²¹ In 2009, the EPO observed again that “There is a trend for applicants to abuse these procedural possibilities by using the divisional application procedure to achieve a "duplication" of the proceedings [...] This is detrimental both to legal certainty for third parties and to patent office workloads” (emphasis added).¹²²²

¹²¹⁶ Pharmaceutical Sector Inquiry, Final Report, 8 July 2009, paragraph 621.

¹²¹⁷ Case C-307/18, *Generics (UK) and Others*, paragraph 81.

¹²¹⁸ Opinion of AG Kokott, Case C-307/18, *Generics (UK) and Others*, paragraphs 67 et seq.

¹²¹⁹ Pharmaceutical Sector Inquiry, Final Report, 8 July 2009, paragraph 546.

¹²²⁰ For secondary patents, the corresponding figure was even 74%. See Pharmaceutical Sector Inquiry, Final Report, 8 July 2009, paragraph 628.

¹²²¹ EPO, Decision of the Enlarged Board of Appeal dated 28 June 2007, G1/05, Divisional/ASTROPOWER.

¹²²² EPO paper CA/145/08 Rev. 1, subject: Divisional applications, Munich, 15 January 2009; as quoted in the Pharmaceutical Sector Inquiry, Final Report, 8 July 2009, paragraph 532.

In 2010, the EPO therefore introduced a time limit (of two years from the Examining Division's first communication concerning the parent patent to the applicant) for filing divisional applications. However, this time limit was subsequently removed in 2014.

- (1049) This legal uncertainty at EPO level is emphasised by the fact that, according to Teva itself, national courts generally do not engage in an in-depth assessment of the validity of the patent invoked in a request for a preliminary injunction and grant these on a *prima facie* basis.¹²²³ This means that even holders of weak patents can generally maintain their exclusive rights over an artificially prolonged and unjustified period of time.
- (1050) The Commission’s Pharmaceutical Sector Inquiry Report also noted that the filing of multiple divisional applications, combined with preliminary injunctions, can allow originators to maintain legal uncertainty and hinder the entry of generic competitors on the market.¹²²⁴ The Commission’s Pharmaceutical Sector Inquiry Report identified the danger of divisional applications being filed for weak patent applications to maintain legal uncertainty for potential competitors¹²²⁵ and extend the duration of validity challenges.¹²²⁶
- (1051) The multiplication of proceedings through the filing of several divisional patents can cause even greater delays when the filing and withdrawal of divisional patents is strategically staggered. National courts have found in certain cases that this allows patent holders to exploit the patent system, deliberately shielding patents from examination.¹²²⁷ Specifically, the staggered filing and strategic withdrawal of divisional patents can be used to repeatedly postpone the moment when competent courts would be afforded the opportunity to decide on the merits of a patent. As the competent court’s decisions could create a damaging precedent for the validity and enforceability of related divisional patents should the challenged patent be declared invalid, withdrawing the challenged patent while there remains another patent with overlapping claims, artificially prolongs the legal uncertainty benefiting the originator (and in some cases, its *de facto* market exclusivity by way of injunctions obtained in enforcement actions). Such conduct is preconditioned by the originator staggering the filing of a series of divisional patent applications over an extended period of time.
- (1052) Indeed, decisions concerning the invalidity of an earlier patent from a divisional family may influence the enforcement of subsequent generations of divisional patents from the same patent family before the EPO and the national courts.¹²²⁸
- (1053) For example, the Higher Regional Court of Munich found in 2018 that a patent holder (or exclusive licensee) “*wanted to prevent an appeal decision [from the EPO’s TBA] for tactical reasons, because of the risk that a revocation of the [parent*

¹²²³ ID 404-876, Teva internal email dated 26 August 2012 from {...} to {...}; ID 455-537; Teva internal email dated 24 May 2018 from {...} to {...} and others.

¹²²⁴ Pharmaceutical Sector Inquiry, Final Report, 8 July 2009, paragraphs 520-522.

¹²²⁵ Pharmaceutical Sector Inquiry, Final Report, 8 July 2009, paragraph 275.

¹²²⁶ Pharmaceutical Sector Inquiry, Final Report, 8 July 2009, paragraph 533.

¹²²⁷ For instance, in the UK case *Fujifilm v Abbvie* from 2017, the High Court found in relation to such behaviour that “the object and cumulative consequence of AbbVie’s conduct is intended to delay the entry of *competing biosimilars, and AbbVie has sought to achieve this by prolonging commercial uncertainty by a series of acts of abandonment of protection, whilst re-filing divisionals for essentially the same subject matter*” and that the intention and the objective effect of this conduct was “*to shield [the] patent portfolio from examination of validity whilst continuing to file further divisionals and to threaten infringement proceedings*” (emphasis added). *Fujifilm v Abbvie* [2017] EWHC 395 (Pat), paragraph 388. In the same vein, see the decision of the Higher Regional Court of Munich OLG München, 4 April 2018, 6 W 164/18, *Teva Pharmaceutical Industriel Ltd. Vs. Mylan dura GmbH*, p. 30 and the decision of the Regional Court of Munich LG München I, *Beschluss v. 24 February 2020 – 7 O 1456/20*, paragraph 51.

¹²²⁸ See Section 8.3.3.4.

patent] would also have entailed a ‘devaluation’ of the [divisional] patent [on which the patent holder has based a preliminary injunction request], rather than merely renouncing the defence of its patent on grounds of ‘inconvenience’ or costs [...]”.¹²²⁹ The Higher Regional Court of Munich also explicitly stated that cost savings were not a plausible explanation for not defending a patent covering a blockbuster drug: “It is more than unlikely to the present Chamber that a patent covering a blockbuster technology [...] and maintained in opposition proceedings initiated by competitors wishing to enter the market with a generic product, is dropped on the basis of economic considerations because the patent holder does not wish to bear the time and costs of defence”.¹²³⁰ In fact, this judgment, which concerned the enforcement of Teva’s patents addressed in the present Decision, rejected Teva’s request for a preliminary injunction on the basis of the Original Dosage Patent because it was not convinced that the patent would be upheld in EPO proceedings.

- (1054) In a decision from 2020, the Regional Court of Munich held that it was unfair competition¹²³¹ if a patent holder (or exclusive licensee) “seeks to prevent the final decision by the Board of Appeal on the validity of the various divisional filings and patents requested by the applicant”, and that “in the case of a large number of available divisionals and where the complex interaction between the European Patent Office, the Bundespatentgericht and the infringement courts is deliberately exploited, the removal of the possibility for the competitor to have the opposing patents reviewed in a timely manner must be regarded as a restraint”.¹²³² The Court also took into account that the current patent system provides for “the possibility to file divisional patents without sufficient consideration of the possibilities for abuse which these divisionals grant patent holders”.¹²³³ This judgment, also, concerned Teva’s patents protecting Copaxone. The Regional Court of Munich ordered Teva to refrain from withdrawing the approval of the text for the divisional patent EP ‘335. Since Teva could not withdraw the patent, the EPO’s TBA was able to issue a reasoned decision and decided to revoke the patent. The OD then later relied on this

¹²²⁹ ID 741-16, OLG München, 4 April 2018, 6 W 164/18, *Teva Pharmaceutical Industriel Ltd. Vs. Mylan dura GmbH*, p. 30. Unofficial translation. Original text reads as follows: “dass die Patentinhaberin eine Beschwerdeentscheidung aufgrund des bestehenden Risikos, dass im Falle eines Widerrufs des EP ‘749 damit auch eine „Entwertung“ des Verfügungspatents verbunden gewesen wäre, aus taktischen Gründen verhindern wollte und das Patent nicht lediglich aus Gründen der „Lästigkeit“ bzw. aus Kostengesichtspunkten nicht mehr gegen die Beschwerde verteidigt hat [...]”.

¹²³⁰ ID 741-16, OLG München, 12 April 2018, 6 W 164/18, *Teva Pharmaceutical Industriel Ltd. Vs. Mylan dura GmbH*, p. 30 (unofficial translation). Original text: “Dass ein Patent, das eine ‘Blockbuster’-Technologie mit abdeckt (vgl. Antragsschrift, Seite 4) und das auf den Einspruch von Konkurrenten, die mit einem Generikum auf den Markt kommen wollen, aufrechterhalten worden war, aus wirtschaftlichen Überlegungen, weil die Patentinhaberin die Zeit und die Kosten für eine Verteidigung nicht aufbringen will, fallen gelassen wird, ist für den Senat mehr als fernliegend”.

¹²³¹ In the sense of the German Act against Unfair Competition (UWG).

¹²³² LG München I, Beschluss v. 24 February 2020 – 7 O 1456/20, paragraph 51 (unofficial translation). Original: “Das belegt bei summarischer Prüfung, dass die Antragsgegenseite eine von der Antragstellerin angestrebte endgültige Entscheidung durch die Beschwerdekammer über den Rechtsbestand der diversen Teilanmeldungen und daraufhin erteilten Patente zu verhindern trachtet“; para 59. Original: „Bei einer Vielzahl von zur Verfügung stehenden divisionals und bei gezielter Ausnutzung des komplexen Zusammenspiels von Europäischem Patentamt, Bundespatentgericht und den Verletzungsgerichten ist indes der Entzug der Möglichkeit für den Mitbewerber, den Rechtsbestand der dem Wettbewerb entgegenstehenden Patente zeitnah überprüfen zu lassen, in der Gesamtschau als Behinderung anzusehen”.

¹²³³ LG München I, Beschluss v. 24 February 2020 – 7 O 1456/20, paragraph 73 (unofficial translation). Original text: “Möglichkeit der Anmeldung von divisionals ohne angemessene Berücksichtigung des Spielraums für Missbrauch, den diese divisionals den Patentinhabern einräumen”.

reasoned revocation decision when revoking other divisional dosage patents from the same family (i.e. EP ‘172 and EP ‘962).¹²³⁴

- (1055) Accordingly, divisional patents are particularly susceptible to misuse of patent proceedings. In particular, staggered filings and strategic withdrawals of patents with overlapping contents can hinder market entry of generic companies by artificially prolonging legal uncertainty as to whether an originator product, for which the primary patent already expired, is nonetheless still protected by secondary patents relating to certain aspects of the product (such as production process, or dosage). As a result, potential generic entrants may either not take the risk to launch their product pending the legal review of the divisional patents, or launch their product and incur the risk of their sales being suspended by preliminary injunctions from national courts.¹²³⁵
- (1056) Teva’s conduct and underlying strategy regarding divisional patents are closely linked to three features of the patent system, which Teva consciously exploited. First, divisional patents have a “*procedural life of their own*” as they can be enforced even after their respective parent patent has been revoked. It is moreover possible to continue filing new divisional applications, as long as there is another pending divisional patent application, even if the original parent patent has already been revoked. Second, statistics show that, in cases involving pharmaceutical preparations, the EPO’s OD is less likely to revoke a granted patent whilst it is more likely that, when the patent is further reviewed by the EPO’s subsequent instance, the TBA, the same patent is revoked. In other words, a significant number of patents that are ultimately revoked are able to “survive” the first instance of review, thus making it worthwhile for the originator to file for and obtain patents even in cases where their validity is doubtful from the beginning. Third, patent holders can easily terminate validity challenges before the EPO by withdrawing the approval of the text of a patent. After such a withdrawal, the patent is revoked on procedural grounds and can no longer be the subject of a reasoned revocation decision, thus enabling the patent holders to avoid a precedent effect for the assessment of its other patents of the same family. This means that, in the case of overlapping patents, the party having challenged the withdrawn patent, would have to start new proceedings all over again against the patent holder’s remaining patent(s).
- (1057) Against this background, in order to establish whether Teva’s comprehensive patenting conduct addressed in this Decision fell outside the boundaries of competition on the merits, the Commission considers that, first, Teva engaged in staggered filings of divisional patents with largely overlapping content and strategic withdrawals of the challenged patents which, second, shielded Teva’s patents from effective legal review of their validity and artificially prolonged legal uncertainty concerning Copaxone’s patent protection (Sections 8.3.2 and 8.3.3). This conduct, third, took place in the context of a strategy to prevent, delay or hinder entry of competing GA products (Sections 8.3.1 and 8.3.4).¹²³⁶ In addition, while the applicable jurisprudence does not require that there can be no plausible alternative

¹²³⁴ TBA dismissed Teva’s appeals and confirmed OD’s decisions thus finally revoking EP ‘962 and EP ‘172 on 7 February 2024 (ID 5731, EP2630962 – Minutes of the hearing before the Technical Board of Appeals 3.3.04, 6-7 February 2024; ID 5729, EP3199172 – Minutes of the hearing before the Technical Board of Appeals 3.3.04, 6-7 February 2024).

¹²³⁵ Pharmaceutical Sector Inquiry, Final Report, 8 July 2009, paragraph 544.

¹²³⁶ On Teva’s divisionals game as a part of the overall CCP strategy see Section 5.2.3.

explanation for Teva's conduct,¹²³⁷ the Commission nevertheless examines Teva's claims regarding alleged legitimate reasons for its conduct in Section 8.3.6.

8.2.4. *Teva's arguments and the Commission's assessment*

- (1058) Teva refers to a number of judgments by the Union Courts and a Commission decision¹²³⁸ to argue that a finding that a certain conduct that is legal under specific areas of law qualifies as an abuse of a dominant position under Article 102 TFEU must be subject to an “*exceptional standard*”.¹²³⁹ This standard should be based on the following legal principles: (i) the conduct cannot in itself constitute an abuse; (ii) to constitute an abuse, the sole purpose of the conduct has to be to exclude competition and (iii) such conduct can only be abusive in exceptional circumstances. Relying on the jurisprudence in *AstraZeneca*, *ITT Promedia* and *Generics UK*,¹²⁴⁰ Teva further argues that the Commission must show the following cumulative criteria: (i) assessed on an objective basis, the conduct must have the object of eliminating competition; and (ii) there is no ‘plausible’ explanation justifying the conduct, other than this anticompetitive object. According to Teva, it follows that, even where it is demonstrated that the dominant undertaking had an anticompetitive objective, its conduct does not depart from competition on the merits so long as there are other – legitimate – explanations for the conduct which are “*plausible*”. Teva maintains that, in other words, actions that are otherwise legal and form part of an application to a decision-making body can be found abusive only if they are manifestly unfounded and aim to exclude competition.¹²⁴¹
- (1059) Teva's arguments are not convincing. First, Teva selectively refers to elements of a number of Court judgments and a Commission decision in order to construe an alleged “*exceptional standard*” that the Commission should attain in the assessment of Teva's conduct and an alleged legal test that should be applied to conduct that is legal under other areas of law (such as the patent filings and patent withdrawals). However, none of the authorities referred to by Teva imposes such an “*exceptional standard*” or sets out the legal test proposed by Teva.
- (1060) As set out above in the Section 8.2.1, the legal test has been clarified by the Court of Justice in that conduct by a dominant company can be considered abusive where it is capable of exclusionary effects and where it does not constitute competition on the merits.¹²⁴² This legal test also applies to conduct which is legal under other areas of

¹²³⁷ See Section 8.2.1. For rebuttal of Teva's claims that the Commission should show there is no “plausible” explanation justifying its conduct, other than this anticompetitive object, see Recitals (1059)-(1061).

¹²³⁸ ID 4032, Teva's Reply to the Statement of Objections, Section 6.1.1: Judgment of the Court of Justice of 5 October 1988, *Volvo*, C- 238/87, EU:C:1988:477, paragraph 8; Judgment of the Court of First Instance of 30 November 2000, *Industrie des poudres sphériques v Commission*, T-5/97, EU:T:2000:278, paragraph 213; Judgment of the Court of Justice of 16 July 2015, *Huawei Technologies*, C-170/13, EU:C:2015:477, paragraph 46; Judgment of the Court of Justice of 29 April 2004, *IMS Health GmbH & Co. OHG v NDC Health GmbH & Co. KG*, C-418/01, EU:C:2004:257, paragraph 34; Commission Decision of 29 April 2014, *Samsung - Enforcement of UMTS Standard Essential Patents*, Case AT.39939, paragraph 55.

¹²³⁹ ID 4032, Teva's Reply to the Statement of Objections, paragraph 431.

¹²⁴⁰ Case C-457/10 P, *AstraZeneca v Commission*, paragraph 154; Judgment of the Court of First Instance of 17 July 1998, *ITT Promedia v Commission*, T-111/96, EU:T:1998:183, paragraph 56 and Case C-307/18, *Generics (UK) and Others*, paragraph 89.

¹²⁴¹ ID 4032, Teva's Reply to the Statement of Objections, Section 6.1.1.

¹²⁴² Case C-377/20, *Servizio Elettrico Nazionale and Others*, paragraph 103; Judgment of the Court of Justice of 10 September 2024, *Google LLC and Alphabet Inc. v European Commission*, C-48/22, EU:C:2024:726, paragraph 165.

law, given that the special responsibility that rests on undertakings in a dominant position means that Article 102 TFEU may prevent them from engaging in conduct which would be permissible if they did not hold a dominant position. This is the legal test set out and followed in both the Statement of Objections and in this Decision. In both acts Section 8.3 analyses whether Teva's conduct falls outside the scope of competition on merits and Section 8.4 whether Teva's conduct was capable of having anticompetitive (exclusionary) effects. Teva's assertions that the legal test followed by the Commission is "*confused*" and not clearly articulated¹²⁴³ can thus not be accepted.

- (1061) Second, basing itself on the *AstraZeneca* judgement, which states that "*the fact that the regulatory framework offers alternative means, which are longer and more costly, to obtain a MA did not prevent the conduct of an undertaking in a dominant position from being abusive where that conduct, considered objectively, has the sole purpose of rendering the abridged procedure [...] unavailable and therefore of excluding the producers of generic products from the market*"¹²⁴⁴ Teva construes two cumulative requirements that should in its view be established by the Commission: objective anticompetitive purpose of the conduct and absence of any other plausible explanation for that conduct. However, the Court in *AstraZeneca* did not mention these two distinctive requirements and, crucially, it did not consider these elements to be necessary for proving an infringement of Article 102 TFEU. More importantly and in line with the jurisprudence establishing that abuse of a dominant position is an objective concept which does not depend on the anticompetitive intent of the dominant undertaking (see Recital (1032)), the Court of Justices expressly condoned the General Court's finding that "*for the purposes of characterising that conduct as an abuse of a dominant position, it is sufficient to demonstrate that it is such as to restrict competition and, in particular, to constitute an impediment to generic products entering the market and to parallel imports*".¹²⁴⁵ The Court of Justice also noted that "*in the majority of cases, abuses of dominant positions consist of behaviour which is otherwise lawful under branches of law other than competition law*" without inferring any "*exceptional standard*"¹²⁴⁶ that should be applied in such case.¹²⁴⁷
- (1062) Third, as to Teva's reliance on the *ITT Promedia* judgment, the Commission notes that this judgment does not set a pertinent legal test for the assessment of Teva's misuse of the patent system. That judgment concerns situations when competition law can interfere with the exercise of the fundamental right of access to courts and establishes that the Commission did not err by holding that recourse to courts did not represent an abuse in those specific circumstances.¹²⁴⁸ While the Commission does not in this case, take issue with Teva's recourse to courts, it does take issue with Teva's filing of multiple, staggered divisional patents with overlapping content and strategic withdrawal of challenged patents before a reasoned decision on their validity could be issued. This way, Teva was artificially extending legal uncertainty

¹²⁴³ ID 4032, Teva's Reply to the Statement of Objections, paragraph 526.

¹²⁴⁴ Case C-457/10 P, *AstraZeneca v Commission*, paragraph 154.

¹²⁴⁵ Case C-457/10 P, *AstraZeneca v Commission*, paragraph 153.

¹²⁴⁶ ID 4032, Teva's Reply to the Statement of Objections, Section 6.1.1.

¹²⁴⁷ Case C-457/10 P, *AstraZeneca v Commission*, paragraph 132. Teva alleged "exceptional standard" cannot be inferred from the case law concerning specific principles in the context of intellectual property rights (see Section 8.2.2 and more specifically Recitals (1043) and (1044)).

¹²⁴⁸ Case T-111/96, *ITT Promedia v Commission*, paragraphs 60-62.

about its remaining patents. It was precisely Teva's conduct that sought to prevent the access of its only competitor to effective legal review.

- (1063) Teva further argues that the Commission's assessment is grounded in an incomplete description of the EPO system regarding divisionals. Teva provides an overview of the relevant EPO rules.¹²⁴⁹ Thus, in order to further its claim that the conduct and its effects are merely an expression of the patent system, Teva resorts to examples and explanations applicable in the context of primary (compound) patents protecting newly launched products.¹²⁵⁰ For example, Teva explains that patent filings are made in very early stages of product development and therefore might require subsequent adjustments by way of divisional applications once the product characteristics became more obvious.
- (1064) However, Teva's descriptions of the EPO patent system are irrelevant to the facts of the case at hand. This Decision addresses divisional applications of Teva's secondary patents (process patents and dosage patents) related to a product that has been commercialised since the early 2000s¹²⁵¹ and related to characteristics that have been fully known at least since 2007. Accordingly, Teva's conduct cannot be regarded as merely protecting novel features of newly launched products.
- (1065) Finally, the Commission notes that this Decision does not address the functioning of the EPO rules, nor does it assess to which extent Teva's conduct is in line with the applicable patent rules. This Decision only assesses whether Teva's conduct is compatible, or not, with Article 102 TFEU.

8.3. Teva's divisionals game falls outside the scope of competition on the merits

- (1066) Teva's conduct regarding its divisional patents consisted of two combined legs. The first leg consisted in the staggered filings of divisional patents before the EPO that largely overlapped in content. These patents shared essential features and related legal weaknesses, which in turn linked their destinies or, in other words, their risk of being revoked after being challenged, due to defects on these essential features. The second leg of Teva's conduct consisted in the obstruction of effective legal review of the validity of challenged patents through the strategic withdrawals of these patents before the competent appeal instances (i.e. the TBA) could adopt a decision.
- (1067) Teva's conduct artificially prolonged the legal uncertainty concerning the validity of its remaining patents. This conduct was capable of hindering market entry and expansion for all potential GA entrants, and Synthron and its licensees in particular, thus delaying price competition for Teva's Copaxone. The objective of Teva's conduct is apparent from its contemporaneous internal documents as well as from the pattern of the conduct itself, in particular the timing and repetition of divisional patent filings and withdrawals.
- (1068) To support its conclusion that Teva's conduct is abusive, the Commission first shows that Teva's strategy and conduct, considered as a whole, combined the filing of multiple patent applications, which shared essential features and thus related legal weaknesses, on the one hand, with the strategic withdrawal of the challenged patents, on the other hand. This comprehensive conduct shared the objective of creating and artificially prolonging legal uncertainty concerning Copaxone's patent protection

¹²⁴⁹ ID 4032, Teva's Reply to the Statement of Objections, paras. 536-621.

¹²⁵⁰ ID 4032, Teva's Reply to the Statement of Objections, for example paras. 541 and 542.

¹²⁵¹ In February 2015, Teva's {...} explained internally that {...}. (ID 404-1898, Teva internal email dated 2 February 2015 from {...} to {...}).

(Section 8.3.1). The Commission then describes, in more detail, the components of Teva's divisionals game: Teva's staggered filing of divisional patent applications with largely overlapping content before the EPO (Section 8.3.2) and strategic withdrawals of the challenged patents (Section 8.3.3). In particular, the Commission presents how the pattern of Teva's filings and withdrawals was carefully timed to artificially prolong legal uncertainty (Section 8.3.4). Finally, the Commission also rebuts Teva's *ex post* alternative explanations for its conduct (Section 8.3.6).

8.3.1. *Teva engaged in a comprehensive patenting conduct consisting of patent filings and withdrawals aimed at hindering the entry and/or expansion of GA competitors*

- (1069) The main patent for Copaxone – EP '888 was set to expire in 2015. Teva was aware that it would then be faced with – in its own words – a {...}.¹²⁵² Several strategic documents of Teva restate this assessment.¹²⁵³ Teva's only option to prolong its exclusive rights on Copaxone was to resort to filing secondary patents, namely the Original Process Patent and the Original Dosage Patent. At the same time, Teva was aware of inherent weaknesses in these patents and that ultimately, they would likely not withstand validity challenges before the EPO.¹²⁵⁴
- (1070) Teva compensated for the weaknesses of its secondary patents by applying for several generations of overlapping divisional patents. Thus, instead of two secondary patents (i.e. the Original Process Patent and the Original Dosage Patent), Teva could rely on eight patents in total, which actual and potential GA competitors would need to overcome in lengthy validity challenges, one at a time, before being able to enter the market without being exposed to the threat of preliminary injunctions.¹²⁵⁵ Teva relied on the fact that a divisional patent filed later would have a later final determination. While staggering the divisional patent applications and therefore the grants of the divisional patents did not affect the overall potential period of patent protection of a patent family,¹²⁵⁶ the time during which at least one patent actually remained in force during that period was extended. This in turn extended the time during which preliminary injunctions could be sought against entrants on the GA market despite a low likelihood of success on the merits of the divisional patent.¹²⁵⁷

¹²⁵² ID 455-9, Global Commercial Strategic Plan, 5 September 2012, p. 17.

¹²⁵³ ID 455-2, Global Strategic Brand Plan Assumptions COPAXONE ® 2014-2017, 5 March 2013, p. 21; ID 455-55, TEVA European Brand Plan format, April 2013, p. 39.

¹²⁵⁴ For details on Teva's concerns about the weakness of its patents see Section 8.3.3.3.

¹²⁵⁵ See Sections 8.3.3.3 and 8.3.3.4 Teva's conduct fits perfectly into description of a problematic patenting behaviour offered by Teva's President and CEO to the US Congress in 2019: "*But some companies have been seen to make a lot of patents which are not that substantial. And they have had to be challenged. That's part of the generic business model that we have to challenge these many patents that are often not really living up to the innovation standard that should be in a patent, and then those patents eventually get revoked or turned down. And then the generic can launch. So, you could argue that somehow it's not the original patent that's the problem. It's not the patent life of the original patent, but it's sometime the sort of exuberance of many surrounding minor patents that really do not have the innovation in them that they ought to have. And that's maybe something you would say that could be looked at more holistically to avoid that you get so many patents around a product that it delays the generic competition.*" (ID 4952, Unsustainable Drug Prices: Testimony from the CEOs, Hearing before the Committee on Oversight and Reform, U.S. House of Representatives, 30 September 2020, p. 52).

¹²⁵⁶ All divisional patents within the same patent family enjoy the same priority date – that of their ultimate parent patent. In this context, potential patent protection of all patents in Teva's process family was 20 years as of filing of the Original Process Patent (9 September 2005) and potential patent protection of all patents in Teva's dosage family was 20 years as of filing of the Original Dosage Patent (19 August 2010) regardless of when specific divisional patents were filed and granted.

¹²⁵⁷ ID 404-678, Teva internal email from {...} to {...}, {...}, {...} and others of 13 October 2015: {...}.

- (1071) Contrary to Teva’s claims on incompleteness of the Commission’s analysis of the overlapping nature of Teva’s divisional patents,¹²⁵⁸ Teva’s divisional patents indeed shared the same essential features.¹²⁵⁹ For example, the first independent claims¹²⁶⁰ of two divisional patents in the process patent family differ from the first independent claim of the Original Process Patent with respect to the formulation of the results of the allegedly innovative improvement of the manufacturing process for GA. While the Original Process Patent in its first independent claim discloses the use of bromine scavenger¹²⁶¹ to remove free bromine from the solution of hydrobromic acid, both divisional patents simply add the levels of free bromine (less than 0.5 in EP ‘528 and less than 0.1 in EP ‘924) while EP ‘528 adds also a level of metal ion impurities (less than 1000 ppm).¹²⁶² However, the allegedly inventive solution to the contamination issue and discoloration issue remains the same across all first independent claims in the process family.¹²⁶³
- (1072) Similarly, the first independent claims of all patents in the dosage patent family provide for a new, allegedly inventive, dosage regime of three subcutaneous injection of GA every seven days (or, as EP ‘335 indicates, every week) with at least one day between two such injections. The only difference between these patents is that each time, the dosage regime is combined either with a different, well established patient

¹²⁵⁸ ID 4032, Teva’s Reply to the Statement of Objections, paragraph 664.

¹²⁵⁹ See Section 8.3.2.1.

¹²⁶⁰ A patent application contains one or more claims directed to the essential features of the invention. These claims are called “independent”. Any such independent claim may be followed by one or more claims concerning embodiments of that invention which must effectively include also the essential features of the invention, and hence must include all the features of at least one independent claim. Any claim which includes all the features of any other claim is termed a “dependent claim” (Guidelines for examination in the European Patent Office, March 2024, Part F, chapter IV, 3.4 Independent and dependent claims).

¹²⁶¹ A bromine scavenger is a chemical substance added to mop up the free bromine (see ID 4032, Teva’s Reply to the Statement of Objections, para. 670). The Commission also notes that use of bromine scavenger in pretreatment of solution of a hydrobromic acid is included in EP ‘528 as well (dependent claims 6 and 7).

¹²⁶² The first independent claim of the Original Dosage Patent reads: “***In a process for obtaining trifluoroacetyl glatiramer acetate, wherein during the process a batch of a mixture of polypeptides, each of which consists essentially of alanine, γ -benzyl glutamate, tyrosine and trifluoroacetyl lysine is deprotected with a solution of hydrobromic acid in acetic acid, the improvement comprising a step of pretreatment of the solution of hydrobromic acid with a bromine scavenger in order to remove free bromine.***” The first independent claim of EP ‘528 reads: “***A process for obtaining a mixture of trifluoroacetyl glatiramer acetate, wherein during the process a batch of a mixture of polypeptides, each of which consists of alanine, γ -benzyl glutamate, tyrosine and trifluoroacetyl lysine is deprotected with a solution of hydrobromic acid in acetic acid, the improvement comprising use of a solution of hydrobromic acid in acetic acid, which solution comprises less than 1000 ppm of metal ion impurities, and less than 0.5% of free bromine.***” The first independent claim of EP ‘924 reads: “***In a process for obtaining a mixture of trifluoroacetyl glatiramer acetate, wherein the mixture has a desired average molecular weight and wherein during the process a batch of a mixture of polypeptides, each of which consists of alanine, γ -benzyl glutamate, tyrosine and trifluoroacetyl lysine is deprotected with a solution of hydrobromic acid in acetic acid, the improvement comprising use of a solution of hydrobromic acid in acetic acid, which solution comprises less than 0.1% of free bromine.***” (highlights added by the Commission indicate overlapping content).

¹²⁶³ Contamination issue relates to the contamination of GA batches with brominated tyrosine. The solution proposed by Teva was use of hydrobromic acid (solution used in the GA manufacturing process) with low levels of free bromine, e.g. after treatment by a bromine scavenger. The discoloration issue relates to certain of GA batches turning pink. Teva identified that the source of issues was presence of metal ion impurities and proposed a solution of using a hydrobromic acid with low levels of impurities or use of glass lined piping (ID 4032, Teva’s Reply to the Statement of Objections, paras. 670-690).

subset (i.e. with a reference to RMS, RRMS or CIS patients),¹²⁶⁴ and/or a known secondary feature of GA, notably the well-known excipient mannitol and a defined pH range (both present already in 20 mg/ml Copaxone).¹²⁶⁵

- (1073) While each of the divisional patents was a separate intellectual property right and enjoyed a procedural life of its own, their validity was ultimately tied to these essential features already included in their respective parent patent (i.e. the Original Process Patent and the Original Dosage Patent) rather than to their individual minor distinguishing features.¹²⁶⁶ As a consequence, Teva's secondary and divisional patents would be fatally weakened by the precedent value of a revocation of the parent patent.¹²⁶⁷
- (1074) The multiplication of overlapping patents in the process and dosage patent families gave Teva the opportunity to strategically withdraw a patent whenever it became subject to an imminent validity decision by the TBA, while still having in place another patent with the same essential features and overlapping claims. After the withdrawal of one divisional, Teva could rely on another divisional to prevent

¹²⁶⁴ For different sub-types of the MS see Section 6.3.1.

¹²⁶⁵ The first independent claim of the Original Dosage Patent reads: "***A medicament comprising glatiramer acetate for use in treating a patient who is suffering from relapsing-remitting multiple sclerosis or who has experienced a first clinical episode and is at high risk of developing clinically definite multiple sclerosis, wherein the medicament is to be administered in a regimen of three subcutaneous injections of a 40mg dose of glatiramer acetate every seven days with at least one day between each subcutaneous injection.***" The first independent claim of EP '962 reads: "***Glatiramer acetate in the form of a pharmaceutical composition for use in treating a human patient suffering from a relapsing form of multiple sclerosis in a regimen of three subcutaneous injections of a 40 mg dose of glatiramer acetate every week with at least one day between every subcutaneous injection and wherein the pharmaceutical composition further comprises mannitol and has a pH in the range of 5.5 to 7.0.***". The first independent claim of EP '335 reads: "***Glatiramer acetate for use in a regimen of three subcutaneous injections of a 40mg dose of glatiramer acetate every seven days with at least one day between each subcutaneous injection for use in treating a patient who is suffering from a relapsing form of multiple sclerosis or who has experienced a first clinical episode and is at high risk of developing clinically definite multiple sclerosis and wherein the pharmaceutical composition further comprises mannitol.***" The first independent claim of EP '172 reads: "***Glatiramer acetate for use in treating a human patient suffering from a relapsing form of multiple sclerosis or who has experienced a first clinical episode and is determined to be at high risk of developing clinically definite multiple sclerosis, comprising administering to the human patient three subcutaneous injections of 40mg glatiramer acetate for every seven days with at least one day between every subcutaneous injection, wherein the glatiramer acetate is present in a pharmaceutical composition having a pH in the range of 5.5 to 7.0.***"

¹²⁶⁶ See Section 8.3.2.1.

¹²⁶⁷ Contrary to Teva's assertion that the Commission's analysis is grounded in IP law considerations falling outside the Commission's competence (for example, ID 4032, Teva's Reply to the Statement of Objections, para. 646 and 870-872, see also ID 5695, Teva's Reply to the Letter of Facts I of 9 February 2024, para. 256), the Commission does not engage in the assessment of validity of the patents nor is such assessment implied in the conclusion that Teva's comprehensive patenting conduct consists of both patent filings and withdrawals. As explained in Recitals (1083)-(1090) and Section 8.3.2, the Commission's finding that Teva's consecutive filings of divisional patents constitutes an element of Teva's abusive patenting conduct within CCP is based on a detailed analysis of Teva's patent filings, their content and timing and on an assessment of Teva's contemporaneous internal documents. Similarly, the finding that Teva was concerned about the strength of its patents in the process and dosage families (Section 8.3.3.3) is not based on the Commission's assessment of whether a particular patent was invalid or not but rather on thorough assessment of Teva's documents evidencing internal communications on patent weaknesses and likely outcomes of the review proceedings. In any event, the analysis of Teva's patents, their content and scope, and their similarities for the purposes of applying Article 102 TFEU clearly falls within the Commission's powers (Case C-193/83, *Windsurfing International v Commission*, paragraph 26).

potential GA entrants to launch their product on the market. Indeed, Teva could enforce multiple patents consecutively as long as it still had another {...}.¹²⁶⁸

- (1075) Potential GA entrants (including Synthron and its licensees) challenged Teva's patents forming part of the process patent family and the dosage patent family before the EPO. Absent Teva's conduct, the TBA would have been able to adopt a reasoned decision on the validity of the Original Process Patent already in 2015¹²⁶⁹ and the Original Dosage Patent already in 2017¹²⁷⁰, clarifying the precise scope of Copaxone's patent protection and significantly reducing the legal uncertainty for both Teva and actual or potential GA entrants. In addition, as illustrated by developments in the dosage family,¹²⁷¹ such decision would likely facilitate (in)validity decisions concerning remaining patents in the family. However, Teva was aware that these validity challenges were likely to lead to the revocation of its Original Process Patent and its Original Dosage Patent and thus decided to withdraw the text of these patents before the adoption of a reasoned decision by the TBA.¹²⁷²
- (1076) The notes of {...}{...} dated January 2017 lay out the strategy of carefully sequencing the patents and clearly show the close link between Teva's patent filings and withdrawals (referred to as "abandoning" in {...} notes):
 {...} (emphasis added).¹²⁷³
- (1077) A telling reminder at the end to obtain antitrust advice echoes concerns expressed on several other occasions that Teva's conduct involved serious perils and that it should be kept covert: {...} (emphasis added).¹²⁷⁴
- (1078) Teva's strategy, so meticulously set out in the notes quoted in Recital (1076), was implemented both in the patent invalidity challenges before the EPO, as well as on national level in the Netherlands, and both with respect to the process patent family and the dosage patent family. For example, Teva withdrew the Original Process Patent (EP '703) on 3 February 2015. Just a day earlier, Teva's {...} had recommended its withdrawal to {...} and received their approval: {...}.¹²⁷⁵
- (1079) The same pattern emerges when examining Teva's decision to withdraw its dosage patents in the Netherlands. Following Synthron's invalidity action against the Original Dosage Patent in the Netherlands, Teva expected that the competent court would revoke it: {...}.¹²⁷⁶ Teva expected a revocation decision in the Netherlands, which would create a damaging precedent for its entire dosage patent family in the Netherlands as well as a persuasive guidance that could be relied on by Synthron and its licensees in other jurisdictions as well. Therefore, discarding the dosage family in

¹²⁶⁸ ID 404-2555, Teva internal email dated 16 March 2016 from {...} to {...} and others.

¹²⁶⁹ See Table 13 below.

¹²⁷⁰ See Table 14 below.

¹²⁷¹ In the dosage family, the revocation of EP '335 by TBA effectively facilitated revocations of other divisional patents in the same family (EP '962 and EP '172; see Section 8.3.3.6.2).

¹²⁷² See Section 8.3.3.3.

¹²⁷³ ID 404-1841, Teva internal email dated 4 January 2017 from {...} to {themselves}, p. 1.

¹²⁷⁴ ID 404-1601, Teva internal email dated 3 February 2017 from {...} to {...}. See also ID 413-25, Teva internal email dated 16 October 2015 from {...} to {...} and others entitled {...}, and ID 404-1877, Teva internal email dated 6 February 2015 from {...} to {...} and others: {...} (emphasis added).

¹²⁷⁵ ID 404-1647, Teva internal communication between {...}, {...}, {...} and others, 2 February 2015, (emphasis added). In a follow-on email, Teva's {...} further explained {...} (ID 455-1205, Teva internal email dated 2 February 2015 from {...} to {...} and others, p. 1.) See also, ID 404-1960, Teva internal email dated 2 February 2015 from {...} to {...} and others.

¹²⁷⁶ ID 455-428, Teva internal email dated 4 March 2015 from {...} to {...}.

the Netherlands (through a withdrawal of the text of the Original Dosage Patent, non-validation of EP ‘335 and de-designation of EP ‘962)¹²⁷⁷ aimed to {...}¹²⁷⁸ as well as before the EPO from any negative inferences.¹²⁷⁹

- (1080) The sole aim of Teva’s conduct was to artificially prolong legal uncertainty concerning Copaxone patents and thereby hinder market entry and uptake of competing GA products. Teva was well aware of the consequences of its conduct for Synthon and its licensees. For example, in a WhatsApp conversation on 16 July 2019 following the rejection of a request for a preliminary injunction in Italy, {...} mentioned that {...}.¹²⁸⁰
- (1081) Teva’s comprehensive patenting conduct was based on the following two considerations made by Teva and evidenced in multiple contemporaneous documents:
- Teva’s patents were weak and would likely not survive validity challenges: {...},¹²⁸¹
 - a negative reasoned decision would both accelerate the revocation of Teva’s remaining patents and reduce Teva’s chances to obtain preliminary injunctions: {...}¹²⁸² In a follow-on email it was further explained: {...}¹²⁸³
- (1082) If Teva genuinely believed that its earlier-generation patents were valid, there was no reason for it to withdraw these patents prior to a final reasoned decision on their validity.¹²⁸⁴ After all, a positive and well-reasoned decision by a TBA (or a reputable national patent court such as a court in the Netherlands) on the validity of earlier-generation patents would have positively affected the validity and enforceability of next-generation divisional patents. If a TBA were to hold earlier-generation patents valid, this would have allowed Teva to keep in place not only preliminary but also permanent injunctions on the basis of these patents until the end of the patent term of their respective families in 2025 and 2030, without the need to enforce, or even file any (further) divisional patents.
- (1083) In its Reply to the Statement of Objections, Teva attempts to establish that the different filings of patent applications in the process and dosage families are not interlinked. According to Teva, there is “*no document in the case file that shows (i) any link between the Filings and the Withdrawals or (ii) any considerations regarding the timing of the Filings and Withdrawals*”. Teva also asserts that there is no evidence that filings would have been considered in combination with

¹²⁷⁷ ID 455-751, FAST DT MS update July 2017, 13 July 2017. The patentee is in full control of the geographic scope of its European patent. It can de-designate certain EPC member states before the grant of the patent, and, even after the grant, may choose not to pursue the required validation process (e.g. with respect to the translation of claims). In both cases the situation is the same: the European patent is not in force in the respective EPC member state.

¹²⁷⁸ ID 404-2142, Teva internal email dated 25 January 2017 from {...} to {...}.

¹²⁷⁹ ID 404-2148, Teva internal email dated 13 February 2017 from {...} {...}: {...}

¹²⁸⁰ ID 455-2158, Teva internal WhatsApp conversation dated 16 July 2019 between {...}) and {...}, p. 6-7.

¹²⁸¹ ID 404-1647, Teva internal email dated 2 February 2015 from {...} to {...} and others. See Section 8.3.3.3.

¹²⁸² ID 404-1647, Teva internal email dated 2 February 2015 from {...} to {...} and others.

¹²⁸³ ID 455-1205, Teva internal email dated 2 February 2015 from {...} to {...} and others, p. 1.

¹²⁸⁴ See Section 8.3.6.

withdrawals. Therefore, Teva claims that these filings and withdrawals could only be assessed separately, as independent distinct practices.¹²⁸⁵

- (1084) Teva’s argument cannot be accepted for at least three reasons. First, Teva’s assertion that the link between the filings and withdrawals is not supported by the Commission’s file is plainly incorrect. As the most prominent example, the Commission notes that an overview of the patenting conduct prepared by {...} clearly illustrates an interplay between patent grants (which presuppose patent filings) and their withdrawals (see Recital (1076)). Not only does this strategic overview expressly link considerations concerning different filings and withdrawals, and thus contradicts Teva’s claim, but also, remarkably, the steps set out by {...} in {...} overview were meticulously followed in practice (on the timing of the executed steps and reasoning behind see Section 8.3.4).¹²⁸⁶
- (1085) Other documents on the Commission’s file also confirm the connection between patent filings and withdrawals and illustrate the comprehensive nature of Teva’s patenting conduct within the CCP. For example, {...}.¹²⁸⁷ This evidence places divisional patent filings (as well as withdrawals)¹²⁸⁸ within the CCP strategy and binds them together with all other activities aiming to artificially prolong Copaxone’s exclusivity rights such as a disparagement campaign targeting competing GA and regulatory litigation against marketing authorisations of competing GA (see Section 5.2.3).
- (1086) Furthermore, {...}.¹²⁸⁹ {...},¹²⁹⁰ {...}.¹²⁹¹
- (1087) Second, Teva’s argument that its filings and withdrawals should be assessed separately is contradicted by Teva’s own Reply to the Statement of Objections. More specifically, Teva often refers to a new divisional patent being “*better suited for*

¹²⁸⁵ ID 4032, Teva’s Reply to the Statement of Objections, for example, paras. 631 and 640; ID 5695, Teva’s Reply to the Letter of Facts I of 9 February 2024, paras. 210-218, ID 5909, Teva’s Reply to the Letter of Facts II of 17 May 2024, para. 102.

¹²⁸⁶ Teva ultimately did not “abandon” EP ‘335 since the competent court in Germany ordered it to abstain from withdrawing approval of the text of EP ‘335 (LG München I, Beschluss v. 24 February 2020 – 7 O 1456/20).

¹²⁸⁷ ID 404-1705, Personal notes by {...} of 27 September 2016, p. 1.

¹²⁸⁸ For strategic considerations regarding withdrawals see especially Section 8.3.3.3 and 8.3.3.4.

¹²⁸⁹ ID 5562, Teva internal correspondence between {...}, {...} and {...} of 25 January 2017, p. 1-2. ID 5557 Teva internal correspondence between {...} and {...} of 25 January 2017, p. 1.

¹²⁹⁰ See also Recital (1086).

¹²⁹¹ Teva argues that the evidence referred to in this Recital should not be taken into account. According to Teva, the objections addressed to Teva are “*that the filings of the divisional applications in the Dosage Family were linked with the withdrawal of EP ‘749’*” (emphasis in the original) while these documents relate to the withdrawal of Dutch designation for EP ‘962 and therefore extend the scope of objections (ID 5695, Teva’s Reply to the Letter of Facts I of 9 February 2024, para. 218). Teva’s assertion should be rejected. Teva again strives to misconstrue the Commission’s analysis and insists on atomising the assessment of Teva’s conduct so that every action by Teva is assessed in isolation. However, the Commission established that Teva’s comprehensive patenting conduct within the CCP consisted of filings and withdrawals which shared the objective of creating and artificially prolonging legal uncertainty concerning Copaxone patent protection. In this context, and in order to rebut Teva’s arguments on the clear separation between patent filings and withdrawals, the Commission relies on the above evidence not only to demonstrate that Teva’s teams in charge of patent filings and withdrawals were closely collaborating but also to illustrate the different considerations that went into Teva’s decisions to file a divisional patent and when to file it. This evidence therefore does not extend the scope of objections against Teva (it should be noted that the withdrawal of the Dutch designation from EP‘962 with a view of avoiding the Arrow declaration was expressly mentioned in the Statement of Objections, Recital 924 and footnote 930).

Teva's enforcement strategy” as a reason for withdrawal of an older one.¹²⁹² Teva's position reveals that withdrawals were influenced by the remaining patent portfolio, in other words, by filings of other (newer) divisional patents.

- (1088) Third, Teva's internal correspondence from February 2014 shows that members of Teva's patent department responsible for the filing and the prosecution of patents were involved in the discussions on Copaxone litigation strategies since at least February 2014. It thus supports the conclusion that patent filings, enforcement and withdrawals all represent elements of a single comprehensive patenting conduct by Teva.¹²⁹³ Similarly, an internal email from Teva's {...} of 2 February 2017 shows that {...}.¹²⁹⁴ This confirms that patent filings (including filings of divisional patents) were not made as {...} but rather as part of the broader patenting strategy that introduced considerations relevant for the {...}, i.e., enforcement considerations, already at the stage of patent filings and not only at the stage of withdrawals where, according to Teva, they played a crucial role.
- (1089) In addition, in the context of Teva's divisionals game addressed in this Decision, its second element (i.e. strategic withdrawals) was feasible only because of the first element (staggered filings). It would be useless to withdraw a patent if there was no other patent with the same essential features that would have remained in place. It would equally be useless to withdraw a patent if the decision on the next one would have occurred almost immediately afterwards. Conversely, the first element (staggered filings) was useful since, by its second element (withdrawals) Teva was able to prevent a negative effect of a revocation decision on the earlier challenged patent.
- (1090) To conclude, Teva intentionally insists on an artificial separation of its comprehensive patenting conduct, despite the evidence that such conduct was driven by a single strategic objective: to artificially maintain exclusivity for Copaxone and keep potential entrants and Synthron and its licensees in particular out of the market. In this context, it is Teva's staggered filings and strategic withdrawals of the challenged patents resulting in an artificially prolonged legal uncertainty about the validity of Teva's exclusive rights flowing from its remaining divisional patents, that constitutes the conduct addressed in this Decision and the conduct capable of having the exclusionary effects described in Section 8.4.¹²⁹⁵ Teva's insistence on separate assessment of filings and withdrawals and denial of a comprehensive patenting conduct comprising of staggered filings of patents affected by the same weaknesses and carefully timed strategic withdrawals obstructing legal review of the challenged patents, while other patents with overlapping claims and the same essential features

¹²⁹² ID 4032, Teva's Reply to the Statement of Objections, para. 801.

¹²⁹³ {...} (ID 266-296, Teva internal emails from {...} to {...} and {...} of 4 and 9 February 2014, p. 1).

¹²⁹⁴ ID 5564, Teva internal email {...} to {...} of 2 February 2017, p. 1.

¹²⁹⁵ Teva argues that the conduct constituting misuse of divisional patents “*however [it] is envisaged, [...] necessarily stopped a long time ago*” (ID 4032, Teva's Reply to the Statement of Objections, para. 1436). Teva maintains that (i) filings of divisional patents as well as Teva's actions in enforcing and defending them were legitimate and cannot be considered as being part of an abuse and that (ii) last Teva's withdrawal of a patent dates back to February 2017 (ID 4032, Teva's Reply to the Statement of Objections, paras. 1433-1435). Teva's arguments do not convince. While Teva's arguments regarding duration of infringement are addressed in detail in Section 12.1, it suffices to underline here that Teva actively defended its two remaining dosage divisionals (EP '962 and EP '172) until the final TBA decision confirming their invalidity as well as maintained their validity in the relevant Member States by payment of the relevant fees. Teva thus actively ensured that it “{...}” (ID 404-2555, Teva internal email dated 16 March 2016 from {...} to {...} and others, p. 1) until 7 February 2024.

remained in place, contradicts the evidence on the file and Teva's own claims submitted in the Reply to the Statement of Objections.¹²⁹⁶

8.3.2. *Teva filed staggered divisional patents with overlapping content to multiply its process and dosage patents, prevent parallel review and prolong legal uncertainty*

(1091) Teva has artificially extended its exclusivity rights regarding Copaxone by creating multiple divisional patents, which shared the same risk of invalidity, tied to their largely overlapping content (Section 8.3.2.1). To compensate for their weaknesses and avoid the risk of quick and simultaneous revocation, Teva strategically staggered the filing of its patents to prevent their parallel review. The staggered filing of divisional patents, together with their strategic withdrawals, have delayed a final decision on the patents' validity (Section 8.3.2.2).

8.3.2.1. Creation of multiple divisional patents with significantly overlapping content

(1092) As summarised in Section 8.1, Teva created a string of divisional patents based on each of its secondary patents, i.e. the Original Process Patent and the Original Dosage Patent. Table 13 and Table 14 below provide an overview of Teva's patents forming part of the process patent family and the dosage patent family respectively. These tables show, for each patent, the date on which the patent was filed, the date on which the patent was granted, the initial expiration date of the patent, the validity challenges brought against each patent before the EPO and the outcome of these validity challenges.

¹²⁹⁶ See Section 8.4.

Table 13: Overview of Teva’s process patents

Patent	Filed on:	Granted on:	Expiration date:	Challenged by:	OD’s decision on:	Appeal of the OD’s decision by:	Withdrawal?	TBA’s decision on:
EP ‘703 ¹²⁹⁷	9.9.2005	6.1.2010	9.9.2025	Synthon	27.2.2012 (patent maintained)	Synthon	Yes, on 3.2.2015 (before the hearing)	10.2.2015 (patent revoked on procedural grounds)
EP ‘528 ¹²⁹⁸	5.1.2010	7.12.2011		Synthon, Mylan, Henkel, Breuer & Partner ¹²⁹⁹	27.5.2014 (patent maintained)	Synthon, Mylan, Henkel, Breuer & Partner	Yes, during the hearing on 13-14.10.2015	14.10.2015 (patent revoked on procedural grounds)
EP ‘924 ¹³⁰⁰	9.12.2010	11.12.2013		Synthon, Mylan, Actavis ¹³⁰¹ , Hexal ¹³⁰²	25.4.2016 (patent maintained)	Synthon, Mylan, Actavis ¹³⁰³ , Hexal, G.L. Pharma ¹³⁰⁴	No	12.9.2017 (patent revoked by reasoned decision) ¹³⁰⁵

¹²⁹⁷ Or the Original Process Patent.

¹²⁹⁸ EP 2 177 528, a divisional application of EP ‘703.

¹²⁹⁹ Although Henkel, Breuer & Partner is listed as one of the opponents (together with Mylan and Synthon) in the proceedings against the divisional patent EP ‘528, it appears likely that they were representing Hexal AG. This is because Hexal AG is represented by Henkel, Breuer & Partner in the proceedings against EP ‘924.

¹³⁰⁰ EP 2 361 924, a divisional application of EP ‘703 and EP ‘528.

¹³⁰¹ Actavis (which became Allergan in 2015) was acquired by Teva in 2016.

¹³⁰² Hexal AG is a subsidiary of Novartis integrated into its Sandoz division notably active in the development of MS treatments. The Sandoz division of Novartis is one of the largest global producers of generic pharmaceuticals and biosimilars. In 2015, Sandoz launched Glatopa in the United-States, the first generic-like version of Copaxone 20 mg (ID 2470, Sandoz’s press release on launch of Glatopa 20 mg, accessed on 19 September 2022). In 2018, Sandoz launched the 40 mg version of Glatopa in the United States (ID 2478, Sandoz’s press release on launch of Glatopa 40 mg, accessed on 19 September 2022).

¹³⁰³ Actavis’s opposition withdrawn before the TBA’s decision.

¹³⁰⁴ G.L. Pharma GmbH is an internationally operating, pharmaceutical company based in Lannach/Graz, Austria which engages in the development, production, marketing and distribution of branded and generic pharmaceuticals products. G.L. Pharma holds the marketing rights for Synthon GA in Austria. ID 2412, G.L. Pharma’s Reply to Article 18(2) Request of 15 June 2021, p.1.

¹³⁰⁵ TBA decided that neither the patent as granted nor any of the amendments proposed by Teva during the appellate proceedings (by way of auxiliary requests) could be upheld since they contained an added matter (in other words, extended the scope over the limits set out in the original patent application). ID 5676, EP2361924 – Decision of the Technical Board of Appeal 3.3.04, 12 September 2017.

Table 14: Overview of Teva’s dosage patents

Patent	Filed on:	Granted on:	Expiration date:	Challenged by:	OD’s decision on:	Appeal of the OD’s decision by:	Withdrawal?	TBA’s decision on:
EP ‘749 ¹³⁰⁶	19.8.2010	8.5.2013	19.8.2030	Synthon Mylan Actavis	19.1.2016 (patent maintained)	Synthon, Mylan, Actavis ¹³⁰⁷	Yes, on 2.2.2017 (before the hearing)	10.2.2017 (patent revoked on procedural grounds)
EP ‘962 ¹³⁰⁸	30.4.2013	27.6.2018		Synthon, Mylan, Alvogen, G.L. Pharma, Hexal	4.2.2022 (patent revoked) ¹³⁰⁹	Teva	No	07.02.2024 (patent revoked by reasoned decision) ¹³¹⁰
EP ‘335 ¹³¹¹	8.6.2015	4.1.2017			13.5.2019 (patent maintained)	Synthon, Mylan Alvogen, G.L. Pharma, Hexal	No ¹³¹²	10.9.2020 (patent revoked by reasoned decision) ¹³¹³
EP ‘172 ¹³¹⁴	23.2.2017	11.7.2018			27.1.2022 (patent revoked) ¹³¹⁵	Teva	No	07.02.2024 (patent revoked by reasoned decision) ¹³¹⁶

¹³⁰⁶ Or the Original Dosage Patent.

¹³⁰⁷ Opposition withdrawn before the TBA’s decision.

¹³⁰⁸ EP 2 630 962, a divisional application of EP ‘749.

¹³⁰⁹ The OD indicated that it found “*itself in position of having to follow the decision of the board of appeal* [i.e. the decision of the TBA dated 10 September 2020 revoking EP ‘335] *as far as the same facts are concerned*” and concluded that “*there was no doubt about the applicability of the principles of res iudicata*”. ID 5693, EP2630962 – Decision of the Opposition Division, 4 February 2022, p.3.

¹³¹⁰ TBA decided the claims of the patent as granted or as amended by Teva during the appellate proceedings (by way of auxiliary requests) could not be upheld since they contained an added matter, or lacked an inventive step or were not disclosed sufficiently. ID 5823, EP2630962 – Decision of the Technical Board of Appeal 3.3.04, 7 February 2024.

¹³¹¹ EP 2 949 335, a divisional application of EP ‘749 and EP ‘962.

¹³¹² In a decision dated 24 February 2020, the Regional Court of Munich (in the context of proceedings for the grant of a preliminary injunction) ordered Teva to refrain from withdrawing the approval of the text for EP ‘335, see LG München I, Beschluss v. 24 February 2020 – 7 O 1456/20. See also Section 8.3.3.6.2.

¹³¹³ TBA decided the claims of the patent as upheld by OD lacked inventive step.

¹³¹⁴ EP 3 199 172, a divisional application of EP ‘749, EP ‘962 and EP 17153450A (a divisional application that was not granted, internally referred to as the “ghost divisional”). See ID 404-870, Teva internal email dated 13 February 2017 from {...} to {...}.

¹³¹⁵ The OD indicated that it found “*itself in position of having to follow the decision of the board of appeal* [i.e. the decision of the TBA dated 10 September 2020 revoking EP ‘335] *as far as the same facts are concerned*” and concluded that “*there was no doubt about the applicability of the principles of res iudicata*”. ID 5694, EP3199172 – Decision of the Opposition Division, 27 January 2022, pp. 2-3.

Patent	Filed on:	Granted on:	Expiration date:	Challenged by:	OD's decision on:	Appeal of the OD's decision by:	Withdrawal?	TBA's decision on:
EP '286 ¹³¹⁷	21.6.2018	12.8.2020		Synthon, Mylan	<i>Proceedings are currently pending before the OD</i>			

¹³¹⁶ TBA decided the claims of the patent as granted or as amended by Teva during the appellate proceedings (by way of auxiliary requests) could not be upheld since they contained an added matter, or lacked an inventive step or were not disclosed sufficiently. ID 5825, EP3199172 – Decision of the Technical Board of Appeal 3.3.04, 7 February 2024.

¹³¹⁷ EP 3 409 286, a divisional application of EP '749 and EP '962.

- (1093) In Sections 8.3.2.1.1 and 8.3.2.1.2 below, the Commission provides a detailed description of Teva’s patents in the process and dosage families. The Commission also demonstrates that the patents belonging to each of the patent families shared essential features exposing them to the same risks as regarding their validity.
- (1094) Teva alleges that by finding that Teva created multiple significantly overlapping patents, “*the SO considers that because there were overlaps between the divisionals (among themselves and with the parent application), Teva was attempting to obtain the same protection for Copaxone, which it kept renewing by filing further divisionals, which it could then withdraw to ‘rely’ on the next divisional.*” In this context, Teva claims that it was not deliberately and artificially seeking overlaps between its patent filings, but that those overlaps are an inevitable consequence of the EPC’s rules. According to Teva, a divisional can only be based on the direct and unambiguous language of its parent patent.¹³¹⁸ Anything that extends the technical content of a divisional beyond that of its parent would be considered invalid due to added matter. It would, therefore, not have been possible for Teva to file divisionals that did not “overlap” with the original patent and the other divisionals in the same family. Teva also argues that the number of Teva’s divisionals is well within the industry standards and cannot be considered as a multiplication.¹³¹⁹
- (1095) Teva misrepresents the Commission’s position. The Commission does not allege that Teva tried to obtain “*the same protection for Copaxone*”, or that Teva’s patents analysed in this Decision should not have been allowed by the EPO as an instance of the prohibited double patenting. This Decision rather establishes that all of Teva’s secondary divisional patents shared material features (see Section 8.3.2.1.1 and 8.3.2.1.2)¹³²⁰ helping to add additional layers of protection for the same claimed invention (the inventions not being the compound – GA – itself or its use for treatment of MS, but rather an alleged improvement in the manufacturing process (process family) and dosing regimen for Copaxone (dosage family)). These shared material features ingrained the same deficiencies in all patents within the same family. While indeed there were differences among the divisional applications and therefore no double patenting, these differences did not remove the obstacles to patentability already embedded in the parent patents. Therefore, a decision on the (in)validity of the parent would entail a cascading effect regarding the validity of all of the divisionals in the same patent family and Teva’s ability to effectively enforce these patents. (see Sections 8.3.3.2, 8.3.3.3 and 8.3.3.4).
- (1096) In this context, whether the number of Teva’s divisionals is within the industry standards is not relevant for the Commission’s analysis. What is relevant is that Teva filed multiple divisional patent applications sharing essential features affected by the same obstacles to patentability (thus multiplying the number of patent barriers for a GA competitor to overcome in litigation), which however did not remove the deficiencies of the parent patents and which were thus exposed to the same challenges to their validity. Teva then withdrew its patents, one after the other, as late as possible when they were contested, while at least another patent of the same

¹³¹⁸ ID 4032, Teva’s Reply to the Statement of Objections, paras. 551-553, 665-666. See also ID 5695, Teva’s Reply to the Letter of Facts I of 9 February 2024, paras. 237-239.

¹³¹⁹ ID 4032, Teva’s Reply to the Statement of Objections, paras. 661-662. See also ID 5695, Teva’s Reply to the Letter of Facts I of 9 February 2024, paras. 229-236. Teva’s arguments concerning alleged distinguishing features of the patents in the process and dosage families are addressed in Section 8.3.2.1.1 and Section 8.3.2.1.2 respectively.

¹³²⁰ See also Recitals (1071)-(1072).

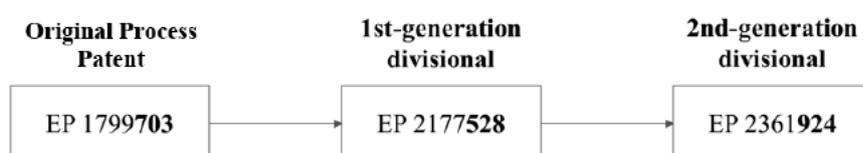
family remained in place, thereby obstructing and delaying the effective legal review of the essential features shared by all the patents of that family and ultimately aiming at hindering the entry of potential GA entrants on the market.

8.3.2.1.1. Multiplication of significantly overlapping process patents

(1097) As described in Table 13 above, Teva filed three patents relating to claimed improvements in the manufacturing process of GA, namely EP ‘703 (or the Original Process Patent) and the divisional patents EP ‘528 and EP ‘924.

(1098) Figure 33 below provides a schematic overview of the process patent family. It shows, through arrows, that the first divisional patent, EP ‘528, was based on the Original Process Patent and that the second divisional patent, EP ‘924, was based on the first divisional patent (in addition to the Original Process Patent).¹³²¹

Figure 33: Structure of Teva’s process patent family



Source: EPO

(1099) The patents belonging to the process patent family claim solutions for two different kinds of impurities that Teva identified in GA regarding (i) the level of brominated tyrosine and (ii) metallic impurities. Teva’s process patents all describe a pre-treatment with a bromine scavenger to reduce the level of brominated tyrosine and the use of a non-metallic reactor to avoid metal impurities. All three process patents make claims for the avoidance (or removal) of these impurities through the same steps. They only differ with regard to the different maximum concentrations of bromine and metal ion impurities, as described in Table 15.

Table 15: Divisional process patents' overlapping and main distinguishing features

Patent	Year of filing	Overlapping features	Main distinguishing features	Resulting product
EP ‘703	2005	A process for making GA with the use of hydrobromic acid in acetic acid pretreated with a bromine scavenger i) with a colour of less than 2000 APHA (colour scale) and ii) measuring the percentage of brominated tyrosine in GA	n/a (original parent patent)	GA with i) no more than 0.1% brominated tyrosine, and ii) less than 1000 ppm (parts per million) metal ion impurities
EP ‘528	2010	A process for making GA with the use of pretreated hydrobromic acid in acetic acid with i) less than 1000	Lower values for the concentration of free bromine and metal ion content and the colour	GA made with any of the processes described in the third column

¹³²¹ As explained above in Section 4.1, pursuant to section “1.1.2 – Sequences of divisional applications” of the EPO’s Guidelines for examination, “[a] divisional application can also be an earlier application [...] for the purposes of one or more further divisional applications. [...] In a sequence of divisional applications, a first-generation divisional application is a divisional application based on an application which is not itself a divisional application, i.e. the root application. A second-generation divisional application is a divisional application based on a first-generation divisional application; and so on”.

		ppm metal ion impurities, ii) less than 0.5% of free bromine, iii) a colour of less than 2000 APHA; and iv) a method for measuring the percentage of brominated tyrosine in GA	intensity (APHA) than in EP ‘703	
EP ‘924	2010	A process for making GA with the use of hydrobromic acid in acetic acid pretreated with i) less than 1000 ppm metal ion impurities, ii) less than 0.1% of free bromine, iii) a colour of less than 2000 APHA, and iv) a method for measuring the percentage of brominated tyrosine in GA	The patent includes altogether 32 claims which repeat the claims present in either EP ‘703 or EP ‘528 further specifying them with respect to values of free bromine, metal ion impurities and measurement of colour. ¹³²²	GA with i) less than 0.1% brominated tyrosine and ii) less than 1000 ppm metal ion impurities or a colour of less than 2000 APHA

Source: ID 2511, Synthon’s Reply to Article 18(2) Request of 5 July 2022 and Commission based on data from the European Patent Office website.

(1100) The OD noted when summarizing the Original Process Patent that: “*The [Original Process Patent] contains 6 independent claims, all of which are linked as to form a common inventive concept. They are claim 1 (an improvement in a process for producing), 2 (a process for producing glatiramer having a desired concentration of a contaminant), 8 (a process to obtain glatiramer having a desired concentration of a contaminant), 11 (glatiramer acetate having a desired purity and concentration of a contaminant), 13 (a process to produce glatiramer having a desired concentration of a contaminant), and 16 (glatiramer trifluoroacetyl acetate having a desired concentration of a contaminant)*”¹³²³ (emphasis added). These “linked” patent claims were then repeated across EP ‘528 and EP ‘924.¹³²⁴

¹³²² It suffices to note that Teva’s claimed “main feature” of EP ‘924 – use of glass-lined equipment (ID 4032, Teva’s Reply to the Statement of Objections, para. 672 and para. 687) – was included already in dependent claims 8 and 9 of EP ‘528.

¹³²³ ID 5958, EP1799703 – Preliminary opinion of the Opposition Division, 30 June 2011, p. 1-2.

¹³²⁴ Similarly, with respect to EP ‘528 the OD summarised that it “*contains 3 independent claims, all of which are technically linked. They are claim 1 (an improvement in a process for producing glatiramer), 11 (a trifluoroacetyl glatiramer as prepared by the process of claim 1), 13 (a method to analyze the brominated tyrosine in a sample of glatiramer acetate).*” (ID 5960, EP2177528 – Preliminary opinion of the Opposition Division, 14 November 2013, p. 5). Teva claims that the Commission’s reliance on the documents quoted in the Recital (1100) shows “*a fundamental misunderstanding of the content of those documents*” (ID 6160, Teva’s Reply to the Letter of Facts III of 16 October 2024, para. 11; emphasis in the original). Teva further explains that it is completely normal that the claims of various patents in the family are linked and that this does not have any bearing on the level of overlaps between the patents. These links, according to Teva, are irrelevant for the assessment of the validity of those patents (ID 6160, Teva’s Reply to the Letter of Facts III of 16 October 2024, para. 11). Teva’s claims should be rejected. First, the Commission’s assessment shows that the validity of the patents in the process family hinged on the same patentability issues and mainly on the question whether the invention embodied in these patents lacked an inventive step (see Recitals (1159)-(1163)). In this context, findings by the OD in its preliminary opinions that both EP ‘703 and EP ‘528 rest on a single inventive concept, support the Commission’s conclusion that the resolution of a question of (lack of) inventive step of that single inventive concept was equally relevant for all patents within the process family, leading to the same outcomes in their validity assessments. In addition, these documents answer Teva’s criticism that the Commission’s alleged binary understanding of the patent validity (that the patent is either valid or not valid) is not accurate because, in its view, certain claims within the patent may be upheld while others may be invalidated (see ID 5909, Teva’s Reply to the Letter of Facts II of 17 May 2024, paras. 105-107). Contrary to Teva’s explanations, the documents show that the

- (1101) The validity of the main claims of the divisional patents in the process family (i.e. EP '528 and EP '924) was tied to the validity of those in the Original Process Patent. While the patents in the process family indeed included distinguishing features, these related to different maximum concentrations of bromine and metal ion impurities and were not sufficient to overcome patenting weaknesses ingrained in the main, overlapping, features (lack of novelty and lack of inventive step)¹³²⁵. Thus, all patents of the process patent family were affected by the same weaknesses (as ultimately confirmed in the reasoned decision of the TBA revoking Teva's last process patent EP '924).¹³²⁶
- (1102) This is confirmed by Teva internal documents. For example, in an email dated 2 February 2015, Teva's {...}(who was acting as a {...}) states that {...}.¹³²⁷ In

assessment of the inventive step of the patents in the process family was indeed binary: the patent claims forming a single inventive concept were either all valid or invalid. For example, when the OD preliminarily established that the claims 1, 2 and 13 of EP '703 possess an inventive step, it also immediately concluded that the claims 8, 11 and 16 of the same patent “*are ipso facto inventive*” (ID 5958, EP1799703 – Preliminary opinion of the Opposition Division, 30 June 2011, p. 5). Similarly, when in its decision the OD established that the amended claims of EP '703 are indeed innovative, it did not do so individually but rather selected the closest prior art and came to the conclusion that “*claims 1, 2, 8, 11 and 14 do possess inventive step*” and that this “*conclusion is also reached for the claims dependent on the above independent claims*” (ID 5959, EP1799703 – Decision of the Opposition Division, 27 February 2012, p. 9). In the same vein, when the TBA reversed the OD's position on prior art it did so automatically, with respect to all the claims of the patent, without assessing it claim by claim (ID 2171, EP1799703 – Preliminary opinion of the Technical Board of Appeal 3.3.04, 8 October 2014, p. 5 proposing assessment of “*all claims*” in the context of discussion of inventive step. See also, ID 5960, EP2177528 – Preliminary opinion of the Opposition Division, 14 November 2013, p. 5 and p. 8).

¹³²⁵ For example, dependent claims 7-18 read: “7. *The process of any one of claims 1-6 [these claims relate to the process of using pretreated hydrobromic acid with low levels of free bromine and metal ion impurities], wherein the solution of hydrobromic acid in acetic acid comprises less than 0.05% of free bromine, preferably less than 0.01% of free bromine, more preferably less than 0.001% of free bromine, yet more preferably the solution of hydrobromic acid in acetic acid is free of free bromine. // 8. The process of claim 7, wherein the solution of hydrobromic acid in acetic acid comprises less than 100 ppm of metal ion impurities. // 9. The process of claim 8, wherein the solution of hydrobromic acid in acetic acid comprises less than 30 ppm of metal ion impurities. // 10. The process of claim 9, wherein the solution of hydrobromic acid in acetic acid comprises less than 20 ppm of metal ion impurities. // 11. The process of claim 10, wherein the solution of hydrobromic acid in acetic acid comprises less than 10 ppm of metal ion impurities. // 12. The process of claim 11, wherein the solution of hydrobromic acid in acetic acid is free of metal ion impurities. // 13. The process of any one of claims 1-12, wherein the color of the solution of hydrobromic acid in acetic acid is less than 2000 APHA. // 14. The process of claim 13, wherein the color of the solution of hydrobromic acid in acetic acid is less than 1000 APHA. // 15. The process of claim 14, wherein the color of the solution of hydrobromic acid in acetic acid is less than 700 APHA. // 16. The process of claim 15, wherein the color of the solution of hydrobromic acid in acetic acid is less than 500 APHA. // 17. The process of any one of claims 1-18, wherein the hydrobromic acid in acetic acid solution is produced in a nonmetallic reactor. // 18. The process of any one of claims 18, wherein the hydrobromic acid in acetic acid solution is prepared in a glasslined or Teflon lined reactor”. While each of these claims indeed includes distinguishing features none of these distinguishing features can override the fact that, as dependent claims, they legally depended on the alleged improvements to the manufacturing process protected by the process family which lacked novelty and/or inventive step. As Teva internally explained it in very succinct way, the process patents {...} (ID 455-1205, Teva internal email dated 2 February 2015 from {...} to {...} and others, p. 1). See also 8.3.3.2.*

¹³²⁶ ID 5676, EP2361924 – Decision of the Technical Board of Appeal 3.3.04, 12 September 2017. The Commission notes that each and every of Teva's patents in the process family was ultimately either invalidated or withdrawn by Teva before a final decision on its validity.

¹³²⁷ ID 404-1647, Teva internal email dated 2 February 2015 from by {...} to {...} and others (emphasis added).

another email to {...}, the {...} further clarifies that {...}.¹³²⁸ As a result, the legal review proceedings of the process patents EP '703, EP '528 and EP '924 carried the same likelihood for these patents to be revoked by the TBA, if they had not been withdrawn by Teva before the adoption of a reasoned decision.¹³²⁹

- (1103) Teva argues that the patents in the process family contained distinct features that were not minor. Teva explains that the filings in the process family were driven by the solution to two separate issues, i.e. to a contamination issue (the contamination of batches of GA with brominated tyrosine) and to a discoloration issue (batches of GA turning pink). It submits a number of technical differences between the claims of the process patents (e.g. use of glass lined equipment to prevent the discoloration). According to Teva, this justified separate filings of the patents in the process family.¹³³⁰
- (1104) Teva explains that the Original Process Patent also contained a product claim characterising GA by reference to low levels of bromine tyrosine impurity and low levels of metal ion impurities (i.e. a patent claim protecting the product itself rather than the process used for manufacturing the product). Since it is generally easier to show an infringement of a product claim than of a process claim, this product claim was "{...}" and, once the OD concluded that this specific product claim was invalid for added matter (i.e. it had no basis in the patent application), Teva decided to include it to a pending divisional application (to be issued as EP '924).¹³³¹ According to Teva, "{...}". According to Teva, this is a typical example of why originators file divisionals of a parent patent as a simple matter of routine management, i.e. for purely formal issues that may occur during the opposition on the parent patent. According to Teva, the fact that the product claim included in EP' 924 was ultimately invalidated again is not relevant since it was invalidated for lack of novelty and not for added matter.¹³³² In a subsequent submission, Teva contradicts this statement and confirms that the relevant claim of EP '924 was indeed invalidated for added matter. This however, according to Teva, is again irrelevant since elements considered by the court in the UK and by the EPO to reach the conclusions on added matter were different.¹³³³
- (1105) Teva's claims are not convincing. First, nothing in Teva's submissions changes the Commission finding that all its process patents share material features with the same obstacles to patentability embedded already in the parent patent. Differences in these patents were marginal and all relevant aspects of their content overlapped (Recital (1099) and Table 15; see also Recitals(1071)-(1073)).¹³³⁴ For example, Teva claims that the use of glass-lined equipment was an inventive solution to the discoloration

¹³²⁸ ID 404-1960, Teva internal email dated 2 February 2015 from {...} to {...} and others (emphasis added).

¹³²⁹ See Section 8.3.3.3.1.

¹³³⁰ ID 4032, Teva's Reply to the Statement of Objections, paras. 669-691.

¹³³¹ The EP '924 patent application characterised GA by reference to a low level of metal ion impurities only and not, as the Original Process Patent, by reference to low levels of bromine tyrosine impurity and low levels of metal ion impurities.

¹³³² ID 4032, Teva's Reply to the Statement of Objections, paras. 678-685. In a different paragraph of the Reply to the Statement of Objections Teva refers to the added matter as a reason for invalidation of EP '924 (see ID 4032, Teva's Reply to the Statement of Objections, para. 868).

¹³³³ ID 5695, Teva's Reply to the Letter of Facts I of 9 February 2024, paras. 242-244. See also ID 4032, Teva's Reply to the Statement of Objections, para. 868.

¹³³⁴ {...} (ID 404-1898, Teva internal email from {...} of 3 February 2015 concerning the withdrawal of Teva's patent EP '703, pp. 1-2).

issues and a “*main feature*” of EP ‘924.¹³³⁵ However, the use of glass-lined equipment was assessed by the OD already in June 2011 (while assessing the Original Process Patent) as “*not contribut[ing] per se to the recognition of an inventive step*” (OD Preliminary opinion of 30 June 2011 concerning EP ‘703, p.5). In addition, this allegedly distinguishing feature of EP ‘924 appeared already in EP ‘528 (dependant claims 8 and 9). The patents of the process patent family suffered by the same weaknesses and the legal review proceedings of the process patents EP ‘703, EP ‘528 and EP ‘924 carried the same likelihood of revocation by the EPO, as eventually happened to EP ‘924, if they hadn’t been withdrawn by Teva before the adoption of a reasoned decision.¹³³⁶

(1106) Second, Teva’s arguments with respect to the product claim transferred from the Original Process Patent to EP ‘924, are contradicted both by contemporaneous evidence on the Commission’s file as well as by the EPO’s decisions on the validity of this claim. Most notably, Teva’s explanation that the claim would have been lost {...} absent the transfer to the EP ‘924 is simply incorrect. It would have been lost because it was invalid. The product claim was held invalid for added matter by the OD in 2012 (within the opposition procedure concerning the Original Process Patent); it was held invalid for added matter by the OD in 2016 (within the opposition procedure concerning EP ‘924); and it was held invalid for added matter by the TBA in 2017 (in the final, reasoned decision on EP ‘924).¹³³⁷ Teva indeed temporarily saved the claim by postponing the validity decision as far back as 2017, due to the withdrawal of the EP ‘703 where the product claim was previously included and, in the meantime, rigorously enforced it in all of the Relevant Member States. Teva’s conduct with respect to the product claim in the process patent family represents a distilled version of Teva’s anticompetitive comprehensive patenting conduct and illustrates its capability to exclude competitors and Synthon and its licensees in particular. Teva faced objections as to the validity of the product claim as early as 2011 (in the context of the assessment of the Original Process Patent) but through a combination of the newly filed divisional (EP ‘924) and the withdrawal of the challenged parent patent, managed to extend its life until 2017 using it throughout this time to keep Synthon GA out of the market.

8.3.2.1.2. Multiplication of significantly overlapping dosage patents

(1107) As described in Table 14 above, Teva holds one parent and four divisional patents relating to a 40 mg dosing regimen for GA, namely, EP ‘749 (or, the Original Dosage Patent) and the divisional patents EP ‘962, EP ‘335, EP ‘172 and EP ‘286.

¹³³⁵ ID 4032, Teva’s Reply to the Statement of Objections, para. 672 and para. 687. The Commission notes that that this “*main feature*” does not appear in any of the independent claims of EP ‘924 but solely in dependent claims 17 and 18.

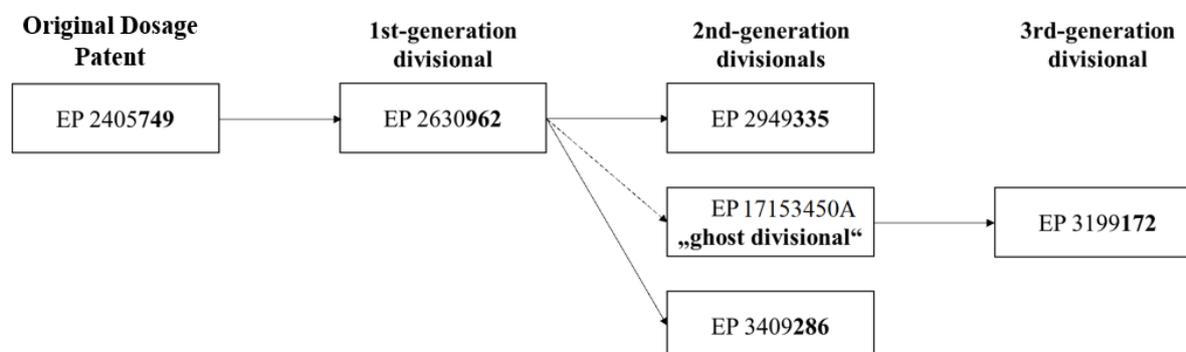
¹³³⁶ The decision to withdraw EP ‘703 was internally explained as a part of the wider strategy to avoid a negative decision by a Technical Board of Appeal (“TBA”) and the *res judicata* effects on process family divisionals with overlapping claims: {...} (ID 4513-62924, Teva internal email from {...} Europe to {...} of 1 February 2015).

¹³³⁷ Teva’s explanation that a product claim within EP ‘924 was invalidated for lack of novelty, clearly contradicts internal contemporaneous document explaining that it was invalidated for added matter: {...} (ID 743-5, Copaxone® PanEU Patent Litigation: Background and Current Risks of 16 August 2017, p. 2). See also ID 5676, EP2361924 – Decision of the Technical Board of Appeal 3.3.04, 12 September 2017, p. 27-28. Even if, as Teva explains, different arguments were used to reach this conclusion (i.e. that the product claim is invalid for added matter), the Commission’s conclusion stays: the product claim was invalidated for added matter each time a competent authority (be it EPO or a UK court) assessed it.

The patents in the dosage family aimed to protect features of the 40 mg three times per week dosing regimen for GA.

- (1108) Figure 34 below provides a schematic overview of the dosage patent family and shows through arrows on the basis of which patent each of Teva’s divisional dosage patents was filed (i.e. the Original Dosage Patent or an earlier generation divisional patent).¹³³⁸

Figure 34: Structure of Teva’s dosage patents



Source: EPO

- (1109) The Original Dosage Patent (EP ‘749) relates to a three-times-a-week (TIW) 40 mg subcutaneous dosing regimen for a MS drug containing GA. The overlapping features of the divisional patents are described in Table 16.¹³³⁹

¹³³⁸ As explained above in Section 4.1, pursuant to section “1.1.2 – Sequences of divisional applications” of the EPO’s Guidelines for examination, “[a] divisional application can also be an earlier application [...] for the purposes of one or more further divisional applications. [...] In a sequence of divisional applications, a first-generation divisional application is a divisional application based on an application which is not itself a divisional application, i.e. the root application. A second-generation divisional application is a divisional application based on a first-generation divisional application; and so on”.

¹³³⁹ Teva argues that the Commission’s presentation of differences between the patents and {...} shows a bias against Teva (ID 4032, Teva’s Reply to the Statement of Objections, paras. 641-654, 731-735; see also ID 6160, Teva’s Reply to the Letter of Facts III of 16 October 2024, para. 10). In particular, Teva argues that Table 15 and Table 16 are simply copied from Synthon’s responses to the Commission’s RFIs and that they are incomplete as they do not mention their “non-minor” distinguishing elements (e.g. reduction in brain atrophy, ID 4032, Teva’s Reply to the Statement of Objections, paras. 742 and 734). However, the fact that the overviews of Teva’s patent families {...} and the Commission’s own assessment (especially with respect to shared material elements between the patents and their distinguishing features) support the same conclusions and the fact that the Commission’s assessment and overviews included in this Decision do not follow the explanations offered by Teva in the proceedings before the Commission, does not constitute bias. It is true that the patent families overviews in Table 15 and in Table 16, {...}. However, they are confirmed by the Commission’s own analysis of the relevant patents, by EPO decisions as well as of the available relevant contemporaneous evidence. For example, the overview of the distinguishing features of the dosage family patents described in Table 16, for which Teva claims that closely follows {...}, corresponds to Teva’s internal “{...}” prepared in 2017. This contemporaneous internal summary of Teva does not include any of the explanations for the alleged major differences between these patents offered by Teva in its Reply to the Statement of Objections, such as reduction in brain atrophy (ID 743-5, Copaxone® PanEU Patent Litigation: Background and Current Risks of 16 August 2017, p. 8). Similarly, the OD noted that the only difference between the independent claims of EP ‘962 and EP ‘172 respectively and EP ‘335 is limited to a preferred pH range of 5.5. to 7.0 which, according to OD, was not capable of changing the outcome of the assessment procedures (ID 5694, EP3199172 – Decision of the Opposition Division, 27 January 2022, paragraph 15, ID 5693, EP2630962 – Decision of the Opposition Division, 4 February

Table 16: Divisional dosage patents' overlapping and main distinguishing features

Patent	Year of filing	Overlapping features	Main distinguishing features (from the Original Dosage Patent)	Distinguishing features as claimed by Teva	Divisional of
EP '749	2010	GA TIW 40 mg dosing regimen ¹³⁴⁰	n/a (Original Dosage Patent)		n/a
EP '962	2013	GA TIW 40 mg dosing regimen ¹³⁴¹	Use of mannitol and pH range of 5.5 to 7.0 ¹³⁴²	Reduction of brain atrophy	EP '703
EP '335	2015	GA TIW 40 mg dosing regimen ¹³⁴³	Use of mannitol ¹³⁴⁴	Targeting RMS as opposed to RRMS	EP '962

2022, paragraph 15). This is again in line with the assessment of the dosage family in Table 16 rather than with Teva's *ex post* explanations.

¹³⁴⁰ Independent claims of the patent read: "1. *A medicament comprising glatiramer acetate for use in treating a patient who is suffering from relapsing-remitting multiple sclerosis or who has experienced a first clinical episode and is at high risk of developing clinically definite multiple sclerosis, wherein the medicament is to be administered in a regimen of three subcutaneous injections of a 40mg dose of glatiramer acetate every seven days with at least one day between each subcutaneous injection.* 2. *Glatiramer acetate for use in a regimen of three subcutaneous injections of a 40mg dose of glatiramer acetate every seven days with at least one day between each subcutaneous injection for uses in treating a patient who is suffering from relapsing-remitting multiple sclerosis or who has experienced a first clinical episode and is at high risk of developing clinically definite multiple sclerosis.*" (emphasis added)

¹³⁴¹ Independent claim reads: "1. *Glatiramer acetate in the form of a pharmaceutical composition for use in treating a human patient suffering from a relapsing form of multiple sclerosis in a regimen of three subcutaneous injections of a 40 mg dose of glatiramer acetate every week with at least one day between every subcutaneous injection and wherein the pharmaceutical composition further comprises mannitol and has a pH in the range of 5.5 to 7.0*" (emphasis added).

¹³⁴² Dependent claims of the patent read "2. *Glatiramer acetate in the form of a pharmaceutical composition for use of claim 1, which reduces brain atrophy.* 3. *Glatiramer acetate in the form of a pharmaceutical composition for use of any one of claims 1 or 2, wherein the human patient has not received glatiramer acetate therapy prior to initiation of the treatment*".

¹³⁴³ Independent claims read: "1. *Glatiramer acetate for use in a regimen of three subcutaneous injections of a 40mg dose of glatiramer acetate every seven days with at least one day between each subcutaneous injection for use in treating a patient who is suffering from a relapsing form of multiple sclerosis or who has experienced a first clinical episode and is at high risk of developing clinically definite multiple sclerosis and wherein the pharmaceutical composition further comprises mannitol.* 2. *A medicament comprising glatiramer acetate for use in treating a patient who is suffering from a relapsing form of multiple sclerosis or who has experienced a first clinical episode and is at high risk of developing clinically definite multiple sclerosis, wherein the medicament is to be administered in a regimen of three subcutaneous injections of a 40mg dose of glatiramer acetate every seven days with at least one day between each subcutaneous injection and wherein the pharmaceutical composition further comprises mannitol*" (emphasis added).

¹³⁴⁴ Dependent claims read: "3. *Glatiramer acetate for use according to claim 1, wherein the tolerability of glatiramer acetate treatment in the human patient is increased by reducing the frequency of an immediate post injection reaction or an injection site reaction.* 4. *A medicament comprising glatiramer acetate for use according to claim 2 wherein the tolerability of glatiramer acetate treatment in the human patient is increased by reducing the frequency of an immediate post injection reaction or an injection site reaction*".

EP ‘172	2017	GA TIW 40 mg dosing regimen ¹³⁴⁵	pH range of 5.5 to 7.0 ¹³⁴⁶	Targeting CIS patients, reduction of T1/T2 lesions, GA TIW 40 mg dosing regimen being as effective as GA 20 mg	EP ‘450 (“ghost divisional”)
EP ‘286	2018	GA TIW 40 mg dosing regimen	Use of a prefilled syringe	Improved tolerability	EP ‘962

Source: ID 2511, Synthon’s Reply to Article 18(2) Request of 5 July 2022 and Commission based on data from the European Patent Office website.

- (1110) None of the distinguishing features of the divisional dosage patents are specifically related to the TIW 40 mg dosing regimen, the claimed novelty which led to the grant of the Original Dosage Patent and was the subject of the legal review. The divisional dosage patents simply narrowed down the scope of the Original Dosage Patent by combining its dosing regimen with certain other features, either related to its composition (i.e. mannitol and pH range) or the device used for administering Copaxone (i.e. prefilled syringe).
- (1111) All distinguishing features of the divisional dosage patents are minor, and not specific to the TIW 40 mg dosing. Mannitol as an excipient, a pH range of solutions or a prefilled syringe were already known and used in the earlier once-per-day 20 mg dosing regimen and mentioned on the product label of Copaxone 20 mg. Although the divisionals of the dosage patent family are procedurally independent from their parent patent (with a “procedural life of their own”), the validity of their independent claims was tied to the validity of the Original Dosage Patent (i.e. to the question of whether the TIW 40 mg dosing regimen is patentable in the first place).
- (1112) The common weakness of all the patents of the dosage patent family was that both the presence of an inventive step and the sufficiency of disclosure concerning the dosage regime itself was debatable.¹³⁴⁷ The fact that these patents shared the same shortcomings was confirmed by the EPO.¹³⁴⁸ After the revocation of EP ‘335 by the TBA which Teva was not able to avoid,¹³⁴⁹ the ODs examining two other divisional patents (i.e. EP’962 and EP’172) considered the findings concerning EP ‘335 to be binding concerning these divisionals under the *res iudicata* principle and revoked them as well.¹³⁵⁰ The TBA dismissed Teva’s appeals and confirmed the OD’s

¹³⁴⁵ Independent claim reads: “1. Glatiramer acetate for use in treating a human patient suffering from a relapsing form of multiple sclerosis or who has experienced a first clinical episode and is determined to be at high risk of developing clinically definite multiple sclerosis, comprising **administering to the human patient three subcutaneous injections of 40mg glatiramer acetate for every seven days with at least one day between every subcutaneous injection**, wherein the glatiramer acetate is present in a pharmaceutical composition having a pH in the range of 5.5 to 7.0.” (emphasis added)

¹³⁴⁶ The patent includes 11 dependent claims specifying the category of the disease (RMS or CIS), symptoms to be alleviated with administration, increase in tolerability and decrease in adverse effects.

¹³⁴⁷ See Section 8.3.3.3.2.

¹³⁴⁸ For Teva’s internal contemporaneous assessments of weaknesses in the dosage family see Section 8.3.3.3.2.

¹³⁴⁹ A decision from the Regional Court of Munich dated 24 February 2020 ordered Teva to refrain from withdrawing the approval of the text for EP ‘335 (LG München I, Beschluss v. 24 February 2020 – 7 O 1456/20).

¹³⁵⁰ See Section 8.3.3.4.

decisions thus finally revoking EP ‘962 and EP ‘172 on 7 February 2024 almost nine years after expiry of EP ‘888 – the main patent protecting Copaxone.¹³⁵¹

- (1113) Teva points to a number of technical differences between the dosage patents and claims that these differences were not minor.¹³⁵² However, nothing in Teva’s claims changes the Commission’s finding that the patents in the dosage family described the same invention, shared material features and the same weaknesses and carried the same likelihood of revocation as ultimately confirmed by EPO.¹³⁵³ None of the minor distinguishing features listed above in Table 16 were capable of, as the OD noted with respect to the independent claim of EP ‘172 and pH ranges, “*chang[ing] the outcome of the [opposition] procedure*”.¹³⁵⁴

Specific arguments with respect to EP ‘962

- (1114) Teva explains that the results of the Glatiramer Acetate Low-Frequency Administration (GALA)¹³⁵⁵ study and the effect of Copaxone on decrease in brain atrophy of MS patients justified the filing of EP ‘962 (application filed on 30 April 2013) as a “*refinement*” of EP ‘749 in order not to lose “*all opportunity to reflect the findings of the ongoing clinical trial in its IP*”.¹³⁵⁶ In support of its arguments, Teva emphasises that a patent claim in EP ‘962 referring to decrease in brain atrophy was gradually amended and tailored following the publication of the GALA study results (especially of the GALA extension study).¹³⁵⁷ Teva also argues that {...} recognised the significance of this distinctive feature.¹³⁵⁸
- (1115) Teva’s claims do not convince. First, the beneficial impact of Copaxone on brain atrophy was confirmed by the GALA study only long after 30 April 2013, i.e., after the application for EP ‘962 was filed and therefore cannot serve as a justification for its filing. Indeed, a summary of the patent applications in the US as of 7 May 2015 indicates that only at this moment (i.e. in May 2015) a new patent application was considered to cover {...} findings about brain atrophy from the GALA study.¹³⁵⁹ Similarly, the results of the GALA study as published on 20 May 2013 do not mention the effect of Copaxone on brain atrophy.¹³⁶⁰ The fact that the patent claim referencing a decrease in brain atrophy was gradually amended does not change the

¹³⁵¹ ID 5731, EP2630962 – Minutes of the hearing before the Technical Board of Appeals 3.3.04, 6-7 February 2024; ID 5729, EP3199172 – Minutes of the hearing before the Technical Board of Appeals 3.3.04, 6-7 February 2024.

¹³⁵² ID 4032, Teva’s Reply to the Statement of Objections, paras. 692-719.

¹³⁵³ See Recital (1112). Similarly, third party observer (market intelligence company {...}) expected *res judicata* effect of EP ‘335 revocation on other patents belonging to the Dosage Family despite their allegedly significant distinguishing elements: {...} (ID 4595-33137, Report by {...} on revocation of EP ‘335 of 10 September 2020).

¹³⁵⁴ ID 5694, EP3199172 – Decision of the Opposition Division, 27 January 2022, paragraph 15.

¹³⁵⁵ The Glatiramer Acetate Low-Frequency Administration (GALA) study was a phase III trial undertaken to assess the efficacy and safety of GA40 in patients with RRMS over a 1-year period. The GALA study was a randomized, placebo-controlled, double-blind, parallel-group study conducted at 142 sites in 17 countries. (ID 4795), for the GALA Study Group, *Three Times Weekly Glatiramer Acetate in Relapsing–Remitting Multiple Sclerosis*, *Annals of Neurology* 73: 705-713, June 2013).

¹³⁵⁶ For example, ID 4032, Teva’s Reply to the Statement of Objections, paras. 619, 698, 745-747. See also ID 5695, Teva’s Reply to the Letter of Facts I of 9 February 2024, paras. 247-250.

¹³⁵⁷ ID 5909, Teva’s Reply to the Letter of Facts II of 17 May 2024, paras. 97-100.

¹³⁵⁸ ID 4032, Teva’s Reply to the Statement of Objections, paras. 694-700.

¹³⁵⁹ {...} (ID 4513-69635, Teva internal {...}, 7 May 2015, p.3; emphasis added).

¹³⁶⁰ ID 4795, Omar Khan (MD), Peter Rieckmann (MD), Alexey Boyko (MD), Krzysztof Selmaj (MD), and Robert Zivadinov (MD, PhD), for the GALA Study Group, *Three Times Weekly Glatiramer Acetate in Relapsing–Remitting Multiple Sclerosis*, *Annals of Neurology* 73: 705-713, June 2013, p. 1.

fact that it was included already in the original filing of EP ‘962 long before any effects of Copaxone on brain atrophy were confirmed.¹³⁶¹ The Commission also notes that the claim referencing brain atrophy was finally revoked by the TBA with the explanation that effects of the GA on brain atrophy were not sufficiently disclosed in the original application. As TBA concluded “*The effect [reduction of brain atrophy] was thus not credibly disclosed to be achievable at the relevant date. [...], this cannot be remedied by post-published evidence (e.g. [results of the GALA study])*”.¹³⁶²

- (1116) Second, one of the claims in the Original Dosage Patent already included a reference to the reduction of brain atrophy among other MS symptoms alleviated by use of Copaxone.¹³⁶³ Therefore, and taking into account that the wording of the reference to brain atrophy in EP ‘962 hardly differed from the initial reference in the Original Dosage Patent, one cannot accept Teva’s explanation that the divisional served to reflect the findings of the ongoing clinical trial in its IP. In addition, despite the reference to the reduction of brain atrophy in EP ‘962 as filed in 2013 Teva was invited by the EPO examining division to amend its EP ‘962 application “*to introduce at least a further additional feature not claimed in the parent application*” which Teva did by introducing mannitol and a specific pH range (see Table 16 which is contested by Teva).¹³⁶⁴

¹³⁶¹ The Commission notes that the “*tailoring of the claim*” referred to by Teva did not involve any substantive changes in a reference to brain atrophy. The wording used in the original filing of EP ‘962 as well as in the Original Dosage Patent read “*The medicament for use according to claim 1 [...] reducing brain atrophy in the patient*” while the “*tailored*” reference in the EP ‘962 read: “*Glatiramer Acetate for use of claim 1, which [...] reduces brain atrophy*”. In both cases, a reference to the brain atrophy was included in the dependent patent claim with the first, independent claim (to which the patent claim including brain atrophy refers to) still being affected with the same weakness and lack of significant distinguishing features described in this Section 8.3.2.1.2. As Teva notes itself, it is this main claim 1 that was referred to by the OD when discussing the *res judicata* effect of the TBA’s decision on EP ‘335 (ID 5909, Teva’s Reply to the Letter of Facts II of 17 May 2024, paras. 103-104 cannot be accepted).

¹³⁶² ID 5823, EP2630962 – Decision of the Technical Board of Appeal 3.3.04, 7 February 2024, p. 28.

¹³⁶³ Dependent claim 3 of the Original Dosage Patent reads: “*The medicament for use according to claim 1 or glatiramer acetate for use according to claim 2, wherein the treating comprises reducing the frequency of relapses, reducing the mean cumulative number of Gd-enhancing lesions in the brain of the patient, reducing the mean number of new T2 lesions in the brain of the patient, reducing the cumulative number of enhancing lesions on T1-weighted images, reducing brain atrophy in the patient, increasing the time to a confirmed relapse in the patient, reducing the total number of confirmed relapses in the patient, reducing the progression of MRI-monitored disease activity in the patient, reducing the total volume of T2 lesions in the patient, reducing the number of new hypointense lesions on enhanced T1 scans in the patient, reducing the total volume of hypointense lesions on enhanced T1 scans, reducing the level of disability as measured by EDSS Score in the patient, reducing the change in EDSS Score in the patient, reducing the change in Ambulation Index in the patient, reducing the level of disability as measured by EuroQoL (EQ5D) questionnaire in the patient, or reducing the level of disability as measured by the work productivity and activities impairment - General Health (WPAI-GH) questionnaire in the patient.*” (emphasis added) By comparison, dependant claim 2 of the EP ‘962 simply reads: “*Glatiramer acetate in the form of a pharmaceutical composition for use of claim 1, which reduces brain atrophy*”.

¹³⁶⁴ ID 5768 EP ‘962 claims as filed on 30 April 2013; ID 5770 EP ‘962 European search opinion of 30 July 2013, p.1; ID 5771 EP ‘962 claims as amended on 6 July 2016. The fact that pH and mannitol were added to EP ‘962 as necessary to overcome the similarity with the Original Dosage Patent is confirmed by Teva (see ID 5909, Teva’s Reply to the Letter of Facts II of 17 May 2024, para. 98 (b) and (c)).

- (1117) Third, the documents on the Commission’s file do not support Teva’s claims. For example, in a 2017 internal summary of the {...}.¹³⁶⁵ A market intelligence company, {...}, acknowledged by Teva’s {...} for their insight, furthermore noted that Teva’s dosage patents cover the same subject matter, mentioning only mannitol and a pH range as their distinctive features without any mention of brain atrophy reduction as a distinctive feature.¹³⁶⁶
- (1118) Teva further refers to a submission by the opponents in the opposition proceedings before the EPO. According to Teva, the opponents (including Synthon and Alvogen) referred to the brain atrophy claim as a “*completely new claim*” thus acknowledging its distinguishing features. However, this is misleading. The opponents in the procedure concerning EP’962 before the EPO referred to the “*completely new claim*” as a procedural objection that the claim concerning the beneficial effects of Copaxone on brain atrophy in MS patients was introduced only in a very late stage of the procedure and should not be admitted by the OD. This submission did not acknowledge its significance as construed by Teva.¹³⁶⁷ Conversely, in its submission to the EPO, Synthon expressly maintained that the addition of a claim in EP ‘962 regarding brain atrophy reduction does not materially change the patent as it is only “*an arbitrary feature (here: one of numerous common symptoms of the disease to be treated)*” whose addition “*cannot change the whole purpose and objective of the opposed patent*”.¹³⁶⁸ This claim in EP ‘962 was invalidated by the OD for lack of novelty.¹³⁶⁹

Specific arguments with respect to EP ‘172

- (1119) As regards EP’172, Teva claims that it contains a number of secondary (dependent) claims including references to CIS, reduction in T1/T2 lesions or GA 40 mg three times per week being as effective as GA 20 mg once per day, which would represent new and distinct features.¹³⁷⁰ However, for the same reasons as regards EP’962, these claims cannot change the Commission’s finding that EP ‘172 describes the same invention (TIW 40 mg dosing regimen for Copaxone) and shares material features with its parent patents.
- (1120) For example, a comparison between EP ‘172 and the Original Dosage Patent reveals that the features regarding treatment of CIS or reduction in T1/T2 lesions were present already in the Original Dosage Patent and therefore, contrary to Teva’s assertion, cannot be considered as new elements distinguishing EP ‘172 from Teva’s other dosage patents.¹³⁷¹ Since EP’172 had the same deficiencies as the other dosage

¹³⁶⁵ ID 743-5, Copaxone® PanEU Patent Litigation: Background and Current Risks of 16 August 2017, p. 8.

¹³⁶⁶ {...}; “*Wow They really know a lot!*” (ID 404-1651, Report by {...} on Copaxone patent situation in Europe of 28 April 2017, pp. 1-7) and subsequent Teva internal email dated 28 April 2017 from {...} to {...}, p. 1).

¹³⁶⁷ “*For OP2-OP4, unlike in the case NARI a, NAR2a presents a completely new claim containing the feature “which reduces brain atrophy” which was not present in the previous requests. This claim should not be admitted at such a late stage of the procedure, specially as it was filed after the time limit of the Article 116 EPC.*” (ID 5693, EP2630962 – Decision of the Opposition Division, 4 February 2022, p. 13).

¹³⁶⁸ ID 4928, Submission by Synthon B.V. in the opposition proceedings concerning EP-B-2630962 of 24 November 2021, p. 8.

¹³⁶⁹ ID 5693, EP2630962 – Decision of the Opposition Division, 4 February 2022, p. 17.

¹³⁷⁰ ID 4032, Teva’s Reply to the Statement of Objections, paras. 710-715.

¹³⁷¹ As to the pH range of 5.5 to 7.0 included in the first independent claim of EP ‘172, this feature is not specific to the TIW 40 mg dosing and was already known and used in the earlier once-daily 20 mg dosing regimen and mentioned on the product label of Copaxone 20 mg (see Recitals (1109)-(1111)).

patents, the legal review proceedings concerning EP ‘172 carried the same likelihood for it to be revoked by the EPO.¹³⁷²

Specific arguments with respect to EP ‘286

- (1121) Teva argues that EP ‘286 is not relevant for the EU as it was only maintained in Turkey after being granted, that it was intended for enforcement in Turkey only and, therefore, that it should be excluded from the present Decision.¹³⁷³ However, EP ‘286 is included in the Commission’s analysis as it is relevant for showing the pattern of Teva’s multiplication of significantly overlapping dosage patents, regarding which Teva does not raise any substantial arguments. As with other divisional patents in the dosage family, the main claim in this patent seeks to protect a GA 40 mg three times per week dosing regimen and any distinct features are minor (which, as regards EP’286 relate to administering fewer injections).
- (1122) EP ‘268 lapsed in Czechia, Poland and Spain on 12 August 2020, in Belgium on 31 August 2020 and in Germany on 2 March 2021. It never applied in the Netherlands. The fact that the patent was never enforced in the EU or that Teva did not maintain it in the Relevant Member States does not affect the Commission’s analysis of Teva’s comprehensive patenting conduct. The limited utility of EP ‘286 in the Relevant Member States is duly taken into account in the Commission’s assessment of limited exclusionary effects that could be attributed to EP ‘286.
- (1123) Teva’s specific arguments with respect to EP ‘335 are addressed in detail in Section 8.3.6.5.
- 8.3.2.2. Filings of divisional patents were staggered to prevent the parallel review of patents and to delay a final reasoned decision on their validity
- (1124) Teva timed its patent filings to obtain staggered grant dates, often with more than a year between the grant by the EPO of divisional patents of the same patent family.¹³⁷⁴ As explained below, while the overall potential period of patent protection did not change, Teva thereby extended the period during which it actually benefitted from its exclusive rights for Copaxone because it forced potential entrants to challenge the validity of these patents one after the other in a series of lengthy proceedings rather than in parallel.
- (1125) At the same time, Teva ensured that the grant date of each divisional patent would predate an upcoming validity decision from the EPO concerning an earlier patent so that it could strategically withdraw this earlier patent prior to such a decision while having another patent of the same family in place. The consequence of these staggered filings is a series of delays in the legal review of the patents’ validity. Getting new divisionals granted as near as possible to the date of an imminent validity decision for existing patents enabled Teva to maximize such delays.
- (1126) The two timelines below (Figure 35 and Figure 36) show the filing dates before the EPO and the grant dates by the EPO for each of the patent families. The process patents were filed over a period of 5 years and 3 months and granted over a period of

¹³⁷² The OD expressly referred to the findings concerning the invalidated EP ‘335 and invalidated various claims of EP ‘172 for added matter, insufficient disclosure or lack of inventive step. The decision was confirmed by TBA on appeal (ID 5825, Decision of Technical Board of Appeal 3.3.04 of 7 February 2004 concerning EP ‘172).

¹³⁷³ See also ID 5695, Teva’s Reply to the Letter of Facts I of 9 February 2024, paras. 258-260.

¹³⁷⁴ See Section 8.3.3.

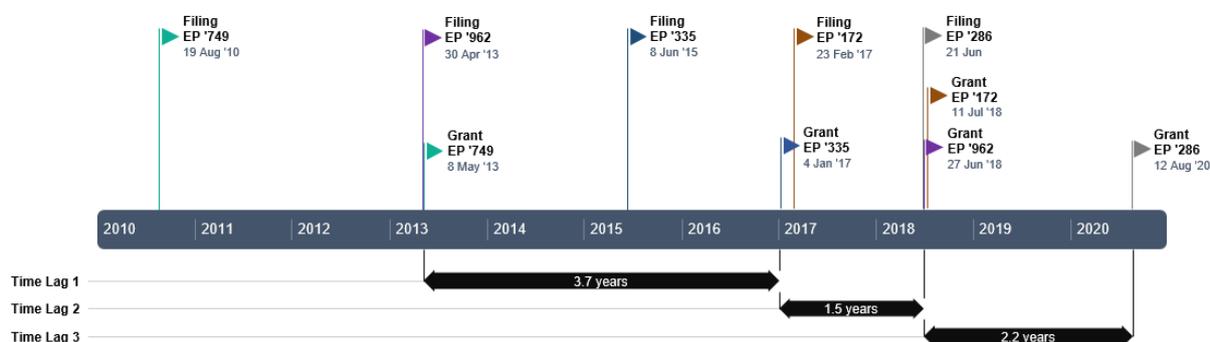
3 years and 11 months. The dosage patents were filed over a period of 9 years and 10 months and granted over a period of 7 years and 3 months.

Figure 35: Filing and grant dates of Teva's process patents



Source: EPO

Figure 36: Filing and grant dates of Teva's dosage patents



Source: EPO

- (1127) The staggered filing of the divisional patents before the EPO resulted in staggered grants, which in turn resulted in staggered legal reviews. Thereby, Teva extended the duration of the legal review of the validity of its patents by the EPO. The time period between the grants of the patents by the EPO allowed Teva to rely on a new divisional patent each time a previous generation patent was at risk to be revoked by the EPO.
- (1128) By staggering the filings of the process divisional patents (in September 2005, January 2010 and December 2010), Teva ensured that it could strategically withdraw a process patent that was challenged (as it did in February and October 2015) while keeping another process patent in place that it could enforce. Accordingly, potential GA entrants had to challenge each of the process patents consecutively, initiating the legal review of the claimed improvement to the manufacturing process for GA not once but three times. Similarly, due to the staggered filings in the dosage family, potential GA entrants had to initiate the legal review of the claimed now dosing regimen not once but five times. As a result, potential GA entrants had to continue to litigate the same questions over an artificially extended period of time.
- (1129) Teva argues that it did not have any influence over the timing of grant decisions and the timing of validity decisions since the timing of prosecution, opposition and appeal proceedings before the EPO are not in the hands of the applicants but are instead largely governed by the workload of the EPO.¹³⁷⁵ Specifically as regards the timelines for EP '335 and EP '962 Teva argues that the Commission's conclusions

¹³⁷⁵ ID 4032, Teva's Reply to the Statement of Objections, paras. 628-630.

“show a lack of understanding of how the EPO prosecution process works” explaining that the EPO examiner assessing the parent application could be a different examiner from the one assessing the divisional applications.¹³⁷⁶

- (1130) Teva’s claims do not convince. First, Teva could in fact exercise at least indirect control over the timing of procedures before the EPO.¹³⁷⁷ On the one hand, Teva could speed up the process. For example, Teva’s patent EP ‘335 was referred to as an {...}.¹³⁷⁸ In that case Teva’s influence over timing consisted of prioritising the process with respect to EP’335 at the expense of its much earlier filed parent patent EP ‘962.¹³⁷⁹ On the other hand, in many instances, Teva relied on the applicable procedural rules to delay the duration of proceedings before the EPO by, for example, stalling communications with the EPO,¹³⁸⁰ requesting the extension of deadlines before the examiner or the OD or rejecting a proposal to hold the oral hearing in the opposition proceedings by videoconference.¹³⁸¹

¹³⁷⁶ ID 5695, Teva’s Reply to the Letter of Facts I of 9 February 2024, para. 280. See also, ID 5909, Teva’s Reply to the Letter of Facts II of 17 May 2024, paras. 132.

¹³⁷⁷ According to Synthon, the EPO patenting process involves a dialogue between the EPO examiners and the applicant filing a patent. In order to delay the grant of the patent, the applicant can drag out this dialogue by: (i) using the maximum term (i.e. the EPO can give instructions to the applicant, e.g. to file observations, amend its claims or pay fees). Instructions from the EPO often come with a time limit for responding. The applicant can use the maximum terms for his responses and to pay the fees, (ii) requesting more time (i.e. applicants can stall the patenting process by (informally) requesting the examiner to slow down. Applicants can request an extension of time limits or postponement of oral proceedings. In other proceedings than opposition proceedings, a request for an extension (even if filed without reasons) is normally allowed if it is for not more than two months and the total period set does not thereby exceed six months), (iii) failing to observe a time limit (i.e. if the applicant misses a time limit, the EPO will notify the applicant that its application is deemed to have been withdrawn. The applicant can remedy this by filing a request for further processing within a limited timeframe after the notification. Applicants can delay the patenting process by intentionally missing deadlines because they know they can revive their application), (iv) filing amendments or corrections (i.e. the applicant can try to increase the amount of communications the EPO needs to issue by filing amendments or corrections to its claims. Applicants can still do this at an advanced stage of the proceedings and even after the EPO communicated its intention to grant. Applicants can artificially delay the patenting process by needlessly rejecting the text proposed for grant and requesting a correction). ID 3658, Synthon’s Reply to Article 18(2) Request of 12 September 2022.

¹³⁷⁸ ID 5513, email dated 21 December 2016 from Teva’s external patent counsel to {...} and others, p. 2.

¹³⁷⁹ EPO has a possibility for the applicants to seek accelerated examination. EPO also opens other possibilities for the applicants to expedite the grant procedure (e.g., by waiving right to receive certain communications from EPO). The Commission understands that when Teva refers to EP '335 as an "accelerated" divisional it refers to use of (at least some of) these possibilities under EPO rules. However, available documents do not reveal the exact mechanism used by Teva. EP '335 was filed on 8 June 2015 and granted on 4 January 2017. EP '962 (its parent application) was filed on 30 April 2013 and granted on 27 June 2018.

¹³⁸⁰ Letter by EPO dated 3 May 2016 shows that Teva’s application for EP ‘962 was at that moment considered withdrawn because Teva did not respond to the EPO examining division’s communication of 28 September 2015 (ID 5590, Letter from EPO to Teva’s external patent counsel of 3 May 2016). The deadline for Teva’s response was initially set at four months and then, on Teva’s request (ID 4950, Teva’s request for extension of deadlines of 1 February 2016), prolonged for additional two months on 5 February 2016. However, Teva avoided the consequences of the presumed withdrawal of the application by requesting further processing of its patent application on 6 July 2016 (ID 5591, Letter from Teva’s external patent counsel to EPO of 6 July 2016). Effectively, Teva answered EPO’s communication of 28 September 2015 not within the initial deadline of four months but within more than nine months, thus prolonging the duration of the proceedings before EPO.

¹³⁸¹ ID 4954, Teva’s request for extension of deadline of 10 November 2017 (opposition against EP ‘335); ID 4953, Teva’s rejection of a request to hold a hearing by a video conference of 7 August 2020 (opposition against EP ‘962); ID 4951, Teva’s request for extension of deadlines of 18 September 2017

- (1131) Second, with respect to Teva’s explanation on different examiners in the context of the dosage family, the EPO’s “*Intention to grant*” documents relating to patents in the dosage family show that all of the patents in the dosage family (including the Original Dosage Patent) were allocated to the same examiners.¹³⁸² This obviously affected their individual workload. As Teva clearly explains how the multiplicity of Copaxone-related EPO proceedings affected the same resources within Teva and led to delays in Teva’s responses to EPO,¹³⁸³ it is only reasonable to conclude that the allocation of parallel prosecutions to the same team of examiners could have led to longer prosecution timelines.
- (1132) Finally, as described in this Section 8.3.2.2, Teva controlled the filings and then by extension indirectly controlled the grants and the validity decisions since patents filed earlier are assessed and challenged earlier. Except for Teva’s divisional process patents (EP ‘528 and EP ‘924) which were filed during the same year because of the EPO rule then in force (but still at the latest possible moment), all other patents were filed with an interval of more than one year between them. Notes of {...} (i.e. {...}) from January 2017 show that Teva expected to be able to influence the time period in which the patents would be granted, as it refers to “{...}”.¹³⁸⁴
- (1133) With the exception of EP ‘962 and EP ‘172, whose opposition proceedings occurred largely in parallel due to the timing of their grants having coincided, and which were revoked by the OD almost at the same time in December 2021, the time lag between patent grants deprived potential GA entrants of the opportunity to challenge Teva’s patents in parallel.

Figure 37: Dates of the grant and Opposition Division decision of Teva’s process patents



Source: EPO

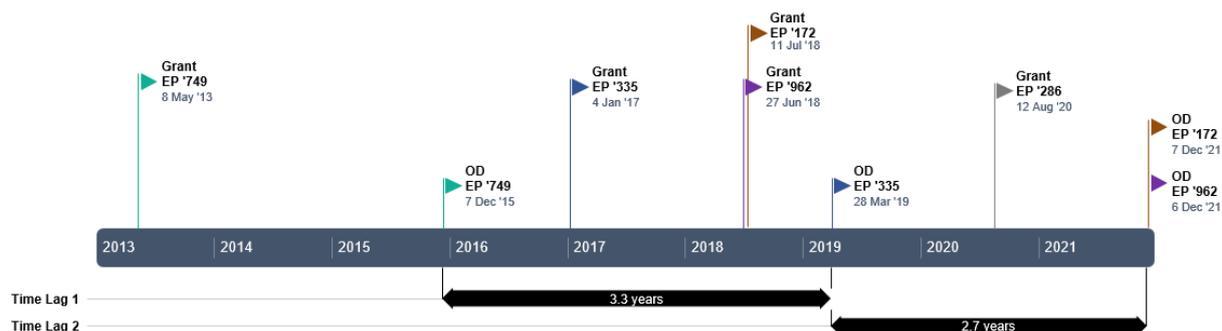
(prosecution EP ‘962); ID 4950, Teva’s request for extension of deadlines of 1 February 2016 (prosecution EP ‘962).

¹³⁸² ID 5765 EP ‘749 Intention to grant of 1 March 2013; ID 5767 EP ‘335 Intention to grant of 10 October 2016; ID 5766 EP ‘962 Intention to grant of 2 February 2018; ID 5769 EP ‘172 Intention to grant of 23 April 2018.

¹³⁸³ ID 5695, Teva’s Reply to the Letter of Facts I of 9 February 2024, para. 285.

¹³⁸⁴ ID 404-1841, Teva internal email dated 4 January 2017 from {...} to {themselves}.

Figure 38: Dates of the grant and Opposition Division decision of Teva's dosage patents



Source: EPO

- (1134) As soon as a new divisional patent was granted, Teva could rely on it (in addition to patents previously relied upon) to request preliminary injunctions before national courts to hinder the market entry and uptake of competing GA products. If one of the previously asserted patents was revoked, Teva would then continue to rely on the newer divisional patent(s), allowing preliminary injunctions to remain in place (or enabling Teva to continue litigation on its preliminary injunction request and thereby create costs and commercial uncertainty for Synthon and its licensees). In addition, by strategically withdrawing the challenged patents, Teva could avoid a negative precedent that might affect the validity assessment of other patents in the same family, thus forcing potential GA entrants and Synthon and its licensees in particular to start new litigation afresh.
- (1135) Through the staggered filing of its patents, generally paired with strategic withdrawals to avoid reasoned EPO decisions,¹³⁸⁵ Teva managed to artificially prolong legal uncertainty which could have been resolved much earlier.
- (1136) Moreover, Teva continued to rely on preliminary injunctions based on patents that would, absent Teva's practice of filing for divisional patents in a staggered manner, likely not had been in force. In some jurisdictions, courts do not make a substantial assessment of the validity of the patent invoked in the request for preliminary injunctions and grant these on a *prima facie* basis.¹³⁸⁶ Teva's {...} accordingly referred to "{...}" as "{...}" (emphasis added) for enforcement and for blocking competitors.¹³⁸⁷ Therefore, as long as a patent is in force, preliminary injunctions will often be granted no matter how unlikely it is that the patent will be upheld in ongoing opposition or appeal proceedings. As a result, in some Member States (i.e. Czechia, Denmark and Portugal) preliminary injunctions remained in force on the basis of EP '962 and EP '172, even after EP '335 had been revoked by the EPO.¹³⁸⁸

¹³⁸⁵ Patents were not withdrawn in cases where Teva did not have any subsequent divisionals to protect (EP '924, EP '962 and EP '172) or where Teva was prohibited from withdrawing by a court order (EP '335).

¹³⁸⁶ See, e.g. for Belgium ID 455-537, Teva internal email dated 24 May 2018 from {...} to {...} and others.

¹³⁸⁷ ID 404-876, Teva internal email dated 26 August 2012 from {...} to {...}; {...}), p. 1.

¹³⁸⁸ ID 2161, Teva's reply to Article 18(2) Request of 13 July 2022, Annex 15.6 (Czechia); ID 2154, Teva's reply to Article 18(2) Request of 13 July 2022, Annex 15.7 (Denmark, the preliminary injunctions were ultimately lifted on 23 August 2021); ID 1646, Teva's reply to Article 18(2) Request of 8 January 2021, Annex 15.24 (Portugal).

- (1137) Teva provides a number of explanations for the filing of the divisional patents in the process and dosage families.¹³⁸⁹ (i) EP ‘528, EP ‘962 and EP ‘286 were filed when Teva became aware of the EPO’s intention to grant the parent patent, thus creating a deadline to file any further divisional; (ii) EP ‘172 was filed when Teva decided to withdraw its application regarding EP ‘450 (“ghost divisional”); (iii) EP ‘924 was filed when the EPO announced its intention to introduce a two-year deadline for filing divisionals; and (iv) EP ‘335 was filed when Teva became aware of the mismatch between the Copaxone label and the wording of EP ‘749.¹³⁹⁰ Teva also argues that the staggered filing was beneficial to Teva for genuine IP reasons as illustrated by the situation described regarding the product claim that was initially included in EP ‘703, and which Teva was able to include in amended form in EP ‘924.¹³⁹¹
- (1138) Teva’s explanations regarding the timing of individual patent filings are consistent with the Commission’s assessment. They reveal that filings of divisional patents were not driven by underlying R&D but rather by external, predominantly procedural, considerations (e.g. because of change in EPO procedural rules in case of both process family divisionals or because of an imminent deadline due to the announced grant of the parent application). They show that Teva filed its patents at the last possible moment (within the existing legal framework) to stagger their grants in time as much as possible with a view to artificially prolong legal uncertainty regarding their validity. Teva’s explanations therefore cannot refute the Commission’s findings presented in Sections 8.3.1 and 8.3.2.2.¹³⁹²

Specific arguments with respect to the patents in the process family

- (1139) Teva explains that it filed all of the patents in the process family before any were withdrawn (both divisionals in the family were filed in 2010, that is five years before the first withdrawal took place in February 2015); that all three patents (EP ‘703, EP ‘528 and EP ‘924) had been filed and granted by 11 December 2013; that their enforcement was not yet anticipated when the last of the process patents were filed – or even granted; and that, with a narrow exception relating to Czechia (where Teva relied on EP ‘528 and EP ‘924 together), Teva almost exclusively relied on EP ‘924.

¹³⁸⁹ Teva also asserts that at the core of the Commission’s allegations is the suggestion that, for Teva, the only value of each divisional patent resulted from their overlapping claims and that Teva sought to prevent the parallel review of those claims by deliberately staggering their filings. Teva also maintains that the Commission did not adduce any "direct" evidence (e.g., internal documents) showing that the rationale behind the Filing of each divisional was indeed to prevent the parallel review of "overlapping" claims (ID 5695, Teva’s Reply to the Letter of Facts I of 9 February 2024, paras. 225-226). However, Teva again strives to misconstrue the Commission’s analysis and findings. Based on the analysis of Teva internal contemporaneous documents, as well as documents originating from the EPO and third parties, the Commission established that all of the patents within the same family shared essential features (in other words that they were overlapping) which interconnected their weaknesses and chances of success in validity challenges. The developments with respect to the patents that were ultimately assessed by the TBA (i.e. not withdrawn by Teva) confirm these findings. As to the lack of “direct evidence” showing a rationale for filings, it suffices to note that the Commission does not necessarily need to rely on direct evidence to show that Teva’s comprehensive patenting conduct was driven by the aim to exclude competitors as long as sufficient indirect evidence presented in this Section 8.3.2.2 support this conclusion. This said, the present Decision indeed refers to direct evidence pointing to the rationale behind filings of patents protecting Copaxone: “{...}” (ID 266-296, Teva internal email exchange dated 4 and 9 February 2014 from {...} to {...} and {...}, p. 1).

¹³⁹⁰ ID 4032, Teva’s Reply to the Statement of Objections, para. 738. See also, ID 5695, Teva’s Reply to the Letter of Facts I of 9 February 2024, para. 272.

¹³⁹¹ ID 4032, Teva’s Reply to the Statement of Objections, para. 740.

¹³⁹² With respect to filing of EP ‘335, see Section 8.3.6.5.

Teva therefore concludes that Teva's strategy in terms of filing divisionals in this family could not have been made by reference to any decision to withdraw a patent and that there is no evidence of sequenced filing, or that divisionals were filed after the unsuccessful prosecution of a previous divisional.¹³⁹³

- (1140) Teva's arguments have to be rejected for the following reasons. First, contrary to Teva's assertions, the Commission does not simply find that a particular filing is made by reference to a particular decision to withdraw the patent but that filings were made in a staggered manner to prevent their parallel review and to delay a final reasoned decision on their validity. As described in Section 8.3.1, Teva combined these staggered filings with strategic withdrawals in a way that guaranteed that there was always at least one other patent that Teva could rely on,¹³⁹⁴ even when it had to withdraw a patent to avoid a reasoned decision on its validity. Teva clearly delayed the filing of its divisional process patents in relation to the parent patent. It has not explained why the divisional applications were filed 5 years after the parent patent, considering that they claimed to protect manufacturing processes that were industrially implemented already in early 2000's (see Recitals (1199), (1245) and (1271)). In addition, the divisional patents in the process family (EP '528 and EP '924) were filed without substantial delay between them (both in 2010). However '528 was filed only one day before the granting of the parent patent – Original Process Patent and EP '924 because of the announced time limit imposed by EPO for the filing of voluntary divisional applications.¹³⁹⁵ In other words, Teva filed those divisional patents at the latest possible moment.¹³⁹⁶
- (1141) Second, the document referred to by Teva (ID 404-2207) to show that Teva did not intend to enforce the patents in the process family also reveals that the reason for that was that they were considered weak.¹³⁹⁷ In any event, these patents were still enforced against Synthron and its licensees.¹³⁹⁸ As to the "narrow exception" of Czechia, mentioned by Teva with respect to enforcement of EP '528, the Commission notes that this patent was enforced exactly where it had the most impact – in Czechia, a country where Synthron GA was manufactured.¹³⁹⁹
- (1142) Finally, as to Teva's assertion that enforcement of the divisional process patents was not yet anticipated when they were filed or even granted by 11 December 2013, it suffices to note that, according to Teva, a product claim was transferred from EP '703 to EP '924 in 2011 to avoid its invalidation "*because it was particularly relevant for enforcement purposes*".¹⁴⁰⁰ This explanation contradicts Teva's claim on lack of enforcement prospects of the divisional patents when they were granted.

¹³⁹³ ID 4032, Teva's Reply to the Statement of Objections, paras. 633-638.

¹³⁹⁴ Reliance on patents does not only include a possibility to seek court enforcement and preliminary injunctions but also a wide scope of other direct and indirect effects (see Section 8.4.1 and 8.4.2).

¹³⁹⁵ The rule that was announced in 2009 and entered into force introduced a time limit for the filing of divisional applications of two years from the first act of the examiner on the parent application. According to Teva, EP '924 was filed when the EPO announced its intention to introduce a two-year deadline for filing divisionals (ID 4032, Teva's Reply to the Statement of Objections, para. 578 and 738).

¹³⁹⁶ ID 4032, Teva's Reply to the Statement of Objections, para. 738. See also ID 5695, Teva's Reply to the Letter of Facts I of 9 February 2024, para. 272.

¹³⁹⁷ ID 404-2207, Teva internal email dated 4 May 2015 from {...} to {...}.

¹³⁹⁸ See Section 8.4.3.

¹³⁹⁹ ID 4032, Teva's Reply to the Statement of Objections, para. 247.

¹⁴⁰⁰ ID 4032, Teva's Reply to the Statement of Objections, para. 679. This product claim was later invalidated by OD in 2015 (ID 4032, Teva's Reply to the Statement of Objections, para. 684).

(1143) As to Teva's claims concerning the filing of EP '924, the Commission reiterates that the product claim which Teva uses to justify the staggered filing of the process patents was ultimately not saved by its transfer from EP '703 to EP '924, but simply invalidated with substantial delay (See Recital (1104)). As noted above, Teva learned of the invalidity of the relevant patent claim, withdrew it from the assessment by the OD of EP '703 (the Original Process Patent is confirmed without this claim) and inserted it in the second generation divisional (EP '924) where it was finally invalidated, but only after Teva had already extensively enforced it. While the staggered filing was beneficial for Teva as it could have relied on the product claim much longer, Teva's argument fully confirms the Commission's conclusion: Teva relied on patenting rules to create substantial delays in the assessment of the validity of its patents and thus to artificially prolong their effectiveness.

Specific arguments with respect to the patents in the dosage family

(1144) Teva claims that the filings in the dosage family were driven by R&D considerations as the results of the GALA study became gradually known. In particular, the effects of Copaxone 40 mg on the reduction of T1/T2 lesions and reduction of progression of MRI disease activity (which are part of the distinguishing features in EP '286) were only reported as the GALA study progressed. The effect of Copaxone 40 mg on, for example, brain atrophy, would only have been established at the conclusion of the two-year open-label extension phase of the GALA Study in 2017.¹⁴⁰¹

(1145) Teva's explanations cannot be accepted. First, as noted in Section 8.3.2.1.2, all distinctive features allegedly driving the staggered filings of the divisional applications in the dosage family were already known since the launch of the 20 mg once per-day Copaxone which was commercialized long before the filing of the Original Dosage Patent in 2010.¹⁴⁰² Even the Public Assessment Report for Copaxone 40 mg confirms that its formulation is identical to the Copaxone 20 mg solution. Furthermore, the timing of the filings of the divisionals in the dosage family does not correspond to the findings of the GALA study. For example, the reduction in brain atrophy was not reported before 2017 while EP '962 (which, according to Teva, sought to cover this distinguishing feature)¹⁴⁰³ was filed in 2013.¹⁴⁰⁴ Similarly, the reduction of T1/T2 lesions and the reduction of the progression of MRI disease were reported already in 2013 while EP '286 (which according to Teva, covers these distinguishing features)¹⁴⁰⁵ was filed only in June 2018. Finally, references to the GALA study do not in any way explain the filings of divisional applications covering distinctive features such as pH values, use of mannitol or use of pre-filled syringes as these were not covered by the GALA study.

8.3.3. *Teva obstructed effective legal review by withdrawing challenged patents thus avoiding damaging precedents*

(1146) When a final decision on the validity of a patent was near, Teva withdrew the approval of the text of the concerned patent as late as possible (in some cases only hours prior to the final decision) preventing a reasoned revocation decision. By

¹⁴⁰¹ ID 4032, Teva's Reply to the Statement of Objections, paras. 744 ff. See also ID 5695, Teva's Reply to the Letter of Facts I of 9 February 2024, para. 272.

¹⁴⁰² Copaxone was marketed in the EU from the early 2000s (see Section 5.1)

¹⁴⁰³ ID 4032, Teva's Reply to the Statement of Objections, paras. 694 ff. See Recital (1115).

¹⁴⁰⁴ ID 4795, Omar Khan (MD), Peter Rieckmann (MD), Alexey Boyko (MD), Krzysztof Selmaj (MD), and Robert Zivadinov (MD, PhD), for the GALA Study Group, *Three Times Weekly Glatiramer Acetate in Relapsing-Remitting Multiple Sclerosis*, *Annals of Neurology* 73: 705-713, June 2013, pp. 1 and 7.

¹⁴⁰⁵ ID 4032, Teva's Reply to the Statement of Objections, para. 746.

preventing such negative decisions, Teva shielded its patents from damaging precedents for as long as possible. With these actions obstructing and delaying the effective legal review of its patents, Teva aimed at hindering the entry of potential GA entrants on the market.¹⁴⁰⁶

(1147) In the following sections, the Commission first explains the damaging precedent effect a reasoned revocation decision by the TBA would have for Teva's remaining divisionals and preliminary injunction requests (Section 8.3.3.1). The Commission then shows how the legal proceedings concerning the validity of Teva's patents hinged on the same issues within each patent family (Section 8.3.3.2); how Teva was concerned about the weakness of its patents (Section 8.3.3.3); that Teva knew that a patent ruling would create a precedent for the remainder of the patent family and negatively influence the grant of preliminary injunctions (Section 8.3.3.4); and that the EPO and national courts confirmed the precedent effect of the TBA's decision specifically for Teva's dosage patents (Section 8.3.3.5). Finally, the Commission shows how Teva strategically withdrew challenged patents in the process and dosage families (Section 8.3.3.6).

8.3.3.1. Revocation decisions could have precedent effect for the whole patent family

(1148) The precedent effect of TBA decisions is well established by the TBA itself. In *Res iudicata in a divisional application / CANON*, the TBA found that “[the] principle of *res iudicata* is generally accepted in the contracting states and acknowledged by the boards of appeal”.¹⁴⁰⁷ The application of the principle of *res iudicata* means that the TBA cannot rule on a subject-matter that has already been the subject of an earlier TBA decision. The *res iudicata* principle “therefore prohibits parties from challenging what has already been decided”.¹⁴⁰⁸

(1149) Moreover, in *Res iudicata in a divisional application / CANON*, the TBA specifically applied the principle of *res iudicata* to decisions concerning divisional patents, holding that “since the aim of the *res iudicata* maxim is to avoid relitigation of the same subject matter by the same parties, it must inevitably apply to a divisional application”.¹⁴⁰⁹ As a result, once the TBA has issued a final decision that certain (or all) claims of a parent patent are invalid, this decision has a binding effect on the TBA that decides on the validity of that parent patent's divisionals.

(1150) If the TBA remits a case to the OD (or Examining Division) whose case was appealed, the OD (or Examining Division) is bound by the *ratio decidendi* of the TBA decision, in so far as the facts are the same (Art. 111(2) EPC). The OD equally

¹⁴⁰⁶ Teva explains that the Commission's reasoning in this Section 8.3.3 to a large extent amalgamates the assessment of whether Teva's conduct fell within the scope of competition of the merits or not, with the assessment of whether this conduct had the potential to have anticompetitive effects and that only the assessment of perceived weakness of Teva's patents and description of Teva's strategic withdrawals of patents are relevant for assessing whether Teva's conduct falls within the scope of competition of the merits. However, Teva's arguments follow from Teva's erroneous insistence that the filings and withdrawals represented two separate conducts and should be assessed separately (see Section 8.3.1). It is also not correct by law as the conclusion on whether a conduct falls outside the competition on merits cannot be made solely based on its objective, as Teva implies, but has to properly include the conduct in its entire context (see Section 8.2).

¹⁴⁰⁷ T 0051/08 (*Res iudicata in a divisional application / CANON*) of 7 May 2009, paragraph 3.

¹⁴⁰⁸ J 3/95, published in OJ EPO 1997, pp. 493-508, paragraph 6.

¹⁴⁰⁹ T 0051/08 (*Res iudicata in a divisional application / CANON*) of 7 May 2009, paragraph 3.1.

considers itself bound by the principle of *res iudicata* as far as the same facts are concerned.¹⁴¹⁰

- (1151) Beyond proceedings before the EPO, decisions of the TBA can also influence the outcome of national patent litigations in the contracting states. While TBA decisions do not have a binding effect on national courts, they have persuasive authority on national courts in the EPC contracting states (including all Relevant Member States). For example, the House of Lords held in *Merrell Dow* that “[these] decisions are not strictly binding upon courts in the U.K. but they are of great persuasive authority... because they are decisions of expert courts... involved daily in the administration of the EPC”.¹⁴¹¹ The German Federal Supreme Court, too, confirmed the persuasive authority of decisions of the EPO’s TBAs.¹⁴¹²
- (1152) It follows from the decisional practice of the EPO that TBA decisions have precedent effect. In particular, in order to deviate from an earlier TBA decision, the TBA has to submit the grounds for its deviation and inform the President of the EPO. A TBA decision also has precedent effect on subsequent proceedings before lower instances, namely ODs and Examining Divisions (responsible for patent granting procedures) of the EPO. They can also have persuasive authority in proceedings before national courts in EPC contracting states.
- 8.3.3.2. The legal proceedings concerning the validity of Teva’s Copaxone patents hinged on the same issues for each patent family
- (1153) In the following recitals, the Commission shows that the validity challenges brought against the different patents of both the process and the dosage patent families hinged on the same weaknesses affecting the shared essential features of those patents (and not on their distinguishing features). This clearly follows from the opposition notices¹⁴¹³ filed against Teva’s patents and from the appeals against OD decisions upholding Teva’s patents as well as from the reasoned decisions issued by the TBA that ultimately ruled on the validity of these patents. Without Teva’s strategic withdrawals, the outcome of the first validity challenge (concerning the Original Process Patent and the Original Dosage Patent) would therefore have had a precedent effect for the divisional patents of the same patent family.

Process patent family

- (1154) Due to the staggered filing dates of the process patents and the significant overlap in the protected subject-matter, potential GA entrants were forced to initiate successive validity challenges against all three patents to “*clear the way*”. Each time, the patent review concerned the same central, overlapping essential features of the parent patents and their divisionals and not the distinguishing features of these patents.

¹⁴¹⁰ ID 3786, EP2630962 – Preliminary opinion of the Opposition Division, 17 February 2021, pp. 3-4; ID 2183, EP3199172 – Preliminary opinion of the Opposition Division, 17 February 2021, pp. 3-4. See also ID 4595-33137, Report by {...} on revocation of EP ‘335 of 10 September 2020 where a third-party observer (market intelligence company {...}) noted that the revocation of EP ‘335 gave Teva’s competitors an advantage in obtaining revocations of other patents belonging to the dosage family. See also Section 8.3.3.5.

¹⁴¹¹ House of Lords, Decision of 26 October 1995, *Merrell Dow Pharmaceuticals Inc. and Others v H.N. Norton & Company Ltd* (UKHL J1026-1).

¹⁴¹² Bundesgerichtshof, Decision of 15 April 2010 (Xa ZB 10/09).

¹⁴¹³ Oppositions to any patent granted by EPO may be started by filing a notice of opposition (opposition notice) by any member of the public except for the patent proprietor himself within nine months of the publication of the mention that the patent has been granted.

- (1155) On 5 October 2010, Synthon filed a first notice of opposition challenging the validity of the Original Process Patent, EP ‘703. Synthon asserted that claims defining maximum amounts of brominated tyrosine and metal ion impurities were not novel.¹⁴¹⁴ Synthon also asserted that all of the patent’s claims lacked an inventive step, as the claimed improvement of the pre-treatment of hydrogen bromide (“HBr”) with a bromine scavenger as well as the production of HBr in a non-metallic reactor would be obvious to the skilled person based on prior art.¹⁴¹⁵
- (1156) On 6 September 2012, Synthon filed a second notice of opposition challenging the validity of EP ‘528, a divisional application of EP ‘703. Synthon again challenged the novelty of the selected sub-ranges of brominated tyrosine and metal ion impurities as these were merely “*an arbitrary specimen of the prior art and not based on a purposive selection*”.¹⁴¹⁶ Synthon also repeated the argument that the claimed improvement of the pre-treatment of HBr with a bromine scavenger as well as the production of HBr in a non-metallic reactor lacked an inventive step.¹⁴¹⁷
- (1157) On 11 September 2014, Synthon filed a third notice of opposition challenging the validity of EP ‘924, a divisional application of EP ‘528. Synthon (again) asserted that the claimed improvement of the pre-treatment of HBr with a bromine scavenger as well as the production of HBr in a non-metallic reactor lacked an inventive step.¹⁴¹⁸ Synthon also argued that the claims defining maximum amounts of brominated tyrosine and metal ion impurities were “*merely artificial and arbitrary*” and thus not novel.¹⁴¹⁹
- (1158) The OD upheld all three patents. Synthon appealed the OD’s decisions in all three cases before the TBA and maintained during all appeal proceedings its arguments alleging (i) a lack of novelty of the claims concerning maximum amounts of brominated tyrosine and metal ion impurities as well as (ii) a lack of an inventive step concerning the pre-treatment of HBr with a bromine scavenger and the production of HBr in a non-metallic reactor.¹⁴²⁰ However, due to Teva’s conduct, Synthon could not obtain a reasoned decision from the TBA until the very last divisional (EP ‘924) was revoked in September 2017 (two and a half years after a reasoned decision on the Original Process Patent, EP ‘703, would have been issued absent its withdrawal in February 2015).¹⁴²¹
- (1159) Teva argues that divisional patents do not share the same “*risks of invalidity*” as, according to Teva, if that were the case the EPC would simply provide that an invalidation of any patent in a family automatically invalidates the other patents in that family, for the same reasons as the invalidated patent. More specifically, Teva also argues that its patents did not hinge on the essential features affected by the same weaknesses and that the EPO afforded every patent a thorough review of each individual claim. Teva notes that the EPC specifically provides for the independence

¹⁴¹⁴ ID 2187, EP1799703 - Notice of opposition, 5 October 2010, pp. 3-4.

¹⁴¹⁵ ID 2187, EP1799703 - Notice of opposition, 5 October 2010, pp. 6-10.

¹⁴¹⁶ ID 2189, EP2177528 - Notice of opposition, 6 September 2012, p. 6.

¹⁴¹⁷ ID 2189, EP2177528 - Notice of opposition, 6 September 2012, pp. 13-22.

¹⁴¹⁸ ID 2190, EP2361924 - Notice of opposition, 11 September 2014, pp. 8-16.

¹⁴¹⁹ ID 2190, EP2361924 - Notice of opposition, 11 September 2014, p. 9.

¹⁴²⁰ In the appeals against the OD’s decision upholding EP’ 703, Synthon also argued that the auxiliary requests contravened Article 80 EPC (addition of new dependent claims having no counterpart in the original patent) and Article 123(3) EPC (added matter).

¹⁴²¹ ID 5676, EP2361924 – Decision of the Technical Board of Appeal 3.3.04, 12 September 2017. As explained in Section 8.3.2.1.1 above, all patents forming part of the process patent family were affected by the same weaknesses (and thus, likelihood to be revoked).

of the review of the validity of divisional patents as evidenced by the fact that EP ‘528 and EP ‘924 were invalidated on different grounds.¹⁴²²

- (1160) Teva’s claims should be rejected. Teva misconstrues the Commission’s analysis as the Commission never concluded that in all cases patent applications within the same family necessarily share the same risk of invalidity, in other words, the same likelihood of being invalidated for the same reasons. However, in the present case, based on the analysis of the contemporaneous internal documents and on the rest of the evidence on file, the Commission establishes that Teva’s patents were overlapping in that they shared essential features¹⁴²³ which were fraught with shared weaknesses. All of Teva’s patents were indeed ultimately invalidated or would have been invalidated had Teva not withdrawn them.
- (1161) As to the Original Process Patent, the OD noted that all of its independent claims “are linked as to form a common inventive concept”. This “common inventive concept” was then tested for novelty and the presence of an inventive step (two cumulative patentability requirements) against the state of prior art primarily included in (i) Teva’s main GA patent – EP ‘888 (see Recital (101)), (ii) an article published in 1966 describing that formation of bromotyrosine is avoided by a pretreatment of the HBr used for the deprotection by a bromine scavenger and (iii) a review and evaluation of pharmacology and toxicology data referring to Copaxone published in 1996 (at the occasion of the FDA approval of Copaxone).¹⁴²⁴
- (1162) While the OD upheld the Original Process Patent, the TBA identified the relevant improvement proposed by the patent as “*treating the deprotecting solution with a bromide scavenger, has the effect of reducing the level of free bromine in the deprotecting solution (HBr) and hence the level of brominated tyrosine in the intermediate (TFA GA) and final (GA) products*” and indicated that the assessment of the inventive step hinges on the determination of the closest prior art.¹⁴²⁵ The TBA then selected the latest document indicated above as the appropriate “springboard”.¹⁴²⁶ Teva then decided to withdraw the Original Process Patent (see Section 8.3.3.6.1).
- (1163) The same discussion on the selection of the closest prior art was then repeated in the proceedings concerning EP ‘528 and again the same documents (i.e. Teva’s main patent EP ‘888 and review of pharmacology and toxicology data published at the time of the FDA’s approval of Copaxone) were chosen by the TBA as novelty destroying or showing that the patent lacks inventive step.¹⁴²⁷ Teva withdrew the patent at the end of the hearing before the TBA. As for EP ‘924, the TBA did not

¹⁴²² ID 4032, Teva’s Reply to the Statement of Objections, paras. 861-869. See also ID 5909, Teva’s Reply to the Letter of Facts II of 17 May 2024, paras. 113-119.

¹⁴²³ See Section 8.3.2.1.

¹⁴²⁴ The Commission also notes that Teva strongly opposed inclusion of this, “*highly pertinent document*” in the EPO proceedings (ID 5959, EP1799703 – Decision of the Opposition Division, 27 February 2012, p. 6).

¹⁴²⁵ Closest prior art is a document that discloses the most promising starting point for development leading to the invention. It must be directed to a similar purpose of effect as the claimed invention or at least belong to the same or closely related technical field. This closest prior art is then used for assessment of an inventive step of the claimed patent (Guidelines for Examination in the European Patent Office, March 2024, Part G, chapter VII, 5.1 determination of the closest prior art).

¹⁴²⁶ ID 2171, EP1799703 – Preliminary opinion of the Technical Board of Appeal 3.3.04, 8 October 2014, p. 5.

¹⁴²⁷ ID 5781, EP2177528 – Minutes of the hearing before the Technical Board of Appeal 3.3.04, 13-14 October 2015.

find it necessary to pronounce itself on the novelty and inventive step of the patent claims (although these were put in question on the same grounds as in case of the Original Process Patent and EP ‘528) simply because it found that all of the claims of the patent were either inadmissible or included added matter (i.e. extended the scope of protection beyond the original application).¹⁴²⁸

- (1164) With respect to EP ‘924, it suffices to say that its most important product claim was never included in EP ‘528 but transferred to EP ‘924 from the challenged Original Process Patent. Both the OD and the TBA found that this product claim extended the scope of EP ‘924 beyond the initially filed application (see Recital (1104)). In addition, as described in this Section 8.3.3.2, EP ‘924 was challenged on a number of legal grounds including on a lack of novelty. The fact that the TBA invalidated the patent for added matter does not preclude that it could also have been declared invalid based on other grounds, including lack of novelty or lack of an inventive step. Finally, Teva was internally concerned about EP ‘528 for added matter as well (see Recitals (1194)-(1195)) and the TBA preliminarily found that “*the subject matter of [the first independent claim of EP ‘528] extends beyond the content of the earlier application*”, in other words, that it included added matter.¹⁴²⁹

Teva’s dosage patents

- (1165) Similarly, due to the staggered filing dates of the dosage patents, actual or potential GA entrants had to initiate successive validity challenges against all five dosage patents. The substance of each of these validity challenges was very similar, as the review concerned the central, overlapping claims of the parent patent (the Original Dosage Patent) and the divisionals and not the differentiating features of these patents.
- (1166) This is illustrated by Synthon’s statement in its opposition notice against EP ‘962, that “*the parties already exchanged all arguments several times, and the patentee as well as his representatives are already fully aware of the following grounds of opposition. [...] Since the patentee’s probable counter-arguments were presented in the parallel proceedings, the opponent does not expect that the patentee’s reply to the grounds of opposition will require any extensive effort*” (emphasis added).¹⁴³⁰
- (1167) On 7 February 2014, Synthon filed a first notice of opposition challenging the validity of the Original Dosage Patent EP ‘749.

¹⁴²⁸ ID 5676, EP2361924 – Decision of the Technical Board of Appeal 3.3.04, 12 September 2017.

¹⁴²⁹ ID 5961, EP2177528 – Preliminary opinion of the Technical Board of Appeal 3.3.04, 9 October 2015, p. 6. Contrary to Teva’s claims (ID 6160, Teva’s Reply to the Letter of Facts III of 16 October 2024, para. 13), the Commission is aware of the fact that EP ‘528 was not invalidated for added matter. However, the Commission finds that, absent Teva’s withdrawal, it would have been invalidated for lack of novelty or inventive step (see Recital (1231)). Moreover, the TBA’s Preliminary Opinion of 9 October 2015 shows that issues related to added matter were not limited to EP ‘924 only. See also the document relied on by Teva (ID 5781, EP2177528 – Minutes of the hearing before the Technical Board of Appeal 3.3.04, 13-14 October 2015, p. 8) which shows that the concerns regarding added matter were raised also with respect to the auxiliary request 3a submitted by Teva in the TBA proceedings concerning EP ‘528.

¹⁴³⁰ ID 2178, EP2630962 - Notice of opposition, 26 March 2019, p. 2. Similarly, and in contradiction to Teva’s claims on complete independence of the patent review process in this investigation, Teva noted before the EPO that “[t]he present oppositions are identical to those submitted against [EP ‘335] and [Teva’s] response is based upon that submitted in those proceedings supplemented with references to the OD decision [upholding EP ‘335] and addressing additional points raised during the course of the ‘335 opposition proceedings.” (ID 5965, EP2630962 – Teva’s reply to the notices of opposition, 20 August 2019, p. 1).

- (1168) First, Synthon asserted that the (three times a week) 40 mg dosing regimen was not, as claimed, novel in view of the (each alternate day) 40 mg dosing regimen disclosed in the US-patent application US 2007/0161566 (“US ‘566A1”) from 2007. Synthon relied on case law of the EPO according to which “*a different dosing regimen can render a claimed medical use of a known product only novel if it is not an arbitrary alternative to the state of the art but reflects a different technical teaching, which causes a particular new technical effect*”.¹⁴³¹ Synthon argued that this requirement was not met, because a dosage of three times in a week instead of a dosing regimen on each alternate day represents “*an arbitrary variation and not a ‘different technical teaching’ and none of the documents [...] describe any particular effect caused by this difference*”.¹⁴³²
- (1169) Second, Synthon asserted that if its argument based on US ‘566A1 was not upheld, the dosing regimen claimed by EP ‘749 lacked an inventive step. In particular, Synthon argued that “[s]ince, compared to the dosing regimen explicitly disclosed by [US ‘566A1], no advantage or surprising effect is yielded by the claimed alternative and because the change from seven to six administrations per 14 days is solely arbitrary, the granted claims must be regarded as absolutely non-inventive in view of the disclose of [US ‘566A1]”.¹⁴³³
- (1170) Third, Synthon argued that the claims granted in EP ‘749 comprised an extension or generalisation of the original disclosure¹⁴³⁴ and that EP ‘749 did not sufficiently disclose the 40 mg dosing regimens teaching, as it did not disclose how RRMS could be cured from the claimed dosing regimen.¹⁴³⁵
- (1171) On 4 October 2017, Synthon filed a second notice of opposition, challenging the validity of EP ‘335. The notice repeated the arguments raised in the proceedings concerning the validity of EP ‘749. Synthon explicitly observed that the contents of the challenges are identical, noting that “*the only feature ‘distinguishing’ the currently claimed subject matter from that of [...] EP 2 405 749, is the mandatory presence of mannitol*” and that this feature is “*technically completely irrelevant*”.¹⁴³⁶ Synthon again claimed that the 40 mg dosing regimen was not novel, as it did not represent a different technical teaching or new technical effect.¹⁴³⁷ With regard to the lack of an inventive step, Synthon stated that “*the presence of an inventive step in the subject matter claimed by opposed patent solely depends on the obviousness of the subject matter already claimed by its grandparent (EP 2 405 749), which was opposed and, finally, withdrawn before the Board of Appeal could come to a decision. [...] In the adversary [EP ‘749] proceedings, the parties already exchanged all arguments several times, and the patentee as well as his representatives are already fully aware of the following grounds of opposition*”¹⁴³⁸ and subsequently repeated the previously submitted arguments concerning the lack of an inventive step.¹⁴³⁹

¹⁴³¹ ID 2168, EP2405749 - Notice of opposition, 7 February 2014, p. 8.

¹⁴³² ID 2168, EP2405749 - Notice of opposition, 7 February 2014, p. 8.

¹⁴³³ ID 2168, EP2405749 - Notice of opposition, 7 February 2014, p. 9.

¹⁴³⁴ ID 2168, EP2405749 - Notice of opposition, 7 February 2014, pp. 3-5.

¹⁴³⁵ ID 2168, EP2405749 - Notice of opposition, 7 February 2014, p. 5.

¹⁴³⁶ ID 2182, EP2949335 - Notice of opposition, 4 October 2017, pp. 2-3.

¹⁴³⁷ ID 2182, EP2949335 - Notice of opposition, 4 October 2017, pp. 14-17.

¹⁴³⁸ ID 2182, EP2949335 - Notice of opposition, 4 October 2017, pp. 2, 4.

¹⁴³⁹ ID 2182, EP2949335 - Notice of opposition, 4 October 2017, pp. 17-39.

- (1172) On 26 March 2019, Synthon filed a third notice of opposition, challenging the validity of the divisional patent EP ‘962. The notice repeated the arguments raised in the opposition to EP ‘335, that “*the only features ‘distinguishing’ the currently claimed subject matter from that of its parent, EP 2 405 749, is the mandatory presence of mannitol in the claimed composition as well as its pH-value of 5.5 to 7.0*” and that this feature was “*technically completely irrelevant*”.¹⁴⁴⁰ Synthon again submitted its arguments concerning the lack of novelty¹⁴⁴¹ and of an inventive step¹⁴⁴² of the 40 mg dosing regimen. Furthermore, while a divisional application may be filed only for a subject-matter that does not extend beyond the content of the parent application as filed, Synthon claimed that the content of EP ‘962 went beyond the content (i.e. subject-matter) of the Original Dosage Patent. Indeed, Synthon submitted that the scope of EP ‘962 extended beyond the content of the parent application through its reference to RMS (rather than RRMS) and to “treating” patients rather than merely to “alleviating symptoms”.¹⁴⁴³ Synthon also attacked the patent for a lack of sufficient disclosure both concerning the claimed “treating” of MS patients and the specific efficacy of a 40 mg dosing regimen.¹⁴⁴⁴
- (1173) On 10 April 2019, Synthon filed a fourth notice of opposition, challenging the validity of the divisional patent EP ‘172. The notice yet again repeated the arguments raised in the oppositions to EP ‘335 and EP ‘962, that the scope of the Original Dosage Patent was “*besides the technical irrelevant ‘pH’-feature*” identical to that of EP ‘172.¹⁴⁴⁵ Synthon submitted, once more, its arguments concerning¹⁴⁴⁶ the lack of novelty,¹⁴⁴⁷ the lack of sufficient disclosure¹⁴⁴⁸ and the lack of an inventive step¹⁴⁴⁹ of the 40 mg dosing regimen, as well as the alleged extension beyond the content of the parent application.¹⁴⁵⁰
- (1174) On 11 May 2021, Synthon filed a fifth notice of opposition, challenging the validity of the divisional patent EP ‘286. Once more, the notice pointed out that “*the only technically relevant feature ‘distinguishing’ the subject matter of present claims 1 and 2 from that of its withdrawn parent, EP 2 405 749, and its revoked sibling, EP 2 949 335, can be seen in the provision of the claimed composition in a prefilled syringe*” which is “*technically just irrelevant*”.¹⁴⁵¹ Synthon also referred to the TBA’s revocation decision as regards EP ‘335 and the opinions of the ODs as regards EP ‘962 and EP ‘172, confirming the applicability of the *res iudicata* principle.¹⁴⁵² Synthon submitted, once more, its arguments concerning the lack of novelty,¹⁴⁵³ the lack of sufficient disclosure¹⁴⁵⁴ and the lack of an inventive step¹⁴⁵⁵

¹⁴⁴⁰ ID 2178, EP2630962 - Notice of opposition, 26 March 2019, pp. 2-3.
¹⁴⁴¹ ID 2178, EP2630962 - Notice of opposition, 26 March 2019, pp. 11-13.
¹⁴⁴² ID 2178, EP2630962 - Notice of opposition, 26 March 2019, pp. 21-52.
¹⁴⁴³ ID 2178, EP2630962 - Notice of opposition, 26 March 2019, pp. 5-10.
¹⁴⁴⁴ ID 2178, EP2630962 - Notice of opposition, 26 March 2019, pp. 13-20.
¹⁴⁴⁵ ID 2165, EP3199172 - Notice of opposition, 10 April 2019, pp. 1-5.
¹⁴⁴⁶ ID 2165, EP3199172 - Notice of opposition, 10 April 2019, pp. 6-10.
¹⁴⁴⁷ ID 2165, EP3199172 - Notice of opposition, 10 April 2019, pp. 11-14.
¹⁴⁴⁸ ID 2165, EP3199172 - Notice of opposition, 10 April 2019, pp. 14-20.
¹⁴⁴⁹ ID 2165, EP3199172 - Notice of opposition, 10 April 2019, pp. 21-54.
¹⁴⁵⁰ ID 2165, EP3199172 - Notice of opposition, 10 April 2019, pp. 6-10.
¹⁴⁵¹ ID 2177, EP3409286 - Notice of opposition, 11 May 2021, pp. 5-6.
¹⁴⁵² ID 2177, EP3409286 - Notice of opposition, 11 May 2021, pp. 6-9.
¹⁴⁵³ ID 2177, EP3409286 - Notice of opposition, 11 May 2021, pp. 11-15.
¹⁴⁵⁴ ID 2177, EP3409286 - Notice of opposition, 11 May 2021, pp. 15-25.
¹⁴⁵⁵ ID 2177, EP3409286 - Notice of opposition, 11 May 2021, pp. 25-58.

of the 40 mg dosing regimen, as well as the extension beyond the content of the parent application.¹⁴⁵⁶

- (1175) The overlapping content of the divisional patents in the dosage family has been recognised by the OD, which noted, in the context of the opposition proceedings against EP ‘962 and EP ‘172 that the only difference between each of EP ‘962 and EP ‘172, and EP ‘335 is limited to a preferred pH range of 5.5. to 7.0.¹⁴⁵⁷ However, due to Teva’s conduct, Synthron could only obtain a reasoned decision from the TBA (regarding EP ‘335) only in September 2020 – almost three years after a reasoned decision on the Original Dosage Patent, EP ‘749, would have been issued absent its withdrawal.¹⁴⁵⁸
- (1176) Contrary to Teva’s claims, the fact that all patents in the dosage family were affected by the same basic flaw is well shown by the immediate impact that the selection of the closest prior art had on them. Much like in the process family (see Recitals (1161)-(1163)), once US ‘566A1 was selected as the closest prior art, the lack of an inventive step in Teva’s dosage patents became obvious. Already the OD assessing the Original Dosage Patent first came to the preliminary conclusion that US ‘566A1 is the closest prior art and that therefore the patent is invalid.¹⁴⁵⁹ While the OD then reversed its preliminary position on the closest prior art in its decision and consequently upheld the patent (OD decided that the 20 mg dosing regimen is a better closest prior art than the US patent addressing the 40 mg regimen),¹⁴⁶⁰ the status of the prior art was finally confirmed by the TBA with respect to EP ‘335.
- (1177) In a decision which was entirely devoted to a discussion of the closest prior art and the presence of an inventive step, the TBA decided that indeed the US patent disclosing the 40 mg/ml dosing regimen (i.e. US ‘566A1) was the closest prior art for Teva’s dosage patents – similarly to what the OD had initially considered in its preliminary conclusions – and consequently revoked EP ‘335 for lack of an inventive step.¹⁴⁶¹ The same approach was then followed both by the OD and the TBA in cases concerning Teva’s remaining dosage divisional patents – EP ‘962 and EP ‘172 – where the US ‘566A1 was also accepted as the closest prior art.¹⁴⁶² While some claims in those patents were invalidated before any discussion of novelty and the presence of an inventive step,¹⁴⁶³ those claims that were assessed from the

¹⁴⁵⁶ ID 2177, EP3409286 - Notice of opposition, 11 May 2021, pp. 10-11.

¹⁴⁵⁷ Because 1) the preferred pH range feature was present in the revoked EP ‘335; 2) the preferred pH range has not been evoked as being particularly pertinent for the question of inventive step any of the parties and 3) the preferred pH range feature is present in the document (the aforementioned US ‘566A1) which was considered by the TBA to be the closest prior art to EP ‘335.

¹⁴⁵⁸ Reasoned TBA decision on EP ‘335 was possible only after the Regional Court of Munich (in the context of proceedings for the grant of a preliminary injunction) ordered Teva to refrain from withdrawing the approval of the text for EP ‘335, see LG München I, Beschluss v. 24 February 2020 – 7 O 1456/20. For details of chronological order of grants, OD decisions and appeals see Figure 38, Figure 40 and Figure 41.

¹⁴⁵⁹ ID 5962, EP2405749 – Preliminary opinion of the Opposition Division, 23 April 2015, p. 6.

¹⁴⁶⁰ ID 5964, EP2405749 – Decision of the Opposition Division, 19 January 2016, pp. 8-11. Teva withdrew the Original Dosage Patent before TBA had a chance to decide on the closest prior art.

¹⁴⁶¹ ID 5963, EP2949335 – Decision of the Technical Board of Appeal 3.3.04, 13 May 2019.

¹⁴⁶² ID 5693, EP2630962 – Decision of the Opposition Division, 4 February 2022; ID 5823, EP2630962 – Decision of the Technical Board of Appeal 3.3.04, 7 February 2024; ID 5694, EP3199172 – Decision of the Opposition Division, 27 January 2022; ID 5825, EP3199172 – Decision of the Technical Board of Appeal 3.3.04, 7 February 2024.

¹⁴⁶³ For example, all claims including a reference to RMS rather than to RRMS were invalidated for added matter (see Section 8.3.6.5). A claim in EP ‘962 referring to reduction in brain atrophy (see (1115)-(1118)) was initially invalidated by the OD for lack of inventive step over the closest prior art (ID 5693,

perspective of the previously selected prior art were unambiguously pronounced as lacking an inventive step as they were obvious when assessed from the perspective of US '566A1.¹⁴⁶⁴

(1178) It follows that the validity challenges brought against the different patents of each patent family hinged on the same weaknesses affecting the patents' shared essential features (and not on their distinguishing features). This is clearly shown in the opposition notices filed against Teva's patents and appeals against the OD decisions upholding them, as well as in the appellate TBA decisions. Without Teva's strategic withdrawals, a reasoned TBA decision ending the first validity challenge (concerning the Original Process Patent and the Original Dosage Patent) would have therefore had a precedent effect for the remaining divisionals of the same patent family. This means that the other patents of the respective patent family would in all likelihood also have been revoked by the OD and/or the TBA (as applicable) on the same grounds. As a result, national courts would have been less likely to grant preliminary injunctions in view of the existence of a (negative) reasoned decision by the TBA. Therefore, Teva's patent protection was maintained in force not due to its merits but due to procedural delays.

8.3.3.3. Teva was concerned about the weakness of its patents and the resulting risk of their revocation.

(1179) Before and during the legal review of its patents, Teva's employees repeatedly expressed their concerns internally that the patents would be revoked. These concerns were further confirmed by the TBA's preliminary opinions and were at the centre of Teva's decision-making process concerning patent litigation at EPO level.¹⁴⁶⁵

EP2630962 – Decision of the Opposition Division, 4 February 2022, pp. 14-15) and finally revoked by the TBA for insufficient disclosure, without even discussing its innovative step. As the TBA noted, "*The effect [reduction of brain atrophy] was thus not credibly disclosed to be achievable at the relevant date. [...], this cannot be remedied by post-published evidence (e.g. [results of the GALA study]).*" (ID 5823, EP2630962 – Decision of the Technical Board of Appeal 3.3.04, 7 February 2024, p. 28).

¹⁴⁶⁴ Teva claims that EPO documents originating from the proceedings concerning patents in Teva's dosage family "*show that there was a genuine debate on closest prior art for each patent in the family*". According to Teva, following a submission of an auxiliary request adding distinguishing features in EP '962, "*[t]he TBA deciding on EP 962 refused to consider that the TBA's decision on EP 335 had any res judicata effect and heard all arguments regarding closest prior art and inventive step anew*" as "***[t]he changes introduced through the auxiliary request led to a new assessment on patentability***" (ID 6160, Teva's Reply to the Letter of Facts III of 16 October 2024, para. 13, emphasis in the original). Teva's arguments should be rejected. There was no "*new assessment on patentability*" as assessment of Teva's auxiliary claim mentioning brain atrophy concerned the same exact issue as the assessment of other claims in EP '962 and led to the exact same result for the exact same reason: this claim lacked inventive step, as it was obvious from the perspective of the closest prior art – patent US '566A1. The OD underlined that brain atrophy is a known symptom of RRMS, that no effect of the 40 mg dosing regimen on brain atrophy had ever been demonstrated, that no improvement in reduction on brain atrophy has been shown in comparison with the closest prior art and that "*the problem to be solved by [the invention embodied in EP '962] is considered as a provision of an alternative regimen for the treatment of RRMS.*" (see ID 5693, EP2630962 – Decision of the Opposition Division, 4 February 2022, p. 14-15). In this context, nothing in Teva's comments submitted in the Reply to the Letter of Facts III of 16 October 2024, can alter the fact that any and all of the patents in the dosage family and all of their tested claims (be it of the patents as issued or as amended through numerous auxiliary requests by Teva) displayed lack of inventive step once US patent '566A1 was selected as the closest prior art. This affected the patentability of the 40 mg dosing regimen irrespective of the distinguishing features in different divisional patents.

¹⁴⁶⁵ Teva notes that it never expressed any doubt as to the validity of the divisionals upon their filing and had received objective, positive indications that its patents may be valid. While, according to Teva,

- (1180) However, Teva claims that it had strong indications of the validity of the patents in both families as it had received positive indications both at EPO level (ODs) and from national courts that its patents may be valid.¹⁴⁶⁶ Teva also refers to an internal note prepared by Teva’s {...} indicating that patents EP ‘335 and EP ‘749 were considered strong.¹⁴⁶⁷ Thus, according to Teva, Teva had genuine, objective reasons to believe that its patents may be valid. Finally, as to the documents relied on by the Commission, Teva contends that these documents are limited in number, and they are all emails from a single individual within the company, Teva’s {...} (who was acting as a {...}), whose views cannot be construed as an accurate portrayal of the undertaking’s views regarding the validity of its patents.¹⁴⁶⁸ Teva also notes that Teva’s internal estimates relied on by the Commission were driven by an overly cautious and conservative approach.¹⁴⁶⁹
- (1181) Teva’s arguments cannot be accepted for the following reasons. First, as to the indications of the strength of the patents received from the OD, the Commission notes that EPO statistics¹⁴⁷⁰ do not support any conclusion that OD decisions would constitute a strong indication of the validity of the patents (see Recital (59)). This view was shared by Teva internally.¹⁴⁷¹ Teva also claims that “*two completely different groups of experts at the EPO*”¹⁴⁷² confirmed the validity of the dosage patents – by which it means the OD, in two different formations, upheld the Original Dosage Patent and the EP ‘335. However, the fact remains that both of these patents were ultimately revoked by the TBA underlining the importance of an appellate process before a TBA which Teva obstructed by withdrawing the Original Dosage Patent before the oral hearing (see Section 8.3.3.6.2). By contrast, the situation before the OD in the opposition proceedings concerning EP ‘962 and EP ‘172 was completely different. Unlike in cases concerning earlier Teva divisionals (where the OD regularly upheld challenged Teva divisional patents), these two divisional

Teva’s perception of the strength of its patents was relevant in the context of the withdrawals, these considerations were entirely absent from the decisions to file divisional applications (ID 4032, Teva’s Reply to the Statement of Objections, paras. 758-760, ID 5695, Teva’s Reply to the Letter of Facts I of 9 February 2024, paras. 263-266). The Commission notes that Teva again propagates a mechanical division of Teva’s comprehensive patenting conduct to patent filings and patent withdrawals. However, such an approach contradicts the Commission’s findings based on *inter alia* contemporaneous Teva internal documents and should be rejected (See Section 8.3.1). In addition, the Commission notes that Teva’s arguments regarding considerations underlying withdrawals of patents supports Commission’s conclusions in this Section 8.3.3.

¹⁴⁶⁶ ID 4032, Teva’s Reply to the Statement of Objections, paras. 761 ff.

¹⁴⁶⁷ “{...}” (ID 404-1705, Personal notes by {...} of 27 September 2016, p. 2; see ID 4032, Teva’s Reply to the Statement of Objections, para. 759).

¹⁴⁶⁸ ID 4032, Teva’s Reply to the Statement of Objections, para 792. See also ID 5695, Teva’s Reply to the Letter of Facts I of 9 February 2024, para. 211.

¹⁴⁶⁹ ID 4032, Teva’s Reply to the Statement of Objections, paras. 795-799.

¹⁴⁷⁰ The statistics are derived from the EPO Board of Appeal decisions database and concern all TBA decisions between 1 January 2017 and 3 April 2019 involving patents that are classified into the IPC codes A61K (Preparations for Medical, Dental or Toilet Purposes) or A61P (Specific Therapeutic Activity of Chemical Compounds or Medicinal Preparations) – which cover the majority of pharmaceutical patent cases. There were 67 TBA decisions falling into this category, 40 (60%) of which involved a TBA taking a decision in circumstances where the OD had maintained the patent as granted or in amended form. In 27 (68%) of these 40 cases, a TBA ultimately revoked the patent (i.e. overturning the OD’s decision to uphold the patent).

¹⁴⁷¹ Teva’s internal correspondence following the revocation of EP ‘528 shows that Teva was aware that a success before the Opposition Division did not imply success in the appellate proceedings: “{...}” (emphasis added) (ID 455-2847, Teva internal correspondence between {...} and {...} of 15 October 2015, p. 1).

¹⁴⁷² ID 4032, Teva’s Reply to the Statement of Objections, para. 769.

patents were directly revoked by the OD (see Section 8.3.3.5)¹⁴⁷³ which benefited from the earlier reasoned revocation TBA decision on EP ‘335.¹⁴⁷⁴

- (1182) As to Teva’s presentation of decisions of national courts, in particular in the UK, with respect to patents in the process family¹⁴⁷⁵, both the High Court of Justice and the Court of Appeal indeed upheld the validity of EP ‘924.¹⁴⁷⁶ However, Teva omits to mention that both of these courts invalidated claim 20 (product claim) of EP ‘924 which, according to Teva was “{...}” and which had to be shielded from invalidation on “{...}” by transferring it from EP ‘703 to EP ‘924 (see Recital (1104) above).¹⁴⁷⁷ In addition, contemporaneous internal documents reveal that Teva did not consider that these UK judgments implied that it would be ultimately successful in its defence of the process patents, or, in other words, that they implied that these patents were strong.¹⁴⁷⁸
- (1183) Second, while indeed the internal notes of Teva’s {...} make references to patents EP ‘749 and EP ‘335, they also include statements summarising an internal presentation {...} (see Recital (1196))¹⁴⁷⁹. In addition, these notes consider, {...} as “{...}”. However this reference to the importance of EP ‘749 contradicts Teva’s explanations from the Reply to the Statement of Objections that already in 2015 EP ‘749 was considered as inappropriate for enforcement and that EP ‘335 was filed in June 2015 (i.e. more than a year before the notes were taken) due to the enforcement gap caused by inappropriateness of EP ‘749.¹⁴⁸⁰ Teva fails to explain how a patent may be considered as “{...}” one year after it was deemed to be so inappropriate for enforcement that it allegedly prompted a hasty filing of another patent to remedy its weakness (see Section 8.3.6.5).
- (1184) Teva’s {...} also noted that negative decisions of the US PTO finding three of Teva’s patents on 40 mg GA as unpatentable might have repercussions on the perceptions of the strength of Teva’s patents in Europe. This shows that even employees outside Teva’s legal teams could perceive the concerns on

¹⁴⁷³ National court judgments on which Teva relies in the context of patents in the dosage family (judgments of the Regional Court and Higher Regional Court of Düsseldorf and of the Danish Maritime and Commercial High Court), were based on the then available decisions of EPO and therefore cannot be considered as independent confirmations of strength of Teva’s dosage patents.

¹⁴⁷⁴ The formal revocation occurred only after the competent court in Germany ordered Teva to abstain from withdrawing approval of the text of EP ‘335 (LG München I, Beschluss v. 24 February 2020 – 7 O 1456/20).

¹⁴⁷⁵ ID 4032, Teva’s Reply to the Statement of Objections, para. 764.

¹⁴⁷⁶ EP ‘528 was revoked by the TBA before the appeal to the Court of Appeal was heard, so the Court of Appeal did not consider the validity of EP ‘528 after it was upheld by the High Court of Justice.

¹⁴⁷⁷ ID 4890-14500, Judgment of the High Court of Justice of 21 May 2015, p. 33; ID 4513-96996, Judgment of the Court of Appeal of 21 March 2017. In contradiction with Teva’s explanations that claim 20 of EP ‘924 was of particular importance for enforcement purposes (since it was a product claim) and that it had to be saved by Teva from invalidation on purely procedural grounds, in a follow up the judgment of the High court of Justice Teva’s {...} {...}: “{...}” (ID 455-2211, Teva internal email dated 21 May 2015 from {...} to {...}, {...}, {...}).

¹⁴⁷⁸ Teva’s internal correspondence from March 2017 reveals that Teva’s {...} considered the judgment of the UK Court of Appeal upholding EP ‘924 as not that valuable: “{...}” (ID 4794-17032, Teva internal correspondence dated 21 March 2017 between {...} and {...}, p. 1). See also ID 4595-2481, Teva internal email dated 9 August 2017 from A {...} to {...}, p. 1.

¹⁴⁷⁹ When referring to the last remaining process patent, the note states “{...}” (emphasis added) (ID 404-1705, Teva internal email dated 27 September 2016 from {...} (to {...}), p. 2.)

¹⁴⁸⁰ See Section 8.3.6.5. The Commission notes that, unlike Teva’s Reply to the Statement of Objections, this contemporaneous document, does not mention the discrepancy between the Copaxone label and the patent claims or the alleged enforcement gap at all when mentioning the Original Dosage Patent and EP ‘335.

interdependence between these decisions and the proclaimed strength of Teva's dosage family. These concerns were subsequently confirmed as the dosage patents were invalidated both in Europe and the US.¹⁴⁸¹ Members of Teva's {...} made the same observations regarding the negative impact of the US decisions on Teva's patents in Europe in January 2017 (see Recital (1221)).

- (1185) Third, Teva's claim that the Commission's analysis relies on a limited number of documents originating predominantly from a single employee is simply not correct. As evidenced in the following Sections 8.3.3.3.1 and 8.3.3.3.2, contemporaneous documents relied on by the Commission include a number of documents such as Teva's strategic and long range Brand Plans, internal communication by Teva's highest ranking officers ({...}, {...}, {...}) as well as notes and communications prepared by other Teva employees (e.g. Teva's {...}).
- (1186) As to the views expressed by Teva's {...}, it suffices to note that the contemporaneous documents reveal that {...} was acting as a {...} within CCP. The evidence show that not only was {...} highly regarded within Teva (with Teva's {...} calling {...} "{...}" after a successful oral hearing in the opposition proceedings concerning EP '528¹⁴⁸²), but also that Teva's strategy and considerations driving it (including the perception of the patents' weakness) enjoyed hierarchical support within Teva.¹⁴⁸³ Finally, as described in detail in Section 8.3.1, it was the strategy so meticulously set out in the notes by Teva's {...} (see Recital (1076)), that was implemented both in the patent invalidity challenges before the EPO, as well as on national level, and both with respect to the process patents and the dosage patents. This shows that, contrary to Teva's contention, the views of Teva's {...} may be considered as an accurate portrayal of Teva's views on this particular topic given {...} involvement on these issues.
- (1187) Fourth, with respect to Teva's explanations on the allegedly conservative nature of its internal estimates, the Commission notes that the documents that Teva refers to do not support the claim that Teva genuinely believed in the strength of its patents.¹⁴⁸⁴ The majority of the documents relied on by Teva show that Teva believed that its patents were more likely than not to be revoked and that even a patent compliant

¹⁴⁸¹ ID 4794-20664, report from {...} dated 12 October 2018 {...} summarizing judgment of the U.S. Court of Appeals for the Federal Circuit and previous decisions on Teva's dosage patents in the US.

¹⁴⁸² ID 455-3411, Teva internal email dated 27 May 2014 from {...} to {...}, p. 1.

¹⁴⁸³ ID 404-1960, Teva internal email correspondence dated 2 February 2015 between {...} and {...}, p. 1. In its answer to question 15 of Article 18(2) Request of 8 January 2021, Teva was asked to provide "*all contemporaneous internal documents, or documents exchanged with {...} or other third parties, discussing the need and the strategic and legal considerations for filing divisional patent applications relating to Copaxone in Europe.*" (emphasis added) In its answer, Teva identified {...} as one of only two custodians relevant for the Commission's request: "*1. Custodians: we have searched for documents contained in the mailboxes of {...} and {...}. Indeed, both were involved in Teva's decisions to file and/or withdraw patents relating to Copaxone at the EU board level and, as such, would in principle have been involved in any documents "discussing the need and the strategic and legal considerations for filing divisional patent applications relating to Copaxone"* (original emphasis). (ID 730, Teva's reply to Article 18(2) Request of 8 January 2021, p. 13).

¹⁴⁸⁴ Teva relies on the documents that include the following references to the chances of success (all documents refer to the Original Dosage Patent only): "{...}" (emphasis added) (ID 413-11, Teva internal email dated 4 March 2015 from {...} to {...} and others, p. 1); "{...}" or "{...}" (emphasis added) (ID 404-849, Teva internal correspondence dated 24/25 November 2015 between {...}, {...} and {...}, pp. 1-2); and "{...}" (emphasis added) (ID 404-1922, Teva internal email dated 16 April 2016 from {...} to {...}; the entire quote, which Teva omits, reads: "{...}" (emphasis added); see also Recital (1134). With respect to the reference to a "strong patent" in the internal notes of Teva's {...} see Recital (1183).

competitor (i.e. a competitor not infringing any other patents except for Teva's ultimately revoked ones) would still be excluded from the market. The number and content of these documents does not in any way put into doubt the Commission's conclusion on Teva being concerned about the weakness of its patents (in particular in more confidential, discrete settings, such as personal notes or WhatsApp correspondence between senior managers).¹⁴⁸⁵

(1188) Therefore, the documents relied on by Teva cannot question the Commission's conclusion, which is based on the preponderance of contemporaneous internal documents as well as the rest of the evidence on the file, presented in Sections 8.3.3.3.1 and 8.3.3.3.2, and showing that Teva was concerned about the weakness of its patents and the resulting risk of their revocation, which lead Teva to strategically withdraw the Original Process Patent and the Original Dosage Patent as well as the first divisional in the process family – EP' 528. As pointedly observed by the Higher Regional Court in Munich concerning the Original Dosage Patent, the decision to withdraw a patent is made for “*tactical reasons*” and as “*an expression of the opinion that there was a not insignificant risk of the parent patent being revoked*”.¹⁴⁸⁶

8.3.3.3.1. Process patents

(1189) Internally, members of Teva's Legal Department, in particular {...}, repeatedly expressed concerns that the process patents were at risk of being revoked, in both opposition and appeal proceedings. These concerns were first discussed concerning the Original Process Patent (i.e. EP '703) and then repeated during the proceedings against its two divisional patents, EP '528 and EP '924.¹⁴⁸⁷

(1190) On the morning of 2 February 2015, shortly before the TBA hearing scheduled for 12 February 2015 regarding EP '703, Teva's {...} wrote to {...} {...}: “{...}” (emphasis added).¹⁴⁸⁸

(1191) On the afternoon of the same day, {...} {...}: “{...}” (emphasis added).¹⁴⁸⁹ {...} “{...}” (emphasis added).¹⁴⁹⁰

(1192) {...}: “{...}” (emphasis added).¹⁴⁹¹ {...}“{...}” (emphasis added).¹⁴⁹²

(1193) Teva withdrew the Original Process Patent by a letter dated 3 February 2015 and it was subsequently revoked by the TBA on procedural grounds on 17 February 2015.

¹⁴⁸⁵ These documents are presented in Sections 8.3.3.3.1 and 8.3.3.3.2.

¹⁴⁸⁶ ID 741-16, OLG München, 4 April 2018, 6 W 164/18, Teva Pharmaceutical Industriel Ltd. vs. Mylan dura GmbH, p. 31. Original: “*Selbst wenn die Antragsgegnerin in die Entscheidung der Partentinhaberin nicht eingebunden gewesen sein sollte, ist deren Entscheidung, eine Entscheidung über die Beschwerde gegen das EP 749 zu verhindern, nach Überzeugung des Senats Ausdruck der Einschätzung, dass ein nicht zu vernachlässigendes Risiko bestand, dass das Stammpatent nicht aufrechterhalten wird*”.

¹⁴⁸⁷ {...} also had reservations concerning the process patents' enforceability against Synthron. When discussing the terms for Teva's proposal for settlement of litigation with Mylan and Sandoz concerning Teva's process patents {...} indicated that these patents are simple to design around: “{...}” (original emphasis) (ID 455-2657, Teva internal correspondence dated 23 May 2014 from {...} and {...}, pp. 1-2). See also ID 404-638, Teva internal email dated 27 May 2014 from {...} to {...} and others and ID 455-404, Teva internal email dated 16 April 2016 from {...} (Teva). Teva also initially did not plan to enforce these patents: “{...}” (ID 404-2207, Teva internal email dated 4 May 2015 from {...} to {...}, p.1.

¹⁴⁸⁸ ID 404-1960, Teva internal email dated 2 February 2015 from {...} to {...} and others, p. 1.

¹⁴⁸⁹ ID 455-651, Teva internal email dated 2 February 2015 from {...} to {...} and others, p. 1.

¹⁴⁹⁰ ID 455-1205, Teva internal email dated 2 February 2015 from {...} to {...} and others, p. 1.

¹⁴⁹¹ ID 404-1877, Teva internal email dated 6 February 2015 from {...} to {...} and others, p. 1.

¹⁴⁹² ID 404-1877, Teva internal email dated 6 February 2015 {...} to {...} and others, p. 1.

Four months later, in June 2015, Teva’s {...} expressed the same concerns about the appeal proceedings against the next process patent, the first divisional EP ‘528: “{...}” (emphasis added).¹⁴⁹³

- (1194) Teva’s chances of success in the appeal against EP ‘528 were initially estimated as “{...}”, but the outlook worsened just before the TBA hearing when “{...}”. Teva’s {...} further explained, on 12 October 2015, that “{...}” concerns relating to EP ‘528 would be “{...}”: “{...}” (emphasis added).¹⁴⁹⁴
- (1195) Internal correspondence suggests that even Teva’s three successes in the intermediate stages of the validity challenges concerning the process patents (when the OD upheld all three process patents in amended form) were unexpected and surprising. In April 2016, after EP ‘924 was upheld in amended form, the {...} wrote that “{...}” (emphasis added).¹⁴⁹⁵
- (1196) Personal notes taken by a Teva marketing manager in September 2016 show that even after this “{...}”, EP ‘924 was, as its predecessors EP ‘703 and EP ‘528, not expected to survive the appeal procedure before the TBA. In particular, the marketing manager wrote in {their} notes: “{...}” (emphasis added).¹⁴⁹⁶
- (1197) A Teva presentation from March 2017, 6 months before the revocation of EP ‘924 by the TBA, listed “{...}” as Contingency Plan to react to “{...}”, but mentioned “{...}” as a “{...}”.¹⁴⁹⁷ This indicates that Teva did not expect it would be able to rely on EP ‘924 to keep the competing 20 mg GA away and to prevent “{...}” as it did not expect it to “{...}” a validity challenge before the TBA. Another presentation from August 2017 summarises Teva’s expectations concerning 20 mg GA, including the lifting of preliminary injunctions after the revocation of EP ‘924 in September by the TBA: “{...}”.¹⁴⁹⁸ This reference also shows that Teva expected EP ‘924 to be revoked by the TBA, which would remove the barrier that was until then preventing market entry of competing 20 mg GA. Similarly, in the context of possible settlement of disputes between Synthon and Teva concerning EP ‘528 and EP ‘924, Teva was internally mentioning June 2018, December 2017 and even June 2017 as possible negotiated entry dates for Synthon GA long before foreseen expiry of Teva’s process patents in 2025.¹⁴⁹⁹
- (1198) Internal emails discussing the revocation of EP ‘924 by the TBA in September 2017 systematically refer to {...} “{...}” and “{...}”.¹⁵⁰⁰ {...} “{...}”.¹⁵⁰¹ {...} “{...}”.¹⁵⁰² These exchanges show that Teva was very well aware of how {...} it was that its process patents would be upheld by the TBA.

¹⁴⁹³ ID 266-231, Teva internal email dated 14 June 2015 from {...} to {...} and others, p. 1.

¹⁴⁹⁴ ID 455-1795, Teva internal email dated 12 October 2015 from {...} to {...}, {...}, {...} and others, p. 1.

¹⁴⁹⁵ ID 404-935, Teva internal email dated 16 April 2016 from {...} to {...} (Teva) and others, p. 1.

¹⁴⁹⁶ ID 404-1705, Teva internal email dated 27 September 2016 from {...} {...}, p. 2.

¹⁴⁹⁷ ID 263-442, Strategic Brand Plan Template COPAXONE, 24 March 2017, p. 70.

¹⁴⁹⁸ ID 404-1961, COPAXONE & FoGA. 29th August 2017, Berlin, p. 8.

¹⁴⁹⁹ ID 266-113, Teva internal correspondence dated 26 and 27 October 2015 between {...} and {...}, pp. 2, 3.

¹⁵⁰⁰ ID 455-1944, Teva internal email dated 12 September 2017 from {...} to {...}; ID 455-1515, Teva internal email dated 12 September 2017 from {...} to {...} and others; ID 404-2463, Teva internal email dated 12 September 2017 from {...} to {...} and others; ID 404-134, Teva internal email dated 12 September 2017 from {...} to the distribution list Market Access Leadership Team Contacts and others; ID 455-3323, Teva internal email dated 13 September 2017 from {...} to {...} and others.

¹⁵⁰¹ ID 455-2958, Teva internal email dated 12 September 2017 from {...} to {...}, p. 1.

¹⁵⁰² ID 455-1998, Teva internal email exchange dated 6 September 2017 between {...} and {...}, p. 2.

- (1199) The Commission also notes that the same concerns were recurring in emails relating to invalidity actions at national level. The weakness of Teva’s process patents made {...} consider their withdrawal in the Netherlands.¹⁵⁰³ In this context, in an email dated 25 March 2015, the {...} informed senior management about the status of invalidity actions concerning the divisional patents EP ‘528 and EP ‘924 in the Netherlands:
- “{...}” (emphasis added).¹⁵⁰⁴
- (1200) Teva was very well aware of the weaknesses of its process patents and knew that the only way to prolong its exclusivity rights for Copaxone was to stagger the filings and engage in strategic withdrawals of its process patents before the EPO.
- (1201) Teva argues that the Original Process Patent was withdrawn because EP ‘528 and EP ‘924 were better suited for enforcement. According to Teva, the Original Process Patent never served as a basis for any preliminary injunction and therefore in February 2015 it was not needed for Teva’s enforcement strategy. In addition, Teva maintains that the fact that EP ‘528 was withdrawn only after a two-day hearing and only after the TBA recorded its decision to revoke the patent in the minutes shows not only that Teva believed in the validity of EP ‘528 but also that it did not engage in any anticompetitive strategy.¹⁵⁰⁵
- (1202) Teva’s arguments are not convincing. First, Teva does not address any of the internal contemporaneous documents referred to in this Section 8.3.3.3.1 which show that the reason for the withdrawal of the Original Process Patent was Teva’s belief that the patent would be invalidated, and that this invalidation would compromise both the validity and the enforcement of the remaining divisional process patents.¹⁵⁰⁶ Moreover, divisional patents arguably better suited for enforcement existed already in 2013 (the second divisional, EP ‘924, was issued on 11 December 2013) and still Teva waited for more than a year to withdraw the Original Process Patent, which according to its explanations in the Reply to the Statement of Objections would not serve any purpose once the divisionals were granted (as these were better suited for enforcement).
- (1203) Second, the fact that Teva never sought to enforce the Original Process Patent is irrelevant as there was no competing product to enforce it against. The patent nevertheless represented a potential enforcement asset and was capable of contributing to the exclusionary effects by allowing Teva to artificially prolong uncertainty.¹⁵⁰⁷
- (1204) Third, as to the allegedly late withdrawal of EP ‘528, the fact that EP ‘528 was withdrawn only after the hearing does not change the Commission’s conclusions. By withdrawing EP ‘528, even at this late stage, Teva still avoided a negative formal precedent which could have impacted the decision on the validity of EP ‘924 and

¹⁵⁰³ See ID 404-1798, Teva internal correspondence dated 3 February 2015 between {...} and {...}, p. 1: “{...}”.

¹⁵⁰⁴ ID 455-3152, Teva internal email dated 25 March 2015 from {...} to {...} and others, p. 2.

¹⁵⁰⁵ ID 4032, Teva’s Reply to the Statement of Objections, paras. 804-809 and 811-815.

¹⁵⁰⁶ For example: “{...}” (ID 455-651, Teva internal email dated 2 February 2015 from {...} to {...} and others, p.1); “{...}” (ID 455-3310, Teva internal email dated 15 October 2015 from {...} to {...} and others, p. 1); “{...}” (ID 404-2085, Teva internal email dated 2 December 2015 from {...} to {...} and others, p. 1).

¹⁵⁰⁷ On direct effects of Teva’s comprehensive patenting conduct see Section 8.4.1.

possibly hindered Teva's ability to obtain preliminary injunctions.¹⁵⁰⁸ Moreover, according to Teva, the main part of EP '924 was its product claim (claim 20). This product claim was shielded by an early withdrawal of EP '703 and was not included in EP '528 (see Section 8.3.2.1.1). Therefore, the hearing minutes regarding EP '528 had no formal or even persuasive effect on the assessment of this part of EP '924. However, in terms of timing, the later a decision was reached on the parent patent (EP '528), the later the substantive analysis of a divisional would start.

- (1205) The late withdrawal of EP '528 clearly shows that the patent was withdrawn not for enforcement or other possibly legitimate reasons, but solely to avoid a formal revocation decision by the TBA and that Teva waited for this withdrawal until the last possible moment thus further delaying the assessment of the following divisional application, i.e. EP '924. The fact that Teva's withdrawal only occurred after the TBA recorded the minutes of the hearing does not change that analysis since there is a stark difference between recorded minutes of a TBA hearing and a formal reasoned opinion on invalidity by a TBA, which Teva managed to avoid.¹⁵⁰⁹

8.3.3.3.2. Dosage patents

- (1206) Teva's employees were also concerned about the weakness and the resulting risk of revocation of its dosage patents. Already in July 2014, only 14 months after the Original Dosage Patent had been granted, an internal presentation stated that Teva expected exclusivity for its 40 mg dosage only until January 2020 (rather than until its regular expiry in 2030): "{...}"¹⁵¹⁰ Similarly, in the context of a possible settlement of disputes between Synthon and Teva, Teva was discussing entry dates for Synthon GA long before the expiry of the relevant dosage patents: "{...}"¹⁵¹¹
- (1207) In June 2016, Teva's {...} replied to a question about the chances of successfully defending the parent patent EP '749 in front of the TBA in light of "{...}" with: "{...}"¹⁵¹² These low chances of success on the appeal were driving Teva's strategic choice to "{...}" EP '749,¹⁵¹³ a strategic choice which Teva put in motion as attested by Teva's {...} in January 2017. At that time, Teva's {...} informed {their} colleagues, including Teva's then {...}, that Teva's plan was "{...}"¹⁵¹⁴
- (1208) In March 2017, a Teva employee made the following notes concerning the EPO proceedings regarding EP '749 (the email is entitled "Cop 40 CCP – deep dive"),

¹⁵⁰⁸ At that moment, there was only one divisional left in the process family – EP '924). EP '924 was also expected to be invalidated (see Recitals (1195)-(1197)).

¹⁵⁰⁹ For example, the minutes do not reflect full arguments of the parties. Most arguments are apparent from the previous written submission or from the written decision which is not drafted in case of withdrawal (T 0642/97 of 15 February 2001, EP:BA:2001:T064297.20010215, T 2370/16 of 14 June 2019, EP:BA:2019:T237016.20190614). The stark difference between the content of the minutes and the content of the reasoned opinion is apparent from simple comparison of documents related to the appellate proceedings on EP '962 and EP '172 (ID 5731, EP2630962 – Minutes of the hearing before the Technical Board of Appeals 3.3.04, 6-7 February 2024; ID 5729, EP3199172 – Minutes of the hearing before the Technical Board of Appeals 3.3.04, 6-7 February 2024; ID 5823, EP2630962 – Decision of the Technical Board of Appeal 3.3.04, 7 February 2024; ID 5825, EP3199172 – Decision of the Technical Board of Appeal 3.3.04, 7 February 2024).

¹⁵¹⁰ ID 834-32, Teva LRP 2015-2019 Overview, Board Meeting, July 2014, p. 8.

¹⁵¹¹ ID 266-113, Teva internal correspondence dated 26 and 27 October 2015 between {...} and {...}, pp. 2, 3.

¹⁵¹² ID 455-3063, Teva internal email dated 29 June 2016 from {...} to {...}, p. 1.

¹⁵¹³ ID 404-1841, Teva internal email dated 4 January 2017 from {...} to {...}, p. 1.

¹⁵¹⁴ ID 404-1699, Teva internal email dated 26 January 2017 from {...} to {...} and others, p. 1.

which clearly shows that internally, EP ‘749 was perceived not to meet the requirements of patentability: “{...}”.¹⁵¹⁵

(1209) Numerous strategy documents were based on the assumption that the patents would be revoked: “{...}”.¹⁵¹⁶ Estimations based on the timing of various invalidity procedures show that in 2014 and 2015, Teva expected around five years of additional product exclusivity for 40 mg Copaxone : “{...}”,¹⁵¹⁷ “{...}”.¹⁵¹⁸ These estimations are not aligned with the natural expiry date of the dosage patent family, which would occur only in 2030. As summarized by Teva’s {...} on the topic of loss of exclusivity for Copaxone: “{...}” (emphasis added).¹⁵¹⁹

(1210) A presentation from March 2017, listed “{...}” as Contingency Plan to react to “{...}”, but mentioned “{...}” as a “{...}”.¹⁵²⁰ In other words, the lack of strength of the patents constituted a barrier to implement Teva’s Contingency Plan to use its dosage patents in order to prevent the entry of generic-like 40 mg GA products. This confirms that Teva considered EP ‘335 (as well as EP ‘924) as likely to be revoked, i.e. as not being able to prevent the entry on the market.

(1211) Even though some Teva employees initially argued that EP ‘335, a divisional application of the dosage patent family, “{...}”¹⁵²¹ than the Original Dosage Patent (EP ‘749), this belief seems to have faded over time. A WhatsApp conversation between two senior managers, dated 28 March 2019, shows that the OD’s decision to uphold EP ‘335 was so unexpected and “{...}” that no plans had been made for such an eventuality:

{...}.¹⁵²²

(1212) In a subsequent exchange concerning the appeal proceedings involving EP ‘335, dated 24 April 2019, the two managers agreed that the patent was not likely to be upheld on appeal (i.e. by the TBA) and would not be in force beyond 2020:

{...}.¹⁵²³

(1213) It follows from the above evidence that Teva was very well aware of the weaknesses of its dosage patents and expected them to be revoked by the TBA.

8.3.3.4. Teva was aware that a patent ruling would create a precedent for the remainder of the patent family and negatively influence the grant of preliminary injunctions

(1214) Internal documents show that Teva was not only concerned that its patents would be revoked by the TBA, but also that a decision revoking one patent would have a damaging precedent effect on subsequent EPO proceedings concerning the validity of the remaining divisionals of the same patent family and also on their enforcement prospects.

¹⁵¹⁵ ID 404-727, Teva internal email dated 19 April 2017 from {...} to {...}, p. 1.

¹⁵¹⁶ ID 455-1102, NOTES FAST MEETING 26-01-2016 Amsterdam, 26 January 2016.

¹⁵¹⁷ ID 455-70, Strategic Brand Plan Europe, 2015-2019, March 2014, p. 11; ID 263-1199, COPAXONE Brand Plan 2015-2019, March 2014, p. 39. See also ID 455-562, Copaxone Local Brand Plan Germany 2015-2017, April 2014, p. 70: “{...}”.

¹⁵¹⁸ “{...}” – ID 455-428, Teva internal email dated 4 March 2015 from {...} to {...}, p. 1.

¹⁵¹⁹ ID 4595-2257, Teva internal email dated 27 July 2017 from {...} to {...}, {...} and others, p. 1.

¹⁵²⁰ ID 263-442, Strategic Brand Plan Template COPAXONE, 24 March 2017, p. 70.

¹⁵²¹ ID 404-1841, Teva internal email dated 4 January 2017 from {...} to {...}, p. 1; ID 404-1699, Teva internal email dated 26 January 2017 from {...} to {...} and others.

¹⁵²² ID 263-799, Teva internal WhatsApp conversation dated 28 March 2019 between {...} and {...}.

¹⁵²³ ID 263-799, Teva internal WhatsApp conversation dated 24 April 2019 between {...} and {...}.

- (1215) Regarding the damaging precedent effect in relation to the processing patents, in an email discussing the OD’s decision to uphold EP ‘528 in May 2014, Teva’s {...} expected a revocation decision to create the perception of weakness of the remaining divisionals: “{...}”¹⁵²⁴
- (1216) In December 2015, Teva’s {...} expressed concerns about the prospect of the OD upholding EP ‘924: “{...}” (emphasis added).¹⁵²⁵ Even though the TBA did not revoke EP ‘528 by a reasoned decision because Teva withdrew its approval of the text during the hearing and therefore prevented an elaborate discussion on the validity of particular claims (including e.g. on the immediate prior art) as well as the formal precedent effects of a substantive TBA decision.¹⁵²⁶ This shows that the {...} was concerned that even arguments raised before and during the hearing would negatively influence the prospects of upholding EP ‘924 in the future.
- (1217) Also in the dosage family, Teva was aware of the impact of validity decisions regarding one patent of a family on the other patents within the same family. An internal document, dated 3 February 2017, entitled “{...}”, states that “{...}” (emphasis added).¹⁵²⁷
- (1218) Teva applied the same logic, although in the inverse sense, to the impact that the expected loss of EP’335 would have on the remaining divisionals in the dosage family. In September 2019, one year before the revocation of EP ‘335, Teva’s {...} issued a warning that the: “{...}” (emphasis added).¹⁵²⁸
- (1219) Similarly, Teva was aware that a reasoned decision invalidating a patent might have a negative impact on the likelihood of obtaining preliminary injunctions in national courts based on other patents belonging to the same patent family.
- (1220) As regards Teva’s process patents, Teva was concerned that a reasoned revocation of EP ‘703 by the EPO “{...}” and “{...}”.¹⁵²⁹ In the same correspondence, Teva’s {...} reiterated that “{...}” (emphasis added).¹⁵³⁰ In response to a question by {...} colleagues on the potential effects of a TBA revocation decision of EP ‘703 on the future enforcement of EP ‘528 and EP’ 924, the {...} responded that “{...}”.¹⁵³¹
- (1221) As regards its dosage patents, internal correspondence within Teva’s legal department from January/February 2017 shows that Teva feared that even a decision of the US courts concerning the invalidity of Teva’s patents may have an effect on the EPO’s decision-making: “{...}”.¹⁵³² Such a belief within Teva’s legal department is a natural consequence of the fact that Teva’s different patents all hinged on the same essential elements and that the validity of these elements was always discussed with reference to the same set of facts regardless of whether the discussion took

¹⁵²⁴ ID 404-547, Teva internal email dated 27 May 2014 from {...} to {...} and others, p. 1.

¹⁵²⁵ ID 455-3368, Teva internal email dated 11 February 2015 from {...} to {...} and others, p. 1. See also ID 455-2847, Teva internal email dated 12 October 2015 from {...} to {...}, {...}, {...} and others, p. 2: “{...}”.

¹⁵²⁶ For analysis of precedent effects of TBA decision see Section 8.3.3.1 and Section 8.3.3.5.

¹⁵²⁷ ID 455-3304, Communications Packet regarding Copaxone Patent 335 EU February 2017, 2 February 2017.

¹⁵²⁸ ID 455-1627, Teva internal email dated 27 September 2019 from {...} to {...} and others, p. 1.

¹⁵²⁹ ID 404-1647, Teva internal email dated 2 February 2015 from {...} to {...} and others, pp. 22 ff.

¹⁵³⁰ ID 404-1647, Teva internal email dated 2 February 2015 from {...} to {...}. See also, ID 404-1798, Teva internal correspondence dated 3 February 2015 between {...} and {...}, p. 23.

¹⁵³¹ ID 404-1647, Teva internal email dated 2 February 2015 from {...} to {...} and others.

¹⁵³² ID 4513-95180, Teva internal correspondence dated 31 January – 1 February 2017 between {...}, {...} and {...}, p. 1.

place before the EPO, national courts of the Member states or the competent authorities in the US.

8.3.3.5. The EPO and national courts confirmed the precedent effect of TBA's decisions specifically for Teva's dosage patents

(1222) In February 2021, following the revocation of EP '335 by reasoned decision of the TBA on 10 September 2020, the OD stated in its preliminary opinion concerning the validity of EP '962 and EP '172, that "*there is no doubt about the applicability of the principles of res iudicata pursuant to Article 111(2) EPC*"¹⁵³³ in relation to EP '335.

(1223) As regards both EP '962 and EP'172, the OD held that the principle of *res iudicata* was applicable and stated that the main difference between EP '335 and the later divisionals was EP '335's additional feature of a pH range of 5,5 to 7.0, which "*has not been evoked as being particular pertinent for the question of the inventive step by none of the parties*".¹⁵³⁴ With regard to EP '172, the OD explicitly held that "[t]he subject-matter of claim 1 is selection of an arbitrary dosage regimen for treating an arbitrary group of MS patients."¹⁵³⁵ The OD accordingly revoked EP '962 and EP '172 on 6 and 7 December 2021 for lack of an inventive step (EP '335 was also revoked for lack of an inventive step).¹⁵³⁶ These decisions confirm that the differences between EP '962, EP '172 and EP '335 were of no material relevance for the outcome of the legal review of their validity. Teva's appeals against the ODs' decisions were dismissed by the TBA.¹⁵³⁷

(1224) A similar conclusion was reached by an Italian court which annulled a national counterpart of EP '962 by expressly referring to the TBA's decision on EP '335. The court, based on the court appointed expert's opinion, concluded that the only difference between the relevant claims of EP '335 and EP '962 was a difference in

¹⁵³³ ID 3786, EP2630962 – Preliminary opinion of the Opposition Division, 17 February 2021, p. 4; ID 2183, EP3199172 – Preliminary opinion of the Opposition Division, 17 February 2021.

¹⁵³⁴ ID 5694, EP3199172 – Decision of the Opposition Division, 27 January 2022, paragraph 15; ID 5693, EP2630962 – Decision of the Opposition Division, 4 February 2022, paragraph 15.

¹⁵³⁵ ID 5694, EP3199172 – Decision of the Opposition Division, 27 January 2022, paragraph 36.

¹⁵³⁶ ID 5694, EP3199172 – Decision of the Opposition Division, 27 January 2022, paragraph 36; ID 5693, EP2630962 – Decision of the Opposition Division, 4 February 2022, paragraph 43.

¹⁵³⁷ ID 5731, EP2630962 – Minutes of the hearing before the Technical Board of Appeals 3.3.04, 6-7 February 2024; ID 5729, EP3199172 – Minutes of the hearing before the Technical Board of Appeals 3.3.04, 6-7 February 2024. Teva notes that during the Oral Hearing concerning EP '962, "[...] TBA explicitly excluded from the debates the question of whether the *res iudicata* principle would apply [...]" and follows to conclude that the "*TBA expressly excluded the application of res iudicata to those 'other 2030 dosing patents'*" (ID 5695, Teva's Reply to the Letter of Facts I of 9 February 2024, paras. 292-295). However, both Teva's representation of TBA's minutes and the conclusion it draws from them are inaccurate. TBA minutes on EP '962 simply indicate that "*The Chairwomen invited the parties to present their arguments leaving aside the question whether the principle of res iudicata in view of decision [invalidating EP '335] applied.*" (ID 5731, EP2630962 – Minutes of the hearing before the Technical Board of Appeals 3.3.04, 6-7 February 2024, p. 2). This single sentence can hardly be interpreted, as Teva suggests, as TBA confirming that *res iudicata* principle is not applicable. In addition, Teva omits to mention that this procedural guidance focusing discussions at the oral hearing came at the moment when the EP '962 as granted was already invalidated for added matter. Furthermore, TBA minutes on other dosage patent discussed the same day (EP '172), do not include such procedural limitation. Finally, despite Teva's efforts the facts remain clear: TBA simply dismissed all Teva's appeals and thus confirmed OD's decisions revoking EP '962 and EP '172 in their entirety, including on applicability of the *res iudicata* principle.

pH range and that EP ‘962 suffered from the same weakness as EP ‘335, i.e. lack of an inventive step.¹⁵³⁸

- (1225) Interestingly, a UK court also made an explicit connection between the fate of EP ‘962 and EP ‘172 and the fate of EP ‘335, which it found to be invalid, by stating that “*If this judgment stands, but 962A and/or 172A proceed to grant, then any claim for infringement by the Defendants against the Claimant in respect of the 40 mg TIW regimen can be met by an application for summary judgment seeking revocation of the patent(s) relying upon issue estoppels arising out of this judgment*”.¹⁵³⁹ In other words, if the validity of EP ‘962 and EP ‘172 were to be challenged in front of a UK court in the future, they would likely be found invalid in a summary procedure on the same grounds as was the case for EP ‘335.¹⁵⁴⁰
- (1226) Teva nevertheless argues that the principle of *res judicata* would not have applied – or only to a limited extent – in the case at hand. According to Teva, this is demonstrated by the OD’s decisions on EP ‘962 and EP ‘172 where the OD did a full-blown independent analysis and thus purportedly confirmed that both of these patents had different claims from EP ‘335.¹⁵⁴¹
- (1227) Teva’s arguments do not convince. The OD expressly confirmed the application of the *res judicata* principle specifically with respect to Teva’s divisionals EP ‘962 and EP ‘172.¹⁵⁴² Even more, in addition to its introductory conclusion on general applicability of the *res judicata* principle, the OD referred to the opinions and conclusions adopted by the TBA when discussing individual arguments in relation to EP ‘335.¹⁵⁴³ For example, when discussing sufficiency of disclosure with respect to

¹⁵³⁸ ID 5730, Judgment of 8 February 2021, Tribunale Ordinario di Milano, no. 14639/2017, p. 4. Teva argues that the assessment of the Tribunale Ordinario di Milano was limited solely to the claim 1 of the EP ‘962 and did not examine claim 2 of this patent which related to the brain atrophy (ID 5909, Teva’s Reply to the Letter of Facts II of 17 May 2024, paras. 128-129) and that therefore cannot serve to establish any relevant conclusion on *res judicata* effect. Teva’s claim should be rejected. First, Teva omits to mention that the Italian court did not revoke only claim 1 of EP ‘962, but the patent in its entirety, without even specifically discussing its dependant claim 2 related to brain atrophy. Simply, once the independent claim 1 fell, the dependant claim 2 fell with it. This once again demonstrates that patentability of Teva’s patents hinged on their essential shared features and not on their distinguishing elements (see Section 8.3.2.1). Second, which is undisputed by Teva, revocation of EP ‘962 by the Italian court, was made with express reference to the TBA’s decision on EP ‘335.

¹⁵³⁹ ID 606, Synthon’s Reply to Article 18(2) Request of 9 July 2020, Annex 9.

¹⁵⁴⁰ Contrary to Teva’s assertion (ID 5909, Teva’s Reply to the Letter of Facts II of 17 May 2024, para. 127), a reference to the judgment of a UK court is not made to extend the scope of investigation to the UK but solely to illustrate that different competent authorities assessing Teva’s patents concluded that they all shared same weaknesses and that the assessment of an earlier patent in a family may provide persuasive guidance and shorten timeline for review of the remaining patents in the same family.

¹⁵⁴¹ ID 4032, Teva’s Reply to the Statement of Objections, paras. 856-860. Teva also argues that judgments of the national courts are irrelevant to assess the EPO’s views concerning the precedent effects of TBA decisions and that they “*can only serve to determine whether the Withdrawals were likely to impact Teva’s ability to obtain PIs*” (ID 5909, Teva’s Reply to the Letter of Facts II of 17 May 2024, paras. 120-125). However, contrary to Teva’s assertion, the Commission does not refer to the relevant judgments of the national courts to establish EPO’s views on precedent effect of TBA’s decisions. These judgments serve to show that TBA revocation decision on EP ‘335 was indeed taken as relevant for assessment of EP ‘962 and EP ‘172 even before national courts and that any competent authority assessing Teva’s dosage patents (be it the OD or national courts) came to the same conclusion: their validity ultimately depended on their essential shared features (see Section 8.3.2.1).

¹⁵⁴² ID 5694, EP3199172 – Decision of the Opposition Division, 27 January 2022, paragraphs 13-15; ID 5693, EP2630962 – Decision of the Opposition Division, 4 February 2022, 4 February 2022, paragraphs 13-15.

¹⁵⁴³ See for example, ID 5694, EP3199172 – Decision of the Opposition Division, 27 January 2022, paragraph 18: “*The Opposition Division follows the argumentation of the Board of appeal that the term*

one of the amended claims in EP ‘962, the OD expressly acknowledged that it followed argumentation adopted by the TBA in the preliminary opinion concerning EP ‘335.¹⁵⁴⁴ The OD also expressly referred back to the earlier TBA decision on EP ‘335 even when invalidating the allegedly differentiating claim of EP ‘962 (i.e. a claim covering the reduction of brain atrophy) for lack of an inventive step.¹⁵⁴⁵

(1228) Following the revocation of EP ‘335 by the TBA, the OD directly invalidated Teva’s other dosage divisionals, EP ‘962 and EP ‘172. This is telling considering the fact that the OD is generally very lenient towards patent holders in its assessment of the challenged patents.¹⁵⁴⁶

8.3.3.6. Teva strategically withdrew its patents before the adoption of a reasoned decision by the TBA, thus avoiding a “damaging” precedent for its remaining divisional patents

(1229) Teva deliberately delayed the legal review process regarding the validity of its patents repeatedly. This section lays out how Teva actively sought to prevent a damaging precedent by strategically withdrawing, sometimes at the very last minute, the approval of the text of some of its patents.¹⁵⁴⁷ Internal documents show that Teva deliberately planned to do this, for example by instructing the agent at the hearing to “{...}”.¹⁵⁴⁸ The current Section presents chronologically Teva’s strategic patent withdrawals as well as the context surrounding these withdrawals and shows how they contributed to delaying the adoption of a reasoned decision on the validity of both patent families.

8.3.3.6.1. Teva’s withdrawal of the process patents

(1230) Following the negative preliminary opinion of the TBA of 8 October 2014 concerning the validity of the Original Process Patent EP ‘703¹⁵⁴⁹ Teva withdrew the approval of the text of that patent on 3 February 2015, prior to the TBA hearing scheduled for 12 February 2015. Thus, a reasoned decision in the legal review process on validity could not be issued and the TBA consequently revoked EP ‘703 “without going into the substantive issues” in a decision dated 10 February 2015.¹⁵⁵⁰

(1231) After the withdrawal and the ensuing revocation of EP ‘703, Teva defended its first divisional process patent, EP ‘528, until the TBA’s hearing on 14 October 2015, during which it withdrew the approval of the text of the patent. Teva’s decision to

‘treating’ can be understood to mean “alleviating a symptom of relapsing-remitting multiple sclerosis [...]” or ID 5693, EP2630962 – Decision of the Opposition Division, 4 February 2022, paragraph 27: “The OD follows the argumentation of the board of appeal set forth in the preliminary opinion (D80) in the case of EP2949335. The sufficiency of disclosure is to be assessed [...]”.

¹⁵⁴⁴ ID 5693, EP2630962 – Decision of the Opposition Division, 4 February 2022, paragraph 31.

¹⁵⁴⁵ ID 5693, EP2630962 – Decision of the Opposition Division, 4 February 2022, paragraphs 42-43.

¹⁵⁴⁶ TBA dismissed Teva’s appeals and confirmed OD’s decisions thus finally revoking EP ‘962 and EP ‘172 on 7 February 2024 (ID 5731, EP2630962 – Minutes of the hearing before the Technical Board of Appeals 3.3.04, 6-7 February 2024; ID 5729, EP3199172 – Minutes of the hearing before the Technical Board of Appeals 3.3.04, 6-7 February 2024).

¹⁵⁴⁷ Teva did not need to withdraw each and every divisional patent to achieve the desired result. In the process family, Teva did not withdraw the last divisional (EP ‘924) because there was no subsequent divisional to be protected from the damaging effect of the revocation decision. Similarly, after revocation of EP ‘335 (which was a result of an order by the Regional Court of Munich prohibiting Teva’s withdrawal) Teva did not withdraw subsequent divisionals EP ‘962 and EP ‘172. These are also the last divisionals in the dosage family protecting Copaxone in the Relevant Member States.

¹⁵⁴⁸ ID 404-2085, Teva internal email dated 2 December 2015 from {...} to {...}, p. 1.

¹⁵⁴⁹ ID 2171, EP1799703 – Preliminary opinion of the Technical Board of Appeal 3.3.04, 8 October 2014. See Recital (1162).

¹⁵⁵⁰ ID 2181, EP1799703 – Decision of the Technical Board of Appeal 3.3.04, 10 February 2015, p. 5.

withdraw EP ‘528 came only after the TBA had already indicated during the hearing that “*claims 11 and 12 of the main request lack novelty, claim 1 of Teva’s auxiliary request 2A lacks novelty and claim of Teva’s auxiliary request 3A lacks an inventive step*”.¹⁵⁵¹

- (1232) However, before the TBA could issue a reasoned revocation decision, Teva withdrew the patent, with Teva reporting internally as follows: “{...}” (emphasis added).¹⁵⁵² As a result, once again, instead of letting the review process run its course via a reasoned decision on the merits, Teva ensured that the TBA revoked the patent on purely procedural grounds, making it unlikely that such a revocation on formal grounds would affect Teva’s preliminary injunction in Czechia.¹⁵⁵³
- (1233) Teva also defended the second divisional process patent, EP ‘924, until a TBA hearing on 12 September 2017, in which the TBA was finally able to pronounce a reasoned decision for this patent. Teva had no strategic reason for a withdrawal of EP ‘924 since it was the last remaining patent in the process family, with no other patent left that needed to be protected. A reasoned revocation decision would therefore have no damaging precedent effect on any remaining patents. Thus, Teva did not withdraw the approval of the patent’s text and at the end of the hearing, the TBA revoked EP ‘924. This shows that the earlier withdrawals were not justified by any procedural efficiencies.

8.3.3.6.2. The withdrawal of the Original Dosage Patent and the revocation of EP ‘335

- (1234) The same pattern can be observed regarding the dosage patents. In December 2015, before the decision of the OD, Teva’s {...} had explained to {...} superiors that {...} could avoid a reasoned decision by “surrendering” the Original Dosage Patent EP ‘749, i.e. by withdrawing the approval of the text of the patent: “{...}” (emphasis added).¹⁵⁵⁴ However, the OD upheld the patent during the hearing on 7 December 2015 and there was therefore no need for Teva to surrender EP ‘749 at that stage.
- (1235) The OD’s decision was appealed and on 5 December 2016, the TBA informed the parties that the oral hearing would take place on 14 and 15 November 2017. The TBA’s preliminary opinion would be communicated closer to that date.¹⁵⁵⁵ On 13 December 2016, Synthron informed the TBA of the grant of EP ‘335 “*which may delay the achievement of legal certainty*” and therefore requested an earlier date for the oral hearing for the parent patent EP ‘749 and the issuance of a preliminary

¹⁵⁵¹ ID 5781, EP2177528 – Minutes of the hearing before the Technical Board of Appeal 3.3.04, 13-14 October 2015, p. 11.

¹⁵⁵² ID 455-3310, Teva internal email dated 15 October 2015 from {...} to {...}, p. 1. It should be noted that Teva did not request the revocation of the patent, in which case the TBA would have revoked it by reasoned decision but withdrew the approval of its text to prevent the adoption of a reasoned decision.

¹⁵⁵³ According to Teva, there is objectively no reason why a reasoned decision of the TBA on EP ‘528 would have had a more significant impact on the EP ‘924 proceedings than the TBA’s minutes containing (i) the outcome and (ii) the grounds for its decision (ID 4032, Teva’s Reply to the Statement of Objections, paras. 868-869). However, this Teva’s explanation contradicts the facts of the case where Teva indeed withdraw the patent as late as possible but still in time to prevent a revocation on substantive grounds. It also contradicts the Commission’s findings on *res judicata* (see Section 8.3.3.4) as it is obvious that (i) *res judicata* effect is connected with decisions only (and not with other steps in the proceedings such as TBA’s minutes) and that (ii) a TBA decision made on purely procedural grounds (revocation because of withdrawal of the text of the patent) cannot have the same effect as a decision reached on substantive grounds.

¹⁵⁵⁴ ID 404-2085, Teva internal email dated 2 December 2015 from {...} to {...} and others, p. 1.

¹⁵⁵⁵ ID 2185, EP2405749 - F3305 Communication of the Board of Appeal (ex parte/inter partes), 5 December 2016.

opinion as soon as possible.¹⁵⁵⁶ On 19 December 2016, Mylan made a similar submission, informing the TBA that it had requested the Examining Division to revoke its decision to grant and stay the examination of EP ‘335 until the appeal proceedings concerning EP ‘749 were concluded.¹⁵⁵⁷ Furthermore, Synthon requested the TBA to issue its preliminary opinion and to exercise its discretion to prevent the grant of EP ‘335 as “[g]iven the historical procedural abuse of the patentee, granting of our request potentially avoids unnecessary opposition and appeal proceedings. Given the patentably indistinct nature of the divisional application, it seems certain that the divisional application will have the same fate as the present patent”.¹⁵⁵⁸

- (1236) Thereafter, Teva decided, in the words of its {...}, to “{...}”¹⁵⁵⁹ and withdrew the approval of the text of EP ‘749 on 2 February 2017. As a result, the TBA did not issue a preliminary opinion and revoked the patent on procedural grounds on 8 February 2017 (rather than by reasoned decision during the hearing scheduled for 14 November 2017).
- (1237) Following Teva’s withdrawal of EP ‘749, the market intelligence company {...} issued an email bulletin entitled {...}.¹⁵⁶⁰ The bulletin shortly described the legal challenges to EP ‘749 and indicated that in January 2017, the EPO granted EP ‘335 {...}. The bulletin reported that {...}.
- (1238) The bulletin concluded that {...} (emphasis added).¹⁵⁶¹
- (1239) The {...} bulletin thus illustrates the effects sought (and achieved) by Teva. Instead of obtaining a final decision on the merits of the dosage patent family through conclusion of the legal review of EP ‘749, Synthon needed to restart lengthy proceedings concerning the next generation patent in the divisional family, EP ‘335. As the title shows, {...}, as an outside observer, considered that by withdrawing EP ‘749 and avoiding a decision by the TBA, Teva sought to delay the resolution of the validity challenge of that patent, as well as of the related divisionals. Teva’s internal reactions to this analysis show that Teva staff did not contest this interpretation of its conduct. {...} commented to the {...}: “{...}” and the latter responded “{...}”.¹⁵⁶²
- (1240) Teva’s intention to avoid reasoned decisions on the validity of its patents and thereby prolong legal uncertainty is further illustrated by Teva’s litigation strategy in the Netherlands. Prior to the withdrawal of EP ‘749 at the EPO level, Teva had already withdrawn the Dutch designation of EP ‘749. On 30 September 2016, Synthon requested the revocation of the Dutch version of EP ‘749 as well as a declaratory judgment, stating that the 40 mg dosing regimen was lacking an inventive step. Such a declaratory judgment would have held not only EP ‘749 invalid, but also any other possible future patents claiming the 40 mg dosing regimen.¹⁵⁶³ Pending these

¹⁵⁵⁶ ID 2172, EP2405749 - Letter dealing with oral proceedings during the appeal procedure, 13 December 2016.

¹⁵⁵⁷ ID 2166, EP2405749 - Letter dealing with oral proceedings during the appeal procedure, 19 December 2016.

¹⁵⁵⁸ ID 2172, EP2405749 - Letter dealing with oral proceedings during the appeal procedure, 13 December 2016.

¹⁵⁵⁹ ID 404-1841, Teva internal email dated 4 January 2017 from {...} to {...}, p. 1.

¹⁵⁶⁰ ID 266-272, email dated 3 February 2017 from {...} to its subscribers.

¹⁵⁶¹ ID 266-272, email dated 3 February 2017 from {...} to its subscribers, pp. 1-3.

¹⁵⁶² ID 266-272, Teva internal emails dated 3 February 2017 between {...} and {...}, p. 1. {...}

¹⁵⁶³ Such declaratory judgments are known as Arrow Declarations. They declare that a particular product, process or feature, was obvious or anticipated at the relevant date. As a result, if a patent holder claims a

revocation proceedings before the Dutch court, Teva withdrew the Dutch designation of EP ‘749 in January 2017. Teva did so in order to deprive Synthon of all legal interest in its revocation actions and to avoid spill over effects¹⁵⁶⁴ from an expected revocation of the Dutch version of EP ‘749 by the Dutch courts.¹⁵⁶⁵

- (1241) In view of Teva’s withdrawal of the Dutch designation of EP ‘749, Synthon could no longer request the revocation of EP ‘749 in the Netherlands, although it could maintain its request for a declaratory judgment stating that the 40 mg dosing regimen was lacking an inventive step (the so-called Arrow declaration). In order to deprive Synthon of this opportunity, Teva withdrew its remaining dosage patents and pending patent applications in the Netherlands.¹⁵⁶⁶ As a result, the Dutch court found that Synthon no longer had the required legal interest in any part of its requests and did not issue such a declaratory judgment on the validity of EP ‘749.¹⁵⁶⁷
- (1242) As regards the next dosage patent, EP ‘335, in light of the conduct described above and Teva’s concern that EP ‘335 was not likely to “{...}”,¹⁵⁶⁸ it seemed likely that Teva would have also withdrawn the approval of the text of EP ‘335 to prevent a reasoned revocation decision by the TBA regarding that patent. The Commission also notes that Teva’s {...},¹⁵⁶⁹ contemplated withdrawing EP ‘335 on the very day it was granted (see Recital (1076)). {...} notes of 4 January 2017 reveal that EP ‘335 was indeed simply a step in a game of patent filings and withdrawals rather than an essential enforcement asset, as Teva now tries to portray it.¹⁵⁷⁰
- (1243) The withdrawal of the approval of the text of EP ‘335 is also what the Regional Court of Munich expected and why it considered it appropriate to issue an order to Teva on 24 February 2020 to abstain from such a course of action, unless it would agree to lift a preliminary injunction based on EP ‘335 in Germany. The court order

product or process to infringe his patent, that patent must be held invalid. Such a declaration was granted in *Fujifilm v Abbvie* [2017] EWHC 395 (Pat).

¹⁵⁶⁴ A judgment by the Dutch courts would have persuasive effects on other national courts as Teva shortly terminated proceedings before TBA by withdrawal of the patent (see Recital (1236)).

¹⁵⁶⁵ ID 404-1841, Teva internal email dated 4 January 2017 from {...} to {...}, p. 1.

¹⁵⁶⁶ By not validating EP ‘335 in the Netherlands and withdrawing the Dutch designation of its next pending dosage divisional, EP ‘962. ID 3636, *Rechtbank Den Haag*, Judgment of 6 September 2017, *SYNTHON B.V., v YEDA RESEARCH & DEVELOPMENT Co., Ltd.*, C/09/521009 / HA ZA 16-1231, paragraph 2.9.

See also ID 404-2142, Teva internal email dated 25 January 2017 from {...} to {...}; ID 455-751, FAST DT MS update July 2017, 13 July 2017, p. 13; ID 2179, EP2630962 - Withdrawal of designation of a Contracting State, 26 January 2017.

¹⁵⁶⁷ Teva claims that Teva’s approach to the Netherlands was motivated by the particular approach of the Dutch court and the fact that the market was fairly small, but litigation costs were high. This is the same reason why Teva withdrew this designation from EP ‘962 and did not validate EP ‘335 for the Netherlands (ID 4032, Teva’s Reply to the Statement of Objections, paras. 892-897). However, nothing in Teva’s arguments or evidence (including the declaration quoted in the footnote 721 of the Reply to the Statement of Objections) contradicts the Commission’s conclusion: patents in the Netherlands were abandoned because Teva was certain they would be revoked and was concerned that a decision of the Dutch courts may have cascading effects in other EU markets (see Recital (1079)). As to the size of the Dutch market, Teva’s statement directly contradicts statement on Teva persistence in defence of its patent portfolio due to the blockbuster status of Copaxone (see Reply to the Statement of Objections, paras. 845 ff.) and the fact that in size Dutch market is comparable to or even bigger than the markets in other Relevant Member States (e.g. (Czechia and Belgium). With respect the Teva’s argument on cost savings, see Section 8.3.6.3.

¹⁵⁶⁸ ID 263-799, Teva internal WhatsApp conversation dated 24 April 2019 between {...} and {...}.

¹⁵⁶⁹ ID 5695, Teva’s Reply to the Letter of Facts I of 9 February 2024, para. 214.

¹⁵⁷⁰ ID 404-1841, Teva internal email dated 4 January 2017 from {...} to {...}: “{...}”.

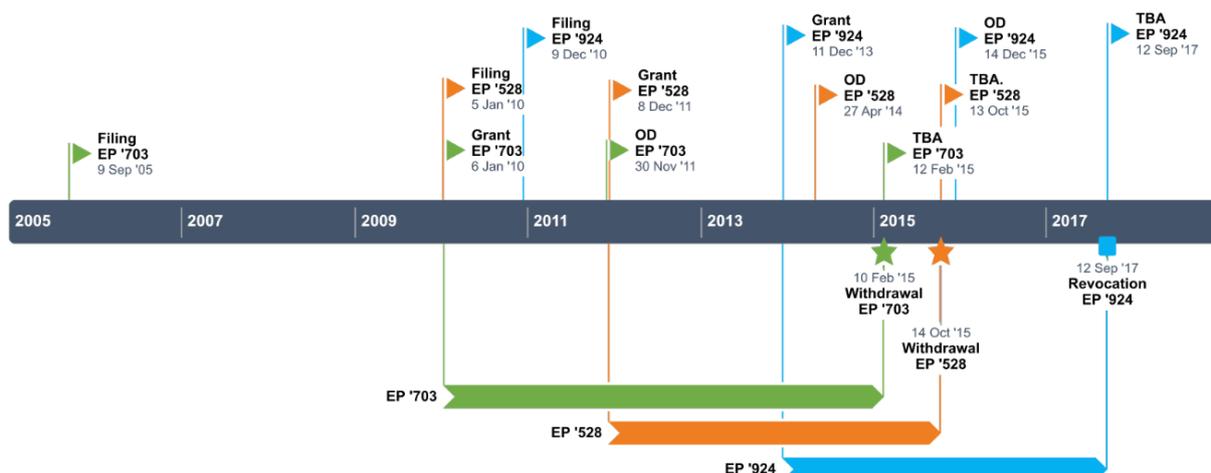
was issued following a written submission by Mylan on 5 February 2020.¹⁵⁷¹ As a result, EP ‘335 was revoked by the TBA by a formal reasoned decision on substantive grounds which directly led the OD to revoke Teva’s divisionals EP ‘962 and EP ‘172 (see Section 8.3.3.5).

8.3.4. *The pattern of Teva’s carefully timed filings and withdrawals of patents demonstrates the existence of a strategy to maximise the delay of legal review*

- (1244) The anticompetitive aim of Teva’s strategy and its comprehensive patenting conduct is demonstrated by the fact that Teva carefully timed both the filings and withdrawals of its patents and thereby maximised the delay of the legal review of their validity.
- (1245) First, there were significant time lags between the filings although all the distinguishing features of the dosage divisionals (i.e. mannitol, pH range, pre-filled syringe) were already present in the original 20 mg Copaxone (marketed since 1997) and in the patent application US ‘566A1, which was filed in 2007. The same applies to the arbitrary sub-ranges of brominated tyrosine and metal ion impurities that allegedly distinguished the process divisionals. Nonetheless, the parent patents and their divisional patents were filed on average every 2 years over a period of 11 years, thereby creating a series of staggered patent grants, in order to artificially extend Teva’s exclusive rights for Copaxone (see Table 13 and Table 14 above).
- (1246) Second, Teva’s staggered filing of divisional patents also shortened the period during which Teva could enforce each respective divisional patent. Considering that all the patents from a divisional patent family share the same priority date, and thus the same expiry date, Teva had nothing to gain (apart from delaying the legal review of their validity) from deferring patent applications for divisional patents. The later the grant of a divisional patent, the shorter the remaining period during which Teva could effectively enforce the particular divisional. For example, the enforcement period for the divisionals EP ‘172 and EP ‘962, granted in 2018, was five years shorter compared to their parent patent EP ‘749, granted in 2013.
- (1247) Teva’s conduct shortened and thereby reduced the value of each of its divisional patents (compared to the parent patent or the earlier divisional). It ensured that the divisional patents could not be challenged in parallel, but had to be challenged consecutively, thus delaying the resolution of the multiple, but largely identical proceedings. This confirms that the decision on the timing of these patent filings was based on a strategy aiming at obstructing and delaying the legal review of their validity.
- (1248) Third, the timelines of Teva’s patent filings and withdrawals and the resulting staggered legal review proceedings suggest a clear pattern of strategically timed actions. This can be observed in Figure 39 and Figure 40.

¹⁵⁷¹ While proceedings before EPO concerned validity of the EP ‘335, the court proceedings before the Regional Court in Munich was instituted by Mylan’s request for preliminary injunction against Teva’s presumed patent withdrawal and based on the German rules on unfair competition. LG München I, Beschluss v. 24 February 2020 – 7 O 1456/20.

Figure 39: The date of the filings, Opposition division decisions and withdrawals of Teva's process patents



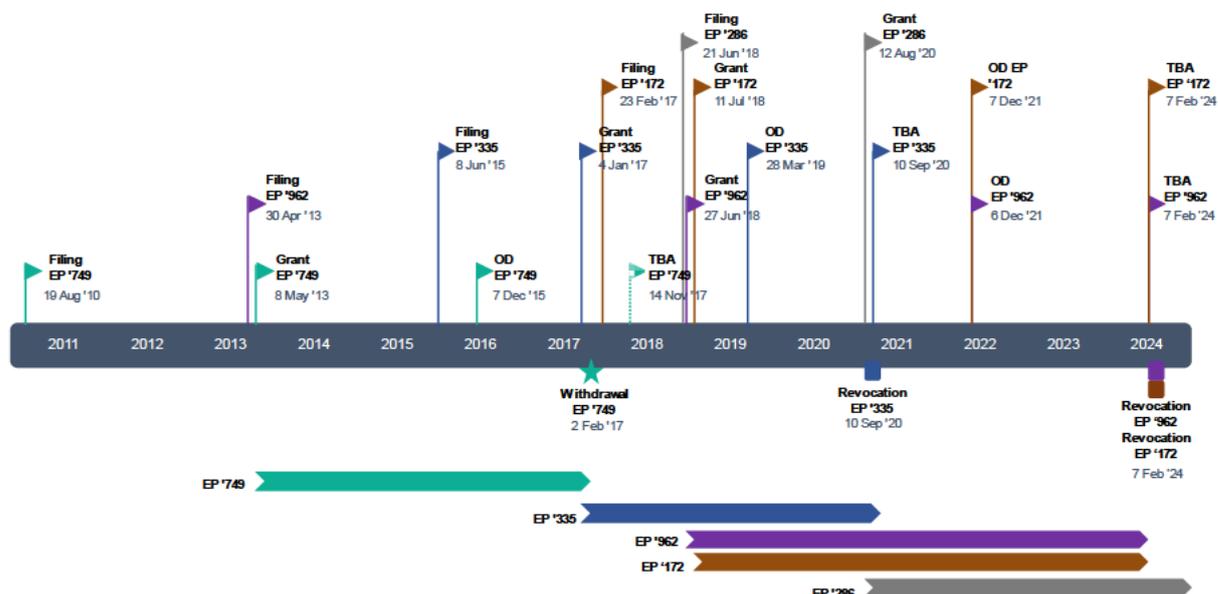
Source: EPO

(1249) As shown in Figure 39, Teva's carefully timed actions concerning the process patents are particularly striking in the following instances. First, EP '528 was filed one day before the parent patent EP '703 was granted, which was the latest possible moment¹⁵⁷² to file EP '528 as a divisional of EP '703, and more than four years after the parent patent had been filed. Second, the approval of the text of EP '528 was withdrawn during the oral hearing just after the TBA found that Teva's claims were invalid but before it concluded the hearing and issued a reasoned decision on the validity of EP '528.¹⁵⁷³ This is the most manifest example of Teva's withdrawal of a patent at the last possible moment.

¹⁵⁷² Pursuant to rule 36 of the EPC “[t]he applicant may file a divisional application relating to any pending earlier European patent application”. The EPO’s guide for applicants clarifies that “[a]n application is pending up to (but not including) the date on which the European Patent Bulletin mentions the grant of the European patent”.

¹⁵⁷³ ID 455-2749, Teva internal email dated 14 October 2015 from {...} to {...} and others.

Figure 40: The date of the filings, Opposition division decisions and withdrawals of Teva's dosage patents



Source: EPO

- (1250) Similarly, the timeline concerning the dosage patents (Figure 40 above) shows Teva's carefully timed actions and its divisional strategy. For example, in the first place, the approval of the text of EP '749 was withdrawn by Teva very shortly after the grant of EP '335, thus showing the link between staggered grants and withdrawals.¹⁵⁷⁴
- (1251) Teva's conduct prolonged the legal uncertainty concerning the validity of its patents. For example, if the divisionals had not been filed with unreasonably long intervals (which were not linked to actual R&D endeavours)¹⁵⁷⁵, allowing a parallel review, the revocation of EP '749 by a reasoned decision¹⁵⁷⁶ would have likely promptly (if not simultaneously) impacted the assessment of the validity of the remaining divisionals. Instead, EP '335 was annulled by the TBA only in September 2020 (following a judgment from the Regional Court of Munich ordering Teva to refrain from withdrawing EP '335).¹⁵⁷⁷ Following the revocation by reasoned decision of the TBA of EP '335, the OD revoked EP '962 and EP '172 on 6 and 7 December 2021.

¹⁵⁷⁴ This link is also explicitly described in a document written by Teva's {...}, see ID 404-1841, Teva internal email dated 4 January 2017 from {...} to {...}.

¹⁵⁷⁵ See, for example, an email from Teva's {...} of 7 April 2013 revealing that the announcement of grant of the Original Dosage Patent (EP '749) was understood as a trigger for filing of "{...}" (ID 5510, Email from {...} to {...} of 7 April 2013, p. 1.) and an email from {...} of 29 May 2018 showing that the announced grant of EP '962 was considered as a "{...}" referring to the EP '286 application which was filed on 21 June 2018 (ID 5583, Email from {...} to {...} of 29 May 2018, p. 8-9). See also Recitals (1138) and (1145) below and Section 8.3.6.2 on disconnect between Teva's patent filings and R&D endeavours.

¹⁵⁷⁶ Absent Teva's withdrawal of the Original Dosage Patent EP '749, the TBA would have issued a reasoned revocation decision providing legal certainty in November 2017.

¹⁵⁷⁷ LG München I, Beschluss v. 24 January 2020 – 7 O 1456/20.

On 7 February 2024, TBA dismissed Teva's appeals against OD's decision and thus ultimately revoked EP '962 and EP '172.¹⁵⁷⁸

- (1252) In the second place, the notes of Teva's {...} from January 2017 suggest that {...} of EP '962, which was filed more than two years before EP '335, but was granted after EP '335.¹⁵⁷⁹ The influence over the timeline indeed materialised as Teva prioritized the process with respect to EP'335 at the expense of its much earlier filed parent patent EP '962. Teva was also stalling in its communications with the EPO with respect to EP '962, requesting the extension of deadlines before the examiner of the OD or rejecting a proposal to hold an oral hearing in the opposition by videoconference (see Recital (1128)).
- (1253) In the third place, EP '962 and EP '172 were granted around the same time (although their filings were staggered; see Figure 40 above) and, as a result, their opposition cases were heard in conjunction.¹⁵⁸⁰ This illustrates that if Teva had not followed a staggered approach to getting the other divisionals granted, Synthon would have been able to challenge the divisionals in parallel, which would have allowed the legal review process to proceed without delays and would have provided legal certainty much earlier.
- (1254) Teva repeated this cycle of carefully timed filings and withdrawals and thereby ensured that it would always "{...}".¹⁵⁸¹ The combined timeline below (Figure 41) illustrates that notwithstanding the weakness of its patents,¹⁵⁸² Teva's "divisional game" allowed it to artificially prolong legal uncertainty and the period during which it could enforce its patents against potential GA entrants and Synthon and its licensees in particular.

¹⁵⁷⁸ ID 5731, EP2630962 – Minutes of the hearing before the Technical Board of Appeals 3.3.04, 6-7 February 2024; ID 5729, EP3199172 – Minutes of the hearing before the Technical Board of Appeals 3.3.04, 6-7 February 2024; ID 5823, EP2630962 – Decision of the Technical Board of Appeal 3.3.04, 7 February 2024; ID 5825, EP3199172 – Decision of the Technical Board of Appeal 3.3.04, 7 February 2024.

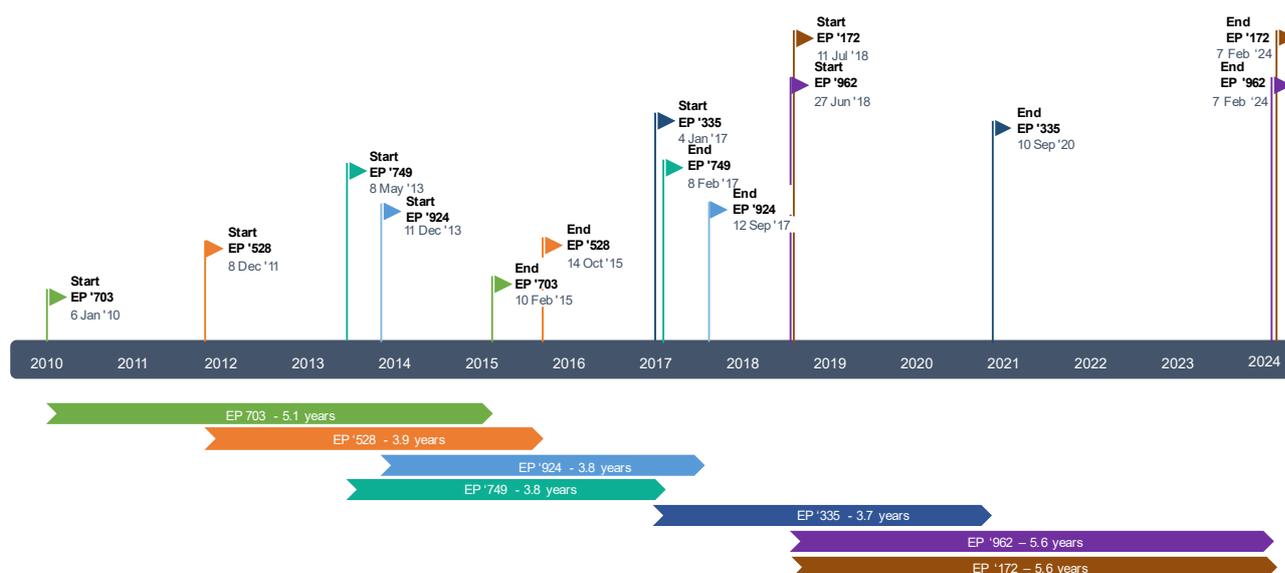
¹⁵⁷⁹ See ID 404-1841, Teva internal email dated 4 January 2017 from {...} to {...} where reference is made to getting granted patents in particular time periods: "{...}". According to Synthon and based on communication exchanges between Teva and the EPO (publicly available), Teva delayed the process as follows. On 28 September 2015, the EPO instructed Teva to correct deficiencies in its application within 4 months (so before 28 January 2016). On 1 February 2016, Teva requested a two-month extension of the time limit. This extension was granted by the EPO. Teva then had until 28 March 2016 to address the EPO's concerns. Teva however failed to file observations on time. On 3 May 2016, the EPO notified Teva that its claims are deemed to have been abandoned and that Teva has two months to request further processing. On 6 July 2016 (3 days after the deadline), Teva requested further processing. The request for further processing was accepted by the EPO. This course of action by Teva contributed to a significant delay in the grant of EP '962. ID 3658, Synthon's Reply to Article 18(2) Request of 12 September 2022.

¹⁵⁸⁰ On interference of EP '335 in timeline of EP '962 see Recital (1300).

¹⁵⁸¹ ID 404-2555, Teva internal email dated 16 March 2016 from {...} to {...} and others, p. 1.

¹⁵⁸² Which is demonstrated by the fact that none of the patents were ever upheld by a TBA and thus, based on the average duration of opposition and appeal should not have remained in force for more than 4 years.

Figure 41: The validity periods of Teva's process and dosage patents



Source: EPO

(1255) Teva's documents show that internally, it was perceived as an important advantage that the dosage patents had been granted more recently (2013 and 2015) than the process patents, so that corresponding validity challenges had at the time not progressed as far. In April 2016, {...} explained to a colleague that "{...}" (emphasis added).¹⁵⁸³ The reference {...} indicates that Teva did not expect the patent to remain valid until 2030, but until the still distant reasoned decision of the TBA. One year later, in March 2017, the same {...} replied to a colleague asking about "{...}" protecting Copaxone 40 mg. {...} (emphasis added).¹⁵⁸⁴

(1256) The repetition of these cycles of recurring filings and strategic withdrawals confirms that these are not isolated occurrences, but elements of a comprehensive patenting conduct and an anticompetitive strategy to obstruct and delay the legal review of the validity of Teva's patents.

8.3.5. *Interim conclusion: Teva's comprehensive patenting conduct obstructed and delayed the effective legal review of the validity of Teva's patents and thus artificially prolonged legal uncertainty concerning Copaxone patents*

(1257) It follows from the foregoing that Teva's strategy and conduct regarding its divisional patents (Teva's divisionals game), considered as a whole and comprising recurrent and staggered patent filings and strategic withdrawals, obstructed and delayed the effective legal review of the validity of its patents¹⁵⁸⁵ allowing Teva to obtain and/or rely on "{...}"¹⁵⁸⁶ until their final revocation by the EPO.

¹⁵⁸³ ID 404-1922, Teva internal email dated 16 April 2016 from {...} to {...}.

¹⁵⁸⁴ ID 404-541, Teva internal email dated 22 March 2018 from {...} to {...} and others.

¹⁵⁸⁵ The withdrawals equally affected national invalidity challenges against the very same – withdrawn – patent, which were thus rendered moot.

¹⁵⁸⁶ ID 455-9, Global Commercial Strategic Plan, 5 September 2012, p. 17.

(1258) As a patentee's withdrawal of the approval of a patent cannot be opposed by third parties or by the EPO itself, Teva successfully prevented the adoption of a reasoned decision by a TBA (i) as regards the process patent family, until there was no other process patent to rely on and thus there was no reason for Teva to withdraw its last divisional process patent and (ii) as regards the dosage patent family, until Teva was prevented from withdrawing the divisional dosage patent EP '335 by the Regional Court of Munich in February 2020 in the context of a *sui generis* preliminary injunction procedure. However, since Teva's other divisional dosage patents (i.e. EP '962, EP '172 and EP '286) were (also) granted on the basis of the Original Dosage Patent EP '749, Teva was able to continue to aggressively enforce especially EP '962 and EP '172 at national level to hinder the market entry or expansion of actual and potential GA entrants. In that respect, it should be noted that, had Teva not withdrawn the text of the Original Dosage Patent, the TBA would have issued a reasoned decision following an oral hearing scheduled for 14 and 15 November 2017 (see Table 14) which would, in all likelihood, have had negative inferences on the legal status and outlook of EP '962, EP '172 and EP '286 as well as on the OD decision upholding EP '335 in March 2019.¹⁵⁸⁷

(1259) This artificial prolongation of obstacles to market entry until the EPO's final revocation of the last remaining patents in the dosage family (i.e. until 7 February 2024 when the TBA confirmed the revocation of EP '962 and EP '172) was not based on either the merits or the strength of Teva's patents but rather on the obstruction and delay of their effective legal review.

8.3.6. *Teva's explanations for its comprehensive patenting conduct cannot be accepted*

(1260) During the administrative proceedings, Teva repeatedly claimed that its conduct pursued legitimate objectives. In the following sections, the Commission reviews the main reasons invoked by Teva and shows that they do not plausibly explain Teva's conduct. Other explanations and arguments invoked by Teva have been answered elsewhere in this Decision.¹⁵⁸⁸

(1261) For the reasons explained below, the Commission finds that Teva is unable to show that its comprehensive patenting conduct had any legitimate objective. Its submissions cannot thus alter the Commission's conclusion that Teva's conduct was aimed at obstructing and delaying the legal review of the validity of Teva's patents, artificially prolonging legal uncertainty regarding those patents and thereby hindering entry and/or expansion of GA competitors and Synthon and its licensees in particular.¹⁵⁸⁹

8.3.6.1. Teva's comprehensive patenting conduct goes against the objectives of the patent system

(1262) Teva claimed that "*its decisions to file and/or withdraw patents relating to Copaxone were recognized as legitimate by the EPO. Indeed, [...] after the patent [EP '749] had been withdrawn, Synthon requested the Board of Appeal to issue a preliminary opinion regarding the patentability of the patent invoking the grounds of procedural economy and "to prevent the patentee/applicant from abusing the system..."*". The

¹⁵⁸⁷ See Section 8.3.3.

¹⁵⁸⁸ See in particular Recitals (1103)-(1104) concerning reasons for filing of divisional applications in the process family and Recitals (1113)-(1120) concerning reasons for filing of divisional applications in the dosage family.

¹⁵⁸⁹ Synthon GA was the only GA product competing with Copaxone in the Relevant Member States (see in particular Section 7.2.1).

EPO, who is responsible for applying the rules of the EPC, did not heed these requests, thus implicitly (but necessarily) acknowledging that Teva's conduct in this regard was fully legitimate".¹⁵⁹⁰

- (1263) First, it should be noted that internal documents show that Teva withdrew the approval of the text of EP '749 to prevent the issuance of a preliminary opinion in which the arguments raised by Synthon might be discussed.¹⁵⁹¹ As a result, contrary to Teva's claims, the TBA did not "*implicitly acknowledge*" the legitimacy of Teva's conduct, but rejected the request to issue a preliminary opinion on patentability of EP '749 because it considered that it was prevented from doing so because of Teva's withdrawal of EP '749. The TBA's revocation decision clearly notes that due to Teva's withdrawal, it was prevented from conducting a substantive examination: "2. Pursuant to Article 113(2) EPC the EPO shall examine, and decide upon, the European patent only in the text submitted to it, or agreed, by the proprietor of the patent. 3. Such an agreement does not exist if the proprietor – as in the present case – expressly states that it no longer approves the text as granted and withdraws all pending auxiliary requests [...]. 4. There is therefore no text of the patent on the basis of which the board can consider the appeal. It is established case law that in these circumstances the patent must be revoked without further substantive examination [...]"¹⁵⁹²
- (1264) Second, Teva's conduct goes against the stated objectives of the EPO. In the first place, the EPO explicitly stated, as early as 2009, that "[t]here is a trend for applicants to abuse these procedural possibilities by using the divisional application procedure to achieve a "duplication" of the proceedings [...] This is detrimental both to legal certainty for third parties and to patent office workloads".¹⁵⁹³ The grant of Teva's divisional patents, therefore, cannot be interpreted as a legitimisation of Teva's underlying objectives.
- (1265) Teva's President and CEO provided a succinct explanation of why patent gaming by pharmaceutical companies and the multiplication of secondary patents extends the patent protection and goes against the objectives of the patent system as understood by Teva: "[...] what I mean with patent gaming is when you have a basic patent for 10 – 12 years and then you make 15 other patents to extend it for another 10 years. now that's not the deal with society. The deal with society is you get a natural monopoly in terms of patents because you give it back to society at the end and then we have generics and everybody gets the benefit".¹⁵⁹⁴
- (1266) The same applies to the withdrawals, which the EPO cannot oppose as it is an exercise of the IP right vested in the patent holder. Teva's withdrawals invalidated the patents *ex tunc* and prevented substantive decisions on their validity.
- (1267) Moreover, the EPO's decisional practice itself favours quick removal of legal uncertainty in opposition proceedings before the EPO. In case T 73/84, the first TBA decision concerning the effects of a withdrawal on ongoing proceedings at the EPO,

¹⁵⁹⁰ ID 656, Teva's reply to Article 18(2) request of 3 June 2020, question 21, p. 74.

¹⁵⁹¹ ID 404-1841, Teva internal email dated 4 January 2017 from {...} to {...}.

¹⁵⁹² ID 2176, EP2405749 – Decision of the Technical Board of Appeal 3.3.04, 8 February 2017, paragraphs 2-4.

¹⁵⁹³ EPO paper CA/145/08 Rev. 1, subject: Divisional applications, Munich, 15 January 2009; as quoted in the Pharmaceutical Sector Inquiry, Final Report, 8 July 2009, paragraph 532.

¹⁵⁹⁴ ID 4400, Keynote by Kåre Schultz (President and CEO, Teva) at Financial Times Global Pharmaceutical and Biotechnology Conference 4 December 2019 and ID 5154, transcript prepared by the European Commission, p. 3.

the TBA held that “*the patent proprietor cannot terminate the proceedings by telling the EPO that he is surrendering the European Patent, since this is not provided for in the Convention. Thus he would only be able, as far as national law permitted, to surrender the patent vis-à-vis the national patent offices of the designated Contracting States under the relevant national law. At the same time, the proceedings ought to be terminated as quickly as possible in the interests of legal certainty, which calls for a clarification of the industrial rights situation. The only possibility in such a case is to revoke the patent, as envisaged for other reasons in Article 102 EPC*” (emphasis added).¹⁵⁹⁵ Thus, the possibility for the patent holder to have proceedings terminated quickly by patent withdrawal was meant to serve the interests of legal certainty.

8.3.6.2. Teva clearly pursued and achieved the exact opposite from its claimed intent and instead sought to obstruct and delay the legal review process of its patents

(1268) Teva has claimed that its “*decision to withdraw these patents was driven by the willingness to simplify and rationalize the enforcement of its patent portfolio*”.¹⁵⁹⁶ Teva argued that generally, “*the first application in a family is in most cases likely to be prosecuted before a holistic enforcement strategy has been developed. This arises in the pharmaceutical and biotech industries as there is pressure to file applications very early in the development of a product. It may be at such an early stage that the actual product to be developed and commercialized has not yet been identified. Prosecution of the patent application is therefore likely to precede the conduct and completion of clinical trials and Regulatory review*”.¹⁵⁹⁷

(1269) However, this explanation is not plausible in the circumstances of Teva’s staggered patent filings concerning both the process and the dosage patent families, because neither of them concerned a product at “*such an early stage that the actual product to be developed and commercialized has not yet been identified*”.¹⁵⁹⁸ To the contrary, both families included secondary patents where divisionals were filed in a staggered manner more than 15 years after the filing of the initial patent protecting a very successfully commercialized product – Copaxone (divisional patents in the process and dosage families were filed between 2010 and 2018 while EP ‘888 was filed in 1995).¹⁵⁹⁹

¹⁵⁹⁵ Decision of 26 April 1985, T 73/84, paragraph 5. Also see, more recently: decision of 3 September 2020, T 1832/16, paragraph 3; decision of 27 September 2021 T 0761/18, paragraph 4.

¹⁵⁹⁶ ID 656, Teva’s reply to Article 18(2) Request of 3 June 2020, question 21, p. 84.

¹⁵⁹⁷ ID 656, Teva’s reply to Article 18(2) Request of 3 June 2020, question 21, pp.73-74. See also Teva’s Reply to the Statement of Objections, for example para. 541 and para. 618. In para. 545 of its Reply, Teva further explains with respect to the divisional applications that “[t]he applicant can decide which aspect of the invention to first subject to prosecution. For example, if an invention relates to a class of chemical compounds, a single most preferred compound may be first subjected to examination. If a patent is granted on the first compound, the applicant may utilise a divisional application to subject the remaining aspects of the invention to examination (e.g., other compounds, a generic formula of the compounds, the use of the compounds, etc).” This explanation is in stark contrast with Teva’s conduct assessed in this Decision which consisted of multiplication of significantly overlapping patents in the process and dosage families. These patents were not covering different compounds belonging to the same class, or use of a compound or its different formulations. Teva’s process patents were covering a process for manufacturing of a product that was at that point already commercialized for many years while dosage patents covered a dosage regime for glatiramer acetate which was known, already at the time of filing, for at least three years.

¹⁵⁹⁸ ID 656, Teva’s reply to Article 18(2) Request of 3 June 2020, question 21, pp.73-74.

¹⁵⁹⁹ See Recital (101). On staggered filings of Teva’s divisional patents see Section 8.3.2.2.

- (1270) Indeed, already in February 2014, {...} {...}.¹⁶⁰⁰ Such close correspondence facilitated enforcement actions including swifter issuance of preliminary injunctions.
- (1271) With regard to the process patents, the filings (of both the parent and the divisional patents) did not, as Teva stated in its RFI reply, “*precede the conduct and completion of clinical trials and regulatory review*”.¹⁶⁰¹ As {...} noted when explaining why the TBA was expected to revoke EP ‘703, the process patents “{...}”.¹⁶⁰² Teva has not substantiated why there was a need to file for divisionals in a staggered manner and so late. Still in 2018 (i.e. 13 years after filing the Original Process Patent protecting alleged innovative changes in the manufacturing process) Teva was affirming to HCPs and reimbursement authorities, that Copaxone “*has a very tightly controlled manufacturing process which has remained the same since the early clinical trials*”.¹⁶⁰³
- (1272) With regard to the dosage patents, all the distinguishing features of the dosage divisionals were also embodied in the already marketed 20 mg Copaxone and had no nexus to clinical or regulatory review of the 40 mg Copaxone. While both the parent patent and the divisionals in the dosage patent family protected the 40 mg dosing regimen as the central inventive concept, the divisionals had a number of distinguishing features (i.e. use of mannitol, pH value, use in a pre-filled syringe, or a combination thereof). However, all these features had already been used by Teva in relation to Copaxone 20 mg (and are featured on the SmPC of Copaxone 20 mg), which had been on the market for a decade when the Original Dosage Patent, EP ‘749, was filed in 2010. Moreover, Teva had already anticipated the combination of a 40 mg GA in a low-frequency regimen and each of these features had already been filed in a single patent application in 2007 in the United States (US ‘566A1).¹⁶⁰⁴
- (1273) Accordingly, contrary to its claims on legitimacy and justifiability of the patent filings and their timings¹⁶⁰⁵, Teva is unable to explain why there was a need to file divisional patents in a staggered manner and over such an extended period of time, long after the invention was made. For example, while Copaxone 20 mg had been marketed in pre-filled syringes since 1996 in the US,¹⁶⁰⁶ Teva only applied for a divisional patent combining the 40 mg regimen with the use of a pre-filled syringe before EPO 22 years later, in 2018.
- (1274) The timelines assessed in Section 8.3.4 show that it is not plausible to suggest that Teva moved to newer patents because of their “*better suited*” content, contrary to Teva’s claim.¹⁶⁰⁷ The reason Teva did not request preliminary injunctions based on the parent patents was not their “*less suited*” content but the fact that by the time it

¹⁶⁰⁰ “{...}” (ID 266-296, Teva internal emails from {...} to {...} and {...} of 4 and 9 February 2014, p. 1).

¹⁶⁰¹ ID 656, Teva’s reply to Article 18(2) Request of 3 June 2020, question 21, p.74.

¹⁶⁰² ID 455-1205, Teva internal email dated 2 February 2015 from {...} to {...} and others, p. 1.

¹⁶⁰³ ID 455-2136, Meeting Report, Copaxone® (glatiramer acetate) in the era of follow-on glatiramer acetate: Key Expert Input Forum Monday 24 September 2018, 09:30-14:30, Royal College of General Practitioners, London, p. 8. The Commission notes that the earliest clinical trials concerning Copaxone were conducted in 1987 and 1995.

¹⁶⁰⁴ See Recitals (1168) and (1169).

¹⁶⁰⁵ See for example ID 4032, Teva’s Reply to the Statement of Objections, paras. 741-752.

¹⁶⁰⁶ Copaxone 20 mg has been marketed in pre-filled syringes in the US since 1996. According to Teva’s website: “*FDA-approved since 1996, daily COPAXONE® 20 mg is injected daily, and it’s also administered manually or with the autoject®2 for glass syringe*”, see ID 2494, Dosage information on the Copaxone website, <https://www.copaxone.com/about-copaxone/dosage-information>, accessed on 23 September 2022.

¹⁶⁰⁷ See for example ID 4032, Teva’s Reply to the Statement of Objections, paras. 801-815.

started enforcing its patents against Synthron, the parent patents had already been revoked: when Teva requested its first preliminary injunction based on a process patent (in Czechia in May 2015), the Original Process Patent EP ‘703 had already been revoked 3 months earlier. Teva requested its first preliminary injunction based on a dosage patent in October 2017 (in Ireland), 8 months after the Original Dosage Patent EP ‘749 had been revoked.

- (1275) By preventing a reasoned decision on the merits of its patents, Teva ensured that subsequent proceedings could not be concluded more rapidly by relying on a precedent, but would involve another full litigation, repeating the exchange of arguments throughout opposition and appeal proceedings that had already occurred in the legal review of the previous patent. Accordingly, Teva’s conduct did not serve to “*simplify and rationalize*” Teva’s patent enforcement, contrary to what Teva alleges.
- (1276) On the contrary, the staggered filing of multiple divisional applications related to well-known and commonly used features allowed Teva to obstruct and delay the legal review of its patents. This shows that the staggered filing (and consequently, the enforcement) and strategic withdrawals of the process and dosage patents was not mandated by the objective needs or outcomes of the product development process but by Teva’s intention to hinder and delay competition by artificially prolonging obstacles to market entry.
- (1277) Finally, Teva’s staggered filing of its divisional patents shortened the time period during which the patents were valid, which contradicts Teva’s claim that its patenting conduct aimed at effectively enforcing its patent portfolio (see Recitals (1246)-(1247)).
- (1278) As Table 13 and Table 14 demonstrate, Teva has systematically timed the filing (thus influencing the timing of the grant) of its divisional patent applications with long intervals. For the process patent family, EP ‘528 was granted 23 months after the parent patent EP ‘703, and EP ‘924 was granted 24 months after EP ‘528. For the dosage patent family, EP ‘335 divisional was granted 44 months after the parent patent EP ‘749, and EP ‘962 and EP ‘172 divisionals were granted 17 and 18 months after the EP ‘335 grant, respectively. These long time-lags between the filing dates cannot be explained by the features distinguishing the different divisional patents in a family since these are limited.¹⁶⁰⁸
- (1279) Since all divisional patents from the same patent family share the same priority date, and thus the same expiry date Teva had nothing to gain from deferring the filing of its divisional patent applications. The later the patent grant, the shorter the period during which Teva could effectively enforce its patents. For example, as the entire dosage family should have expired in 2030 (absent validity challenges), the enforcement period for the divisional patents EP ‘172 and EP ‘962, granted in 2018, was five years shorter compared to the parent patent EP ‘749, granted in 2013.
- (1280) The pattern of staggered filings of Teva’s divisional patent applications can thus best be explained by Teva’s objective to avoid the parallel review of the (divisional) patents from the same family, which would have allowed the legal uncertainty about the patents to be resolved earlier, to the benefit of third parties but to Teva’s detriment.

¹⁶⁰⁸ See Section 8.3.2.

8.3.6.3. Teva's conduct did not reduce Teva's costs for maintaining its patents

- (1281) Teva has claimed that its patent withdrawals were motivated by cost reductions: “*if a company considers that a patent that has already been granted is no longer best suited for the protection of its rights (e.g. as a new patent has been approved), there may no longer be any reason to incur costs to maintain the previous patent*”.¹⁶⁰⁹
- (1282) First, the impact of these patent withdrawals needs to be assessed within the broader context of Teva's comprehensive patenting conduct consisting in the repeated staggered filings and strategic withdrawals of patents. There are no overall cost savings where, in parallel to withdrawing an earlier patent challenged by a competitor, Teva incurs additional costs by filing new divisional patents, which are in turn subject to legal review on similar grounds and defended by Teva until their withdrawal shortly before a decision by a TBA. For example, concerning the process patent, Teva incurred the cost of three subsequent opposition and appeal proceedings before the EPO's OD and TBA. A significant part of these costs could have been avoided if Teva had allowed (i.e. had not withdrawn its patent) the first legal review concerning the parent patent (EP '703) to proceed to a reasoned decision by the TBA.
- (1283) Second, while each patent from both divisional patent families was challenged by Synthon and others before the EPO and subsequently defended by Teva (see Table 13 and Table 14 above), Teva's withdrawals of the patents only took place at a late stage during the appeal proceedings before a TBA. On two occasions, Teva withdrew these patents just days¹⁶¹⁰ or even moments¹⁶¹¹ before the TBA was supposed to adopt its decision. The withdrawal of patents at such a late stage, after years of litigation, brings, at best, only minimal cost savings, especially when compared to the alternative of letting the procedure be concluded by a reasoned final decision that would provide legal certainty and procedural efficiency (through the *res iudicata* rule) for the other patents in the same family.
- (1284) Third, the Commission notes that also the Higher Regional Court of Munich considered that cost savings are not a plausible explanation for Teva not defending a patent covering a blockbuster drug: “*It appears rather far-fetched to the present Chamber that a patent covering a blockbuster technology (see application, page 4) and maintained in opposition proceedings initiated by competitors wishing to enter the market with a generic product, is dropped on the basis of economic considerations because the patent holder does not wish to bear the time and costs of defence*”.¹⁶¹²
- (1285) Fourth, none of Teva's internal documents on the Commission's file mentions cost savings as the reason for the withdrawals and Teva does not claim otherwise.

¹⁶⁰⁹ ID 656, Teva's reply to Article 18(2) Request of 3 June 2020, question 21, p. 74. Similar claim is implied in ID 4032, Teva's Reply to the Statement of Objections, para. 894.

¹⁶¹⁰ EP '703 was withdrawn 9 days before the scheduled TBA hearing.

¹⁶¹¹ EP '528 was withdrawn on the second day of an oral hearing before the TBA, after the TBA found that the patent was invalid, but before the proceedings would be concluded and a reasoned decision would be issued by the TBA (see ID 455-2749, Teva internal email dated 14 October 2015 from {...} to {...} and others).

¹⁶¹² ID 741-16, OLG München, 12 April 2018, 6 W 164/18, Teva Pharmaceutical Industriel Ltd. Gegen Mylan dura GmbH. Original text: “*Dass ein Patent, das eine 'Blockbuster'-Technologie mit abdeckt (vgl. Antragsschrift, Seite 4) und das auf den Einspruch von Konkurrenten, die mit einem Generikum auf den Markt kommen wollen, aufrechterhalten worden war, aus wirtschaftlichen Überlegungen, weil die Patentinhaberin die Zeit und die Kosten für eine Verteidigung nicht aufbringen will, fallen gelassen wird, ist für den Senat mehr als fernliegend*” (emphasis added).

(1286) To conclude, Teva’s claim that the withdrawal of patents was intended to save costs must be rejected as implausible.

8.3.6.4. Teva’s claimed reasons for withdrawing process patents EP ‘703 and EP ‘528 cannot be accepted

(1287) Teva claimed that it withdrew its process patents EP ‘703 and EP ‘528 because EP ‘924 was better focused on the inventive concepts to protect Teva’s rights. Specifically, Teva stated that “*the withdrawal of the process patents was motivated by the fact that the divisionals were considered to be more focused on the inventive concepts to protect Teva’s rights. In particular [sic], EP ‘924 contained inventive concepts derived from both EP ‘528 and EP ‘703 in respect of bromotyrosine contamination and the metal ion limitation to a specific ppm. Further, EP ‘924 contained a claim directed to a product obtained by the patented methods. On this basis, the claim language of EP ‘924 was better suited to assessing and determining infringement before national courts*”.¹⁶¹³

(1288) If the purportedly more appropriate scope of EP ‘924 (combining certain claims of EP ‘703 and EP ‘528) provided Teva a better position in patent enforcement and was therefore the real reason for the withdrawal of the two older patents, Teva would have had no interest in defending the two less well-suited earlier patents following the grant of EP ‘924 in December 2013. The two older patents could have been withdrawn already in December 2013 rather than in February and October 2015, which would have allowed Teva to avoid the procedural costs incurred during that period.

(1289) Instead, Teva defended EP ‘703 and EP ‘528 in lengthy proceedings (including numerous auxiliary requests that were necessary to avoid a revocation by the OD), only to withdraw the approval of the texts of these patents in separate successive proceedings once the TBA’s final decision on their validity was imminent and once the bulk of procedural costs had already been incurred. In the TBA proceedings concerning EP ‘528, Teva withdrew the patent on the day of the oral hearing during which the TBA would have delivered its decision.

(1290) Furthermore, Teva’s internal documents reveal that Teva withdrew its process patents because it perceived them as weak and as likely to be revoked by the TBA, creating a damaging precedent for the remaining divisionals.¹⁶¹⁴ Teva’s allegation that the withdrawals of EP ‘703 and EP ‘528 were motivated by the fact that EP ‘924 was better suited¹⁶¹⁵ is not reflected in internal strategy documents on the Commission’s file in which those withdrawals were discussed. These documents do not refer to EP ‘924 being “*more focused on the inventive concepts to protect Teva’s rights*” and “*better suited to assessing and determining infringement before national courts*”, as Teva claims, but refer instead to the advantage of avoiding a negative decision on the merits of its process patent family (see Section 8.3.3.6.1).

8.3.6.5. Teva’s claimed reasons for withdrawing its Original Dosage Patent EP ‘749 cannot be accepted

(1291) Teva claims that it withdrew the approval of the text of EP ‘749 because the patent claims of EP ‘335 better matched the regulatory documents. The main distinguishing

¹⁶¹³ ID 656, Teva’s reply to Article 18(2) Request of 3 June 2020, p. 85.

¹⁶¹⁴ See Section 8.3.3.3.1.

¹⁶¹⁵ ID 656, Teva’s reply to Article 18(2) Request of 3 June 2020, p. 85. See also ID 4032, Teva’s Reply to the Statement of Objections, paras. 13 and 18.

feature of EP '335 is that it relates to RMS as opposed to RRMS. This difference was allegedly intended to address a gap in Teva's enforcement of its IP rights, resulting from the difference between the label for Copaxone which was authorised in January 2015 with a reference to RMS, on the one hand, and the claims included in EP '749 which referred to RRMS, on the other hand. In March 2015, {...} became aware of this discrepancy.¹⁶¹⁶

- (1292) In support of its explanation, Teva refers to a number of internal emails from March 2015 in which Teva's employees ({...}) discuss finding out about the discrepancy, their discontent that the change in the label for Copaxone had happened without their knowledge and the related risks and mitigation measures. According to Teva, the sense of concern and urgency that are apparent from these emails is confirmed by the fact that EP '335 was filed (i) within three months of this correspondence; (ii) with a request for accelerated treatment by the EPO and from the fact that (iii) Teva dropped a number of claims specifically to expedite prosecution.¹⁶¹⁷ Based on these facts, Teva concludes that EP '335 was filed without any objective of delaying legal review and within a time period which cannot be considered as unreasonably long.¹⁶¹⁸
- (1293) According to Teva, EP '749 was withdrawn shortly after the grant of EP '335. The legitimate purpose of withdrawing EP '749 would follow from the fact that it occurred (i) after EP '749 had been maintained by the OD, and (ii) before any preliminary opinion as to the validity of EP '749 had been issued by the TBA. According to Teva, the Higher Regional Court Düsseldorf, when deciding to maintain the preliminary injunction based on EP '335 on 26 September 2019, concluded that there was no abusive conduct because, inter alia, EP '749 had been withdrawn before the preliminary opinion had been issued.¹⁶¹⁹
- (1294) Teva's claims are unfounded for the following reasons: (i) the broadening of the therapeutic indication in the divisional patent EP '335, compared to its parent patent EP '749, could not have survived legal scrutiny; (ii) the alleged enforcement gap could have been overcome by additional evidence; (iii) Teva could have achieved its aim by pursuing an amendment to the already pending patent application (EP '962) rather than by filing a new divisional patent; (iv) Teva's internal documents show that the Original Dosage Patent was withdrawn to prevent a final reasoned decision and a damaging precedent for Teva's remaining dosage divisional patents; and (v) Teva failed to substantiate with contemporaneous documents its explanation that EP '335 was filed due to a discrepancy between the Copaxone label and the patent claims.
- (1295) First, it was predictable that the change of the therapeutic indication of Copaxone in the divisional patent EP '335, compared to the one in its parent patent EP '749, would be incompatible with patent law. Indeed, a divisional patent application cannot cover a subject-matter going beyond the parent patent.¹⁶²⁰ Thus, any product falling within the scope of the divisional EP '335 would have to fall within the claims of the Original Dosage Patent EP '749. In this case, the parent patent EP '749 claimed the

¹⁶¹⁶ See, especially, ID 4032, Teva's Reply to the Statement of Objections, paras. 702-709, 816-824.

¹⁶¹⁷ ID 4032, Teva's Reply to the Statement of Objections, paras. 703-705.

¹⁶¹⁸ ID 4032, Teva's Reply to the Statement of Objections, paras. 707, 750. See also ID 5695, Teva's Reply to the Letter of Facts I of 9 February 2024, paras. 253-254.

¹⁶¹⁹ ID 4032, Teva's Reply to the Statement of Objections, paras. 816-824.

¹⁶²⁰ Pursuant to Article 76(1) EPC, a divisional application "*may be filed only in respect of subject-matter which does not extend beyond the content of the earlier application as filed.*"

use of Copaxone for treatment of a relapsing remitting form of MS (RRMS) and therefore the claim in its divisional EP '335 referring to another form of MS (relapsing MS or RMS), which is broader in scope as attested also by Teva's internal contemporaneous discussions,¹⁶²¹ clearly constituted added subject-matter (based on which a divisional application cannot be granted).

- (1296) The added matter deficiency of the EP '335 divisional application was confirmed by the OD in its preliminary opinion in August 2018. In order to avoid a finding of invalidity due to added matter, Teva filed an Auxiliary Request in January 2019 proposing to amend the claims of EP '335 so as to no longer refer to RMS, but to RRMS like its parent patent. The patent was validated by the OD in this amended form.¹⁶²² Thus, with respect to the therapeutic indication, Teva effectively reverted the claims in EP '335 to the claims of the parent patent, whose reference to RRMS had allegedly been the reason for its withdrawal, while EP '335 eventually relied on the same claims.¹⁶²³
- (1297) The Commission also notes that the difference between EP '749 and EP '335 based on the scope of indication (i.e. RRMS vs. RMS) was not mentioned by contemporaneous third-party sources discussing the difference between the patents which contradicts Teva's claims regarding the distinguishing features of the patents in the dosage family.¹⁶²⁴ The relevant report solely mentions that EP '335 also includes mannitol as the key distinguishing feature compared to the parent patent: {...}.¹⁶²⁵ The same conclusion was reached by the Higher Regional Court in Munich: *"The injunction patent [EP '335] differs from the teaching of EP '749 only in that the pharmaceutical composition according to claim 1 and/or claim 2 also includes mannitol in each case, although it has not been explained or otherwise shown in how far this additional component might be relevant to affirming protectability"*.¹⁶²⁶

¹⁶²¹ ID 4912-1683, Teva internal email correspondence dated 4 March 2015 between {...} and {...}, p. 1.

¹⁶²² ID 2163, EP2949335 – Decision of the Opposition Division, 13 May 2019.

¹⁶²³ Teva explains that it never expressed any doubts as to the validity of the claim in EP '335 and particularly not upon its filing. According to Teva, the Commission's finding on obvious unpatentability of the broader claim in the divisional inherently contradicts the entire theory set out by the Commission that the differences between the divisionals were "minor". According to Teva, the Commission cannot, on the one hand, build a case around the lack of material difference between the patents' claims, and on the other hand consider that it was "predictable" that said claims would be invalidated for reasons of added matter – that is, because they were too different from the subject matter covered in the parent patent (ID 4032, Teva's Reply to the Statement of Objections, para. 726). Teva's arguments should be rejected. First, part of EP '335 broadening its scope over the parent patent (i.e. its reference to RMS rather than to RRMS) was not capable of de-linking its validity outcome probabilities from the parent patent (and other divisionals in the dosage family since it was obviously invalid as an added matter. Second, the actual development on EP '335 corroborates the Commission's *ex ante* findings based on the contemporaneous documents. In the proceedings before the OD, Teva had to revert the claim from RMS back to RRMS to avoid a decision of invalidity for EP '335 (i.e. there was again the initial discrepancy Teva now uses as a justification for EP '335). Teva then continued to enforce EP '335 showing that this discrepancy between the label and the patent claim was in no way an obstacle for enforcement. Finally, when the TBA had the chance to assess the patent (since the Regional Court of Munich prohibited Teva to withdraw it), it invalidated the patent.

¹⁶²⁴ See Section 8.3.2.1.2.

¹⁶²⁵ ID 266-272, email dated 3 February 2017 from {...} to its subscribers.

¹⁶²⁶ ID 741-16, OLG München, 4 April 2018, 6 W 164/18, Teva Pharmaceutical Industriel Ltd. Vs. Mylan dura GmbH, p. 24. Original text: *"Das Verfügungspatent unterscheidet sich von der Lehre des EP 749 lediglich dadurch, dass die pharmazeutische Zusammensetzung gemäß Anspruch 1 bzw. Anspruch 2 jeweils zusätzlich Mannitol enthält, wobei nicht dargetan noch sonst ersichtlich ist, inwiefern dieser zusätzliche Bestandteil für die Bejahung der Schutzfähigkeit von entscheidungserheblicher Bedeutung sein könnte"*.

- (1298) Second, according to Teva’s own internal assessment, the alleged “enforcement gap” would manifest itself merely as a requirement for Teva to submit additional evidence to the judge(s) deciding on its application for a preliminary injunction of EP’749. As an internal presentation on patent enforcement explained: “{...}”.¹⁶²⁷ Teva’s internal email correspondence of 4 March 2015 reveals that the same discrepancy between indication on the Copaxone regulatory documents and in the patent claims occurred also in the US and that it was not considered as an insurmountable obstacle to enforcement: “{...}”.¹⁶²⁸
- (1299) Third, the internal email correspondence of 4 March 2015, on which Teva relies to justify filing EP ‘335, shows that internally, Teva was considering amending the existing patent application (EP’749 which was granted at that time and could not have been amended), rather than applying for a new divisional: “{...}”.¹⁶²⁹ Teva’s submission to the EPO of 1 September 2015 shows that Teva indeed amended the earlier, already pending patent application no. 13166080.5 (issued as EP ‘962) so that the claims referred to RMS rather than to RRMS, only after filing a second-generation application¹⁶³⁰ for EP ‘335.¹⁶³¹ Teva does not explain why, in the context of addressing an alleged enforcement gap in the already issued (EP ‘749) and pending (EP ‘962) dosage patents, it was necessary to both (i) amend the existing patent application (EP ‘962) and, even before this amendment, (ii) file for another divisional (EP ‘335) with accelerated treatment.
- (1300) As to Teva’s claim that the “urgent” filing of EP ‘335 and its accelerated examination reveal that there was no objective to delay the process, the Commission notes that the grant of EP ‘962, filed before the EP ‘335, was delayed as a result of the filing of EP ‘335. As noted in Table 14, EP ‘962 was filed on 30 April 2013 and granted only on 27 June 2018 (about 62 months later) while EP ‘335 was filed on 8 June 2015 and granted on 4 January 2017 (about 16 months later). Two other Teva divisionals in the patent family, EP ‘172 and EP ‘286 were granted within about 16 and half months and about 26 months, respectively.
- (1301) In addition, the urgency of the EP ‘335 filing does not rebut the Commission’s finding that Teva delayed the legal review in this case since that finding is based on the staggered filing of multiple overlapping divisional applications and the strategic withdrawal of the challenged patents before the reasoned decision on their validity (see Sections 8.3.2 and 8.3.3).¹⁶³² Regardless of its urgency, the filing of EP ‘335, is part of such a strategy. Teva’s claims concerning the alleged enforcement gap, do not convince in light of the fact that EP ‘335 contained questionable “distinguishing features” (see Section 8.3.2.1.2). Not only did EP ‘335 include a non-patentable

¹⁶²⁷ ID 404-668, Copaxone Europe ®, Patent Enforcement, 8 June 2016, p. 12. See also ID 404-2140, Teva internal email dated 10 January 2017 from {...} to {...}, p. 1. Immediately after learning about the discrepancy and the alleged “enforcement gap” {...} assessed the chances of obtaining the preliminary injunctions as over {...}%. (ID 4912-1668, Teva internal email correspondence dated 4 March 2015 between {...} and {...}).

¹⁶²⁸ ID 4912-1689, Teva internal correspondence dated 4 March 2015 between {...} and {...}, p. 1.

¹⁶²⁹ ID 4912-1668, Teva internal email correspondence dated 4 March 2015 between {...} and {...}, p. 2.

¹⁶³⁰ See Recital (50).

¹⁶³¹ ID 4937, Submission by Teva to EPO amending claims in the patent application no. 13166080.5 (EP ‘962) of 1 September 2015.

¹⁶³² Considering Teva’s overall conduct and Teva’s concerns about validity of EP ‘335, it seems likely that Teva would have also withdrawn the approval of the text of EP ‘335 to prevent a reasoned revocation decision by the TBA. This is also what the Regional Court of Munich expected and why it considered it appropriate to order Teva to abstain from withdrawing EP ‘335, see LG München I, Beschluss v. 24 February 2020 – 7 O 1456/20, paragraphs 51 and 91.

claim, but it also concerned a product characteristic (use of mannitol) featured in Copaxone for 15 years already. After filing EP ‘335, Teva continued to pursue divisionals with similarly minor differentiating features (e.g. pH value, combination of mannitol and pH values, pre-filled injection, see Table 16). This allowed Teva to avoid the prohibition of “double patenting” and to have three additional divisional patents granted in the following 5 years. These features also clearly show that the discrepancy between the label and the patent claims was not the key driver for the filing of divisionals in the dosage family.

- (1302) Fourth, Teva’s internal documents show that the ultimate goal of withdrawing EP ‘749 was to prevent a final reasoned decision that could establish a damaging precedent for Teva’s remaining dosage divisional patents.
- (1303) Some of Teva’s documents indeed state that “{...}”¹⁶³³ ({...}),¹⁶³⁴ However, Teva’s internal policy encouraged Teva’s reluctance to state the real reasons behind the withdrawal. The claim that the alleged mismatch between the patent claims and the label was the reason for Teva’s withdrawal of the patent appears primarily in emails with broader circulation and appears to have been vetted by various line managers.¹⁶³⁵ At the same time, {...} were careful to minimise the paper trail when it came to internal discussions concerning the merits of their patents. In June 2016, {...}, wrote in a bilateral email: “{...}”.¹⁶³⁶ Thus, the notes and correspondence between {...}, outside the conventional corporate communication channels, allow the most reliable insight into the real reasons for the withdrawal.
- (1304) In this context, {...} expose what appears to be the true reasons for the withdrawal of EP ‘749. {...}. {...}. The document allows for a double conclusion. It not only confirms that Teva withdrew EP ‘749 “{...}”, but also that prior to revoking EP ‘749, Teva was already planning to also “{...}” for the same reason – to avoid invalidity.
- (1305) Similarly, internal correspondence {...} from January/February 2017 shows that withdrawal of EP ‘749 was urgent to avoid any possible negative impact of the US decisions¹⁶³⁷ as Teva feared that even a decision of the US courts concerning invalidity of Teva’s dosage patents may have effect on EPO’s decision-making: “{...}”.¹⁶³⁸
- (1306) In addition, a report by a third-party observer ({...}) also describes the evident reasons behind Teva’s withdrawal of EP ‘749: {...}. This report was acknowledged by {...} in an internal follow up email: “{...}”.¹⁶³⁹
- (1307) Teva was careful to withdraw EP ‘749 before any preliminary opinion because of a number of divisionals relying on EP ‘749 as its parent. In this context, Teva’s argument that its withdrawal of EP ‘749 before any opinion on its validity shows that Teva’s conduct was not anticompetitive does not convince. Even though the withdrawal of EP ‘749 occurred shortly after the grant of EP ‘335, it also fits into

¹⁶³³ ID 404-1841, Teva internal email dated 4 January 2017 from {...} to {...}, p. 1.

¹⁶³⁴ ID 404-2142, Teva internal email dated 25 January 2017 from {...} to {...}, p. 1.

¹⁶³⁵ ID 404-2142, Teva internal email dated 25 January 2017 from {...} to {...}.

¹⁶³⁶ ID 455-3063, Teva internal email dated 29 June 2016 from {...} to {...}, p. 1.

¹⁶³⁷ See Recital (1184).

¹⁶³⁸ ID 4513-95180, Teva internal correspondence dated 31 January – 1 February 2017 between {...}, {...} and {...}, p. 1.

¹⁶³⁹ ID 404-1651, Report by {...} on Copaxone patent situation in Europe of 28 April 2017 (pp. 1-7) and subsequent Teva internal email dated 28 April 2017 from {...} to {...}, pp. 1, 5.

Teva's overall strategy of withdrawing as late as possible. Teva wanted to ensure that there is an issued patent in the dosage family that could be enforced against the potential GA entrants and Synthon and its licensees in particular (i.e. EP '335) while also ensuring that there is no TBA opinion (even preliminary) on the patentability of the dosage family. As shown in Section 8.3.3.2, the inventiveness of the entire dosage family hinged on selection of the closest prior art which would be certainly indicated in the TBA's preliminary opinion. It therefore follows that the explanation referring to a "*better enforcement profile*" was not the decisive reason, but rather served to veil Teva's assessment that EP '749 faced a serious threat of being declared invalid.¹⁶⁴⁰

- (1308) Fifth, Teva's response to the Commission's request for information failed to produce evidence to support its claim that EP '335 was filed due to a discrepancy between the Copaxone label and the patent claims. The Commission requested Teva Questions 7(b) and 7(c) of the Article 18(3) Decision of 25 May 2023) to submit all internal documents concerning Teva's decisions to start preparing new divisional applications as well as Teva's decisions to formally file new divisional applications, and the underlying reasons.¹⁶⁴¹ Teva was also asked to specify who in Teva took the decision to file a divisional application and on which date. In its response, Teva failed to provide responsive documents.
- (1309) Initially, Teva explained that "*documents responsive to Questions 7(b) and 7(c) will be contained in the productions in response to Question 7(a)*".¹⁶⁴² The Commission informed Teva that the review of the documents delivered in response to Question 7(a), did not allow the Commission to identify documents that would be clearly and directly responsive to the Questions 7(b) and 7(c) of the Article 18(3) Decision of 25 May 2023.¹⁶⁴³ In an email from 10 October 2023, Teva explained that "*only a very limited number of documents provided would be responsive to questions 7(b) or (c)*". According to Teva, this was because the relevant discussions very often took place

¹⁶⁴⁰ As to Teva's claim that Higher Regional Court Düsseldorf concluded that Teva's withdrawal of EP '749 is not abusive because it had been withdrawn before the preliminary opinion had been issued, it suffices to say that the Higher Regional Court Düsseldorf assessed Teva's conduct from the perspective of different set of rules (and not under Article 102 TFEU) and therefore its legal qualification of Teva's conduct cannot persuade in the present case. Teva, on the other hand, omits to mention that the same Higher Regional Court Düsseldorf also recognised that that EP '749 and EP '335 are "*parallel patents*" implying that there is a connection between their validities thus corroborating Commission's analysis (ID 4032, Teva's Reply to the Statement of Objections, Annex 7.28, p. 22).

¹⁶⁴¹ It should be noted that Questions 7(b) and 7(c) of the Article 18(3) Decision of 25 May 2023 effectively repeat the request from Question 20 of Article 18(2) Request of 3 June 2020. Question 20 of Article 18(2) Request of 3 June 2020 reads "*Please explain the **strategic and legal considerations for filing each divisional patent** application relating to Copaxone parent patents (EP1799703 for process, EP2405749 for dosage regimen and EP3050556 for cold filtration). **Please provide all contemporaneous internal documents discussing the need and the strategic and legal considerations for filing divisional patent applications relating to Copaxone.** [...]*" (emphasis added). The Commission notes that Teva's reply to Question 20 of Article 18(2) Request of 3 June 2020 did not include documents that were subsequently submitted as Annexes 7.10-7.22 of the Reply to the Statement of Objections.

¹⁶⁴² ID 4894, Teva's reply to Article 18(3) Decision of 25 May 2023, p. 6. By Question 7(a) of Article 18(3) Decision of 25 May 2023 the Commission asked Teva to deliver all Documents that have been prepared by or for, or received by {...}.

¹⁶⁴³ ID 4926, Email from the European Commission to Teva's external counsel of 4 October 2023, p. 1. See also ID 4971, Email from the European Commission to Teva's external counsel of 11 October 2023, p. 1.

orally between {...} or because responsive documents may be protected by LPP.¹⁶⁴⁴ In an email of 11 November 2023, Teva further explained that “*the decision to prepare and file divisionals in the dosage family might have been either exclusively or predominantly orally (other than EP '335, for which we provided relevant communication in our RSO)*”.¹⁶⁴⁵

- (1310) In reply to these comments, the Commission informed Teva that the documents referred to by Teva (Annexes 7.10-7.22 of the Reply to the Statement of Objections) do not include any express confirmation of Teva’s intention to start preparing a new divisional application (to be issued as EP ‘335) and that these documents in themselves could not be considered as responsive to Questions 7(b) and (c) of the Article 18(3) Decision of 25 May 2023.¹⁶⁴⁶ In response, Teva noted that Annexes 7.10-7.22 of the Reply to the Statement of Objections “*are not responsive to those Q7bc Parameters*” (i.e. they do not reveal a decision to start preparing or actually file an application for EP ‘335), allegedly because “*EP '335 was filed in the context of very specific circumstances, where multiple discussions took place before a decision was made to start preparing a filing*”. According to Teva, “*the other divisionals were filed routinely and would not have given rise to similar discussions*”.¹⁶⁴⁷
- (1311) With respect to the amendment of the application for EP ‘962, Teva noted that “{...}”.¹⁶⁴⁸ This, however, is in contrast to Teva’s allegations that there were multiple discussions related to the filing of EP ‘335 (according to Teva, EP ‘335 was filed and EP ‘962 was amended for the same reason – to remedy the alleged enforcement gap) all the while the contemporaneous documents mention only “{...}”.¹⁶⁴⁹
- (1312) In sum, Teva’s documents submitted in reply to Questions 7(b) and (c) of the Article 18(3) Decision of 25 May 2023 do not clarify the factual situation as alleged by Teva concerning the reasons and the timing of the decision to file EP ‘335. Teva’s response to the Article 18(3) Decision of 25 May 2023 thus failed to substantiate with contemporaneous documents its explanation that EP ‘335 was filed due to a discrepancy between the Copaxone label and the patent claims.
- (1313) In view of the foregoing, the Commission concludes that contrary to what Teva alleges, Teva’s explanations do not reveal plausible legitimate objectives for its comprehensive patenting conduct. In any event, Teva’s claims are unable to rebut the Commission’s finding that Teva’s conduct was part of a broader anticompetitive strategy to obstruct and delay the legal review of the validity of Teva’s patents, artificially prolonging legal uncertainty regarding those patents and thereby hindering entry and/or expansion of GA competitors (in particular, Synthon GA and its licensees).

¹⁶⁴⁴ ID 4963, Email dated 10 October 2024 from Teva’s external counsel to the European Commission, pp. 1-2.

¹⁶⁴⁵ ID 5187, Email dated 6 November 2023 from Teva’s external counsel to the European Commission, p. 1.

¹⁶⁴⁶ ID 5197, Email dated 10 November 2023 from the European Commission to Teva’s external counsel, p. 1. The Commission also informed Teva that the search method proposed by Teva would not identify documents referred to by Teva (Annexes 7.10-7.22 of the Reply to the Statement of Objections) as responsive to Questions 7(b) and (c) of Article 18(3) Decision of 25 May 2023.

¹⁶⁴⁷ ID 5497, Email dated 24 November 2023 from Teva’s external counsel to the European Commission, p. 2.

¹⁶⁴⁸ ID 4905, Teva’s reply to Article 18(2) Request of 20 July 2023, p. 9.

¹⁶⁴⁹ See Recital (1299).

8.3.7. *Conclusion: Teva's comprehensive patenting conduct did not constitute competition on the merits*

- (1314) Teva artificially extended exclusivity for Copaxone by creating multiple divisional patents with largely overlapping content. To compensate for their weakness and risk of revocation, Teva strategically staggered their filing and thereby prevented the parallel review of its patents.
- (1315) When faced with the expected revocation of a patent, Teva withdrew the approval of the text of the patent concerned (just) in time to prevent a reasoned revocation decision. Since the legal proceedings concerning the validity of Teva's patents hinged on the same subject-matter for each patent family, Teva was concerned about the possible invalidation of its patents by reasoned decision, which would have a damaging precedent effect (“{...}”) for its remaining divisionals and preliminary injunction requests (“{...}”¹⁶⁵⁰). However, it is part of normal competition in the pharmaceutical product that patents are open to challenge and that such challenges are concluded with well-reasoned decisions by a competent authority regarding the validity of the patent concerned. Such decisions resolve legal uncertainty as early as possible – either by upholding the patent, or by invalidating it.
- (1316) Although, in isolation, a patent holder may exercise its rights by filing and withdrawing its patents, such conduct falls outside the scope of competition on the merits in cases where the regulatory procedures are used in such a way as to prevent or to hinder the entry of competitors on the market and where the conduct serves no legitimate interests. The combination of staggered divisional filings and strategic withdrawals enabled Teva to game the system and shield its patents from damaging precedents for as long as possible. Accordingly, considered as a whole, Teva's conduct reveals a strategy to delay the legal review of its patents, prolonging legal uncertainty regarding their validity. This hindered the entry and expansion of GA competitors, Synthron and its licensees in particular. Teva thus artificially prolonged obstacles to market entry until the EPO's final revocation of the last remaining patents in the dosage family (i.e. until 7 February 2024 when TBA confirmed the revocation of EP '962 and EP '172).
- (1317) Contrary to Teva's claims, the withdrawal of patents cannot be explained by the avoidance of procedural costs when patents are withdrawn shortly before a final decision on validity only to continue litigation of the same issues regarding subsequent divisional patents.¹⁶⁵¹ In those instances, a withdrawal may even increase overall procedural costs, as it prevents a reasoned decision which would act as a precedent and thereby avoid re-examination and re-litigation of the same subject-matter.
- (1318) Similarly, Teva's conduct cannot be explained by the claim that it was motivated by its willingness to simplify and rationalize the enforcement of its patent portfolio. Both the process and the dosage divisional patent families concerned minor variations to a product that had been very successfully commercialised since 1997 and thus patent portfolio management is no valid explanation for Teva's staggered filing of its divisionals. Finally, the claim that Teva's conduct can be explained by the fact that later generation patents would have been stronger or better suited for enforcement is contradicted by Teva's own internal contemporaneous documents

¹⁶⁵⁰ ID 455-1205, Teva internal email dated 2 February 2015 from {...} to {...} and others, p. 1.

¹⁶⁵¹ The Higher Regional Court of Munich similarly considered that cost savings are not a plausible explanation for Teva not defending a patent covering a blockbuster drug (see Recital (1284)).

revealing that the patents were considered as weak and likely to be revoked by the TBA and that, by withdrawing its patents, Teva aimed at avoiding a damaging precedent for the remaining divisionals.

- (1319) It follows that Teva’s divisionals game obstructed and delayed the effective legal review of Teva’s patents, not due to their strength but by misusing the patent system and gaming patent procedures. Teva’s explanations cannot alter the Commission’s conclusion that such conduct does not constitute competition on the merits.

8.4. Teva’s divisionals game was capable of having anticompetitive effects

- (1320) As set out in Section 8.2 above, “conduct is capable of constituting an abuse of a dominant position if it is demonstrated that it has – at least potential – anticompetitive effects that hinder the maintenance of the degree of competition existing on the market as a whole or the growth of that competition”.¹⁶⁵² The capability of anticompetitive effects is assessed ex ante, from the perspective at the time of the conduct and is independent from subsequently occurring separate events which may increase or limit the effects of the conduct. As the General Court held in *AstraZeneca*, whether a conduct “is abusive in nature cannot depend on the contingencies of the reactions of third parties”.¹⁶⁵³ The Court of Justice confirmed in the same case that “the existence of an abuse is not affected by the fact that that strategy did not succeed in some countries”.¹⁶⁵⁴
- (1321) Teva’s comprehensive patenting conduct was capable of having anticompetitive effects on the market for GA as it: (i) artificially prolonged legal uncertainty (see Section 8.4.1) and in addition (ii) strengthened Teva’s ability to enforce its patents in national courts beyond the merits of those patents (see Section 8.4.2). As such, Teva’s conduct was capable of excluding Synthon and its licensees in the Relevant Member States by deterring and hindering their market entry and expansion (see Section 8.4.3)
- (1322) First, in Section 8.4.1, the Commission describes the direct effects of Teva’s comprehensive patenting conduct on the effective legal review of its patents at EPO level and demonstrates how it artificially prolonged legal uncertainty concerning the validity of Teva’s patents for a significant period of time. This conduct was capable of having anticompetitive effects as it hindered market entry and/or expansion of GA competitors (in particular, Synthon and its licensees). This is illustrated *inter alia* by the fact that the market entry of Synthon GA was both delayed in time and restricted in scope. Furthermore, the artificially prolonged legal uncertainty was capable of deterring potential entrants from entering the market with a competing GA. To date, nine years after the expiry of Teva’s EP ‘888 (main patent protecting composition of GA within a specific molecular weight range) and despite the high turnover achieved with GA in the EU (which, in markets where competition is not hindered, would

¹⁶⁵² Case C-549/10 P, *Tomra Systems*, paragraphs 41 to 45; Case T-612/17, *Google and Alphabet v Commission (Google Shopping)*, paragraph 504.

¹⁶⁵³ Case T-321/05, *AstraZeneca v Commission*, paragraph 360.

¹⁶⁵⁴ Case C-457/10 P, *AstraZeneca*, paragraph 111. See also Case C-377/20, *Servizio Elettrico Nazionale and Others*, paragraph 53 and judgment of the Court of first instance of 18 November 2020, *Lietuvos geležinkeliai v Commission*, T-814/17, ECLI:EU:T:2020:545, paragraph 80.

normally attract entry),¹⁶⁵⁵ Synthron GA remains Teva's only competitor for Copaxone and its entry was significantly delayed by Teva's conduct.¹⁶⁵⁶

- (1323) Second, in Section 8.4.2, the Commission outlines how Teva enforced its patents in national courts. While Teva's enforcement of its patents is not considered anticompetitive in itself, it was enabled by Teva's divisionals game (see Section 8.3). The Commission finds that Teva's comprehensive patenting conduct enabled Teva to enforce its patents beyond what would have been possible based on the merits of its patents. In particular, Teva was able to apply for preliminary injunctions based on its exclusive rights that it could artificially extend via the multiplication of significantly overlapping patents in two complementary patent families (see Sections 8.3.2.1.1 and 8.3.2.1.2) and by obstruction and delay of their effective legal review (see Section 8.3.3.6.1 and 8.3.3.6.2).
- (1324) Teva first attempted to prevent market entry by sending warning letters to potential GA entrants. When market entry occurred nonetheless, Teva initiated litigation and sought to obtain preliminary injunctions. In particular, in 5 Relevant Member States, Teva succeeded in obtaining preliminary injunctions preventing the commercialisation of Synthron GA based on the patents obtained and shielded by Teva's comprehensive patenting conduct. This confirms that the described anticompetitive deterrent effect was not hypothetical, but at least potential via temporary market exclusion through preliminary injunctions.
- (1325) Third, in Section 8.4.3, the Commission sets out in detail how Teva's comprehensive patenting conduct was capable of having anticompetitive effects in the Relevant Member States and in fact resulted in such effects. The effects in these Member States were further amplified in two ways: (i) due to the price referencing rules that apply across the EU, the delayed or hindered market entry (and thus delay of price competition) in one Member State also influenced the pricing level in other Member States, and (ii) the two patent families were complementary¹⁶⁵⁷ and enabled Teva to sequentially hinder first the market entry of generic-like versions of 20 mg GA (by relying on the Process Patent Family) and, subsequently, that of generic-like versions of 40 mg GA (by subsequently relying on the Dosage Patent Family).¹⁶⁵⁸
- (1326) In Section 7.4 of its Reply to the Statement of Objections, Teva claims that since "*the Filings [were] legitimate, only the possible impact on competition of Withdrawals*

¹⁶⁵⁵ Based on the Commission's calculation derived from IQVIA, the market for GA in the EU can be estimated at approximately {...} in 2021.

¹⁶⁵⁶ On deterrent effect on other potential market entrants see Section 8.4.1.3.

¹⁶⁵⁷ On complementarity between the two families and importance of dosage patenting being granted later than the process patents see Section 8.3.4 and Recital (1255).

¹⁶⁵⁸ Teva reiterates that the patent filings covered by this Decision fell within the scope of competition on the merits as they were made (i) independently from the withdrawals, and (ii) for legitimate reasons related to IP considerations as to how to best protect Copaxone (ID 4032, Teva's Reply to the Statement of Objections, paras. 827-830, 873-878). Teva's arguments on (i) separate assessment of filings and withdrawals and on (ii) Teva's explanations for individual filings have been rebutted above (see in particular Sections 8.3.1, 8.3.2.1.1, and 8.3.2.1.2). It suffices to repeat that Teva's insistence that filings and withdrawals should be looked at as two separate conducts and assessed accordingly contradicts: (i) contemporaneous documents explaining that both patent filings and withdrawals were constituent elements of Teva's comprehensive patenting conduct/strategy; (ii) Teva's own arguments which repeatedly associates withdrawals of earlier patents with existence of the subsequent divisionals as well as (iii) contemporaneous third party assessments (e.g. Regional Court of Munich (LG München) and market intelligence company {...}).

should be considered".¹⁶⁵⁹ Teva further argues that the Commission's theory is grounded on the premise that absent the withdrawals, the patents in question would have been invalidated. However, according to Teva, the Commission should actually show that invalidation would have accelerated the oppositions and appeals on the remaining patents and that the OD and/or TBA would have been bound by the outcome of the previous TBA's decision. In addition, the anticompetitive effects of the investigated conduct cannot only be "hypothetical". They must be sufficiently demonstrated and, in fact, "likely", in light of all the prevailing circumstances, for the conduct to be considered an abuse.¹⁶⁶⁰ Teva then attempts to show that the Commission's analysis did not meet these requirements.

- (1327) Teva's arguments should be rejected. Most importantly, Teva's arguments are grounded on three incorrect premises: (i) that filings and withdrawals are two separate conducts which should be assessed separately, including with respect to their effects; (ii) that any impact of patent filings should not be taken into account; and (iii) that the Commission should show that each and every withdrawal was likely to have anticompetitive effects (in isolation from the filings, which are not to be taken into account).
- (1328) As regards these premises, the Commission has established that Teva's comprehensive patenting conduct consisted of a combination of patent filings and patent withdrawals. The evidence, Teva's own all-inclusive approach to patenting, as well as the legal and economic background of Teva's comprehensive conduct support conclusion that Teva's staggered filings and strategic withdrawals represent a single conduct and should not be assessed separately (see Section 8.3.1). Therefore, the capability of Teva's actions to exclude competition should be assessed considering Teva's conduct as a whole (see Section 8.2), including both the multiple filings of the overlapping divisional patents in a staggered way (see Section 8.3.2) and the obstruction of the legal review of the challenged patents by way of their strategic withdrawals (see Section 8.3.3). As shown in the following sections, this comprehensive patent conduct by Teva, i.e. its "divisionals game", as summarized in Teva's own words: "{...}"¹⁶⁶¹, was capable of having the effect of restricting or distorting competition by excluding GA competitors, Synthron and its licensees in particular, in the Relevant Member States through deterring and hindering their market entry and expansion (see Section 8.4.3).
- (1329) As to the legal standard to assess the effects of Teva's conduct, it suffices to reiterate (see Recitals (1038)-(1040)) that Article 102 TFEU prohibits behaviour that tends to restrict competition or is capable of having that effect, regardless of its success.¹⁶⁶² In this context, and contrary to Teva's assertion, the Commission is not required to show that each particular action as a constituent part of a comprehensive patenting conduct (i.e. each and every withdrawal) is likely – or more likely than not - to produce anticompetitive effects on its own or that an invalidation of an earlier patent would have actually accelerated the oppositions and appeals on the remaining

¹⁶⁵⁹ ID 4032, Teva's Reply to the Statement of Objections, paras. 827-830. See also ID 5695, Teva's Reply to the Letter of Facts I of 9 February 2024, para. 274.

¹⁶⁶⁰ ID 4032, Teva's Reply to the Statement of Objections, paras. 831-837. See also ID 5695, Teva's Reply to the Letter of Facts I of 9 February 2024, para. 273.

¹⁶⁶¹ ID 404-2555, Teva internal email dated 16 March 2016 from {...} to {...} and others.

¹⁶⁶² C-165/19 P, *Slovak Telekom*, paragraph 109; Case C-549/10 P, *Tomra and Others v Commission*, paragraph 68; Case T-321/05, *AstraZeneca v Commission*, paragraph 347; confirmed on appeal in Case C-457/10 P, *AstraZeneca v Commission*, paragraphs 109 and 111. See also T-219/99, *British Airways v Commission*, paragraphs 297 and 298.

patents.¹⁶⁶³ In Sections 8.4.1 and 8.4.2, the Commission explains why the conduct – as a whole – was objectively capable of having anticompetitive effects, and also establishes that, in certain instances, Teva’s conduct had actual anticompetitive effects.¹⁶⁶⁴

- (1330) A clear example of the capability of Teva’s conduct to restrict or distort competition, in particular by excluding Synthon and its licensees, can be found with respect to the process patents. When a product claim incorporated in the EP ‘703 parent process patent was invalidated by the OD for added matter on 27 February 2012 Teva simply incorporated the product claim in the second generation divisional (EP ‘924), where the validity challenge would come much later, and where it survived until the revocation by the TBA several years later on 12 September 2017 (see Recital (1104)). In the meantime, this product claim enabled Teva to obtain interim injunctions barring Synthon GA from the market in Czechia, Italy and Poland. Had Teva not obstructed and delayed the legal review of this claim (by withdrawing the parent patent and inserting the claim in the second generation divisional) the question of the validity of this product claim (and the related legal uncertainty) would have been resolved much earlier, to the likely benefit of Teva’s competitors, and ultimately patients and health care systems.
- (1331) Finally, contrary to Teva’s claims,¹⁶⁶⁵ the Commission does not, and does not need to, independently conclude on the validity of Teva’s patents.¹⁶⁶⁶ It does however take into account Teva’s contemporaneous documents, including those in which Teva assesses the strength and validity of its patents as well as the documents originating from the EPO (including ODs and TBAs decisions on Teva’s patents) to show that, from an *ex ante* perspective, Teva’s comprehensive patenting conduct was capable of having exclusionary effects.

8.4.1. *The direct anticompetitive effects of Teva’s comprehensive patenting conduct*

- (1332) By staggering the filing of divisional patent applications, combined with strategic withdrawals to prevent reasoned revocation decisions by the TBA, Teva artificially prolonged the legal uncertainty concerning the validity of its patents. Such, artificially prolonged, legal uncertainty was capable of deterring and hindering the market entry and uptake of generic-like versions of GA. As a result, Teva’s conduct was capable of hindering the emergence and/or growth of price competition to Copaxone from such generic-like version of GA. Teva’s conduct did in fact hinder and delay the market entry of, and thus price competition from, Synthon GA.
- 8.4.1.1. Teva’s conduct contributed to artificially prolonging legal uncertainty for significant periods
- (1333) The timely legal review of a patent’s validity is an essential part of the overall balance of interests in the patent system and competition in the pharmaceutical sector. The risk of false positives (i.e. unmeritorious patents granted but subsequently

¹⁶⁶³ As to Teva’s claim that the Commission should establish that the OD and/or TBA would have been bound by the outcome of the previous TBA’s decision, it suffices to reiterate that the Commission indeed shows that the revocation decisions could have precedent effect for the entire patent family (Section 8.3.3.1) and that the EPO and national courts confirmed the precedent effect of TBA’s decisions specifically for Teva’s dosage patents (Section 8.3.3.5).

¹⁶⁶⁴ For assessment of actual effects of Teva’s conduct in individual Relevant Member States see Section 8.4.3.

¹⁶⁶⁵ ID 4032, Teva’s Reply to the Statement of Objections, para. 646 and 870-872, see also ID 5695, Teva’s Reply to the Letter of Facts I of 9 February 2024, para. 256.

¹⁶⁶⁶ See Recital (1073) and footnote 1267.

revoked on appeal) must be balanced with the risk of false negatives (i.e. meritorious patents granted only after an unduly extended examination or on appeal). The timely resolution of proceedings is part of this balance of interests. If proceedings to revoke unmeritorious patents are artificially prolonged, the negative effects of false positives are significantly increased, contrary to the “*public interest to eliminate any obstacle to economic activity which may arise where a patent was granted in error*”.¹⁶⁶⁷ Thus, obstructing and/or delaying the legal review of patents undermines the effectiveness of the patent system as a whole.

- (1334) This is exactly what Teva’s comprehensive patenting conduct did. It rendered legal review of its patents ineffective by preventing their timely resolution and thereby artificially prolonging legal uncertainty concerning the validity of its patents.¹⁶⁶⁸
- (1335) In line with the objective to reduce legal uncertainty, the EPO has strived to substantially accelerate its proceedings in the last years. In 2019, the average duration of opposition proceedings was 18.7 months (compared to 30 months in 2014¹⁶⁶⁹), and more than 65% of appeal proceedings were settled within 30 months.¹⁶⁷⁰ Legal review consisting of both opposition and appeal proceedings is thus likely to last about four years.¹⁶⁷¹ Moreover, the patent examination and appeal instances of the EPO adhere to the *res iudicata* principle,¹⁶⁷² which fosters efficiency and reduces legal uncertainty in situations where, identical issues are at stake, as in the case of divisional patents.
- (1336) These efforts to increase the effectiveness of the legal review are undermined when a patent holder misuses the system by preventing the EPO from issuing a final decision on the validity of a patent claim and forcing competitors to restart proceedings concerning a new divisional, which essentially contains the same claims.¹⁶⁷³ By withdrawing the approval of the text of a patent before a final decision can be issued, the patent holder may prolong legal uncertainty as long as there are other divisional patents to rely on or – in the words of Teva – as long as there are enough “{...}”.¹⁶⁷⁴ The patent holder may withdraw its patent at any time. For example, Teva withdrew EP ‘528 at the latest possible moment – during the EPO hearing (see Section 8.3.3.6.1).¹⁶⁷⁵

¹⁶⁶⁷ Case C-193/83, *Windsurfing International v Commission*, paragraph 92.

¹⁶⁶⁸ Teva was able to influence and prolong the timing of prosecution of its patents and thus push back effective resolutions of their validity as later granted patents would reach opposition and appeal stages at later dates. Delays in patent grants did not affect the ability of Teva’s conduct to exclude competitors as Teva always had at least a granted patent “{...}” (see Section 8.3.2.2 and particularly Recital (1128)).

¹⁶⁶⁹ EPO Quality Report 2019, p. 26.

¹⁶⁷⁰ TBA Annual Report 2019, pp. 7 and 9.

¹⁶⁷¹ And in the pharma sector it is likely that the revocation of an unmeritorious patent would only occur in appeal proceedings. See statistics on TBA decisions revoking patents upheld by the OD involving patents classified into the IPC codes A61K and A61P in Section 4.1.

¹⁶⁷² See Section 8.3.3.4.

¹⁶⁷³ As explained by {...} ahead of the OD hearing on EP ‘749: “{...}” (ID 404-2085, Teva internal email dated 2 December 2015 from {...} to {...} and others, p. 1).

¹⁶⁷⁴ ID 404-2555, Teva internal email dated 16 March 2016 from {...} to {...} and others, p. 1.

¹⁶⁷⁵ Teva argues that in almost all Relevant Member States where Teva requested a preliminary injunction based on a given patent family, all such PI requests were *ab initio* based on all relevant patents. Teva did not, in any Relevant Member State, apply for a preliminary injunction based on a given patent, and then, following the withdrawal of that patent at the EPO, apply for a preliminary injunction based on another patent in the same family. As a consequence, manufacturers/distributors of competing GA products did not have to repeatedly fight before the same national courts for the different patents of the

- (1337) Since the abolition of the time limit for filing divisional patents by the EPO in 2014, patent holders can continue filing additional divisionals as long as the direct parent patent application (be it the original parent patent or an earlier generation divisional patent) is still pending, in other words, before its grant (see Recital (49)). This allowed Teva to strategically file its last dosage divisional patent (i.e. EP ‘286) in June 2018, almost eight years after filing the Original Dosage Patent (and just 6 days before the grant of EP ‘962, the direct parent patent of EP ‘286). While the filing fees increase depending on the generation of the divisional patents, the costs incurred are insignificant compared to the profits that may be protected by such practices.¹⁶⁷⁶
- (1338) As illustrated in Figure 39 and Figure 40, Teva not only staggered filings of multiple divisional patents that needed to be challenged by a potential competitor but also multiplied the procedural delays by strategically withdrawing those patents when challenged, in order to prevent a precedent that would have accelerated the remaining proceedings. As a result, potential entrants (including Synthon) had to repeatedly challenge the validity of Teva’s patents on similar grounds in a staggered manner but did not obtain a final reasoned decision by a TBA on the process patents until 2017 as Teva withdrew its EP ‘703 and EP ‘528 patents before such a decision could be issued. Thus, Teva effectively prevented its process patents from being revoked by the TBA on the merits for a significant period (and the same applies to its dosage patents). Each divisional was in force for three and a half to four years (EP ‘962 and EP ‘172 were in force for five and half years) and contributed to delaying a reasoned decision on the validity of Teva’s patents’ claims by the TBA.
- (1339) Teva was able to delay the adoption of a reasoned decision by the TBA on a process patent (i.e. EP ‘924, the last divisional patent of the process patent family) until 12 September 2017 and on a dosage patent (i.e. EP ‘335) until 10 September 2020. Teva’s conduct with respect to its process patents delayed a reasoned TBA decision on their validity by two years and seven months (eight and 23 months via withdrawals of EP ‘703 and EP ‘528 respectively), during which legal uncertainty hindered market entry. As regards the dosage patents, Teva was able to delay the first reasoned TBA decision by two years and 10 months via the withdrawal of EP ‘749. When a TBA was finally able to issue a reasoned decision, it revoked both the process divisional patent EP ‘924 and the dosage divisional patent EP ‘335. Teva’s two remaining dosage patents (EP ‘926 and EP ‘172) were then revoked on 7 February 2024.

same Family as a consequence of the withdrawal of any Process or Dosage Family patent (ID 4032, Teva’s Reply to the Statement of Objections, para. 876). Teva’s argument does not convince. The fact that Teva immediately relied on all of the available patents does not in any way preclude the Commission’s conclusion that subsequent divisionals were grounds for preliminary injunctions following the withdrawal/revocation of the parent patent. This just explains how Teva always had a “{...}”. Teva’s argument is also clearly contradicted by the facts relied on by Teva. For example, in Czechia, while indeed preliminary injunctions were granted initially based on all of the available divisionals, they stayed in force based on the subsequent ones (EP ‘924 in the process family and EP ‘962 and EP ‘172 in the dosage family) after the withdrawal (EP ‘528 in the process family) or revocation (EP ‘335 in the dosage family) of the earlier patent (see Recitals (1395)-(1398)). Also, in Belgium there was no need for Teva to rely on the subsequent patents since {...} (‘335). The facts in Belgium also disprove Teva’s claim that it always filed for PIs based on all available patents (see Recitals (1392)-(1394)).

¹⁶⁷⁶ For example, a Teva presentation of June 2017 refers to “{...}” as a result of measures to reduce the impact of competing GA (ID 455-247, CCP DT, June 2017, p. 9).

- (1340) As a result, validity challenges, which are “*part of normal competition in the sectors where there exist exclusive rights in relation to technology*”¹⁶⁷⁷ were rendered ineffective and legal uncertainty was prolonged, allowing Teva to benefit from artificially extended patent protection until 7 February 2024, stretching far beyond the expiry of its main patent for Copaxone, EP ‘888, on 23 May 2015. This extension was not based on the qualitative strength of Teva’s patents, but resulted from its “divisionals game”, which provided it with more “{...}” with the ultimate objective to “{...}” effective competition from Synthon GA.¹⁶⁷⁸
- (1341) Teva maintains that withdrawals could not have prolonged legal uncertainty or delayed the process since, in the case of a revocation by the OD of a subsequent patent, Teva would have appealed the decision with suspensive effects.¹⁶⁷⁹ The timeline for appeal would be exactly the same as in appeals launched by the opponents. Teva further notes that the opponents could have sought the acceleration of the ongoing appeal proceedings on EP ‘962 and EP ‘172 but did not do so. Teva also argues that any influence Teva might have had over the prosecution of individual patents could not have contributed to delays in the effective legal review of its patents and to an artificial prolongation of legal uncertainty.¹⁶⁸⁰ Therefore, according to Teva, insofar as there was any prolongation of the “legal uncertainty” as to the validity of its patents, this was due to the opponents’ failure to take the necessary steps to accelerate the proceedings and resolve any such legal uncertainty earlier.¹⁶⁸¹
- (1342) Teva’s arguments do not convince. Teva isolates the effects that can be attributed to the withdrawals only and completely disregards the staggered filings of multiple patents sharing essential features, which equally contributed to the effects of Teva’s conduct. Teva’s arguments therefore cannot rebut the Commissions conclusions presented in the Recital (1328) and this Section 8.4.1.1.¹⁶⁸² Contrary to Teva’s truncated analysis, the effects of Teva’s conduct follow not only from the prolonged appeal timelines but, more importantly, also from Teva’s ability to rely on consecutive, patents with overlapping claims regardless of those timelines and in the necessity for potential GA entrants to challenge these multiple patents filed in a staggered manner one after the other. The limits of Teva’s analysis can be illustrated with the developments in Teva’s process family. As explained in Section 8.3.2.1.1, it was not only the withdrawal of the Original Process Patent that contributed to the legal uncertainty but also the staggered filing of the divisionals. The second one of

¹⁶⁷⁷ Case C-307/18, *Generics (UK) and Others*, paragraphs 51 and 81.

¹⁶⁷⁸ ID 404-2555, Teva internal email dated 16 March 2016 from {...} to {...} and others, p. 1. ID 404-1705, Teva internal email dated 27 September 2016 from {...} to {...}, p. 2.

¹⁶⁷⁹ Teva also alleges that the Commission’s conclusion on withdrawals having the effect of prolonging legal uncertainty is based on a limited number of internal documents, which all rely upon the view of a single former Teva employee ({...}). According to Teva, the fact that a limited number of documents show that one individual within Teva was concerned by the possible effect of a given event (here, the invalidation of the withdrawn patents) do not objectively demonstrate that this concern was likely to materialise (ID 4032, Teva’s Reply to the Statement of Objections, paras. 842-853). Teva’s arguments on role played by {...} and evidentiary background of the Commission’s conclusions have been answered in detail in Recital (1185) above.

¹⁶⁸⁰ ID 5695, Teva’s Reply to the Letter of Facts I of 9 February 2024, paras. 271-285.

¹⁶⁸¹ ID 4032, Teva’s Reply to the Statement of Objections, paras. 842-853. See also ID 5695, Teva’s Reply to the Letter of Facts I of 9 February 2024, paras. 286-290, 308-311.

¹⁶⁸² The Commission’s assessment of the effects of Teva’s conduct is based on the conclusion that Teva’s conduct contributed to delays in legal review and to prolonging legal uncertainty. In this context, the entire conduct (including filings and withdrawals) must be considered as a whole (see Section 8.3.1 above) in order to assess its capability to cause exclusionary effects.

these divisionals (EP'924) was then used, as Teva explains, to salvage the crucial product claim (see Recital (1104)).

- (1343) In addition, while the application of the *res iudicata* principle based on the reasoned invalidation of a patent may not lead to an automatic and immediate subsequent decision on the patents from the same family, it still leads to quicker outcomes compared to a situation where the same substantive questions need to be reassessed each time. For example, the opposition proceedings against both EP '962 and EP '172 benefited from the earlier reasoned revocation of EP '335 by the TBA and it took a little bit more than a year for the OD to invalidate both patents. Furthermore, a negative reasoned decision from the TBA makes it more difficult for a patent holder to continue enforcing the remaining patents from the same family in national courts. For example, in Germany Teva did not bring any requests for preliminary injunctions based on the remaining divisionals after the revocation of EP '335.¹⁶⁸³
- (1344) Finally, the Commission notes that third party contingencies, such as actions of Teva's competitors, are not relevant for the Commission's assessment of whether Teva's conduct was capable of having anticompetitive effects. The assessment of whether a conduct is capable of having exclusionary effects is based on the facts and circumstances existing at the time when the conduct was implemented.¹⁶⁸⁴ Moreover, where it is established that a conduct is objectively capable of restricting competition,¹⁶⁸⁵ this cannot be called into question by the actual reaction of third parties.¹⁶⁸⁶ In any event, the Commission notes that Teva's procedural actions before the EPO did in fact effectively contribute to the prolongation of the proceedings.¹⁶⁸⁷

8.4.1.2. The artificially prolonged legal uncertainty was capable of hindering the market entry and expansion of Synthron GA

- (1345) In this section, the Commission outlines how the artificially prolonged legal uncertainty was capable of hindering the market entry of Synthron and its licensees, in particular by (i) delaying entry and reducing it in scope, and (ii) ensuring that a timely market entry would only be possible by launching at risk.
- (1346) The mere possession by an originator company of an exclusive right can deter generic competitors from entering the market.¹⁶⁸⁸ This effect can be amplified when a company misuses the patent system and more specifically misuses divisional patent procedures. In the Commission Pharmaceutical Sector Inquiry, market participants reported that patent holders maintain pending divisional applications as "*a constant threat and uncertainty to generic companies over years*"¹⁶⁸⁹ and that even if the "*grant of one of them be denied, the other still pending applications are such a threat to the generic companies that many of them are extremely reluctant to enter the*

¹⁶⁸³ Some other preliminary injunctions could have also been avoided. For example, if one assumes that the OD reviewing EP '335 would have reacted to the revocation of the Original Dosage Patent (which Teva withdrew to avoid the revocation) in the same way that the ODs reviewing EP '962 and EP '172 reacted to the revocation of EP '335 by TBA (ODs revoked these two patents), EP '335 would not have survived the OD review and would not have been the basis for the grant of preliminary injunctions as of 2019.

¹⁶⁸⁴ C-457/10 P, *AstraZeneca*, paragraph 110.

¹⁶⁸⁵ The Court of Justice also refers to the 'intrinsic capacity' of the conduct to produce effects: see Case C-413/14 P, *Intel v Commission*, paragraph 140; Judgment of 14 September 2022, T-604/18, *Google and Alphabet v Commission (Google Android)*, EU:T:2022:541, paragraphs 640-641.

¹⁶⁸⁶ Case T-321/05, *AstraZeneca v Commission*, paragraph 360.

¹⁶⁸⁷ For examples of Teva's efforts aiming at prolongation of the EPO proceedings, see Recital (1130).

¹⁶⁸⁸ Case T-321/05, *AstraZeneca v Commission*, paragraph 362.

¹⁶⁸⁹ Pharmaceutical Sector Inquiry, Final Report, 8 July 2009, paragraph 533.

market”.¹⁶⁹⁰ This legal uncertainty can only be removed by obtaining decisions by the competent bodies, in particular the EPO, as some national courts are reluctant to invalidate patents as long as opposition and appeal proceedings are pending before the EPO.¹⁶⁹¹

- (1347) The artificially prolonged legal uncertainty created by Teva’s misuse of regulatory procedures (namely, the combination of multiple divisional patents with overlapping content, their staggered filing and their strategic withdrawal to avoid a reasoned decision on their validity) was in itself capable of hindering the market entry or expansion of Synthon GA. These direct anticompetitive effects of Teva’s divisionals game are independent of the anticompetitive effects brought about by Teva’s increased ability to enforce its patents (see Section 8.4.2). In other words, Teva’s comprehensive patenting conduct was capable of having anticompetitive effects irrespective of whether Teva tried and succeeded to obtain preliminary injunctions against Synthon GA before national courts.
- (1348) In fact, the market entry of Synthon GA was delayed and reduced in scope due to Teva’s conduct at issue. Teva anticipated that “{...}”¹⁶⁹² instead of launching at risk. As explained in Teva’s internal email from July 2017, “{...}”.¹⁶⁹³
- (1349) As a result of the artificially prolonged legal review of the process patents before the EPO (lasting from October 2010 until September 2017), Synthon’s licensees, despite having tried to “clear the way” by launching separate invalidity actions against all three patents before the EPO, decided to launch 20 mg Synthon GA at risk¹⁶⁹⁴ and thereby exposed themselves to Teva’s enforcement of its process patents.¹⁶⁹⁵
- (1350) Similarly, the artificially prolonged legal review of the dosage patents before the EPO (which started in February 2014 and ended with the final revocation of EP ‘962 and EP ‘172 on 7 February 2024) together with the conversion of patients to 40 mg meant that the launch of a generic-like version of a 40 mg GA by Teva’s competitors¹⁶⁹⁶ would only be possible by launching their generic-like version of GA at risk (rather than waiting for the resolution of the legal review proceedings concerning the dosage patents). This in turn exposed Synthon and its licensees to Teva’s enforcement of its dosage patents.
- (1351) Limiting Synthon’s licensees’ commercial options to launching and supplying Synthon GA at risk is discussed in a series of Teva’s internal documents. A Teva email from March 2017 refers to Synthon GA’s unsuccessful market entry with Synthon GA 20 mg (which was delayed by Teva who, in the meantime, converted the majority of Copaxone users and prescribers from 20 mg to 40 mg GA). A Teva employee stated that Synthon might “{...}” and decide to launch its 40 mg GA at risk at some point since they “{...}”.¹⁶⁹⁷ In August 2017, Synthon considered the

¹⁶⁹⁰ Pharmaceutical Sector Inquiry, Final Report, 8 July 2009, paragraph 534.

¹⁶⁹¹ Pharmaceutical Sector Inquiry, Final Report, 8 July 2009, paragraph 291.

¹⁶⁹² ID 455-439, Teva internal email dated 27 September 2016 from “{...}” to “{...}”, p. 2.

¹⁶⁹³ ID 4595-2257, Teva internal email dated 27 July 2017 from “{...}” to “{...}”, “{...}” and others, p. 1: “{...}”.

¹⁶⁹⁴ For launch dates of Synthon GA in the relevant Member States see Section 6.3.3.4.

¹⁶⁹⁵ In an internal email from December 2015, “{...}” explained that while the appellate procedure concerning EP ‘924 would be pending, Teva would continue to consider the enforcement strategies and therefore Teva’s competitors would be only able to enter the GA markets at risk: “{...}” (ID 455-3368, Teva internal email dated 11 December 2015 from “{...}” to “{...}”, “{...}”, “{...}” and others, p. 1).

¹⁶⁹⁶ Synthon GA is the only generic-like GA drug authorised in the Relevant Member States and the only GA product competing with Copaxone in the Relevant Period (see in particular Section 7.2.1).

¹⁶⁹⁷ ID 455-556, Teva internal email dated 24 March 2017 from “{...}”, p. 1.

possibility of launching its 40 mg GA at risk in Germany, Italy, Spain and France by the end of 2017.¹⁶⁹⁸

- (1352) A Teva presentation from August 2017 outlining “{...}” shows that Teva expected a baseline scenario whereby Synthon GA (distributed by Mylan) would launch at risk, but only after January 2019 (when Teva expected the EP ‘335 to be revoked):

“{...}”.¹⁶⁹⁹

- (1353) By November 2017, Teva’s assessment evolved to the point that it expected Synthon GA to be launched at risk because of the long duration of proceedings before the EPO: “{...}”.¹⁷⁰⁰ According to an internal email from November 2017, it was assumed that Synthon GA would be launched at risk: “{...}”.¹⁷⁰¹ In January 2018, a Teva employee noted that the opposition proceedings at the EPO (regarding EP’335) could still continue for “{...}”, but that {...} expected Synthon GA “{...}”.¹⁷⁰² These documents show that the fact that Synthon (and its licensees) had to launch Synthon GA at risk was directly linked to Teva’s conduct, which artificially prolonged the duration of proceedings before the EPO. The legal uncertainty persisted in all national markets where the patents were still in force.

- (1354) When Synthon’s licensees launched Synthon GA at risk, Teva responded by launching comprehensive national patent enforcement actions, including several successful requests for preliminary injunctions, which will be outlined in Section 8.4.2 below.

8.4.1.3. The artificially prolonged legal uncertainty had a deterrent effect on potential further market entrants

- (1355) Teva’s conduct was also capable of adversely affecting potential competition from other entrants.¹⁷⁰³ The artificially prolonged legal uncertainty was capable of deterring further competitors from developing and/or entering the market with a generic-like version of GA. Teva’s GA patents were also challenged by two other generic manufacturers, namely the Novartis subsidiary Hexal AG¹⁷⁰⁴ and Actavis.¹⁷⁰⁵

- (1356) This is further confirmed by a Teva internal email from January 2017, in which it is reported that Teva had “{...}”.¹⁷⁰⁶ This shows that there were further potential market entrants and that Teva’s conduct was capable of delaying or preventing their market entry (to date, none of these companies is marketing a GA product in the EU).

¹⁶⁹⁸ ID 455-1140, Price competition workshop – COPAXONE & LONQUEX, 20-21 June 2017.

¹⁶⁹⁹ ID 404-1961 (attachment), COPAXONE & FoGA, 29 August 2017, p. 10. This timeline can be contrasted with the fact that in the context of a possible settlement of disputes between Synthon and Teva, Teva was considering even “{...}” for 40 mg Synthon GA entry (ID 266-113, Teva internal correspondence dated 26 and 27 October 2015 between {...} and {...}, pp. 2, 3).

¹⁷⁰⁰ ID 455-3114, Copaxone EU AOP2018, 13 November 2017, p. 4.

¹⁷⁰¹ ID 455-3425, Teva internal email dated 26 November 2017 from {...} to {...} and others, p. 3.

¹⁷⁰² ID 455-3452, Teva internal email dated 11 January 2018 from {...} to {...}, p. 1.

¹⁷⁰³ Case C-457/10 P, *AstraZeneca v Commission*, paragraph 108.

¹⁷⁰⁴ Which challenged the process patents EP ‘528 and EP ‘924 as well as the dosage patents EP ‘335, EP ‘172 and EP ‘962. Sandoz, who has also developed a generic-like version of GA but currently only commercialises it in the US, also belongs to the Novartis group.

¹⁷⁰⁵ Actavis (which became Allergan in 2015) was acquired by Teva in 2016.

¹⁷⁰⁶ ID 404-1656, Teva internal email dated 27 January 2017 from {...} to {...} and others, p. 1.

8.4.2. *Effects from Teva's increased ability to enforce its patents in national courts*

- (1357) Teva's comprehensive patenting conduct also hindered the market entry and uptake of competing GA products by contributing to Teva's ability to enforce its patents in national courts. Without the divisionals game, Teva would have lost its exclusive rights for Copaxone at a much earlier date and would have been unable to initiate infringement actions before national courts. Teva's ability to enforce its patents was capable of hindering the emergence or growth of competition to Copaxone. By, first, sending warning letters, Teva increased the commercial uncertainty and litigation costs for Synthon's licensees (Section 8.4.2.1). The deterrent effect of these actions was further increased by the fact that Teva requested (and obtained) preliminary injunctions in several of the Relevant Member States and thereby temporarily excluded Synthon GA from the respective national markets (Section 8.4.2.2). Furthermore, Teva's divisionals game increased the obstacles Synthon's licensees had to face to successfully launch their product in the Relevant Member States (Section 8.4.2.3).
- (1358) The absence of competing GA products on the market prevented likely price competition in the Relevant Member States (directly and indirectly), resulting in the maintenance of high Copaxone prices for patients and health care systems (Section 8.4.2.4).
- (1359) Teva argues that the Commission should demonstrate, for each Relevant Member State, that given the patent landscape, the invalidation by the TBA of the withdrawn patents was "likely" to have impacted the court proceedings, having regard to (i) the conditions for obtaining preliminary injunctions in these countries and (ii) the fact that national courts generally apply these conditions when issuing preliminary injunctions.¹⁷⁰⁷
- (1360) Teva's arguments should be rejected for the reasons already elaborated above. More specifically: Teva (i) erroneously limits its analysis and arguments to withdrawals while completely disregarding the contribution of divisional filings to the overall effects of Teva's comprehensive patenting conduct (see Recital (1328)); (ii) laconically dismisses the contemporaneous evidence relied on by the Commission (see Recital (1185)); and (iii) proposes the wrong legal standard for the assessment of effects (see Recital (1329)). As to obtaining preliminary injunctions against Synthon GA, the Commission's conclusions are based on a number of Teva's internal contemporaneous documents which show that Teva was indeed concerned that a negative decision on the validity of a patent (be it by the EPO, a national court or even a foreign (US) competent authority) may negatively impact its ability to obtain preliminary injunctions (see Section 8.3.3.4).

8.4.2.1. Teva used warning letters to deter market entry by Synthon GA

- (1361) At national level, Teva's first actions against Synthon and its licensees consisted of warning letters sent to their external legal counsels. These letters served to prepare the ground for potential future litigation¹⁷⁰⁸ in those Member States where Teva suspected that Synthon and its licensees were planning to start commercialising Synthon GA.¹⁷⁰⁹ It was because of Teva's comprehensive patenting conduct

¹⁷⁰⁷ ID 4032, Teva's Reply to the Statement of Objections, paras. 879-882.

¹⁷⁰⁸ ID 2220, Teva's reply to Article 18(2) Request of 13 July 2022, question 2, pp. 1-2.

¹⁷⁰⁹ Teva suggests that the warning letters are sent at the sole discretion of the patentee and that nothing suggests that Teva would not have sent the exact same letters had the patents been invalidated rather than withdrawn (ID 4032, Teva's Reply to the Statement of Objections, para. 874). Teva's arguments

combining patent filings and withdrawals of the challenged patents, that Teva was able to send warning letters over an artificially prolonged period.

- (1362) Since March 2016, Teva has sent more than 70 warning letters to Synthon and its licensees in 21 Member States, invoking both its process and dosage patents. In many cases, Synthon and its licensees decided to delay market entry after receiving such warning letters. In October 2016, an internal Teva document entitled “{...}” {...}. The document states that “{...}” in the UK, Sweden and Finland.¹⁷¹⁰
- (1363) An internal Teva email from March 2017 discussing the validity challenge before EPO against the last process divisional (EP ‘924) mentions two more Member States in which Mylan undertook to give prior notice and had not launched yet: “{...}”¹⁷¹¹ Shortly before the revocation of (EP ‘924), a Teva employee again recalled that this would mean losing the {...}.¹⁷¹² {...}.¹⁷¹³
- (1364) Thus, Synthon’s licensees delayed their market entry in multiple Member States as a direct result of Teva’s conduct, implemented notably through warning letters. This is also what Teva expected, as {...} wrote to {...} in February 2015 that “{...}”.¹⁷¹⁴
- (1365) On this basis, the Commission concludes that Teva’s comprehensive patenting conduct, the effects of which materialised on the market in the first place through Teva’s use of warning letters, was capable of hindering competition by dissuading competitors, Synthon and its licensees in particular, from market entry (and frequently succeeded in doing so).

8.4.2.2. Teva enforced its patents and sought preliminary injunctions against Synthon GA

- (1366) Where Teva’s warning letters were not sufficient to deter Synthon GA’s market entry, Teva enforced its patents by requesting preliminary injunctions before national courts.
- (1367) In the first phase, Teva was able to enforce its process patents over an artificially prolonged period of time and thereby hindered the market entry of Synthon GA’s 20 mg. Synthon (and/or its licensees) entered the market with its 20 mg GA at risk (before the revocation of the last process patent in September 2017) in 5 Relevant Member States.¹⁷¹⁵ In two Relevant Member States, Czechia and Italy, Teva’s preliminary injunctions delayed the earliest possible market entry date for Synthon GA’s 20 mg¹⁷¹⁶ while in Poland a preliminary injunction interrupted its

are not convincing. First, in its analysis Teva again disregards the fact that warning letters are driven not only by patent withdrawals but by the overall, comprehensive Teva’s patenting conduct including filings. In addition, Teva’s threats of litigation based on patents that are affected by reasoned invalidity decisions within the same family would not only be easier for the addressees to ignore but would likely attract a certain measure of additional risks for Teva (e.g. exposure to damages actions).

¹⁷¹⁰ ID 266-95 (attachment), Copaxone Litigation Internal Update for week ending 28 October 2016, p. 3.

¹⁷¹¹ ID 404-541, Teva internal email dated 22 March 2017 from {...} to {...} and others, p. 3.

¹⁷¹² ID 404-1795, Teva internal email dated 6 September 2017 from {...} to {...} and others, p. 1.

¹⁷¹³ ID 404-1847, Copaxone Update, September 2017, p. 2 (attached to Teva internal email dated 13 September 2017 from {...} to {...} and others).

¹⁷¹⁴ ID 455-1205, Teva internal email dated 2 February 2015 from {...} to {...} and others, p.1.

¹⁷¹⁵ Synthon (and/or its licensees) entered the market with its 20 mg GA at risk in altogether 10 Member States: Austria, Bulgaria, Croatia, Germany, Hungary, Italy, Latvia, the Netherlands, Poland and Spain. See ID 3645, Synthon’s Reply to Article 18(2) Request of 23 September 2022.

¹⁷¹⁶ In nine Member States Teva requested preliminary injunctions. Eight of these were granted and delayed the earliest possible market entry date for Synthon GA’s 20 mg in six Member States: Czechia (1 June 2015-11 October 2017), Italy (preliminary injunction delayed MA grant, 20 July 2016-8 October 2016), Estonia (12 December 2016-26 October 2017), Latvia (2 January 2017-13 October 2017), Slovakia (14 February 2017-24 August 2017), Slovenia (2 February 2017-28 March 2017). See ID 976, {...} Reply

commercialisation.¹⁷¹⁷ These preliminary injunctions remained in force for periods ranging from six months to two and a half years. This made Synthon GA's 20 mg market entry less successful, as Teva meanwhile converted patients to 40 mg Copaxone (see Section 5.2.3.1).¹⁷¹⁸

- (1368) In the second phase, once Teva had converted most of its patients to Copaxone 40 mg, Teva enforced its patents over the 40 mg dosage regimen and thereby excluded Synthon's (and its licensees') sales of (i) its 20 mg GA (most patients had already been converted to Copaxone 40 mg), and (ii) its 40 mg GA (Teva's enforcement of its dosage patents was sustained over an artificially prolonged period of time).¹⁷¹⁹ Synthon (and/or its licensees) launched its 40 mg GA at risk in 6 Relevant Member States.¹⁷²⁰ Teva's preliminary injunction delayed the earliest possible market entry date for Synthon GA's 40 mg in Czechia,¹⁷²¹ while the preliminary injunctions interrupted its commercialisation in Belgium, Germany and Poland.¹⁷²² These preliminary injunctions remained in force (the preliminary injunction in Czechia was in force at least until revocation of EP '962 and EP '172 on 7 February 2024) for periods ranging from six months to more than 4 years.
- (1369) Overall, in the Relevant Member States, Teva obtained preliminary injunctions based on both patent families in Czechia and Poland; preliminary injunctions based on its dosage patents in Belgium and Germany; and preliminary injunctions based on its process patents in Italy.¹⁷²³
- (1370) These preliminary injunctions had the effect of prohibiting Synthon's licensees from marketing Synthon GA. Accordingly, Teva's conduct, leading to higher commercial uncertainty and litigation costs for potential entrants, was capable of hindering the market entry of generic-like versions of GA (and successfully hindered the market

to Article 18(2) Request of 22 October 2022 (for Italy); ID 1127, {...} Reply to Article 18(2) Request of 22 October 2021 (for Czechia, Estonia, Latvia and Slovakia) and ID 597-5, Teva's reply to Article 18(2) Request of 3 June 2020, Annex 15.27.

¹⁷¹⁷ Teva's preliminary injunctions interrupted commercialization of Synthon GA's 20 mg in two Member States: Croatia: 14 March 2017-7 November 2017 (ID 1127, {...} reply to Article 18(2) Request of 22 October 2021), Poland: 4 April 2017-28 April 2017 (ID 1127, {...} reply to Article 18(2) Request of 22 October 2021).

¹⁷¹⁸ Teva's preliminary injunction in Czechia was particularly harmful to Synthon as it was forced to move its production facilities to Argentina (see Recital (143)).

¹⁷¹⁹ See, for example, an internal note on the outlook for 20 mg GA in Czechia in 2017: "{...}", ID 404-862, Teva internal email dated 19 September 2017 from {...} to {...}.

¹⁷²⁰ Synthon (and/or its licensees) launched its 40 mg GA at risk in altogether 19 Member States: Austria, Belgium, Bulgaria, Croatia, Denmark, Estonia, France, Germany, Greece, Hungary, Ireland, Italy, Latvia, Lithuania, the Netherlands, Poland, Portugal, Romania and Spain. All launches are considered at risk, as Teva still retains one dosage divisional covering the 40 mg three-times-a-week dosage regime. ID 3645, Synthon's reply to Article 18(2) Request of 23 September 2022.

¹⁷²¹ In 14 Member States, Teva requested preliminary injunctions. Eight of these were granted and delayed the earliest possible market entry date for Synthon GA's 40 mg in four Member States: Croatia: 6 February 2018-28 September 2020, Czechia: 16 May 2019-ongoing; Latvia: 26 September 2019-20 October 2020, Slovakia: 3 July 2018-8 December 2020. See ID 1127, {...} reply to Article 18(2) Request of 22 October 2021.

¹⁷²² Teva's preliminary injunctions interrupted commercialization of Synthon GA's 40 mg in four Member States: Belgium: 15 May 2018-5 May 2020, Denmark: 15 March 2019-23 August, Germany: 14 June 2019-10 September 2020, Poland: 25 September 2019-6 March 2020. See ID 976, {...} Reply to Article 18(2) Request of 22 October 2022 (for Belgium, Denmark and Germany) and ID 1127, {...} reply to Article 18(2) Request of 22 October 2021 (for Poland).

¹⁷²³ In addition, Teva obtained preliminary injunctions based on both patent families in Croatia, Estonia, Latvia, and Slovakia; preliminary injunctions based on its dosage patents in Austria, Denmark and Portugal; as well as preliminary injunctions based on its process patents in Estonia.

entry of Synthon GA for extensive periods of time). Teva pursued vigorous enforcement of its patents irrespective of the perceived weakness of the underlying patents.¹⁷²⁴ In addition, internal documents reveal that Teva would have continued to enforce its patents (specifically the EP ‘924) during the suspensive appeal against the OD decision invalidating the patent.¹⁷²⁵

- (1371) Teva notes that according to the Commission’s own findings, national courts only rarely look into the validity of the underlying patent when issuing a preliminary injunction. Thus, according to Teva, the Commission should conduct a detailed, case-by-case assessment of the general position of the national courts in each Relevant Member State. The Commission should thus establish if the likelihood that a patent may be valid is a key condition for granting a preliminary injunction. According to Teva the Commission should also establish that the Courts take into account the reasoned decision of the TBA on other patents in the family and/or the OD’s decision on the validity of the parent at stake in considering this likelihood.¹⁷²⁶
- (1372) Teva’s arguments do not convince. It is indeed common ground that national courts generally do not engage in an in-depth assessment of the validity of the patent invoked in a request for a preliminary injunction and grant these on a *prima facie* basis (see Recital (1049)). As illustrated below (see Recital (1373)), this however does not imply that a decision on the validity of the patent in question from the EPO or from a patent court would not have had any persuasive authority and would not have been damaging for Teva. In effect, concerns regarding such a damaging effect from a potential invalidity decision were the main reason for the withdrawals of Teva’s patents in the process and dosage families (see Section 8.3.3.4). In addition, data relied on by Teva¹⁷²⁷ on the percentage of granted preliminary injunctions across Member States are not informative for the case at hand. For example, Teva’s data indicate that in both Spain and Czechia preliminary injunctions are issued in 30% of requested cases. However, in the case at hand, results of Teva’s actions in these two Relevant Member States were completely different. While courts in Czechia have consistently granted a series of injunctions to Teva, courts in Spain consistently rejected Teva’s applications (see Section 8.4.3).
- (1373) Teva’s enforcement of the EP ‘335 dosage patent is a good illustration of how the decision by the EPO can influence the success of preliminary injunction requests. Teva made two preliminary injunction requests based on an alleged infringement of EP ‘335 in Germany. Teva’s first request, submitted in 2017 to the Regional Court in Munich, was rejected.¹⁷²⁸ Then, on 11 April 2019, following the OD’s decision upholding EP ‘335, Teva again requested a preliminary injunction based on that divisional, this time from the Regional Court in Düsseldorf. This request was granted on 14 June 2019 and the appeals against the preliminary injunctions were rejected.

¹⁷²⁴ ID 404-678, Teva internal email dated 13 October 2015 from {...} to {...}, {...}, {...} and others.

¹⁷²⁵ ID 455-3368, Teva internal email dated 11 December 2015 from {...} to {...}, {...}, {...} and others, p. 1: “{...}”

¹⁷²⁶ ID 4032, Teva’s Reply to the Statement of Objections, paras. 883-887.

¹⁷²⁷ ID 4032, Teva’s Reply to the Statement of Objections, para. 883.

¹⁷²⁸ Teva first requested a preliminary injunction from the Regional Court in Munich on 6 December 2017. It was rejected on 14 December 2017. On appeal, the Higher Regional Court in Munich confirmed the rejection on the grounds that, *inter alia*, EP ‘335 and EP ‘749 did not differ in any relevant manner. According to the Higher Regional Court in Munich, Teva’s withdrawal of the Original Dosage patent, EP ‘749, was for “*tactical reasons*” and pointed to a “*not insignificant*” risk that EP ‘749 would have been revoked (ID 741-16, OLG München, 4 April 2018, 6 W 164/18, Teva Pharmaceutical Industriel Ltd. Vs. Mylan dura GmbH, pp. 24, 30, 31).

However, on 30 September 2020, after the revocation of EP ‘335 by the TBA, Teva simply waived the preliminary injunction issued by the Regional Court in Düsseldorf and did not request further preliminary injunctions based on the two other dosage patents (EP ‘962 and EP ‘172). These facts confirm the Commission’s conclusion that decisions on validity from the EPO indeed have a persuasive authority before national courts.

- 8.4.2.3. Teva’s divisionals game increased the obstacles Synthon’s licensees had to face to successfully launch their products in the Relevant Member States
- (1374) National enforcement of the divisional patents in the context of Teva’s comprehensive patenting conduct not only locked Synthon GA out of the market for significant periods of time, but also led to significant indirect effects.
- (1375) First, Teva’s patent enforcement before national courts hindered Synthon GA’s market entry by making it impossible to predict when Synthon’s licensees would be able to effectively commercialise Synthon GA. Consequently, numerous pre-launch activities required for successful commercialisation (such as preparation of promotional materials; attendance of conferences and execution of other promotional activities; communication with health care professionals, reimbursement authorities, procurement bodies and patient associations) had to be delayed thereby weakening Synthon GA’s launch.
- (1376) Second, preliminary injunctions had a negative impact on the credibility of Synthon GA even after they were lifted, as some Payers and HCPs were reluctant to prescribe Synthon GA out of fear that it may again become unavailable in the future as a result of new preliminary injunctions.¹⁷²⁹ Teva also actively used pending proceedings for preliminary injunctions to discourage HCPs from switching their patients to Synthon GA, warning them that the product could soon be banned from the market.¹⁷³⁰ Similarly, internal documents confirm that in some instances, the mere fact that Teva had requested preliminary injunctions influenced decisions by reimbursement bodies.¹⁷³¹
- (1377) For example, a warning letter used by Teva in Germany reveals that Teva was actively reaching out to pharmacists to inform them that the EP ‘335 patent had been upheld in a “*slightly amended*” form and about the preliminary injunction by the Düsseldorf Regional Court against Clift issued in June 2019. The letter was intended to discourage HCPs from switching their patients to Synthon GA, warning them that the product could soon be banned from the market.¹⁷³²
- (1378) It follows from the above that Teva’s conduct was capable of hindering the market entry and uptake of Synthon GA by increasing obstacles to its pre-launch activities and dissuading HCPs and reimbursement authorities from switching to Synthon GA.

¹⁷²⁹ ID 2763, {...} Reply to Article 18(2) Request of 11 February 2022, p. 16.

¹⁷³⁰ ID {...}.

¹⁷³¹ ID 455-1509, Teva internal email dated 5 December 2018 from {...} to {...} and others.

¹⁷³² ID 5036, Letter to be sent to the pharmacists “Apotheken Anschreiben EV Mylan”, 26 June 2019. Associated excerpt from Teva’s internal database shows that that the document was approved on 25 June 2019, then reapproved on 21 April 2021, with first recorded use on 16 June 2019 (ID 4897, List of documents registered on Teva’s {...}).

8.4.2.4. Teva's patent enforcement prevented likely price competition in the Relevant Member States

- (1379) As shown in the sections above, Teva's comprehensive patenting conduct was capable of delaying and/or reducing market entry of Synthron GA, by issuing warning letters and by obtaining and enforcing preliminary injunctions. It was also capable of increasing obstacles to pre-launch activities and dissuading HCPs and reimbursement bodies from switching to Synthron GA. These actions prevented the sale of Synthron GA in the Relevant Member States.
- (1380) In numerous instances, anticompetitive effects actually occurred and were analysed in Teva's internal documents. These instances constitute anecdotal evidence that illustrates the capability of Teva's conduct to produce anticompetitive effects. A slide of an internal Teva presentation entitled "{...}" from October 2020 compares the average selling price evolution in the time period from Q1 2019 to Q1 2020 in markets with and without preliminary injunctions in place. The graphic shows that selling prices in markets without preliminary injunctions were {...}% lower, which confirms the significant impact of Teva's patent enforcement at national level to maintain high prices for Copaxone.¹⁷³³ This shows that Teva's preliminary injunctions were capable of preventing price decreases and provides concrete examples for their actual impact on prices in various Member States.
- (1381) A presentation from September 2017 outlines the impact of the impending loss of exclusivity (abbreviated as "LOE") as a result of the revocation of the last process divisional EP '924. A slide entitled "{...}" presents the following bullet points:
"{...}"¹⁷³⁴
- (1382) Similarly, TPI and TPE minutes show that Teva linked delayed generic entry to positive financial results for the company. The delayed entry of Synthron GA 20 mg was thus the main reason for the increase in sales and profit in Europe in 2018 while the markets with preliminary injunctions accounted for two thirds of sales volumes in 2020.¹⁷³⁵
- (1383) In an email from July 2018, a {...} qualified a preliminary injunction as an example showing that "{...}"¹⁷³⁶ Teva's earning calls with investors show that Teva directly connected Copaxone's commercial outlook (in terms of pricing or in terms of overall sales) with its ability to prevent market entry of Synthron GA through patent enforcement.¹⁷³⁷
- (1384) Thus, Teva's patent enforcement at national level was not only capable of preventing price reductions but also, as confirmed by Teva's contemporaneous documents, in fact actually did so in a number of Member States, including Teva's largest EU market, Germany, as well as in Czechia (see Section 6.3.3.4.3).
- (1385) Moreover, due to price referencing rules (whereby the price of a given medicine in one country is taken into account for the calculation of the price of the medicine in another country), market entry and the resulting price cuts for Copaxone in one Member State would often also lead to price cuts in other Member States.

¹⁷³³ ID 806-36, "TPE Board Meeting Finance – Q3 2020", p. 6.

¹⁷³⁴ ID 404-1850, Copaxone Update, 13 September 2017, p. 4.

¹⁷³⁵ See Recital (501).

¹⁷³⁶ ID 404-577, Teva internal email dated 6 July 2018 from {...} to {...} and others, p. 1.

¹⁷³⁷ ID 5198, Teva Earnings Call Q3 2019, 7 November 2019, p. 35; ID 5201, Teva Earnings Call Q1 2020, 7 May 2020, p. 26,

- (1386) In May 2018, a Teva employee reported, following the grant of a preliminary injunction for 40 mg GA in Belgium, that without the preliminary injunction, the market entry would have led to a price cut “{...}” (emphasis added).¹⁷³⁸ A note from January 2017 concerning the Spanish market also refers to the possible impact of preliminary injunctions on price referencing.¹⁷³⁹
- (1387) Delaying and/or obstructing market entry by comprehensive patenting practices therefore not only delayed the ensuing price competition in the Member State where such practices occurred, but also had broader effects on the price level for GA across the EU.
- 8.4.3. *Effects of Teva’s comprehensive patenting conduct in the Relevant Member States*
- (1388) In this section, the Commission sets out in detail how Teva’s comprehensive patenting conduct was capable of having anticompetitive effects in the different Relevant Member States.
- (1389) While the effects of Teva’s conduct¹⁷⁴⁰ in each Relevant Member State depended “*on the contingencies of the reactions of third parties*”,¹⁷⁴¹ in particular the level of scrutiny applied by national courts examining Teva’s preliminary injunction requests, and the respective success of the commercial and legal strategies of Synthon and its licensees, such contingencies do not alter the abusive nature of Teva’s conduct.
- (1390) Teva argues that in each of the Relevant Member states an invalidation of the withdrawn patents by the TBA would not have impacted Teva’s chances of obtaining or maintaining preliminary injunctions.¹⁷⁴² In addition, according to Teva, the alleged effects of the withdrawals in the Relevant Member States are based on the assumption that they allowed Teva to “*continue relying on preliminary injunctions that would otherwise likely not have been in force*”. Teva claims that the Commission should therefore show, for each Relevant Member State, that the withdrawals allowed Teva to obtain (or maintain) preliminary injunctions that (either) would not have been granted (or that would have been lifted).¹⁷⁴³ However, Teva fails to rebut the Commission’s conclusions on the capability of Teva’s conduct

¹⁷³⁸ ID 455-2443, Teva internal email dated 23 May 2018 from {...} to {...}, p. 1.

¹⁷³⁹ ID 404-993, Teva internal email dated 6 January 2017 from {...} to {...}.

¹⁷⁴⁰ ID 4862, Answering Template Patent Enforcement and Market Access-092023 {...} on 18 September 2023 shows overview and status of preliminary injunctions as of September 2023 in each of the Relevant Member States.

¹⁷⁴¹ Case T-321/05, *AstraZeneca v Commission*, paragraph 360.

¹⁷⁴² ID 4032, Teva’s Reply to the Statement of Objections, paras. 889-905.

¹⁷⁴³ ID 4032, Teva’s Reply to the Statement of Objections, paras. 873-878. See also ID 5695, Teva’s Reply to the Letter of Facts I of 9 February 2024, paras. 305-306. With respect to Czechia, Teva explains that the position of local courts regarding requests to have preliminary injunctions lifted demonstrates that an invalidation of the withdrawn patents was not likely to impact Teva’s chances to obtain or maintain preliminary injunctions (ID 4032, Teva’s Reply to the Statement of Objections, paras. 906-911). With respect to the Netherlands, Teva explains that it never obtained any preliminary injunctions in the Netherlands and therefore withdrawals by definition cannot have any effects before national courts (ID 4032, Teva’s Reply to the Statement of Objections, paras. 892-897). With respect to Belgium, Germany and Poland, Teva notes that the Commission did not demonstrate that an invalidation of the withdrawn patents would have impacted the likelihood that Teva would have obtained or maintained preliminary injunctions. (ID 4032, Teva’s Reply to the Statement of Objections, paras. 912-916). With respect to Italy and Spain, Teva explains that Teva’s requests for Pis were rejected and therefore withdrawals by definition cannot have any effects before national courts. (ID 4032, Teva’s Reply to the Statement of Objections, paras. 898-905; see also ID 5695, Teva’s Reply to the Letter of Facts I of 9 February 2024, paras. 303-304).

to produce anticompetitive effects or to address any of the factual and legal conclusions made by the Commission.

- (1391) In particular, Teva again solely focuses on one of the components of its comprehensive patenting conduct addressed in this Decision, i.e. the isolated effect of withdrawals on preliminary injunctions that had been issued previously. However, Teva completely ignores the fact that (i) its capability to obtain preliminary injunctions follows not only from the strategic withdrawals but from the combination of multiple staggered filings and strategic withdrawals¹⁷⁴⁴ and the fact that (ii) Teva's conduct was capable of having anticompetitive effects even beyond the preliminary injunctions as the mere existence of a patent can be sufficient to deter entry or expansion (see Section 8.4.1). In this context Teva's claim that the Commission relies on assumptions cannot be accepted either. The Commission's conclusions on the capability of Teva's conduct to produce anticompetitive effects is based on the thorough assessment and analysis of the relevant evidence (see Section 8.4.1 and Section 8.4.2). This analysis is specified for each of the Relevant Member States in the following recitals.

Belgium

- (1392) In Belgium, Teva sent warning letters to Synthon and its licensee Mylan (now Viatris) between 15 November 2017 and 6 March 2018 and requested a preliminary injunction based on the dosage divisional patent EP '335 from the Commercial Court of Brussels on 9 March 2018. The preliminary injunction was granted on 15 May 2018 and remained in force until 5 May 2020.¹⁷⁴⁵
- (1393) The significant effects of the preliminary injunction are reported in contemporaneous documents. In an email from July 2018, a Teva employee stated that "{...}"¹⁷⁴⁶ {...}.¹⁷⁴⁷ An internal Teva presentation from 2020 reports that Mylan withdrew its reimbursement dossier in Belgium in June 2018 and that "{...}"¹⁷⁴⁸
- (1394) Thus, in addition to the prolonged legal uncertainty concerning the validity of Teva's patents via the proceedings before the EPO (see Section 8.4.1.1) resulting in an increased commercial uncertainty for potential GA entrants as to whether they would be able to launch their GA product on the market, the actual anticompetitive effects of Teva's conduct in Belgium consisted of the further increase in commercial uncertainty for Synthon and its licensee Mylan (now Viatris), resulting from the actions pursued by Teva between 15 November 2017 and May 2020 and of its exclusion, as the only competitor for Copaxone, from the market due to the preliminary injunction in place for 40 mg GA between May 2018 and May 2020.

Czechia

- (1395) In Czechia, Teva sent warning letters to Synthon and its licensee Zentiva/Alvogen, concerning both its process and dosage patents, between 24 October 2016 and 7 June 2020.¹⁷⁴⁹ Teva also requested a preliminary injunction based on the process divisionals EP '528 and EP '924 from the Prague Municipal Court on 28 May 2015,

¹⁷⁴⁴ For example, Teva's ability to enforce a second-generation process patent (EP '924) after it "saved" its main claim from the invalidity decision as a part of the Original Process Patent. See also Section 8.3.2.1.

¹⁷⁴⁵ ID 2162, Teva's reply to Article 18(2) Request of 13 July 2022, Annex 15.2.

¹⁷⁴⁶ ID 404-577, Teva internal email dated 6 July 2018 from {...} to {...} and others, p. 1.

¹⁷⁴⁷ ID 455-2443, Teva internal email dated 23 May 2018 from {...} to {...}, p. 1.

¹⁷⁴⁸ ID 455-2743, Scenario's FoGA launch in Belgium & Impact on Copaxone, 2018, p. 4.

¹⁷⁴⁹ ID 2161, Teva's reply to Article 18(2) Request of 13 July 2022, Annex 15.6.

which was granted on 1 June 2015 and remained in force until its revocation on 11 October 2017 (following the revocation of EP ‘924 by the TBA on 12 September 2017). Teva then switched its enforcement actions to the dosage patent family. On 15 May 2019, Teva requested a preliminary injunction based on the dosage divisionals EP ‘335, EP ‘962 and EP ‘172 from the Prague Municipal Court. The request was granted on 16 May 2019. An appeal against the preliminary injunction based on the dosage divisionals EP ‘335, EP ‘962 and EP ‘172 was rejected on 31 March 2020. Thereafter, two separate requests to lift the preliminary injunction were again rejected on 7 October 2020 and on 14 April 2021.¹⁷⁵⁰

- (1396) On 11 February 2022, Zentiva/Alvogen filed a new request to lift the preliminary injunction based on the dosage divisionals EP ‘335, EP ‘962 and EP ‘172 granted by the Prague Municipal Court, in light of the revocations of EP ‘172 and EP ‘962 by the OD in December 2021. On 17 March 2022, the Prague Municipal Court rejected Zentiva's request on the ground that although EP ‘172 and EP ‘962 had been revoked, these decisions are not final as Teva can still appeal before the EPO's TBA (the decisions were indeed both appealed by Teva). Zentiva has appealed that judgment.¹⁷⁵¹ The appeal was still pending and the preliminary injunction was therefore still in force on the date of the revocation of EP ‘962 and EP ‘172 by the TBA.¹⁷⁵² Teva's patent enforcement in Czechia had a particularly significant effect, as it not only stopped the commercialisation of Synthon GA in Czechia but also halted the operations of Synthon's API manufacturing site in Czechia, which hindered the supply of Synthon GA outside of Czechia as well, and forced Synthon to relocate its production to non-EU facilities.¹⁷⁵³
- (1397) The significant effects of the preliminary injunctions in Czechia are also reported in Teva's contemporaneous documents. In September 2017, an employee of a Teva subsidiary replied to an email concerning the revocation of the last process patent EP ‘924 and emphasised the successes achieved in enforcing it against Alvogen: “{...}”.¹⁷⁵⁴ In January 2018, a Teva employee reported that Synthon's licensee had not applied to the reimbursement authorities “{...}”.¹⁷⁵⁵
- (1398) Thus, in addition to the prolonged legal uncertainty concerning the validity of Teva's patents via the proceedings before the EPO (see Section 8.4.1.1) resulting in an

¹⁷⁵⁰ ID 2161, Teva's reply to Article 18(2) Request of 13 July 2022, Annex 15.6.

¹⁷⁵¹ ID 2161, Teva's reply to Article 18(2) Request of 13 July 2022, Annex 15.6

¹⁷⁵² In its reply to the Article 18(2) Request of 15 February 2024, Teva explains that “*nothing has prevented Zentiva from selling Remurel 20mg in the Czech market since late 2017*” and that as of April 2023, “*nothing has prevented Alvogen from transferring its MA to Zentiva, and Zentiva from applying for pricing and reimbursement (“P&R”) for Remurel 40 mg and launching Remurel 40 mg immediately thereafter.*” (ID 5673, Teva's Reply to Article 18(2) Request of 15 February 2024, p. 1). Teva's explanations however do not change the established facts that the preliminary injunction was in force in Czechia on the date of revocation of the relevant dosage patents and that Teva's preliminary injunctions in Czechia have prevented the effective uptake of Synthon GA during the period of infringement (see Section 12.1).

¹⁷⁵³ Synthon used to produce the GA active pharmaceutical ingredient (API) in Czechia and to send the API batches to {...} in Spain to be filled in injection syringes. Teva requested preliminary injunctions in both countries. As a result, Synthon was forced to move its production facilities to Argentina, a country with which no mutual recognition agreement is in place. ID 2161, Teva's reply to Article 18(2) Request of 13 July 2022; ID 2150, Teva's reply to Article 18(2) Request of 13 July 2022. Furthermore, Teva successfully obtained a court order to suspend Synthon's export licences in Chile and prevent Synthon from exporting GA produced there to the EU/EEA, see ID 455-2848, Teva internal email dated 8 February 2017 from {...} to {...} and others concerning “{...}”.

¹⁷⁵⁴ ID 404-824, Teva internal email dated 12 September 2017 from {...} to {...} and others, p. 1.

¹⁷⁵⁵ ID 455-407, Teva internal email dated 19 January 2018 from {...} to {...} and others, p. 6.

increased commercial uncertainty for potential GA entrants as to whether they would be able to launch their GA product on the market, the actual anticompetitive effects of Teva's conduct in Czechia consisted of the further increase in commercial uncertainty for Synthon and its licensee Zentiva/Alvogen. This uncertainty resulted from the litigation pursued by Teva since May 2015. The actual anticompetitive effects of Teva's conduct in Czechia also consisted of exclusion of Synthon and its licensee Zentiva/Alvogen, as the only competitor for Copaxone, from the market due to the preliminary injunctions in place for 20 mg GA between June 2015 and October 2017 and for 40 mg GA since May 2019.

Germany

- (1399) In Germany, Teva sent warning letters to Synthon's licensee, Mylan, in 2017 and 2019.¹⁷⁵⁶ Teva also requested a first preliminary injunction based on the process divisional EP '924 from the Regional Court in Munich on 29 September 2016, but withdrew its application on 5 October 2016. On 6 December 2017, Teva requested a preliminary injunction based on the dosage divisional EP '335 from the Regional Court in Munich. Teva's request was rejected on 14 December 2017. On 11 April 2019, following the OD's intermediate decision upholding EP '335, Teva again requested a preliminary injunction based on that divisional, this time from the Regional Court in Düsseldorf. This request was granted on 14 June 2019. An appeal against this decision and a subsequent request for a suspension of the preliminary injunction at the Higher Regional Court in Düsseldorf were both rejected. A further request for a termination or suspension of the preliminary injunction was dismissed on 24 June 2020. On 30 September 2020, after the revocation of EP' 335 by the TBA, Teva waived the preliminary injunction issued by the Regional Court in Dusseldorf.
- (1400) Teva's contemporaneous documents also show that its actions in Germany sought to discourage tender bodies from procuring Synthon GA even before Teva obtained a preliminary injunction, and were capable of hindering Mylan's market entry and expansion with Synthon GA. In March 2017, a Teva employee made the following notes concerning the effect of the pending preliminary injunction requests on tenders: "{...}" (emphasis added).¹⁷⁵⁷ In August 2017, the agenda of a meeting describes how warning letters concerning the dosage patents should be sent not only to Mylan but to "all stakeholders" as a result of which "{...}"¹⁷⁵⁸
- (1401) After the OD issued a preliminary opinion indicating it would rather uphold EP '335 in August 2018, Teva employees again discussed the possibility to use the artificially prolonged legal uncertainty to make health insurers postpone tenders until the final decision on the validity of EP '335.¹⁷⁵⁹ Although two colleagues expressed concerns about these plans,¹⁷⁶⁰ a letter was sent to a major health insurance in September 2018, informing it that a validity challenge against EP '335 was pending and would

¹⁷⁵⁶ ID 2151, Teva's reply to Article 18(2) Request of 13 July 2022, Annex 15.11.

¹⁷⁵⁷ ID 404-727, Teva internal email dated 19 April 2017 from {...} to {...}, p. 2. The Lauer Taxe contains lists of all medicine products that have an MA in Germany. Pharmacists use it to look up information on medicines (though there are other companies offering similar products). It includes information on prices and rebate contracts, as well as medical/pharmaceutical information such as side effects and drug interactions.

¹⁷⁵⁸ ID 404-1913, Teva internal email dated 21 August 2017 from {...} to {...} and others, attached Teva document entitled "Agenda_internes Expertenmeeting_v02_Minutes_V2 (2)", p. 2.

¹⁷⁵⁹ ID 404-2291, Teva internal email dated 28 August 2018 from {...} to {...} and others.

¹⁷⁶⁰ ID 404-1944, Teva internal email dated 21 September 2019 from {...} to {...} and others; ID 455-1687, Teva internal email dated 29 August 2018 from {...} to {...} and others.

be decided upon in March 2019, that Teva’s request for a preliminary injunction based on that patent had been refused and that Teva had been granted, since that refusal, additional patents that had not been the subject of litigation between Teva and other GA distributors yet, and asking it to take this information into account.¹⁷⁶¹

- (1402) A German Payer confirmed to the Commission that “*uncertainties concerning the exclusivity of the original product made both tenders and open house contracts with Mylan Health Care GmbH concerning Clift® impossible.*”¹⁷⁶² Thus, in Germany, Teva successfully increased the effect of the legal uncertainty it artificially created through its comprehensive patenting conduct at EPO level by creating doubts about its competitor’s ability to continue to commercialise GA, even when the courts had rejected Teva’s requests for preliminary injunctions.
- (1403) Once the preliminary injunction against Synthon GA 40 mg was imposed, its significant effects were reported in numerous Teva contemporaneous documents. An internal email from July 2019 explains that “{...}”.¹⁷⁶³ Similarly, an email from September 2019 reports a decline of both 20 mg and 40 mg Synthon GA after the imposition of the preliminary injunction against 40 mg GA.¹⁷⁶⁴ {...}.¹⁷⁶⁵ {...}.
- (1404) Thus, in addition to the prolonged legal uncertainty concerning the validity of Teva’s patents via the proceedings before the EPO (see Section 8.4.1.1) resulting in an increased commercial uncertainty for potential GA entrants as to whether they would be able to launch their GA product on the market, the actual anticompetitive effects of Teva’s conduct in Germany consisted of the further increase in commercial uncertainty for Synthon and its licensee Mylan (now Viatrix) resulting from the litigation pursued by Teva between September 2016 and September 2020 and of its exclusion as the only competitor for Copaxone from the market due to the preliminary injunctions in place for 40 mg GA between June 2019 and September 2020.¹⁷⁶⁶

The Netherlands

- (1405) In the Netherlands, Teva did not request any preliminary injunctions against Synthon GA, since it had to withdraw and de-designate its dosage patents to prevent a reasoned revocation decision.¹⁷⁶⁷
- (1406) On 4 April 2017, the deadline for the national validation of EP ‘335 in the Netherlands lapsed. Teva did not validate the dosage divisional patent EP ‘335 and had previously withdrawn the Dutch designation of the other dosage divisional patent

¹⁷⁶¹ ID 404-1993, Teva internal email dated 24 September 2018 from {...} to {...} and others, attachment document entitled “{...}”.

¹⁷⁶² ID 1258, {...} reply to Article 18(2) Request of 15 December 2021, p. 3 (unofficial translation). Original text: “*Unklarheiten zur Exklusivität des Originalarzneimittels sowohl Ausschreibungen als auch Open House Verträge mit der Mylan Health Care GmbH zu Clift® nicht möglich gewesen seien.*”

¹⁷⁶³ ID 263-2098, Teva internal email dated 31 July 2019 from {...} to {...} and others, p. 1.

¹⁷⁶⁴ ID 263-1294, Teva internal email dated 2 September 2019 from {...} to {...} and others.

¹⁷⁶⁵ ID 263-1871, LRP 2019, Cluster DE presentation, 12 November 2019, p. 37.

¹⁷⁶⁶ Internal correspondence concerning introduction of Copaxone SDD/PEN in Germany reveals that {...} (ID 4729-138, Teva internal email dated 13 November 2020 from {...} to {...} and others; ID 4733-66, Teva internal email dated 18 April 2022 from {...} to {...}; ID 4733-14, “Wochenbericht”). In this context, the preliminary injunction stopped the rapidly growing uptake of Clift 40 mg which was never resumed after the injunction was lifted (as Teva managed to switch to the pen pending the injunction, curbing the substitution by Clift). Also, unlike before the injunction, German insurers were no longer organising exclusive tenders, more favourable to generic-like price competition from Clift (see Recitals (787) and (802)-(812)).

¹⁷⁶⁷ See Recitals (1240)-(1241).

EP ‘962 on 26 January 2017. Since this withdrawal preceded their filing dates, the remaining dosage divisionals EP ‘172 and EP ‘286 could no longer be granted for the Netherlands.¹⁷⁶⁸ Thus, since the lapse of the validation deadline for EP ‘335 in April 2017, Teva no longer held any dosage patents and was not able to obtain any further dosage patents in the Netherlands. Teva’s patenting conduct was therefore no longer been capable of hindering the market entry or expansion of generic-like versions of GA in the Netherlands since April 2017.¹⁷⁶⁹

- (1407) The effects of Teva’s comprehensive patenting conduct in the Netherlands were therefore limited to the general effects resulting from the prolonged legal uncertainty concerning the validity of Teva’s patents as well as the indirect effect of price referencing resulting from the delayed entry of Synthron GA in other markets, in particular in Belgium, which would have also affected the pricing level in the Netherlands. A contemporaneous document explicitly refers to such price effects in the Netherlands.¹⁷⁷⁰
- (1408) As to the effects in the Netherlands of the national withdrawal of EP ‘749, combined with the de-designation and non-validation of the Netherlands in EP ‘962 and EP ‘335, it meant that no dosage patents (or process patents) were in place in the Netherlands. As a result, the market became open to competing GA products as of 4 April 2017.¹⁷⁷¹
- (1409) Accordingly, Teva’s misuse of divisional patents in the Netherlands stopped on 4 April 2017, when Teva abandoned all dosage patents in the country. In addition, the impact of the absence of patent barriers has been duly taken into account in the assessment of dominance in the Netherlands (see Sections 7.2.1.5 and 7.3).

Italy

- (1410) In Italy, Teva filed a request for a preliminary injunction based on the process divisional EP ‘924 with the Court of Milan on 13 July 2016. The Court imposed a preliminary injunction preventing Synthron and Mylan from pursuing their requests for obtaining a marketing authorisation and for including Synthron GA in the transparency list (to make it substitutable with Copaxone). This preliminary injunction was in force between 20 July 2016 and the hearing held on 8 October 2016. The Court finally rejected Teva’s request on 18 June 2017. Teva’s appeal was dismissed on 13 October 2017. On 20 July 2018, Teva filed a request for a preliminary injunction based on its dosage divisionals EP ‘335 and EP ‘962, which was rejected. Teva’s appeal against this decision was dismissed on 24 October 2019.
- (1411) Thus, in addition to the prolonged legal uncertainty concerning the validity of Teva’s patents via the proceedings before the EPO (see Section 8.4.1.1) resulting in an increased commercial uncertainty for potential GA entrants as to whether they would be able to launch their GA product on the market, the actual anticompetitive effects of Teva’s conduct in Italy consisted of the further increase in commercial uncertainty for Synthron and Mylan (now Viatrix) resulting from the litigation pursued by Teva between July 2016 and October 2019 and in particular the preliminary injunction

¹⁷⁶⁸ ID 3636, Rechtbank Den Haag, Judgment of 6 September 2017, SYNTHON B.V., v YEDA RESEARCH & DEVELOPMENT Co., Ltd., C/09/521009 / HA ZA 16-1231, paragraph 2.9.

¹⁷⁶⁹ Through the withdrawal of all dosage patents in the Netherlands, Teva succeeded in preventing an Arrow Declaration which would have acted as a precedent in other national jurisdictions as well. Thereby, Teva contributed to artificially prolong legal uncertainty in other Member States.

¹⁷⁷⁰ ID 455-2443, Teva internal email dated 23 May 2018 from {...} to {...} and others.

¹⁷⁷¹ ID 4032, Teva’s Reply to the Statement of Objections, paras. 892-897.

which prevented Synthon and Mylan from pursuing their request for a marketing authorisation between July and October 2016.

Poland

- (1412) In Poland, Teva sent warning letters to Synthon's licensee, Zentiva/Alvogen, in 2016, 2017 and 2018.¹⁷⁷² Teva also requested a preliminary injunction based on the process divisional EP '924 from the District Court in Warsaw on 26 October 2016. This request was rejected. Teva then requested a preliminary injunction based on the same divisional from the Regional Court in Gliwice on 27 March 2017, which was granted on 4 April 2017 and remained in force until 16 June 2017. On 27 July 2018, Teva requested a preliminary injunction based on the dosage divisional EP '335 from the Poznań District Court. This request was rejected. Teva then requested a preliminary injunction based on the more recent dosage divisional EP '962 from the Lublin District Court on 16 September 2019, which was granted on 25 September 2019 and remained in place until 6 March 2020 when it was revoked on appeal.
- (1413) Thus, in addition to the prolonged legal uncertainty concerning the validity of Teva's patents via the proceedings before the EPO (see Section 8.4.1.1) resulting in an increased commercial uncertainty for potential GA entrants as to whether they would be able to launch their GA product on the market, the actual anticompetitive effects of Teva's conduct in Poland consisted of the further increase in commercial uncertainty for Synthon and Zentiva/Alvogen resulting from the litigation pursued by Teva between October 2016 and March 2020 and of its exclusion as the only competitor for Copaxone from the market due to the preliminary injunctions in place for 20 mg GA between April and June 2017 and for 40 mg GA between September 2019 and March 2020.

Spain

- (1414) Finally, in Spain, Teva sent several warning letters to Synthon and its licensee, Mylan between 2016, and 2019.¹⁷⁷³ Teva also requested a preliminary injunction based on its process divisional patent EP '924 from the Barcelona Commercial Court No. 4 on 10 February 2017 and 17 March 2017. Both requests were rejected. On 11 July 2019, Teva filed a request for preliminary injunction based on its dosage divisionals EP '335, EP '962 and EP '172 from the Barcelona Commercial Court No. 4, which was also rejected. Teva's appeal against this decision was withdrawn on 13 January 2021.
- (1415) Thus, in addition to the prolonged legal uncertainty concerning the validity of Teva's patents via the proceedings before the EPO (see Section 8.4.1.1) resulting in increased commercial uncertainty for potential GA entrants as to whether they would be able to launch their GA product on the market, the actual anticompetitive effects of Teva's conduct in Spain consisted of the further increase in commercial uncertainty for Synthon and Mylan (now Viatris) resulting from the litigation pursued by Teva between February 2017 and January 2021.

8.4.4. Conclusion: Teva's comprehensive patenting conduct was capable of having exclusionary effects

- (1416) In view of the above, the Commission has reached the conclusion that Teva's conduct was capable of hindering and delaying the market entry and expansion of

¹⁷⁷² ID 2153, Teva's reply to Article 18(2) Request of 13 July 2022, Annex 15.23.

¹⁷⁷³ ID 2150, Teva's reply to Article 18(2) Request of 13 July 2022, Annex 15.28.

generic-like versions of GA, and that it actually hindered the market entry of Synthon GA.¹⁷⁷⁴ Teva's conduct enabled it to enforce its patents in national courts over an artificially prolonged period of time, delaying, often via preliminary injunctions, the entry and expansion of potential GA entrants, Synthon and its licensees in particular, on the market. Since the market entry and expansion of Synthon GA would have been likely to expose Copaxone to price competition (see Section 6.2 and Section 6.3.3.1.2), this conduct was capable of eliminating such price competition and maintain high prices for Copaxone on the market, as illustrated for Belgium, Czechia, Germany, Italy, the Netherlands, Poland and Spain.

8.5. Teva's divisionals game has no objective justifications and generates no efficiencies

(1417) Teva has not argued the existence of or substantiated any objective justifications or efficiencies stemming from its conduct and benefitting consumers beyond those discussed and rejected above (see in particular Section 8.3.5)

8.6. Conclusion: Teva abused its dominant position in the Relevant Member States

(1418) It follows from the foregoing that Teva's comprehensive patenting conduct regarding Copaxone does not constitute competition on the merits and was capable of restricting competition in the Relevant Member States. Teva has therefore committed an abuse of its dominant position in the relevant markets for GA in Belgium, Czechia, Germany, Italy, the Netherlands, Poland and Spain by misusing regulatory procedures such as to prevent or make more difficult the entry of competitors, Synthon and its licensees in particular, on the relevant markets. In particular, Teva created multiple divisional patents with overlapping content, intentionally staggered their filing and repeatedly and strategically withdrew them to avoid a reasoned decision on their validity, thus obstructing effective legal review and prolonging legal uncertainty concerning its remaining patents. This conduct was capable of hindering and/or delaying the market entry and uptake of competing GAs on the market and eliminating price competition.

9. SECOND ABUSE: EXCLUSIONARY DISPARAGEMENT

(1419) In this chapter, the Commission sets out the reasons supporting the conclusion that Teva abused its dominant position, in breach of Article 102 TFEU, by conducting a disparagement campaign targeting Synthon GA.

(1420) The following sections demonstrate that, in the context of its CCP strategy (see Chapter 5), Teva implemented a disparagement campaign against Synthon GA, to hinder and/or delay its market entry and uptake. In direct contradiction to the findings of the competent health authorities, Teva explicitly and implicitly questioned the safety and efficacy of Synthon GA, and its therapeutic equivalence with Copaxone, by emphasising clinically irrelevant compositional differences between the two products, by questioning the soundness of the GATE study as a scientific basis for Synthon GA's MA, and by making misleading inferences from experiences with other glatiramer-related substances. Teva specifically targeted the

¹⁷⁷⁴ The infringement in Belgium, Czechia, Germany and Spain ended on 7 February 2024 when the TBA effectively revoked EP '962 and EP '172. The infringement in Italy ended on 31 December 2021 and in Poland on 31 December 2022 on the last day of Teva holding a dominant position on the GA markets in Italy and Poland, respectively. The infringement in the Netherlands ended on 4 April 2017 when the deadline for the national validation of EP '335 lapsed. See Section 12.1.

market players that could influence the demand for Synthon GA, such as – on the one hand – pricing and reimbursement authorities, insurance funds as well as other healthcare organisations and – on the other hand – HCPs. This disparagement campaign was capable of restricting competition from Synthon GA, the only GA product competing with Copaxone in the EU.

- (1421) This chapter is structured as follows. Section 9.1 provides an overview of Teva's disparagement strategy and related conduct. Section 9.2 sets out the legal principles relevant in the context of exclusionary disparagement in pharmaceutical markets under Article 102 TFEU. Sections 9.3 to 9.5 set out the Commission's assessment underlying its conclusion that Teva's disparagement campaign amounts to an abuse of Teva's dominant position.
- (1422) In particular, the Commission shows first, that Teva disseminated objectively misleading information capable of discrediting Synthon GA (Section 9.3.1); and second, that Teva put in place effective mechanisms for the dissemination of the objectively misleading messaging to the stakeholders in the Relevant Member States (Section 9.3.2). Such conduct does not constitute competition on the merits.
- (1423) The Commission then shows that Teva's conduct was capable of producing exclusionary effects. In this context, the Commission analyses and describes how Teva targeted Payers and HCPs as key drivers of demand on the markets for GA (Section 9.4.1) and how Teva's objectively misleading messaging was capable of influencing the demand for Synthon GA (Section 9.4.2). The Commission also shows that Teva relied on its strong position on the market for disseminating the objectively misleading messaging (Section 9.4.3) and that Teva's dissemination of the objectively misleading messaging to the Payers and HCPs had significant coverage in the Relevant Member States (Section 9.4.4.).
- (1424) Finally, the Commission shows that there was no objective justification for Teva's communication campaign disparaging Synthon GA (Section 9.5).

9.1. Overview of Teva's disparagement strategy and conduct

- (1425) Teva's communication concerning specifically Synthon GA, the only competing GA product in the EU, was part of its CCP, a strategy consisting of a bundle of actions put in place to protect the revenues of Copaxone at a time when the expiry of its exclusivity was approaching.
- (1426) The three problematic prongs of Teva's communication assessed in this Chapter were focused, first, on questioning the GATE study on which the findings in the Decentralised Procedure for granting Synthon GA an MA were based and, second, on creating the false perception that minor chemical differences in GA structures may affect the safety and efficacy of Synthon GA (whereas chemical differences exist even between different batches of Teva's Copaxone)¹⁷⁷⁵. In so doing, Teva also questioned, either directly or indirectly, the therapeutic equivalence of Synthon GA to Copaxone, i.e. the fact that the safety and efficacy of Synthon GA is equivalent to that of Copaxone, by implying that Synthon GA's safety and/or efficacy were not

¹⁷⁷⁵ As explained in Section 5.1, GA is a complex mixture of synthetic proteins in random sequence. The complexity is mirrored in production, where not even two batches of GA of the same producer are exactly the same – small differences are characteristic even of different batches of Teva's Copaxone (see ID 906, Teva's reply to the Article 18(2) Request of 3 June 2021, p. 40).

equivalent to that of Copaxone.¹⁷⁷⁶ Third, Teva also insinuated that certain negative experiences with other glatiramer-related substances marketed outside the EU were somehow relevant for Synthon GA and its safety, efficacy and therapeutic equivalence with Copaxone. However, these claims are clearly at odds with the findings of the competent medicines' authorities in the Decentralised Procedure for the issuance of MAs to Synthon GA which rejected these claims and found that these minor chemical differences are clinically irrelevant, and that the GATE study provided an adequate scientific basis for those findings.¹⁷⁷⁷

(1427) Teva claims that its communications do not question the therapeutic equivalence between Synthon GA and Copaxone, but merely question the automatic substitution between Copaxone and Synthon GA, i.e. whether a pharmacist can freely dispense Synthon GA to a patient with a Copaxone prescription, or *vice versa* (see Recitals (87) and (260)).¹⁷⁷⁸ It is true that, in principle, Teva had a broader margin in questioning the automatic substitution between Copaxone and Synthon GA, an issue on which a more definite scientific position was still outstanding, than as regards their therapeutic equivalence, which had been established by the relevant authorities. However, even if Teva's misleading messages were sometimes disseminated in the context of a discussion on automatic substitution, Teva was in fact questioning the therapeutic equivalence between Synthon GA and Copaxone in order to protect its market position and delay or hinder Synthon GA's entry and uptake in the Relevant Member States. This behaviour does not constitute competition on the merits. The fact that this behaviour sometimes took place in the context of a discussion on automatic substitution, which in principle was legitimate, does not exonerate Teva's conduct from antitrust scrutiny.

9.1.1. Context of Teva's disparagement campaign

(1428) Long before the expiry of the exclusivity for Copaxone, Teva started preparing the ground for its disparagement campaign with the Copaxone Life Cycle Initiative ("LCI") that preceded the CCP. Its goal was to {...}.¹⁷⁷⁹

(1429) Teva referred to this multifaceted message concerning Copaxone's complexity (and the alleged safety and efficacy risks resulting therefrom) as the "complexity message" (hereinafter: "Complexity Message").

(1430) Teva also fostered the development of a narrative around the so-called "Non-Biologic Complex Drugs" or "NBCDs", and it extensively referred to generic or generic-like versions of Copaxone as "Follow-on Glatiramoids" (or "FoGAs").¹⁷⁸⁰

¹⁷⁷⁶ For the avoidance of doubt, Teva's communications considered as misleading for the purpose of this Decision, may cover one or more of the three relevant features of Synthon GA: efficacy, safety, and its therapeutic equivalence with Copaxone. It is not required that they cumulatively cover all these features.

¹⁷⁷⁷ For example, MEB concluded in the Public Assessment Report (which was then accepted by the competent authorities in all of the Member States included in the Decentralised Procedure for authorisation of Synthon GA): "*With regard to non-clinical and clinical aspects, no relevant dissimilarities to the reference product were seen*" (emphasis added) (ID 455-2483, Public Assessment Report Brabio, Conclusions, p. 17).

¹⁷⁷⁸ See Section 9.2.3.5.

¹⁷⁷⁹ ID 404-37, Power Point presentation "LCI COPAXONE – EU", February 2014, p. 4.

¹⁷⁸⁰ ID 455-705, FoGA White Paper, Copaxone and Follow-on Glatiramoids ("FoGAs"), September 2014: As noted by {...} (which was acquired by Teva in 2015) in {...} comments to a Briefing Document, {...}, dated September 2014, p. 1: {...}.

- (1431) “NBCD” was a novel term with the aim of signalling that there was a class of chemical (i.e. non-biological) drugs whose generic-like versions would have to undergo a more demanding, lengthy, and expensive approval process than the one required for standard “non-complex” generic medicines. The term was propagated by a working group (the “NBCD Working Group”) that was co-founded and sponsored by Teva. Teva viewed its participation in the NBCD Working Group as a tool to protect its originator¹⁷⁸¹ business interests including the Copaxone franchise: the {...} giving Teva {...}.¹⁷⁸² One of the objectives of Teva’s MSL (Medical Science Liaison) staff was to {...}.¹⁷⁸³
- (1432) Teva used the allegedly scientific term “NBCD” to “educate” the relevant stakeholders (medicines agencies competent for the approval of medicines, Payers¹⁷⁸⁴ and HCPs) about the “complexity” of GA and the allegedly resulting concerns about the safety, the efficacy and the therapeutic equivalence of would-be generic versions of Copaxone.¹⁷⁸⁵ As explained by {...} when defending Teva’s participation in the NBCD Working Group despite the opposition from Teva’s own generic business, {...}¹⁷⁸⁶ would not have been possible. The fact that the LCI team introduced terms such as “glatiramoid” and “NBCD”, and changed the way relevant stakeholders perceived Copaxone is reflected in Teva’s internal documents: {...}.¹⁷⁸⁷ A report from a meeting with neurologists shows that before Teva promoted this term, it was generally not known: {...}.¹⁷⁸⁸
- (1433) The utility of the newly coined term (as well as of the terms “glatiramoid” and the abovementioned “FoGA”) for Teva’s purposes and its background were underlined by {...} during an internal exchange: {...}¹⁷⁸⁹ as opposed to standard generic medicines.
- (1434) Internally, certain Teva staff responsible for Copaxone challenged the credibility of using the term “NBCD” as it had not been officially sanctioned or endorsed by any official bodies: {...}.¹⁷⁹⁰

¹⁷⁸¹ Participation in the NBCD Working Group was also important for Teva’s generic business. As noted by {...}, loss of a veto power afforded to the members would mean that Teva was {...} (ID 266-301, email dated 27 June 2017 from {...}). However, at the same time Teva’s participation in the NBCD Working Group was increasingly viewed as damaging for Teva’s generic business since, as explained by {...}, {...} (ID 455-2572, email dated 8 September 2017 from {...} to {...} and {...}). On the one hand, the NBCD Working Group (and Teva in the context of Copaxone) was propagating that “NBCDs” are complex and cannot be substituted by generics. On the other hand, Teva was developing a number of generics of “NBCDs” (directly or through Actavis). In the end, Teva withdrew from the NBCD Working Group in 2017 {...} (ID 455-2572, email dated 8 September 2017 from {...} to {...} and {...}). Participation in the NBCD Working Group was therefore agreeable only as long as it was possible {...} (ID 266-301, Teva internal email dated 27 June 2017 from {...} to {...} and others.

¹⁷⁸² ID 266-301, Teva internal email dated 27 June 2017 from {...} to {...}.

¹⁷⁸³ ID 263-1556, Regional Medical GO to Market Action Plan 2015, pp. 2, 3.

¹⁷⁸⁴ As defined in Recital (82), the notion of Payers in this Decision refers to health insurance companies, procurement bodies, such as hospitals and tender authorities, and Member State authorities, including all actors involved in the drug pricing and reimbursement process including those that are in a position to influence or inform pricing and reimbursement policies.

¹⁷⁸⁵ ID 263-51, Copaxone Continuation Project, February 2014, pp. 8, 9.

¹⁷⁸⁶ ID 266-301, Teva internal email dated 27 June 2017 from {...} to {...}.

¹⁷⁸⁷ ID 404-715, The Copaxone Life Cycle Initiative (LCI), December 2012, (attached to ID 404-712), pp. 4, 5, 6.

¹⁷⁸⁸ ID 263-2994, TPE Country visit: deep dive session, Berlin, 27 June 2017, pp. 52-55.

¹⁷⁸⁹ ID 455-2678, Teva internal email dated of 30 September 2014 from {...} to {...} and others.

¹⁷⁹⁰ ID 404-1815, Teva internal email dated 1 November 2017 from {...} to {...} and others (unofficial translation) – original text: {...}.

- (1435) In spite of the doubts about its scientific solidity, the term “NBCD” permeates all CCP documents and all of Teva’s communication in an apparent effort to make Teva’s complexity messaging appear to be of a scientific and unbiased nature, while in reality it had the sole purpose of delaying and obstructing the entry and uptake of Synthon GA.¹⁷⁹¹ {...}, noted in June 2017 in the context of the discussion on Teva’s continued participation in the NBCD Working Group: {...}.¹⁷⁹²
- (1436) The specific nature of Teva’s communication campaign evolved to reflect the progress in Synthon’s activities in its effort to launch and commercialise its GA. Teva organised the campaign according to two main periods – the one before and the one after the completion of the Decentralised Procedure for Synthon GA. Prior to the completion of the Decentralised Procedure in 2016, Teva pursued “Phase I” activities to “*educate*” regulators (responsible for the procedures for the grant of national MAs) and external experts (i.e. key opinion leaders in the field of neurology/MS).¹⁷⁹³ Teva kept emphasising the complexity of GA aiming at raising public health concerns regarding copies of GA. For example, already in 2008, Teva submitted a White Paper on glatiramoids to the European regulators, which, according to Teva, {...}.¹⁷⁹⁴ One of Teva’s Key Strategic Objectives was to educate stakeholders: {...}.¹⁷⁹⁵ That document also confirms that Teva’s campaign was driven by commercial goals (such as {...}).¹⁷⁹⁶
- (1437) During Phase I, Teva’s campaign essentially sought to convince marketing authorisation bodies in the EU to raise the bar for the MA grant to competing GA products in two ways. First, Teva tried to persuade the authorities to apply the procedural authorisation track for entirely new molecules, which is a more cumbersome and costly procedure (instead of an abridged procedure common in cases of generic or hybrid products).¹⁷⁹⁷ Second, Teva raised doubts¹⁷⁹⁸ as to whether Synthon GA or any other competing GA would meet the relevant regulatory requirements prompting the medicines authorities to stop the clock and thus delay the MA grant to Synthon GA.¹⁷⁹⁹ As regards Teva’s efforts to impose the authorisation track reserved for new molecules, those efforts were eventually unsuccessful but Synthon GA nonetheless had to go through a much more demanding and lengthy

¹⁷⁹¹ See ID 455-1155, Teva internal email dated 9 October 2014 from {...} to {...} and others in which {...}. More details on Teva’s complexity messaging, its objectively misleading elements and its dissemination are presented in Sections 9.3.1 and 9.3.2.

¹⁷⁹² ID 266-301, Teva internal email dated 27 June 2017 from {...} {...} and others.

¹⁷⁹³ See ID 263-47, Copaxone Continuation Project Focus, November 2013, p. 7; ID 263-48, Copaxone Continuation Project Focus, January 2014, p. 6; Teva established several workstreams: {...}; ID 263-49, Copaxone Continuation Project Focus, February 2014, p.7; ID 263-1556, Regional Medical GO to Market Action Plan 2015, p. 2, 3, 5, 11 – this document shows that one of Teva’s key medical strategic objectives was to educate stakeholders, preparing the ground for dissemination of its messages (analysed in Section 9.3) before the successful conclusion of the Decentralised Procedure for Synthon GA : {...}. The teams in charge of this were LCI, R&D, Marketing, Medical Affairs, publications Group, Legal. The tactical initiatives included {...}.

¹⁷⁹⁴ ID 327, Copaxone Europe: Recent Developments and Activities, September 2014, p. 3.

¹⁷⁹⁵ ID 264-1756, COPAXONE® Continuation Project (CCP) – Pricing & Market Access Follow-on Glatiramer Acetate (FoGA) TRAINING, 3,4 February 2016, p. 16.

¹⁷⁹⁶ ID 264-1756, COPAXONE® Continuation Project (CCP) – Pricing & Market Access Follow-on Glatiramer Acetate (FoGA) TRAINING, 3, 4 February 2016, p. 17.

¹⁷⁹⁷ See Recital (75) of the Decision.

¹⁷⁹⁸ As noted by {...} in {...} email dated 9 September 2014 to {...} and others concerning a draft of {...} (ID 455-698, Teva internal email dated 9 September 2014 from {...} to {...} and others.

¹⁷⁹⁹ ID 263-52, CCP FoGA Action Plan – Phase IIb materials development roll-out, 15 March 2016, p.2; ID 263-69, Copaxone Continuation Project, CCP, June 2016.

procedure for hybrid products which, *inter alia*, required an additional study to prove therapeutic equivalence with Copaxone (GATE study).¹⁸⁰⁰ As regards Teva's efforts to raise doubts, Teva's arguments managed to delay, but not to prevent the MA grant.

- (1438) The successful conclusion of the Decentralised Procedure for Synthon GA triggered Phase II of Teva's communication campaign. In parallel, Teva was systematically challenging the MAs in a series of legal actions that ultimately all failed, but nonetheless led to delays in certain markets where MAs for Synthon GA were temporarily suspended, enabling Teva to benefit from additional months or weeks of exclusivity.¹⁸⁰¹ For the sake of clarity, these legal actions were not part of the abusive communication campaign as assessed in the present Section, and this Decision does not take a position on their compatibility with Article 102 TFEU.
- (1439) The Commission's assessment of whether Teva's communication campaign constitutes disparagement in violation of Article 102 TFEU focuses on this Phase II. Teva's activities preceding Phase II (including the communication campaign during Phase I) are assessed only as relevant context to the abusive conduct, in as much as they show that Teva's campaign, which amongst others also targeted certain HCPs and Payers, started well before the MA grant to Synthon GA, and may have laid the ground for making these market players more receptive to Teva's messages. Teva's arguments remained broadly the same before and after the MA grant, despite the fact that the competent bodies such as the MEB had explicitly rejected these arguments during the Decentralised Procedure.¹⁸⁰²

9.1.2. *Overview of Teva's disparagement strategy and campaign after the end of the Decentralised Procedure*

- (1440) By completing the Decentralised Procedure for Synthon GA in 2016, after intense scrutiny, the competent health authorities, established that Synthon GA and Copaxone are therapeutically equivalent and that the compositional differences between the two products were irrelevant from a therapeutic point of view.¹⁸⁰³ However, Teva persistently undertook major efforts to curb the uptake of Synthon GA by systematically suggesting to Payers and HCPs that Synthon GA should not substitute Copaxone or be prescribed because (i) differences inherent in the GA structures were allegedly not fully appreciated during the Decentralised Procedure and might affect the safety and efficacy of Synthon GA (see Section 9.3.1.1); (ii) the risks and adverse effects associated with other glatiramer-based products may equally apply to Synthon GA (see Section 9.3.1.2); and (iii) the GATE study, which was designed by Synthon based on the scientific advice from the competent public authorities and relied upon during the Decentralised Procedure, was allegedly not

¹⁸⁰⁰ The Commission notes that GA products have been approved by the US Food and Drug Administration as "generics", i.e. in the abbreviated procedure which confirmed their sameness and bioequivalence to Copaxone.

¹⁸⁰¹ See Section 5.2.3.4.

¹⁸⁰² The messages in Phase II are essentially the same as in Phase I – see ID 404-2419, COPAXONE® Continuation Project (CCP) Complexity COPAXONE® Campaign, CCP LOC Executional Excellence Plan 2014-2015, pp. 18, 21 - for example: {...}; ID 455-2880, CCP: agreed project scope and deliverables, November 2015, outlining the CCP Phase II strategy and shows that the criticism or automatic substitution was to be added to the already existing messages concerning the complexity of GA: {...}; see also Recital (1685) and footnote 2163; For MEB rejecting Teva's claims similar to those communicated to Payers and HCPs, see also ID 742-42, Assessment report with respect to quality Mylan and Synthon's glatiramer products; ID 742-163, Klinisch beoordelingsrapport Glatirameerproducten van Mylan en Synthon.

¹⁸⁰³ ID 455-2843, Public Assessment Report Brabio, Conclusions.

scientifically sound enough (see Section 9.3.1.3). However, even six years after the Decentralised Procedure for Synthon GA was completed, Teva has still not submitted any evidence to the authorities that requested it¹⁸⁰⁴ (or to those competent for pharmacovigilance) in support of its claims questioning the safety and efficacy of Synthon GA, as well as questioning its therapeutic equivalence with Copaxone.

- (1441) During Phase II of its communication campaign, Teva focused its disparagement activities towards Payers (“Phase IIa” – national pricing & reimbursement bodies, health insurers/funds, hospitals) and HCPs (“Phase IIb”) with a view to avoid losing patients to Synthon GA. This is because Synthon GA threatened Copaxone with generic-like competition affecting its entire patient base. After the finalisation of the Decentralised Procedure for Synthon GA,¹⁸⁰⁵ Teva implemented a campaign with the goal {...}.¹⁸⁰⁶ Teva’s campaign aimed at either directly or indirectly (especially at a later stage) artificially differentiating Copaxone from Synthon GA and at insinuating problems related to the safety, efficacy and, directly or indirectly, the therapeutic equivalence of Synthon GA. Tellingly, a Teva draft internal document from 2017 states that: {...}.¹⁸⁰⁷ {...}.
- (1442) In short, Teva insinuated that {...}.¹⁸⁰⁸ Teva was even suggesting that {...}¹⁸⁰⁹ or that the active substances in Synthon GA are {...}¹⁸¹⁰. Teva made these statements despite the fact that Teva itself recognised in internal documents that such differences in GA structures were as such inconclusive, because {...}¹⁸¹¹ {...}¹⁸¹².
- (1443) Moreover, the Public Assessment Report (PAR) based on which the Decentralised Procedure for Synthon GA was finalised expressly confirmed that Synthon GA “can be regarded as therapeutic equivalent to [Copaxone]”, where “*‘Therapeutical equivalence’ means that the efficacy and safety of this hybrid formulation [Synthon GA] is similar to the efficacy and safety of the reference product [Copaxone]*” (emphasis added).¹⁸¹³ Consequently, the SmPCs of the two products are identical. MEB also stated that “[n]o specific difference in efficacy or safety between the patients who were on Copaxone and later switched to Brabio [Synthon GA] and the patients who were treated with Brabio for the entire period were observed.

¹⁸⁰⁴ See Recital (1929).

¹⁸⁰⁵ On 30 July 2014 Synthon submitted MA applications in the Decentralised Procedure to MEB (the Dutch Medicines Evaluation Board) as a RMS in accordance with Article 10(3) of the Directive 2001/83/EC with Copaxone as reference product. The applications included all EU Member States as CMSs. On 11 March 2016 MEB issued a notification that the procedure had closed and that Synthon's product would be approved for the treatment of RRMS. Starting April 2016, CMSs were granting the national MAs (following the conclusion of the assessment part of the procedure, the CMSs have 30 days in which to adopt the decision of the RMS to grant MAs in their respective Member States).

¹⁸⁰⁶ ID 263-75, Go To Market Action Plan (GTMAP) Copaxone, 12 October 2017, p. 6.

¹⁸⁰⁷ ID 751-328, Copaxone evolved campaign e-detailed implementation guide, 30 June 2017, p. 15.

¹⁸⁰⁸ ID 806-2, Assessing the Value of COPAXONE® in Relation to Follow-on Glatiramer Acetate Payer White Paper, 8 June 2016, p. 11. See also ID 455-2210, COPAXONE® and the introduction of FoGA Payer objection handler, 8 December 2016, pp. 16 and 20.

¹⁸⁰⁹ ID 266-105, COPAXONE® and the introduction of FoGA, Objection handler for MSLs, Version 4, March 2019, p. 8.

¹⁸¹⁰ ID 455-2630, The value of COPAXONE® (glatiramer acetate): Considerations when assessing the use of follow-on glatiramer acetate (FoGA), Latest version available to the Commission dated 29 January 2019, pp. 23 and 85.

¹⁸¹¹ ID 455-1347, Teva internal email dated 14 April 2017 from {...} to {...} and others.

¹⁸¹² ID 413-172, Survey to inventory EU needs for a retrospective real-world database study with Copaxone, June/July 2019, p. 2.

¹⁸¹³ ID 455-2843, Public Assessment Report Brabio, p. 17.

Therefore, there is no evidence against switching".¹⁸¹⁴ Teva's statements thus contradicted the findings of medicines agencies in the EU.

- (1444) The purpose of Teva's communication campaign was to manipulate the perception of the alleged risks associated with the use of Synthron GA and {...}¹⁸¹⁵ in relation to Synthron GA's safety, efficacy, and, directly or indirectly, its therapeutic equivalence with Copaxone. As remarked in 2017 by Teva's {...} in the context of Teva's efforts to undermine the validity of the GATE study¹⁸¹⁶ {...}.¹⁸¹⁷
- (1445) In the case of Payers, Teva's messaging sought to instil doubt artificially as to whether Synthron GA is safe, efficacious and therapeutically equivalent to Copaxone, in order to influence the Payers' decision regarding automatic substitution (i.e. general ability for the pharmacist to dispense a different, typically cheaper GA to patients with a prescription for original GA, i.e. Copaxone).¹⁸¹⁸ Teva's efforts to influence the Payers were typically strengthened by opinions from "key opinion leaders" ("KOLs") and other external experts presented as independent, with Teva failing to disclose the existing links it had with those experts.¹⁸¹⁹ These influential professionals were expected to be engaged by the Payers as purportedly independent experts to advise them on decisions, including as regards automatic substitution, which could affect the conditions of competition between Synthron GA and Copaxone.
- (1446) Where Teva's attempts to avoid automatic substitution by pharmacists – in Phase IIa of the CCP – failed, Teva would reach out to HCPs in an attempt to instil doubts about Synthron GA's safety, efficacy, and therapeutic equivalence with Copaxone, to discourage individual switching (i.e. switching the prescription for Copaxone to Synthron GA for individual patients) by disseminating misleading messages (see Sections 9.4.1, 9.4.2., 9.4.4.2.2, 9.4.4.3.2, 9.4.4.4.2). Teva also lobbied against switching with patient organisations and pharmacists associations (e.g. in Germany, see Section 9.4.4.4), to discourage switching in Phase IIb in individual cases.
- (1447) In certain communications concerning Synthron GA, Teva used factually incorrect statements or implied that the use of Synthron GA entailed safety and efficacy risks. For example, Teva explained to the FAMHP (Belgian Federal Agency for Medicines and Health Products) that {...}¹⁸²⁰ despite the fact that the Dutch medicines agency – MEB as the reference competent authority with the agreement of all concerned Member States in the Decentralised Procedure, unequivocally established that Synthron GA was therapeutically equivalent to Copaxone which means equivalent in terms of safety and efficacy.
- (1448) In messaging concerning Synthron GA, Teva also resorted to cherry-picking information furthering Teva's ultimate commercial goal – the protection of

¹⁸¹⁴ ID 742-172, Klinisch beoordelingsrapport Glatirameerproducten van Mylan en Synthron, p. 9.

¹⁸¹⁵ ID 404-2017, Teva internal email dated 27 October 2014 from {...} to {...} and others regarding {...}.

¹⁸¹⁶ See Section 9.3.1.3 and particularly Recitals (1604), (1605), (1613) - (1619).

¹⁸¹⁷ ID 455-383, Teva internal email dated 4 May 2017 from {...} to {...} and others, p. 1.

¹⁸¹⁸ For more details on the automatic substitution of medicines see Section 4.3.

¹⁸¹⁹ See e.g. ID 455-269, CCP strategy, In the face of evolving FoGA competition, p. 14 showing that Teva's MSL team was tasked with reactively educating external experts in response to questions raised during discussions with the Market Access teams. It should be noted that Teva created a special class of White Papers and Presentations targeting specifically external experts (see Section 9.3.2 and ID 455-269, CCP strategy, In the face of evolving FoGA competition, p. 18).

¹⁸²⁰ ID 262-724, Substitution considerations for follow on glatiramer acetate products, Meeting with Federal Agency for Medicines & Health Products, Brussels, 23 January 2017, p. 57.

Copaxone’s market position. For example, when arguing against substitution between Copaxone and Synthon GA in the context of Phase IIa of the CCP in the proceedings before AIFA in Italy, it reproduced the statement in the Public Assessment Report that “[t]he Member States took into consideration that there are inherent limitations far drawing a conclusion on similarity/comparability of highly heterogeneous mixtures such as glatiramer.[...] Therefore the similarity needed to be further supported with (non)clinical data”,¹⁸²¹ but omitted to add the sentence that immediately followed and that was very relevant to what preceded: “These [(non)clinical data] are presented in section III and IV of this report” (emphasis added).¹⁸²²

- (1449) Teva’s selective use of relevant facts and information is also demonstrated by the manner in which it used the formal findings of medicines authorities in a misleading manner and to its favour. For as long as a decision against automatic substitution was in force in Italy, Teva abundantly referred to that decision in its communications. However, as soon as Teva received a negative decision from AIFA (i.e. that Synthon GA was to be included in the transparency list together with Copaxone allowing for automatic substitution), Teva issued an internal instruction not to {...}.¹⁸²³
- (1450) The campaign leveraged Teva’s dominance in the market for GA¹⁸²⁴, including its unrivalled access to HCPs and its strong reputation in the MS field as the holder of the originator medicine, and – also due to the understandable risk aversion of HCPs – was capable of countering Synthon’s and its licensees’ efforts to convince the doctors to prescribe Synthon GA. As bluntly underscored internally by {...} {...}.¹⁸²⁵
- (1451) Teva’s CCP efforts and communication campaign were capable of protecting Copaxone’s market position and of hindering and/or delaying the entry and uptake of Synthon GA. For example, in May 2017, {...}.¹⁸²⁶ {...}.¹⁸²⁷ {...}.¹⁸²⁸
- (1452) Teva’s campaign started before the successful conclusion of the Decentralised Procedure for the MA grant to Synthon GA was announced in April 2016 (an event which marked the start date of the infringement).¹⁸²⁹ The period before April 2016 is however important for a full understanding of the entirety of Teva’s campaign. The above facts and context will be further assessed in Sections 9.3 to 9.5 after first recalling the general and specific legal principles governing this assessment (see Section 9.2).

9.2. Applicable principles and analytical framework under Article 102 TFEU

9.2.1. General principles

- (1453) The general principles set out above under Section 8.2 apply also with respect to exclusionary disparagement under Article 102 TFEU. In particular, the Commission

¹⁸²¹ ID 742-109, Teva’s reply to Article 18(2) Request of 3 June 2020, Annex Q39 IT 1, Teva’s letter to AIFA of 6 July 2016, p. 6.

¹⁸²² ID 455-2843, Public Assessment Report Brabio, p. 6.

¹⁸²³ ID 404-2551, Teva internal email dated 19 April 2017 from {...} to {...} and others.

¹⁸²⁴ See Section 9.4.3.

¹⁸²⁵ ID 404-2367, Teva internal email dated 16 August 2017 from {...} to {...}.

¹⁸²⁶ ID 455-2280, Teva internal email 8 May 2017 from {...} to {...} and others, concerning “*FoGA country template*”.

¹⁸²⁷ ID 404-1640, Teva internal email dated 6 June 2017 from {...} to {...}.

¹⁸²⁸ ID 413-150, EU CCP Strategy, Amsterdam, March 2017, p. 9.

¹⁸²⁹ See Section 12.2 below.

recalls that Article 102 TFEU imposes a special responsibility on dominant undertakings not to allow their conduct to impair genuine undistorted competition on the internal market¹⁸³⁰ and that Article 102 TFEU does not include an exhaustive enumeration of the practices that may constitute abuses.¹⁸³¹

- (1454) Further, the Commission recalls that Article 102 TFEU prohibits a dominant undertaking from eliminating or marginalising a competitor and thereby strengthening its position by using methods other than those that come within the scope of competition on the merits.¹⁸³² Concerning the effects of the dominant undertaking's conduct, Article 102 TFEU prohibits behaviour that is capable of restricting competition, regardless of its success.¹⁸³³ Finally, the Commission recalls that there is no requirement to establish that the dominant undertaking has an anticompetitive intent, but evidence of such an intent may be taken into account to determine that a dominant position has been abused.¹⁸³⁴

9.2.2. Principles specifically applicable to exclusionary disparaging conduct on pharmaceutical markets

- (1455) According to the Court's ruling in the *Enel* case, "Article 102 TFEU must be interpreted as meaning that a practice which is lawful outside the context of competition law may, when implemented by an undertaking in a dominant position, be characterised as "abusive" for the purposes of that provision if it is capable of producing an exclusionary effect and if it is based on the use of means other than those which come within the scope of competition on the merits".¹⁸³⁵
- (1456) The Commission assessed, first, whether Teva's disparaging conduct constitutes competition on the merits, and second, whether it is capable of having exclusionary effects.
- (1457) Disparagement, consisting of the dissemination of misleading messages is an example of conduct falling outside competition on merits. In its 2018 *Hoffmann-La Roche* judgment, the Court of Justice ruled that an arrangement "which concerns the dissemination, in a context of scientific uncertainty, to the EMA, healthcare professionals and the general public of misleading information relating to adverse reactions" allegedly resulting from using a competing drug "for the treatment of diseases not covered by the MA for that product, with a view to reducing the competitive pressure [...] constitutes a restriction of competition by object" under Article 101 TFEU.¹⁸³⁶ While the *Hoffmann-La Roche* judgment concerned an infringement of Article 101(1) TFEU, its principles apply by analogy to abuses under

¹⁸³⁰ Judgment in *Michelin v Commission*, C-322/81, EU:C:1983:313, paragraph 57; Case C-209/10, *Post Danmark*, paragraph 23; Case C-377/20, *Servizio Elettrico Nazionale and Others*, paragraphs 74.

¹⁸³¹ Judgement of the Court of Justice 18 April 1975, *Europemballage and Continental Can v Commission*, C-6/72, EU:C:1973:22, paragraph 26 Judgment of 14 October 2010, *Deutsche Telekom v Commission*, C-280/08 P, EU:C:2010:603, paragraph 173; Judgement of the Court of 17 February 2011, *TeliaSonera Sverige*, C-52/09, EU:C:2011:83, paragraph 26.

¹⁸³² Case C-377/20, *Servizio Elettrico Nazionale and Others*, paragraphs 75-77.

¹⁸³³ Case C-377/20, *Servizio Elettrico Nazionale and Others*, paragraphs 53-57.

¹⁸³⁴ Case C-377/20, *Servizio Elettrico Nazionale and Others*, paragraphs 60-63.

¹⁸³⁵ Case C-377/20, *Servizio Elettrico Nazionale and Others*, paragraph 103; Judgment of the Court of 21 December 2023, *European Superleague Company*, C-333/21, EU:C:2023:1011, paragraph 102.

¹⁸³⁶ Case C-179/16, *F. Hoffmann-La Roche and Others*, paragraphs 92-95. The Court added that "given the characteristics of the medicinal products market, it is likely that the dissemination of such information will encourage doctors to refrain from prescribing that product thus resulting in the expected reduction in demand for that type of use", see paragraph 93. See also AG SaugmandsgaardØe's Opinion in that case, paragraphs 158 and 160.

Article 102 TFEU, especially considering the “special responsibility” of dominant undertakings not to abuse their market power.¹⁸³⁷

- (1458) An undertaking – even if dominant – can promote the qualities of its own product, reflecting its skills and abilities. However, in view of its special responsibility under Article 102 TFEU not to use means outside the scope of competition on the merits, a dominant firm in the pharmaceutical sector cannot – through promotion or other means – disparage a rival product by creating misleading perceptions about that product’s characteristics including its safety and efficacy.
- (1459) This applies, in particular when a dominant undertaking that holds an established position with relevant stakeholders, such as medicines agencies, Payers and HCPs, relies on this position in order to target these stakeholders with a campaign aimed at creating the misleading perception of the existence of health risks related to patients switching to a competing product. Such a campaign has no other economic motive than to weaken or eliminate competition and to enable the undertaking to take advantage of its dominant position, and is clearly not “*in keeping with the special responsibility of an undertaking in a dominant position*” and does not constitute competition on the merits.¹⁸³⁸ Furthermore, when it comes to promotional communication with patients and doctors, pharmaceutical legislation expressly prohibits misleading information and statements that the effects of taking a medicine are better than those of another treatment: Article 87(3) of Directive 2001/83 states that “[t]he advertising of a medicinal product [...] shall not be misleading” and Article 92(2) requires that “[a]ll the information contained in the documentation [transmitted as part of the promotion of a medicinal product to persons qualified to prescribe or supply it] shall be accurate, up-to-date, verifiable and sufficiently complete to enable the recipient to form his or her own opinion of the therapeutic value of the medicinal product concerned”, while Article 92(3) provides that “*Quotations as well as tables and other illustrative matter taken from medical journals or other scientific works for use in the documentation [transmitted as part of the promotion of a medicinal product to persons qualified to prescribe or supply it] shall be faithfully reproduced and the precise sources indicated*”.¹⁸³⁹ Concerning promotional communication with patients, Article 90(b) of Directive 2001/83 provides that “[t]he advertising of a medicinal product to the general public shall not contain any material which: [...] (b) suggests that the effects of taking the medicine [...] are better than, or equivalent to, those of another treatment or medicinal product [...] (k) uses, in improper, alarming or misleading terms, pictorial representations of changes in the human body caused by disease or injury, or of the action of a medicinal product on the human body or parts thereof”. Therefore, pharmaceutical legislation also prohibits the advertisement and promotion of medicinal products through misleading information.
- (1460) Against this background, in order to establish whether Teva’s conduct violated Art. 102 of the Treaty, the Commission first assesses whether Teva’s conduct falls

¹⁸³⁷ Case C-333/21, *European Superleague v Commission*, paragraph 119. The French Autorité de la Concurrence has pursued several cases where disparagement was found to constitute abusive conduct under Article 102 TFEU. Several of its decisions have been confirmed on appeal before national courts. See, for example, Decision n°13-D-11 of 14 May 2013 of the Autorité de la Concurrence against Sanofi Aventis France, which was upheld on appeal. The case originated from a complaint by Teva Santé.

¹⁸³⁸ See Case T-321/05, *AstraZeneca v Commission*, paragraph 355.

¹⁸³⁹ Directive 2001/83/EC of the European Parliament and of the Council of 6 November 2001 on the Community code relating to medicinal products for human use, OJ L 311, 28.11.2001, p. 67 and subsequent amendments.

outside the boundaries of competition on the merits¹⁸⁴⁰ because the information communicated was objectively misleading,¹⁸⁴¹ (i.e. inaccurate or incomplete information capable of confusing its addressees,¹⁸⁴² including by inducing them in error), such that it was capable of discrediting a competing product. Then, the Commission assesses whether such conduct was capable of producing exclusionary effects and whether it was objectively justified. These elements are addressed in more detail below.

9.2.2.1. Objectively misleading information capable of discrediting a competing product

- (1461) Pursuant to the case law of the Union Courts, in particular the *Hoffmann-La Roche* judgment, misleading information is not only information that is inaccurate but also information that is strictly speaking correct, though presented in an incomplete manner with the purpose to confuse the authorities and manipulate the public perception around the safety risks of a competing medicine.¹⁸⁴³
- (1462) This also reflects the Advocate General’s Opinion in *Hoffmann-La Roche*, finding that a communication is misleading where “*because of that manner of presentation*” the disseminated information may mislead those who receive it.¹⁸⁴⁴ According to the Advocate General, the communication of misleading allegations may include instances where a company omits “*to state that the risks created by using the medicine are uncertain, or [exaggerates] such risks with a lack of objectivity with regard to the available evidence*”.¹⁸⁴⁵ Accordingly, establishing exclusionary

¹⁸⁴⁰ Case C-457/10 P, *AstraZeneca v Commission*, paragraph 98 – the Court found that using misleading representations with the aim of leading authorities into error was not consistent with competition on the merits.

¹⁸⁴¹ It is not necessary to show that the addressees of the misleading information were actually misled. See Case T-321/05, *AstraZeneca v Commission*, paragraph 360.

¹⁸⁴² The terms “to confuse” and “to induce into error” may be used as synonyms since, in the *Hoffmann-La Roche* judgment, the English translation uses the term “to confuse”, while the Italian version (which was the original language of the case) and the French version use the terms “induce in error” - see Case C-179/16, *F. Hoffmann-La Roche Ltd, Novartis and Others v AGCM*, paragraph 92: “*dette informazioni miravano, da un lato, a indurre l’EMA e la Commissione in errore*” and “... lesdites informations visaient, d’une part, à induire l’EMA et la Commission en erreur” (emphasis added).

¹⁸⁴³ See Case C-179/16, *F. Hoffmann-La Roche and Others*, paragraph 92: “[...] with regard to the misleading nature of the information at issue, it must be held that the information whose notification to the EMA and the general public, according to the AGCM’s decision, was the subject of a cartel agreement between Roche and Novartis, are, **failing compliance with the requirements of completeness and accuracy laid down in Article 1(1) of Regulation No 658/2007, to be regarded as misleading if the purpose of that information, which is a matter for the referring court to determine, was (i) to confuse the EMA and the Commission and have the adverse reactions mentioned in the summary of product characteristics so as to enable the MA holder to launch a communication campaign aimed at healthcare professionals, patients and other persons concerned with a view to exaggerating that perception artificially [...]**” (emphasis added).

¹⁸⁴⁴ Opinion of Advocate General Saugmandsgaard Øe in Case C-179/16, *Hoffmann-La Roche and Others*, paragraph 158. Although the English translation of the Advocate General’s Opinion refers to the disseminated information’s “likelihood” of misleading its addressees, the French original rather refers to its “capability” to induce in error: “*Selon moi, la communication d’allégations trompeuses inclut la diffusion de données en elles-mêmes exactes mais présentées de façon sélective ou incomplète lorsque, au vu de ces modalités de présentation, cette diffusion est susceptible d’induire en erreur ses destinataires*” (emphasis added). Similarly, in its *Avastin-Lucentis* case, the French NCA found that Novartis and Roche abused their collectively dominant position *inter alia* on the basis that Novartis made a selective and biased presentation of the results of scientific studies comparing the safety and efficacy of the use of two competing products. See Décision n° 20-D-11 du 9 septembre 2020, paragraph 812 et seq.

¹⁸⁴⁵ Opinion of Advocate General Saugmandsgaard Øe in Case C-179/16, *Hoffmann-La Roche and Others*, paragraph 160. Interestingly, Advocate General Saugmandsgaard Øe refers in this connection to the

disparagement under competition law does not require showing that the information disseminated by the dominant undertaking is scientifically inaccurate. It is sufficient to show that information was presented in a manner that was capable of misleading, i.e. that it was able to confuse the addressees, taking into account all the relevant circumstances of the case.

- (1463) In addition, it must be assessed whether the representations by the dominant undertaking are objectively misleading. This means that there is no need to establish that the misleading information actually misled the targeted addressees. The abusive nature of the conduct does not depend on the contingencies of the reactions of the addressees of the information.¹⁸⁴⁶ Accordingly, it is sufficient to show that the disseminated information was of such a nature as to be capable of misleading the targeted addressees. In the present case, the misleading information related to essential characteristics of the product which had already been assessed by the MEB: the safety and efficacy of Synthon GA and its therapeutic equivalence with Copaxone.
- (1464) Moreover, the misleading nature of the representations must be established *in concreto*, by taking into account the circumstances at issue.¹⁸⁴⁷
- (1465) The present Decision does not take a position as to whether Teva's messages went against the letter and the spirit of Directive 2001/83. However, even in the case where an undertaking's conduct was compliant with other legal rules, this would not preclude the possibility that, under certain conditions, the same undertaking may be sanctioned for infringing Article 102 TFEU through the same conduct.¹⁸⁴⁸
- (1466) As observed in the Advocate General's Opinion in *Hoffmann-La Roche*, in the specific context of the pharmaceutical sector and of the aversion to risk of HCPs in light of deontological considerations as well as applicable legal provisions governing medical liability, the dissemination of objectively misleading information about the risks associated with a medicinal product "*is inherently likely to discredit that product among doctors and stimulate demand for competing medicinal products*".¹⁸⁴⁹
- (1467) By the same token, the dissemination to Payers of objectively misleading information about essential characteristics of a competing product is also capable of discrediting such a product. When those Payers are responsible for deciding on automatic substitution, the discrediting nature of the disseminated misleading information concerning, for example, Synthon GA's therapeutic equivalence with Copaxone is likely to discredit Synthon GA with regard to its substitutability with Copaxone and is therefore also capable of negatively affecting demand for that competing product.

European Medicines Agency Periodic safety update report, which states that the periodic safety update reports (which MA holders must submit) must characterise the potential risks communicated, mentioning, in particular, the "***strength of evidence and its uncertainties, including analysis of conflicting evidence***". See Module VII — Periodic safety update report (Rev 1) (EMA/816292/2011 Rev 1), 9 December 2013, p. 28 (emphasis added).

¹⁸⁴⁶ Case T-321/05, *AstraZeneca v Commission*, paragraphs 360-361. See also Case C-457/10 P, *AstraZeneca v Commission*, paragraph 99.

¹⁸⁴⁷ Case C-457/10 P, *AstraZeneca v Commission*, paragraph 99.

¹⁸⁴⁸ Case C-280/08 P, *Deutsche Telekom v Commission*, paragraphs 81-84; judgment of 10 July 2014, *Telefónica and Telefónica de España v Commission*, C-295/12 P, EU:C:2014:2062, paragraph 133; Case T-321/05, *AstraZeneca v Commission*, paragraphs 813-817 and 864; Case C-377/20, *Servizio Elettrico Nazionale and Others*, paragraph 77.

¹⁸⁴⁹ Opinion of AG Saugmandsgaard Øe, paragraph 169.

(1468) As a result, by disseminating objectively misleading messages about essential characteristics of a competing product to HCPs and Payers, a dominant undertaking is capable of creating a negative perception of that competing product with regard to key features for its successful therapeutic and commercial uptake, thereby departing from competition on the merits.

(1469) In the case at hand, Teva’s dissemination of objectively misleading information on the safety and efficacy of Synthon GA and on its therapeutic equivalence with Copaxone was capable of discrediting Synthon GA with key drivers of demand (namely HCPs and Payers), thereby departing from competition on the merits, and of artificially shielding the demand for Copaxone from Synthon GA’s direct and immediate competition.

9.2.2.2. Capability to produce exclusionary effects

(1470) According to the Union Courts, in order to establish that an exclusionary practice is abusive, a competition authority must show that the practice was capable, when implemented, of producing exclusionary effects, by making it more difficult for competitors to enter or to remain on the market in question.¹⁸⁵⁰ In particular, conduct may be categorised as abusive where it has “*the actual or potential effect – or even the object – of impeding potentially competing undertakings at an earlier stage, through the placing of obstacles to entry or the use of other blocking measures or other means different from those which govern competition on the merits, from even entering*” the market(s) concerned and, in so doing, “*preventing the growth of competition therein to the detriment of consumers, by limiting production, product or alternative service development or innovation*”.¹⁸⁵¹

(1471) The uptake of prescription medicines, like GA, depends largely on the decisions of pricing and reimbursement authorities and on the prescribing practices of HCPs. Pricing and reimbursement authorities decide on the reimbursement status of a medicine and the automatic substitution of one medicine with another and thus determine how therapeutically equivalent medicines are dispensed. HCPs, in turn, make decisions on which medicine to prescribe to individual patients amongst available alternatives. As such, pricing and reimbursement authorities and HCPs are the key drivers of demand for prescription medicines.

(1472) A disparagement campaign that methodically targets these main stakeholders and focuses on essential characteristics of a prescription medicine such as its safety, efficacy and therapeutical equivalence with another medicine, is capable of weighing heavily on the decisions of pricing and reimbursement authorities and HCPs. It may, therefore, steer demand away from the medicine targeted by such a campaign and thus have the effect of excluding that medicine.

(1473) First, HCPs tend to be conservative (or “inert”) about switching away from the medicine they have previously been treating patients with in the absence of a pressing medical need.¹⁸⁵² Prescribing doctors are primarily guided by considerations

¹⁸⁵⁰ Case C-377/20, *Servizio Elettrico Nazionale and Others*, paragraph 61.

¹⁸⁵¹ Judgment of 21 December 2023, *European Superleague Company*, C-333-21, EU:C:2023:1011, paragraph 131.

¹⁸⁵² See Case T-321/05, *AstraZeneca v Commission*, paragraph 105: “‘inertia’ is a factor which is liable to reinforce the market position of an incumbent product by creating barriers to entry or expansion for competing products newly introduced on the market.” See also Case C-457/10 P, *AstraZeneca v Commission*, paragraph 50 where the Court concluded that “enjoying a solid brand image and reputation, was further supported by the fact that doctors generally require time in order to learn about

of therapeutic appropriateness, the efficacy and the safety of medicines.¹⁸⁵³ They are generally risk averse and avoid prescribing medicines surrounded by scientific controversy (whether founded or not) concerning their safety or efficacy. Accordingly, any doubts raised regarding the safety and efficacy of a new alternative product may strongly affect their prescribing behaviour.¹⁸⁵⁴ This is particularly the case where the alleged concerns relate to serious adverse side-effects. As pointed out by the Advocate General¹⁸⁵⁵ in *Hoffmann-La Roche*, their risk-aversion is likely to increase due to the legal provisions governing professional liability of HCPs. As a result, HCPs are inert and tend to prescribe the incumbent originator product.¹⁸⁵⁶ For similar reasons, pricing and reimbursement authorities may refrain from granting a favourable reimbursement status or from allowing automatic substitution in favour of a medicine for which there are (actual or alleged) safety concerns.

- (1474) Second, HCPs will typically not have an incentive to switch to a cheaper medicinal product as the treatment cost is covered by a third party (for example, insurers).
- (1475) Third, pricing and reimbursement authorities as well as HCPs are unlikely to have the time, or the capacity, to undertake a detailed scientific assessment of the information disseminated by the dominant undertaking. When presented with misleading information, in particular coming directly from an established and well-reputed producer in the field, they will not be able or willing to question, complement or correct such information. Typically, neither Payers (such as health insurances) nor HCPs (such as doctors, pharmacists and nurses) will typically be versed in recognising the differences in the molecular composition of medicines or the resulting differences in pharmacological properties.¹⁸⁵⁷
- (1476) In light of the above, pharmaceutical markets, like the one at issue in the present case, are particularly vulnerable to disparaging practices.¹⁸⁵⁸ Tellingly, the Advocate

a new medicinal product and thus that they will hesitate to prescribe PPIs of other producers entering that market”.

¹⁸⁵³ Case C-179/16, *F. Hoffmann-La Roche and others*, paragraph 65.

¹⁸⁵⁴ See in this regard, judgment of the French Cour de Cassation of 18 October 2016, *Chambre commerciale*, N° de pourvoi : 15-10.384, which upheld that Sanofi had abused its dominant position as a result of “*a communication strategy targeting healthcare professionals (...)*” because *inter alia* “*the dissemination of negative information, or even instilling doubt about the intrinsic qualities of a medicinal product, can discredit it immediately for these professionals*”, (unofficial translation).

¹⁸⁵⁵ Opinion of Advocate General Saugmandsgaard Øe of 21 September 2017, *F. Hoffmann-La Roche Ltd and Others*, Case C-179/16, *F. Hoffmann-La Roche and others*, paragraphs 169-170.

¹⁸⁵⁶ See also Decision n°13-D-11 of 14 May 2013 of the Autorité de la Concurrence against Sanofi Aventis France, paragraph 346; Decision n° 13-D-21 of 18 December 2013 of the Autorité de la Concurrence against Schering-Plough and others, paragraph 350; and Decision n° 17-D-25 of 20 December 2017 of the Autorité de la Concurrence against Janssen-Cilag SAS, paragraph 415.

¹⁸⁵⁷ Accordingly, Directive 2001/83 on the Community code relating to medicinal products for human use requires that all the information transmitted as part of the promotion of a product to persons qualified to prescribe or supply it “*shall be accurate, up-to-date, verifiable and sufficiently complete to enable the recipient to form his or her own opinion of the therapeutic value of the medicinal product concerned*” (Article 92(2)).

¹⁸⁵⁸ It also comes as no surprise that pharmaceutical advertising, and more specifically making comparisons with a competing medicinal product, is subject to specific rules mandating that information relating to a medicinal product which is transmitted to persons qualified to prescribe or supply shall be accurate, up-to-date, verifiable and complete so that HCPs are enabled to form their own opinion of the therapeutic value of the medicinal product concerned. See *Directive 2001/83/EC of the European Parliament and of the Council of 6 November 2001 on the Community code relating to medicinal products for human use*, Art. 92(3); The European Federation of Pharmaceutical Industries and Associations Code of Practice 2019, Section 3.01. Moreover, as long as the disseminated information refers to a competitor’s goods and services, it must objectively compare one or more material, relevant, verifiable and

General in *Hoffmann-La Roche* considered (in the context of an infringement of Article 101 TFEU) that “*the concerted communication of misleading allegations of the lesser safety of one medicinal product compared to another is, by its very nature, harmful to the proper functioning of normal competition, so much so that an examination of its effects on competition is not necessary*”.¹⁸⁵⁹ In the same vein, the General Court has also ruled that misleading statements can infringe competition rules, even if they ultimately fail to confuse the authorities (i.e., irrespective of such authorities’ reactions).¹⁸⁶⁰

- (1477) A disparagement campaign is all the more capable of producing exclusionary effects if the undertaking engaging in it enjoys a strong reputation. When the disparaging undertaking is the large dominant incumbent on the market, it will typically enjoy the trust placed in it by HCPs, which is generally likely to strengthen the impact of its messages.¹⁸⁶¹ Through this reputation and its strong presence on the market as well as its established relationship with HCPs and health authorities, a dominant incumbent has unrivalled capacity to influence HCPs and health authorities.¹⁸⁶²
- (1478) In sum, the systematic dissemination by a dominant undertaking of misleading information about the safety or efficacy of a competing medicinal product (or its therapeutic equivalence with another medicinal product) is capable of discrediting that product among the relevant stakeholders, including HCPs and Payers.¹⁸⁶³ In pharmaceutical markets, disparagement not only causes reputational harm, but is also capable of having a direct effect on the competitive process and the market structure. Misrepresentations targeting the main drivers of demand (such as national pricing and reimbursement authorities and HCPs), especially when originating from a dominant incumbent enjoying an established relationship with these stakeholders, can hinder or delay the uptake of competing products and eventually lead to competitors being effectively excluded from the relevant market. The harm to the competitive process is all the more significant where the disparaged medicine is a close rival to that of the dominant undertaking.

representative features of those goods and services. See Directive 2006/114/EC of the European Parliament and of the Council of 12 December 2006 concerning misleading and comparative advertising, Article 4(c). In addition, from a pharmacovigilance point of view, information which is often communicated while competent authorities are conducting their evaluations to raise concerns as to the safety of a given medicinal product need to be balanced against the potential for confusion if uncertainties are not properly represented. European Medicine Agency Guidelines on good pharmacovigilance practices, Module XV – Safety communication, p. 5.

¹⁸⁵⁹ Opinion of Advocate General Saugmandsgaard Øe of 21 September 2017, *F. Hoffmann-La Roche Ltd and Others v Autorità Garante della Concorrenza e del Mercato*, Case C-179/16, *F. Hoffmann-La Roche and Others*, paragraph 156.

¹⁸⁶⁰ Case T-321/05, *AstraZeneca v Commission*, paragraph 360.

¹⁸⁶¹ See in this regard Décision n° 20-D-11 du 9 septembre 2020 relative à des pratiques mises en œuvre dans le secteur du traitement de la dégénérescence maculaire liée à l’âge (DMLA), *Avastin-Lucentis*, paragraph 779.

¹⁸⁶² See also Case C-457/10 P, *AstraZeneca v Commission*, paragraph 50 where the Court concluded that “*enjoying a solid brand image and reputation, was further supported by the fact that doctors generally require time in order to learn about a new medicinal product and thus that they will hesitate to prescribe PPIs of other producers entering that market*”.

¹⁸⁶³ Case C-179/16, *F. Hoffmann-La Roche and Others*, paragraph 93. Opinion of Advocate General Saugmandsgaard Øe of 21 September 2017, Case C-179/16, *F. Hoffmann-La Roche and Others*, paragraph 169.

9.2.2.3. Lack of objective justification

- (1479) According to the case law, a dominant undertaking faced with the allegation that its conduct is liable to be caught by the prohibition laid down in Article 102 TFEU may provide an objective justification for that conduct.¹⁸⁶⁴
- (1480) First, the demonstration of such an objective justification must be based on evidence that the conduct of the dominant undertaking was objectively necessary to achieve a legitimate aim.¹⁸⁶⁵ While such aim may relate, for instance, to public health considerations, the Union Courts have confirmed that it is not the dominant undertaking's task to take steps on its own initiative to eliminate products which, rightly or wrongly, it regards as dangerous or as inferior in quality to its own products¹⁸⁶⁶, nor more generally to enforce other undertakings' compliance with the law¹⁸⁶⁷.
- (1481) In the specific context of conduct consisting of disparaging a competing medicine, the Court of Justice clarified that the responsibility to report information concerning the risks associated with a medicinal product (i.e. pharmacovigilance obligations) rests, as a general matter, "*solely with the holder of the MA for that medicinal product and not with another undertaking marketing a competing medicinal product covered by a separate MA*".¹⁸⁶⁸ Thus, it is not for a dominant undertaking to "warn" HCPs about alleged issues regarding the efficacy and safety of competing products. The Court also ruled that collusion between two undertakings to disseminate information relating to a product marketed by only one of these undertakings might even constitute evidence that such undertakings pursue objectives unrelated to pharmacovigilance.¹⁸⁶⁹
- (1482) Second, an objective justification will be accepted only if the actual or potential exclusionary effects resulting from the conduct are proportionate to the alleged legitimate aim.¹⁸⁷⁰ The proportionality condition is not met where the same aim could be achieved through means that are less restrictive of competition.¹⁸⁷¹

¹⁸⁶⁴ Judgment of the Court of Justice of 27 March 2012, *Post Danmark*, C-209/10, EU:C:2012:172, paragraphs 40 and 41 see, also, Judgment of the Court of Justice of 6 October 2015, *Post Danmark*, Case C-23/14, EU:C:2015:651, paragraph 49 and Case C-413/14 P, *Intel v Commission*, paragraph 140.

¹⁸⁶⁵ See to that effect judgment of 3 October 1985, *CBEM*, C-311/84, EU:C:1985:394, paragraphs 26 and 27.

¹⁸⁶⁶ Case T-30/89, *Hilti v Commission*, paragraph 118; Judgment of 6 October 1994, *Tetra Pak v Commission*, T-83/91, EU:T:1994:246, paragraph 138.

¹⁸⁶⁷ See to that effect Case T-30/89, *Hilti v Commission*, paragraphs 116-118.

¹⁸⁶⁸ See Case C-179/16, *F. Hoffmann-La Roche and Others*, paragraph 91. More generally, the Court has found that "[...] it is clearly not the task of an undertaking in a dominant position to take steps on its own initiative to eliminate products which, rightly or wrongly, it regards as dangerous or at least as inferior in quality to its own products"; Case T-30/89, *Hilti v Commission*, paragraphs 115-119.

¹⁸⁶⁹ Case C-179/16, *F. Hoffmann-La Roche and Others*, paragraph 91: "*the requirements for pharmacovigilance that might call for steps to be taken such as the dissemination to healthcare professionals and the general public of information relating to the risks associated with the off-label use of a medicinal product, as well as the initiation of a procedure before the EMA with a view to including such information in the summary of characteristics of the product, rest, [...] solely with the holder of the MA for that medicinal product and not with another undertaking marketing a competing medicinal product covered by a separate MA. Accordingly, the fact that two undertakings marketing competing pharmaceutical products collude with each other with a view to disseminating information specifically relating to the product marketed by only one of them might constitute evidence that the dissemination of information pursues objectives unrelated to pharmacovigilance*".

¹⁸⁷⁰ Case C-377/20, *Servizio Elettrico Nazionale and Others*, paragraph 103. See to that effect, Case T-604/18, *Google and Alphabet v Commission (Google Android)*, paragraph 883.

¹⁸⁷¹ *Ibid.*

(1483) Accordingly, in the context of disparaging conduct, in the pharmaceutical sector, an alleged objective justification claiming that such conduct served the purpose of warning the public or the HCPs and the Payers about risks associated with a competing product cannot succeed. The obligations of pharmacovigilance rest solely with the holder of the MA, and an undertaking who is not the holder of the MA cannot bypass the procedures set out in the relevant pharmaceutical legislation by communicating to Payers and HCPs information, on alleged safety risks connected with the use of that medicinal product.

9.2.3. *Teva's arguments and the Commission's assessment*

9.2.3.1. Teva's claim that the Commission wrongly relied on Article 101 TFEU principles

(1484) Teva claims that the Commission has mistakenly relied on principles established for the assessment of anticompetitive agreements (i.e. violations of Article 101 TFEU) while the present case concerns a violation of Article 102 TFEU.¹⁸⁷²

(1485) The Commission rejects these claims as unfounded.

(1486) First, it is well established case law that Articles 101 and 102 TFEU “*seek to achieve the same aim on different levels, viz. the maintenance of effective competition within the [Internal] Market. The restraint of competition which is prohibited if it is the result of behaviour falling under Article [101], cannot become permissible by the fact that such behaviour succeeds under the influence of a dominant undertaking*”.¹⁸⁷³ The Court of Justice has also recently confirmed that Articles 101 and 102 TFEU must be interpreted and applied consistently.¹⁸⁷⁴

(1487) Second, contrary to what Teva argues, the Commission did not blindly transpose Article 101 TFEU principles to an Article 102 TFEU case. Rather, the Commission took duly into account the elements of the *Hoffmann-La Roche* judgment that were directly relevant, by analogy, for this case. More specifically, the Commission took into account two elements: first, the threshold for determining what constitutes, for pharmaceutical companies, permissible conduct with respect to communication on competing products, and second, when such communication can be considered as misleading.

9.2.3.2. Teva's claim that the Commission failed to apply the legal test of undue interference

(1488) Teva claims that communications with decision-making bodies (for example, AIFA in Italy, or AFMHP in Belgium) may be regarded as abusive only if they constitute an undue interference for the purposes of obtaining a decision that could otherwise not legitimately be obtained.¹⁸⁷⁵ Teva claims that a decision by a regulatory body is “*undue*”, in the sense that it is not legally permissible, where: (i) it is based on erroneous information; (ii) the decision is reached due to illegal pressures; (iii) the decision would be contrary to the applicable legal framework; and (iv) the decision is the result of the dominant companies' unjustified refusal to cooperate.¹⁸⁷⁶ According to Teva, communications with a decision-making body cannot be regarded as “*undue*” if Teva sought a decision that the relevant decision-making body could have

¹⁸⁷² ID 4032, Teva's Reply to the Statement of Objections, paras. 484-489 and paras. 451-453.

¹⁸⁷³ See Case C-6/72, *Europemballage and Continental Can v Commission*, paragraph 25.

¹⁸⁷⁴ See Case C-333/21, *European Superleague v Commission*, paragraph 119.

¹⁸⁷⁵ ID 4032, Teva's Reply to the Statement of Objections, paras. 454, 457- 472, 919, 920, 921, 922, 926, 927, 928, 929, 930, 931, 946, 1057, 1065-1078, 1088, 1094; see also ID 5695, Teva's Reply to the Letter of Facts I of 9 February 2024, paras. 329, 330.

¹⁸⁷⁶ ID 4032, Teva's Reply to the Statement of Objections, para. 466.

reached independently, regardless of the content of the communications (that is, even if it did contain inaccurate or misleading information).¹⁸⁷⁷

- (1489) In support of its claims, Teva argues that, in the *AstraZeneca* judgment, the General Court established that conduct was abusive if it involved “*the submission to the public authorities of misleading information liable to lead them into error and therefore to make possible the grant of an exclusive right to which an undertaking is not entitled*”¹⁸⁷⁸, or, as per the Court of Justice’s judgment, whether the representations had been made “*for the purpose of improperly obtaining exclusive rights*”.¹⁸⁷⁹
- (1490) The Commission notes that this claim only relates to Teva’s communications with Payers, but is not relevant for Teva’s communications targeting HCPs. In any event, Teva’s claim does not convince, not only because it wholly disregards the *Hoffmann-La Roche* judgment, but also for the following reasons.
- (1491) First, Teva incorrectly implies that the focus of the Commission’s analysis should be in proving that the Payers’ decision that Teva was seeking (in this case, not to allow automatic substitution) would not comply with the applicable legal framework, rather than that Teva’s conduct was not competition on the merits.
- (1492) In the first place, the question is not whether the authority was actually misled¹⁸⁸⁰ or whether it would have taken the same decision absent Teva’s misleading communications. The question is rather whether Teva’s conduct objectively sought to mislead Payers in adopting a certain decision, irrespective of whether Teva’s misleading communications were actually successful. It follows that the relevant question is not whether the outcome sought by the disparaging company would be compliant with the applicable rules, but whether the disparaging conduct was capable of unduly influencing that outcome.
- (1493) In the second place, Teva’s proposition would effectively render dominant companies’ conduct immune from antitrust scrutiny whenever it is possible that the targeted body has some discretion and can reach an outcome favourable to the disparaging company without violating the legal conditions for reaching such decision. In other words, the dominant company could legitimately influence the decision of an authority by providing it with misleading information about a competitor, as long as that authority’s ultimate decision is not contrary to the applicable legal framework. This premise is obviously flawed.
- (1494) In the third place, the test suggested by Teva would effectively require the Commission to take a final position on the scientific/technical, or health-economics question ultimately at stake for which the relevant body is competent to decide (in

¹⁸⁷⁷ ID 4032, Teva’s Reply to the Statement of Objections, paras. 467, 932, 933.

¹⁸⁷⁸ Case T-321/05, *AstraZeneca v Commission*, paragraph 355.

¹⁸⁷⁹ Case C-457/10 P, *AstraZeneca v Commission*, paragraph 99.

¹⁸⁸⁰ Indeed, the case law of Union Courts has confirmed that, to consider abusive the dissemination of misleading information to public authorities, there is no need for the Commission to show that the authority was actually misled by the dominant undertaking at stake, resulting in a decision unduly benefitting it. See Case T-321/05, *AstraZeneca v Commission*, paragraph 331. Similarly, in *Hoffmann-La Roche*, the Court of Justice confirmed that the concerted dissemination of misleading information to the EMA, healthcare professionals and the general public constituted a restriction of competition “by object” when its purpose was to reduce the competitive pressure resulting from the use of one product not covered by the related marketing authorisation (in other words, the Court did not require to show that the disseminated information actually misled its addressees). See Case C-179/16, *F. Hoffmann-La Roche and Others*, paragraphs 92 and 95.

this case, that of automatic substitution), and to substitute its own decision for the decision of that body.

(1495) Second, even if Teva's position were to be followed, Teva's conduct may still be found in violation of Art. 102 TFEU. Indeed, the General Court did not set in *AstraZeneca* a one-size-fits-all legal test concerning misleading representations to authorities and even clarified that the assessment may vary according to the circumstances of each case.¹⁸⁸¹ This is also confirmed by the fact that, in the *AstraZeneca* case, the General Court observed that the concerned undertaking's behaviour may lead authorities "wrongly to create" several types of "obstacles to competition", "for example by the unlawful grant of exclusive rights to the dominant undertaking" (emphasis added).¹⁸⁸² This position was confirmed by the Court of Justice.¹⁸⁸³ In the case at hand, although Teva did not approach the Payers to seek an undue grant of an exclusive right, Teva was still trying to influence these addressees so as to wrongly create an obstacle to competition, namely by leading them to question Synthron GA's safety, efficacy and therapeutic equivalence with Copaxone and, on these grounds, to adopt decisions not to allow the automatic substitution of Copaxone with Synthron GA. Similarly to the conduct involved in *AstraZeneca*, such conduct does not constitute competition on the merits and, for the reasons detailed below, is capable of producing anticompetitive effects without any objective justification.

9.2.3.3. Teva's claim that the Commission should apply a different test depending on the addressee of Teva's disparaging messages

(1496) In addition, Teva claims that a different legal test should have been used depending on the addressees of Teva's disparaging messages. More precisely, Teva claims that the Commission must consider the ability of the addressee to discern the accuracy or veracity of its messages and to critically review Teva's communications.¹⁸⁸⁴

(1497) The Commission rejects this claim for the following reasons.

(1498) First, the case law of Union Courts does not support Teva's allegation. Indeed, Teva's claim completely disregards the judgment by the Court of Justice in *Hoffmann-La Roche*, although it dealt with a comparable conduct. In its judgment, the Court found that an agreement on the dissemination of misleading messages was a restriction of competition without differentiating on the basis of its addressees. More precisely, the Court did not differentiate in any way the test to be applied depending on whether the misleading information was being disseminated to (i) public authorities such as the EMA, (ii) HCPs, or (iii) the general public.¹⁸⁸⁵ In addition, as noted above, the General Court has already confirmed in *AstraZeneca* that the fact that certain addressees do not let themselves be misled and themselves detect the inaccuracies of the disseminated information is irrelevant, as the question whether the conduct is abusive in nature cannot depend on the contingencies of the reactions of third parties.¹⁸⁸⁶ By the same token, it must be concluded that it is not decisive whether the addressees had sufficient expertise to detect the inaccuracies of the disparaging messages and not be misled. Lastly, the General Court has confirmed

¹⁸⁸¹ Case T-321/05, *AstraZeneca v Commission*, paragraphs 355 and 357.

¹⁸⁸² Ibid.

¹⁸⁸³ Case C-457/10 P, *AstraZeneca v Commission*, paragraph 99.

¹⁸⁸⁴ See ID 4032, Teva's Reply to the Statement of Objections, paras. 492, 1046, 1058, 1059, 1061, 1062, 1063

¹⁸⁸⁵ Case C-179/16, *F. Hoffmann-La Roche and Others*, paragraph 92.

¹⁸⁸⁶ Case T-321/05, *AstraZeneca v Commission*, paragraph 360.

in *AstraZeneca* that the absence of any obligation on the addressee's part to verify the accuracy or veracity of the information provided may be a relevant factor in assessing whether the practice in question violates Article 102 TFEU.¹⁸⁸⁷

(1499) Second, Teva's Complexity Message targeted both Payers and HCPs alike. Although its presentation was tailored on the type of addressee, Teva's goal for disseminating such a message was the same: influencing the demand for GA, either by obtaining decisions ruling against the automatic substitution between Synthron GA and Copaxone or by influencing individual prescriptions. In order to attain this goal, it was sufficient to cast doubt on Synthron GA's safety and efficacy and on its therapeutic equivalence with Copaxone. Indeed, as will be explained below, HCPs tend to be conservative (or "*inert*") about switching to a medicine other than the one they have been treating patients with in the absence of a pressing medical need and since they are unlikely to have the time or the capacity to undertake a detailed scientific assessment of the information disseminated by a dominant, disparaging undertaking.¹⁸⁸⁸ At the same time, Payers are sometimes not equipped to properly analyse highly scientific submissions, and in particular to reconcile seemingly contradicting scientific findings.¹⁸⁸⁹ As a result, in the present case, the same principles can be applied to assess whether a given message was capable of inducing in error its Payer/HCP addressees.

(1500) As to Teva's claim that applicable regulations would only require marketing authorisation holders to communicate with decision-makers in a "*complete and accurate manner*", and would not require such communications to be "*objective and ... not misleading*" (as per regulations governing communications to healthcare organisations and HCPs),¹⁸⁹⁰ the Commission observes that even if that were the case, the Court of Justice has recently confirmed that the notion of "abuse" under Article 102 TFEU is based on an objective assessment and the illegality of an abusive conduct is unrelated to its characterisation under other areas of law.¹⁸⁹¹ In other words, the special responsibility enjoyed by a dominant undertaking requires to refrain from disseminating misleading information to decision makers, even if such conduct would otherwise be allowed under other areas of law. At any rate, it is questionable that information that is "*not objective and/or misleading*" could be qualified as "*complete and accurate*" under any applicable regulations.

9.2.3.4. Teva claims that messages are "misleading" only if they cast doubt on the safety of a competing product

(1501) Teva claims that messages are "misleading" only if they cast doubt on the safety of a competing product.¹⁸⁹² Teva also claims that it follows from the French *TDF/Itas Tim* case that a communication can only be disparaging where it directly targets a rival product, and not where it merely points out the risks of two products working in combination.¹⁸⁹³

(1502) As shown in Section 9.3.1, the core aim of Teva's statements which are the subject-matter of this Decision consisted precisely in instilling doubt as to the safety and

¹⁸⁸⁷ Case T-321/05, *AstraZeneca v Commission*, paragraph 357.

¹⁸⁸⁸ See Section 9.4.2 below.

¹⁸⁸⁹ For example, this is the reason why Teva was envisaging that KOLs would assist Payers in deciding on automatic substitution between Copaxone and Synthron GA, see Section 9.4.1.3 below.

¹⁸⁹⁰ ID 4032, Teva's Reply to the Statement of Objections, para. 931 (a).

¹⁸⁹¹ Case C-377/20, *Servizio Elettrico Nazionale and Others*, paragraph 67.

¹⁸⁹² ID 4032, Teva's Reply to the Statement of Objections, paras. 477-484.

¹⁸⁹³ ID 4032, Teva's Reply to the Statement of Objections, para. 491.

efficacy of Synthron GA as well as its therapeutic equivalence with Copaxone. Such messages contradicted the relevant regulatory findings on Synthron GA. As such, the content and nature of these messages, which targeted a competing product, was analogous to the ones assessed in the cases of the French competition authority to which Teva refers. Teva's claim is thus ineffective as it does not undermine the Commission's case even if it were accepted. The fact that the misleading messages about Synthron GA's safety, efficacy and therapeutic equivalence with Copaxone were disseminated in the context of discussing automatic substitution is irrelevant, as explained in the following Section.

9.2.3.5. Teva's claim that its communications were legitimate as they did not challenge therapeutic equivalence but focused on automatic substitution is unfounded

(1503) According to Teva, its messages were not misleading, because they allegedly focussed on the potential patient safety risks that could arise from "*repeated and uncontrolled substitution*" between Copaxone and Synthron GA.¹⁸⁹⁴ Teva also argued that, being the holder of an MA for Copaxone, it was entitled to put forward its views on matters directly relevant to patient safety, which would not have been settled by the MA granted to Synthron GA.¹⁸⁹⁵ Teva also claims that it was entitled to make submissions to bodies deciding on automatic substitution in light of the scientific debate regarding automatic substitution and of certain decisions, judgments and guidelines adopted in Sweden and in Germany.¹⁸⁹⁶ Teva argues that the MA grant for Synthron GA did not settle the status of its automatic substitution with Copaxone despite the finding of their therapeutic equivalence. Decisions on automatic substitution are made by bodies responsible for pricing and reimbursement (Payers, most often not responsible for MAs) following a set of criteria that may only partly overlap with those for MAs. Therefore, the fact that Synthron GA has been found to be therapeutically equivalent to Copaxone would not mean that the scientific evidence and analysis which served as the basis for the MA is sufficient to conclude that Synthron GA should be automatically substitutable to Copaxone.¹⁸⁹⁷

(1504) Teva's claim is flawed for the following reasons.

(1505) First, this Decision does not take issue with Teva's messages which related only to automatic substitution¹⁸⁹⁸, where there may have existed a degree of genuine scientific uncertainty leading the relevant bodies to come to possibly diverging conclusions. Neither does the Commission take a position on whether Copaxone and Synthron GA should be automatically substitutable or not, as such decisions pertain to the exclusive competence of Member States. Thus, this Decision only relates to Teva's messages that, whether in the context of discussing automatic substitution or not, directly contradicted the settled findings by Member States' medicines authorities concerning Synthron GA's safety, efficacy and therapeutic equivalence

¹⁸⁹⁴ ID 4032, Teva's Reply to the Statement of Objections, para. 32.

¹⁸⁹⁵ ID 4032, Teva's Reply to the Statement of Objections, paras. 32, 924, 948, 949, 950, 951, 979-989, 1029; see also ID 5695, Teva's Reply to the Letter of Facts I of 9 February 2024, paras. 322, 343, 344, 345, 355.

¹⁸⁹⁶ ID 4032, Teva's Reply to the Statement of Objections, paras. 1281-1283; ID 4032, Teva's Reply to the Statement of Objections, paras. 949, 951, 952, 953-962, 967, 979-989; see also ID 5695, Teva's Reply to the Letter of Facts I of 9 February 2024, paras. 322, 343, 344, 345.

¹⁸⁹⁷ ID 4032, Teva's Reply to the Statement of Objections, paras. 979-989.

¹⁸⁹⁸ For example, Teva's messaging concerning the GATE Extension study which examined the question of patient switches. Not to be confused with the initial GATE study which concerned Synthron GA's therapeutic equivalence with Copaxone.

with Copaxone. These authorities had already assessed and rejected Teva's concerns.¹⁸⁹⁹

- (1506) Second, Teva's CCP communications assessed in this Decision consistently challenged the safety, efficacy and therapeutic equivalence of Synthon GA, contradicting the settled findings in the Decentralised Procedure, and were not addressed to the relevant pharmacovigilance bodies, but to HCPs and Payers, and on grounds that were already assessed and rejected by the competent medicine authorities, as demonstrated by Sections 9.3 and 9.4. For example, Teva questioned the therapeutic equivalence of Synthon GA and Copaxone by insinuating that the compositional difference between the two may have therapeutically relevant effects: {...} (emphasis added).¹⁹⁰⁰ Teva also communicated a message that {...}.¹⁹⁰¹ Also, it is notable that Teva did not only challenge the GATE Extension study, dealing specifically with the issue of switching patients from Copaxone to Synthon GA and was thus arguably more relevant for the question of substitution, but also challenged the initial GATE study, which was concerned with the more fundamental questions of safety and efficacy of Synthon GA, and its therapeutic equivalence with Copaxone: {...};¹⁹⁰² {...}.¹⁹⁰³ Teva communicated the message that {...} (emphasis added).¹⁹⁰⁴ Teva also communicated the message that {...} (emphasis added);¹⁹⁰⁵ {...} (emphasis added).¹⁹⁰⁶ As demonstrated in Sections 9.3.1.1.3, 9.3.1.2.3 and 9.3.1.3.3, these claims had already been addressed and rejected by the relevant authorities in the course of the Decentralised Procedure for Synthon GA.
- (1507) Thus, it is incorrect to say that Teva's communications only focussed on issues that were "*not settled*" and were thus directly and specifically related to automatic substitution. The issues of safety, efficacy and therapeutic equivalence of Synthon GA and Copaxone constituted key conditions for the successful finalisation of the Decentralised Procedure for Synthon GA as a therapeutically substitutable medicine to Copaxone and also, in a second step, for the Payer's decisions at national level to consider Synthon GA and Copaxone as automatically substitutable. Synthon GA's safety, efficacy and therapeutic equivalence to Copaxone had been established by the MEB during the course of the Decentralised Procedure and cannot be said to constitute the object of any debate after the successful conclusion of this procedure.
- (1508) Third, the fact that Teva disseminated misleading messages concerning Synthon GA's safety and efficacy and its therapeutic equivalence with Copaxone in the

¹⁸⁹⁹ Teva itself recognises the distinction between conditions for automatic substitution and those for MA grant. ID 4032, Teva's Reply to the Statement of Objections, para. 951 (h).

¹⁹⁰⁰ ID 651-21, Substitution considerations for follow on glatirameracetate products Meeting with Federal Agency for Medicines & Health Products Brussels, 23 January 2017, p. 27.

¹⁹⁰¹ ID 806-2, Assessing the Value of COPAXONE® in Relation to Follow-on Glatiramer Acetate, Payer White Paper, 8 June 2016, p. 11. See also ID 455-2210, Payer objection handler, 8 December 2016, pp. 16 and 20; ID 455-1452, The Complexity of COPAXONE® and Considerations for Substitution with Follow-on Glatiramer Acetate, May 2016, p. 9.

¹⁹⁰² ID 651-21, Substitution considerations for follow on glatirameracetate products Meeting with Federal Agency for Medicines & Health Products Brussels, 23 January 2017, p. 54.

¹⁹⁰³ ID 266-105, Copaxone and the introduction of FoGA, Objection handler for MSLs, March 2019, Version 4, p. 8.

¹⁹⁰⁴ ID 651-21, Substitution considerations for follow on glatirameracetate products Meeting with Federal Agency for Medicines & Health Products Brussels, 23 January 2017, p. 54.

¹⁹⁰⁵ ID 651-21, Substitution considerations for follow on glatirameracetate products Meeting with Federal Agency for Medicines & Health Products Brussels, 23 January 2017, p. 52.

¹⁹⁰⁶ ID 404-2001, Complexities of Glatiramoids – Biological characterisations of glatiramoids, Warsaw June 2016.

context of its campaign to prevent its automatic substitution between the two medicinal products is irrelevant for the qualification of its conduct as abusive under Article 102 TFEU.

- (1509) In the first place, as already mentioned, since the successful completion of the Decentralised Procedure for Synthon GA, and the underlying PAR report by the MEB, the issues of Synthon GA’s safety, efficacy and its therapeutic equivalence with Copaxone, including the methodologic soundness of the GATE study, have been “settled” : *“Based on all data presented, the Board concluded that Sclerthon 20 mg/ml [Synthon GA] can be regarded as therapeutic equivalent to the reference product. ‘Therapeutical equivalence’ means that the efficacy and safety of this hybrid formulation is similar to the efficacy and safety of the reference product. Agreement on this conclusion was reached between Member States”*.¹⁹⁰⁷ For the sake of completeness, the MEB also stated clearly that *“[n]o specific difference in efficacy or safety between the patients who were on Copaxone and later switched to Brabio [Synthon GA] and the patients who were treated with Brabio for the entire period were observed. Therefore there is no evidence against switching”*.¹⁹⁰⁸ The “Summary Public Assessment Report” confirms that *“[p]atients can switch from Copaxone to Brabio [Synthon GA] without problems”*,¹⁹⁰⁹ meaning that there are no safety or efficacy concerns related to switching from Copaxone to Synthon GA.
- (1510) In the second place, given the alleged scientific uncertainty surrounding automatic substitution of GA medicinal products, Teva had the option to invest into scientifically sound studies dedicated to this question. Instead, it invested into a campaign to second-guess the “settled” basic tenets on which the successful completion of Synthon GA’s Decentralised Procedure was based on grounds which had already been rejected by the competent authorities. In Germany, the umbrella organisation of health insurance funds, GKV-SV requested Teva {...}.¹⁹¹⁰ Teva actually never generated such evidence, in Germany or elsewhere. There is no scope to reopen a scientific debate questioning these findings in the absence of relevant new scientific evidence, as Teva was well aware.¹⁹¹¹ Under such circumstances, it is even less appropriate to raise such issues with market players such as HCPs and Payers, and not with pharmacovigilance bodies entrusted with safeguarding public health.
- (1511) In the third place, therapeutic equivalence is a condition precedent for the finding of automatic substitution (where the prescribing physician no longer decides whether the patient is dispensed the original product or its therapeutic equivalent). Therefore, the dissemination of misleading information questioning therapeutic equivalence either directly or indirectly (via messages related to safety and efficacy) is capable of confusing Payers and HCPs and discrediting Synthon GA, as will be shown below, to influence not only individual prescriptions, but also decisions on automatic substitution. If Teva successfully instilled doubt as to Synthon GA’s safety and efficacy and its therapeutic equivalence with Copaxone – despite these issues having been determined by the competent authorities – Teva would have likely succeeded in convincing the Payers not to authorise automatic substitution.

¹⁹⁰⁷ ID 2013, MEB Public Assessment Report on Synthon’s GA product, p. 17.

¹⁹⁰⁸ ID 742-172, Klinisch beoordelingsrapport Glatirameerproducten van Mylan en Synthon, p. 9.

¹⁹⁰⁹ ID 455-2840, Summary Public Assessment Report, p. 3.

¹⁹¹⁰ ID 455-539, Teva internal email dated 23 September 2016 from {...} to {...} and others.

¹⁹¹¹ See, for example, paras. (1582)-(1583).

- (1512) In the fourth place, a communication that is capable of misleading the addressees as to Synthon GA’s characteristics that have been established by the relevant authorities does not cease to be misleading because the alleged purpose of the communication is not to avert individual switching but to prevent automatic substitution. As shown above in Recital (1506), Teva’s messages did not merely take issue with automatic substitution but challenged Synthon GA’s key characteristics as established by the MEB, in contradiction with Teva’s stated objective.
- (1513) In the fifth place, Teva was wrong to raise alleged public health concerns with HCPs and Payers. As demonstrated above, Teva questioned the very safety and efficacy of Synthon GA and its therapeutic equivalence with Copaxone. In case of genuine concerns related to the safety and efficacy of a product, these should be raised with the competent authorities and not with HCPs and Payers.¹⁹¹² Moreover, as stated in Recital (1483), the responsibility to report risks associated with a medicinal product (i.e. pharmacovigilance obligations) rests, as a general matter, with the holder of the MA, i.e. not with its competitors.¹⁹¹³ It is not for the dominant firm to “warn” HCPs about alleged safety issues of its competitors, all the more so in the absence of any therapeutically relevant evidence, and when its concerns had already been assessed and rejected by the relevant authority during the Decentralised Procedure.
- (1514) Fourth, Teva did not instigate, or participate in, the alleged “*evidence based*” scientific debate in good faith. Even if, as alleged by Teva, the communications in question indeed pertained to the narrower question of automatic substitution and not the broader one of therapeutic equivalence (*quod non* for the reasons explained above), Teva was internally aware that its claims, used in its campaign against automatic substitution, were unsupported by evidence and could therefore not have contributed to the alleged scientific debate: {...}.¹⁹¹⁴ As will be shown below, Teva knew that their claims were not evidence based.¹⁹¹⁵ {...} emphasised in May 2017 that: {...}.¹⁹¹⁶ However, this did not prevent Teva from relying on these arguments in its campaign against automatic substitution.
- (1515) Moreover, some of Teva’s HCP materials can clearly not be described as supporting, or as being conducive to, an objective, scientific discussion. For example, Teva’s “fake Elvis” or “zebra vs horse” leaflets¹⁹¹⁷ implicitly took aim at Synthon GA and aimed at visually suggesting it was different from Copaxone and a lesser version of it (despite there being no therapeutically relevant dissimilarities).
- (1516) Fifth, the Commission also rejects Teva’s claims that where it communicated with HCPs specifically in the context of the scientific debate around automatic substitution, those HCPs were unlikely to consider that Teva was raising doubts about the safety and efficacy of Synthon GA *per se* and were therefore unlikely to be misled by Teva’s message.¹⁹¹⁸ On a preliminary note, the Commission notes that HCPs are not the ones deciding on the automatic substitution status between two or more medicinal products, therefore targeting them means that Teva was seeking to

¹⁹¹² Article 106(a) of Directive 2001/83/EC.

¹⁹¹³ Article 106(a) of Directive 2001/83/EC.

¹⁹¹⁴ ID 455-3034, Teva internal email dated 6 November 2015 from {...} to {...} and others (Teva and to {...} ({...})).

¹⁹¹⁵ See Recitals (1574)-(1589), (1599)-(1603), (1589)-(1599) and (1634).

¹⁹¹⁶ ID 404-2519, Teva internal email dated 29 May 2017 from {...} to hierarchy. See also ID 404-2367, Teva internal email dated 16 August 2017 from {...} to {...}: {...}.

¹⁹¹⁷ See Recitals (1971)-(1975).

¹⁹¹⁸ ID 4032, Teva’s Reply to the Statement of Objections, para. 1047.

influence individual prescriptions. Teva ubiquitously embedded the misleading Complexity Message in the communications destined to be used with HCPs (such as the External Expert White Paper or the Presentation),¹⁹¹⁹ and criticised the soundness and appropriateness of the main GATE study¹⁹²⁰ (which established Synthon GA as therapeutically equivalent to Copaxone). There was no reason to include this type of messages, targeting Synthon GA's essential characteristics as established by the MEB, in HCP materials if not to instil doubt as to the scientific basis on which the Decentralised Procedure for Synthon GA was finalised, thereby challenging Synthon GA's safety, efficacy and therapeutic equivalence with Copaxone, and therefore to discourage doctors from prescribing Synthon GA.

- (1517) Sixth, Teva's campaign against automatic substitution between Copaxone and Synthon GA was based on commercial rather than public health concerns and patient safety, and cannot therefore justify Teva's conduct from an antitrust perspective.
- (1518) In the first place, evidence shows that Teva's campaign seeking to convince Payers and HCPs that Copaxone and Synthon GA should not be automatically substitutable was driven by the purely commercial goal of preventing the high degree of competitive pressure from Synthon GA.¹⁹²¹ Teva's internal documents reveal that the real objective behind Teva's participation in the alleged "scientific debate" was to {...}.¹⁹²²
- (1519) In the second place, campaigning to influence the views of the stakeholders that are directly shaping demand for GA is not an appropriate avenue to raise purported public health concerns. In case Teva had genuine, evidence-based patient safety concerns concerning "*repeated and uncontrolled substitution*" (that ran counter the finding of the MEB that "[p]atients can switch from Copaxone to Brabio [Synthon GA] without problems"¹⁹²³) it could have petitioned pharmacovigilance bodies to include a warning to this effect in the SmPC. Incidentally, if granted, such a warning would likely apply to both Copaxone and Synthon GA products, meaning that consequently also no substitution from Synthon GA to Copaxone should take place. Such a warning could have been contrary to Teva's interest, which explains why this is not the route Teva pursued and how it was not genuine safety concerns guiding Teva's actions.
- (1520) To conclude, the fact that Teva had disseminated communications instilling doubt as to Synthon GA's safety, efficacy and therapeutic equivalence with Copaxone also in the context of its activities to achieve the commercial goal of preventing automatic substitution of Synthon GA (for which therapeutic equivalence was crucial) in no way impacts the finding that Teva used misleading messages to pursue that objective. Teva's Complexity Message was objectively misleading irrespective of whether it was included in the criticism of automatic substitution. In any event, there is extensive evidence on the file that Teva pursued a purely commercial advantage with this communication and was not raising these matters in the interest of public health.

¹⁹¹⁹ See Section 9.3.2.2.

¹⁹²⁰ For the rebuttal of Teva's claims specifically related to the GATE study, see Recitals (1605)-(1634).

¹⁹²¹ See for example Recitals (1764), (1774), (1834), (2004).

¹⁹²² ID 404-2017, Teva internal email dated 27 October 2014 from {...} to {...} and others regarding {...}.

¹⁹²³ ID 455-2840, Summary Public Assessment Report, p. 3.

9.2.3.6. Teva's claims that the Commission should have carried out an *in concreto* assessment and established the likelihood of effects

(1521) Teva asserts that the Commission applied the wrong standard for assessing effects and that the finding that Teva's conduct was capable of exclusionary effects is not sufficient to prove a breach of Article 102 TFEU. Specifically, Teva claims that the Commission must perform an *in concreto* assessment and take into account the target of Teva's communications, the ability of the recipient to discern the veracity of the message, the actual impact of Teva's message and the scientific and regulatory context.¹⁹²⁴ Teva also claims that the Commission has to carry out a detailed effects analysis¹⁹²⁵ and establish the likelihood of effects, which cannot be merely hypothetical.¹⁹²⁶ Teva claims that the Union Courts have made clear that the Commission's effects analysis, cannot be "vague" but should¹⁹²⁷ produce "*precise and consistent evidence*" or "*accurate, reliable and consistent evidence*" to support its case.¹⁹²⁸ Accordingly, the Commission must pay "*due attention to the observations thus submitted by [Teva], examining carefully and impartially all the relevant aspects of the individual case, and, in particular, the evidence submitted by [Teva]*".¹⁹²⁹ Teva claims that the anticompetitive effects alleged in the Statement of Objections adopted by the Commission in this case are "*purely hypothetical*".¹⁹³⁰ Teva also claims that the Commission does not establish a causal link between Teva's communications and the alleged "*actual*" effects and allegedly attempts to make up for this evidentiary gap by asserting that Teva's conduct "*appears to have contributed*" to these actual effects, or that it was only "*likely*" to produce the actual effects.¹⁹³¹

(1522) The Commission rejects these claims.

(1523) First, the Commission is only bound to establish that Teva's conduct was capable of producing exclusionary effects, and does not need to demonstrate that the conduct was successful. The Court of Justice in *ENEL* restated that conduct by a dominant company which is legal under other areas of law can be considered abusive where it is capable of exclusionary effects and where it does not constitute competition on the merits.¹⁹³² The Court also recalled that the qualification of an abuse does not depend on its success: "*it must be borne in mind that the characterisation of a practice of a dominant undertaking as abusive does not mean that it is necessary to show that the result of a practice of such an undertaking, intended to drive its competitors from the market concerned, has been achieved and, accordingly, to prove an actual exclusionary effect on the market. The purpose of Article 102 TFEU is to penalise abuse by one or more undertakings of a dominant position within the internal market*

¹⁹²⁴ ID 4032, Teva's Reply to the Statement of Objections, paras. 490-494.

¹⁹²⁵ ID 4032, Teva's Reply to the Statement of Objections, paras. 501-521, 923, 1062, 1063, 1064 1086,1087, 1128, 1095; ID 5695, Teva's Reply to the Letter of Facts I of 9 February 2024, para. 321 3rd indent.

¹⁹²⁶ ID 4032, Teva's Reply to the Statement of Objections, paras. 502, 503.

¹⁹²⁷ ID 4032, Teva's Reply to the Statement of Objections, paras. 521, 1077.

¹⁹²⁸ ID 4032, Teva's Reply to the Statement of Objections, para. 521.

¹⁹²⁹ ID 4032, Teva's Reply to the Statement of Objections, para. 521.

¹⁹³⁰ ID 4032, Teva's Reply to the Statement of Objections, paras. 502, 503, 521, 1097, 1103.

¹⁹³¹ ID 4032, Teva's Reply to the Statement of Objections, para. 1089.

¹⁹³² Case C-377/20, *Servizio Elettrico Nazionale and Others*, paragraph 103.

or in a substantial part of it, irrespective of whether such practice has proved successful.”¹⁹³³

- (1524) Second, contrary to Teva’s allegations the Commission did carry out a detailed analysis of the capability of the conduct to have anticompetitive effects and, in certain cases, established that Teva’s conduct may have also had actual anticompetitive effects.
- (1525) The Commission duly took into account *in concreto* all evidence in the file, including all of Teva’s submissions including any evidence and claims submitted in response to the Statement of Objections or to the Letters of Facts.¹⁹³⁴
- (1526) The Commission took in particular into consideration the following factual elements: (i) the role generally played by the Payers and HCPs respectively in influencing demand for GA medicines (Section 9.4.1); (ii) the role played by KOLs in amplifying the dissemination of Teva’s Complexity Message (Section 9.4.1.3); (iii) the nature of Teva’s Complexity Message and its capability to influence decisions of the Payers/HCPs, including Teva’s own internal views on the nature of the messaging (Section 9.4.2 and others); (iv) the special position enjoyed by Teva in its communication with the Payers and HCPs (Section 9.4.3); (v) the dissemination undertaken by Teva in each of the Relevant Member States targeting Payers and HCPs Sections 9.4.4.2 to 9.4.4.8); (vi) Teva’s internal documents as well as other available documents evidencing that Teva’s Complexity Message may have actually influenced certain HCPs and Payers (e.g. Sections 9.4.4.2, 9.4.4.3). On the basis of that analysis, the Commission reaches the conclusion that Teva’s conduct was capable of producing exclusionary effects in each of the Relevant Member States in Section 9.4.5.
- (1527) Teva also claims that the Commission concluded that Teva’s conduct was capable of producing anticompetitive effects even where – contrary to applicable case law – that conduct remained at a project stage and was “*clearly never implemented*”.¹⁹³⁵
- (1528) The Commission rejects these arguments, which are not supported by the evidence on the Commission’s file. Contrary to Teva’s claims, Teva’s communication campaign and its dissemination of the Complexity Message did not remain merely at a project stage, but were actually implemented. This is shown by a consistent body of evidence, which does not consist only of Teva’s own internal documents, as erroneously asserted by Teva. Sections 9.3.2 and 9.4 below specifically show that the misleading messages, as contained in the centrally created CCP documents as well as in bespoke documents specifically created for use in the national markets, were actually disseminated in all the Relevant Member States.

¹⁹³³ Case C-377/20, *Servizio Elettrico Nazionale and Others*, paragraphs 50, 53, 61, 64, 71. See also: C-165/19 P, *Slovak Telekom v Commission*, paragraph 109; Case C-549/10 P, *Tomra and Others v Commission*, paragraph 68; Case T-321/05, *AstraZeneca v Commission*, paragraph 347, confirmed on appeal in Case C-457/10 P, *AstraZeneca v Commission*, paragraphs 109 and 111. See also T-219/99, *British Airways v Commission*, paragraphs 297 and 298.

¹⁹³⁴ ID 1866, Teva’s spontaneous submission of 25 May 2022; ID 4032, Teva’s Reply to the Statement of Objections; ID 5695, Teva’s Reply to the Letter of Facts I of 9 February 2024; ID 5909, Teva’s Reply to the Letter of Facts II.

¹⁹³⁵ ID 4032, Teva’s Reply to the Statement of Objections, paras. 1103-1106.

9.2.3.7. Teva’s claim that its communications concerning Synthron GA amount to an exercise of its freedom of speech

- (1529) Teva claims that it only exercised its freedom of speech and engaged in legitimate scientific discourse. In this context, Teva refers to the judgment of the Paris Court of Appeals in the *Avastin* case.¹⁹³⁶ Teva claims that even if its communications were disparaging, they would fall within the limits of Teva’s right to freedom of expression (and not infringe Article 102 TFEU) as Teva’s messages allegedly “*contributed to a public interest debate, was sufficiently grounded in fact, and had an objective and neutral tone*”.¹⁹³⁷
- (1530) The Commission rejects these arguments.
- (1531) First, the legal test for whether Teva’s communications deviate from competition on the merits and are capable of producing exclusionary effects needs to be based on the relevant case law of the Court of Justice, as set out in section 9.2.3.2. The judgment of the Paris Court of Appeals is not relevant to that effect, as that judgment relates to an infringement that differs from Teva’s conduct analysed in this Decision. Most importantly, that case concerned communications concerning an off-label (i.e. unauthorised) use of a medicine, while the present case concerns misleading communications challenging an approved use of the product.¹⁹³⁸ In the present case, Teva’s campaign concerns an authorised therapeutic use of a medicine whose essential properties (safety, efficacy and therapeutic equivalence with Copaxone) had been confirmed by a competent authority. This means that there is no room for scientific debate on these points in the absence of relevant new evidence. Moreover, this evidence would have to be brought to the authorities that are competent to modify Synthron GA’s MA through appropriate procedures, not to Payers or HCPs. This distinction as to the scope for legitimate scientific discourse is moreover fully consistent with the position of the Paris Court of Appeals.¹⁹³⁹
- (1532) Second, Teva’s communication cannot be perceived as a genuine attempt to engage in a scientific discourse – it was not driven by the alleged public health concerns, or new relevant scientific findings, but by its commercial interest to foreclose Synthron GA.
- (1533) Third, unlike the situation referred to by the Paris Court of Appeals, Teva did not have concrete evidence for its allegations. On the contrary, Teva did not even attempt to bring any relevant evidence to the competent authorities to support its messages casting doubts into the competent authorities’ findings that Synthron GA was safe, efficacious, and therapeutically equivalent to Copaxone.
- (1534) Under such circumstances, Teva’s freedom of speech cannot extend to knowingly submitting misleading information concerning key features of a competing product,

¹⁹³⁶ ID 4032, Teva’s Reply to the Statement of Objections, paras. 469, 925, 1066; ID 5695, Teva’s Reply to the Letter of Facts I of 9 February 2024, para. 321; see also para. 342.

¹⁹³⁷ ID 5695, Teva’s Reply to the Letter of Facts I of 9 February 2024, para. 321.

¹⁹³⁸ Decision of the Cour d’appel de Paris of 16 February 2023.

¹⁹³⁹ Decision of the Cour d’appel de Paris of 16 February 2023. The Court noted that the *Avastin* case differed from the previous French cases (see references below) where disparaging conduct targeted authorised use of generic medicines, in that safety and efficacy of off-label use of Avastin were never confirmed by a MA (see, for example, paragraph 439). The Court therefore considered that the freedom of speech was legitimately exercised as there was a debate of general interest on these issues (i.e. on whether the off-label use of Avastin is indeed safe and efficacious). Earlier decisions by the French competition authority: Decision of 14 May 2013, 13-D11 (Plavix); Decision of December 2013 in Case No 13-D-21 (Subutex); Decision of 20 December 2017, 17-D-25, paragraph 391 (fentanyl).

found to be safe, efficacious and therapeutically equivalent to Copaxone by the competent authorities. At any rate, even if there were genuine public health concerns (*quod non*), it is established case law that it is not for a dominant company to take action to remedy such concerns (see Recital (1481)).

9.2.4. Conclusion

(1535) In light of the above, this Decision will assess under Article 102 TFEU whether the information communicated by Teva to HCPs and Payers (i) is objectively misleading, (i.e. inaccurate or incomplete information capable of confusing its addressees, including by inducing them in error), such that it is capable of discrediting a competing product; (ii) is capable of producing exclusionary effects and (iii) is not objectively justified.

9.3. Teva disseminated objectively misleading information capable of discrediting Synthon GA

(1536) This Section shows that, Teva's conduct, through the dissemination of objectively misleading information capable of discrediting Synthon GA to Payers and HCPs departed from competition on the merits. This misleading messaging suggested that Synthon GA was not safe, not efficacious and/or not therapeutically equivalent to Copaxone, in contradiction with the findings of the competent health authorities (that had already rejected similar arguments).

(1537) Teva's campaign promoted the idea that since Synthon GA and Copaxone are not identical, the finding of therapeutic equivalence between them is questionable and would raise health risks for the patients switching from Copaxone to Synthon GA. This is despite the fact that, in Teva's own words {...} (emphasis added).¹⁹⁴⁰

(1538) GA consists of a mixture of four amino acids which is stable in proportion but random in order. The randomness in the GA structure implies certain inherent structural differences between GA medicines such as Copaxone and Synthon GA. These differences have been found to be **clinically irrelevant** by health authorities which clearly stated that the two medicines are therapeutically equivalent (a condition for successfully completing the Decentralised Procedure for the hybrid application related to Synthon GA). However, despite these authoritative regulatory findings to the contrary, Teva maintained and actively communicated to Payers (including Member State authorities, that can decide on, or significantly influence, various pricing or reimbursement parameters)¹⁹⁴¹ and HCPs that these differences affect the safety and efficacy profile of Synthon GA, and its therapeutic equivalence with Copaxone, and thus imply health risks and lower efficacy of the treatment. Indeed, Teva was, implicitly or explicitly, communicating to stakeholders that Synthon GA was not therapeutically equivalent to Copaxone, and that therefore switching to generic-like alternatives, namely Synthon GA, or a decision allowing automatic substitution would be hazardous.¹⁹⁴² As noted above, Teva referred to this multifaceted message about the safety and efficacy risks allegedly resulting from the complexity of the molecule as the "*Complexity Message*".

(1539) The Complexity Message accentuated the molecular differences between Copaxone and Synthon GA and explicitly or implicitly suggested that they could have

¹⁹⁴⁰ ID 455-1347, Teva internal email dated 14 April 2017 from {...} to {...} and others.

¹⁹⁴¹ See definition of Payers in Recital (1766).

¹⁹⁴² For the content and scope of the complexity messaging see e.g. ID 751-238 "*Copaxone complexity training video script*" from December 2019.

therapeutically meaningful consequences, in clear contradiction to the relevant regulatory findings. As explained in Recital (1481) and in Section 9.2.3.5, Teva did not follow proper pharmacovigilance procedures to challenge these findings before the competent authorities, instead targeting HCPs and Payers. The Complexity Message also cast doubt on the scientific validity of the clinical study relied on by the competent health authorities to bridge the observed differences between Copaxone and Synthon GA as a basis for finding therapeutic equivalence between those medicinal products and for successfully completing the Decentralised Procedure for Synthon GA. The Complexity Message therefore artificially created the perception that Synthon GA is not safe to use as a substitute for Copaxone.

- (1540) The Complexity Message had a central role in the overall CCP strategy, with Teva considering it a {...} in its Medical Plan for 2018.¹⁹⁴³ It permeated all CCP documents, including White Papers, Objection Handlers, expert and non-expert presentations¹⁹⁴⁴ and it was relentlessly and consistently communicated both to Payers as well as to HCPs. Importantly, a significant part of Teva's Complexity Message did not relate to the merits of Teva's own product, but to Synthon GA's features, namely its safety, efficacy as well as therapeutic equivalence with Copaxone.
- (1541) In Section 9.3.1, the Commission sets out the different forms and expressions that Teva's Complexity Message took in its communication to Payers and HCPs. The Commission then analyses and shows that each of these forms and expressions of the Complexity Message was (i) misleading, i.e. inaccurate or incomplete information capable of confusing Payers and HCPs including by inducing them into error, and (ii) that it was capable of discrediting Synthon GA. In Section 9.3.2, the Commission describes the mechanisms, including, especially, centrally created CCP documents and workflows, designed by Teva to formulate and disseminate the Complexity Message in its different forms and expressions.
- (1542) As noted above, this Decision only relates to Teva's messages that directly contradict settled findings by Member States' medicines authorities concerning Synthon GA's safety, efficacy, and therapeutic equivalence with Copaxone (irrespective of whether they were disseminated in the context of discussions on automatic substitution between Copaxone and Synthon GA).¹⁹⁴⁵

¹⁹⁴³ ID 265-853, Medical Plan Copaxone 2018. It was also one of key messages prepared for the annual congress of the European Committee For Treatment and Research in Multiple Sclerosis (ECTRIMS) in Paris (2017), ID 265-22, ECTRIMS update, Paris, 14 September 2017. Similarly the complexity messaging figures prominently in Teva's business priorities (see e.g. ID 1151-11, 2019 Annual Operating Plan, BeLux, p. 11 and in the 2018 EU Strategic Brand Plan where awareness of complexity among HCPs is indicated as one of the critical success factors to attain a strategic imperatives of gaining new patients and retaining the current ones (ID 265-851, 2018 EU Strategic Brand Plan, pp. 8, 9, 18, 31, 40, 42, 49, 54, 55, 56). See also draft Medical training eLearning module on Complexity prepared by Teva's outside consultants (ID 265-142, Copaxone, Medical Training: eLearning, Complexity of Copaxone).

¹⁹⁴⁴ These were different types of documents guiding Teva's communication on Synthon GA. Teva created a number of different CCP materials to be used (i) in communication with different targeted stakeholders (e.g. there are different White Papers for the Payers and for external experts) and (ii) by different Teva's teams (e.g. some of the documents were allocated to Teva's medical teams and some to the sales representatives). The content and scope of the CCP materials as well as the roles of different Teva's teams included in the CCP efforts are described in detail in Section 9.3.2.

¹⁹⁴⁵ See Section 9.2.3.5 above.

9.3.1. *Forms and expressions of Teva's Complexity Message and their misleading and discrediting nature*

- (1543) The Complexity Message took different forms and expressions, or facets¹⁹⁴⁶, including (i) emphasising clinically irrelevant differences in the molecular structures of Copaxone and Synthon GA (Section 9.3.1.1); (ii) pointing to the risks observed in the use of other glatiramer-related substances (Section 9.3.1.2); and (iii) calling into question the scientific validity of the GATE study as the basis for finding therapeutic equivalence between Copaxone and Synthon GA (Section 9.3.1.3).
- (1544) Teva claims that its communications did not raise doubts as to the issues settled by the MA.¹⁹⁴⁷ As this Section 9.3.1 (together with Section 9.4.4) demonstrates, there is abundant evidence that Teva's statements precisely aimed to sow doubt about the safety and efficacy of Synthon GA, and its therapeutic equivalence with Copaxone, the very essential features established by its MA. In each of the following subsections, the Commission shows that each of the three facets of Teva's Complexity Message is objectively misleading and capable of discrediting Synthon GA.¹⁹⁴⁸ The Commission (i) identifies the relevant messages based on a non-exhaustive collection of representative quotes from the various documents produced and used by Teva in the context of its communication campaign; and (ii) demonstrates that these messages are misleading and are capable of discrediting Synthon GA. The Commission's analysis also shows that Teva was aware of the misleading nature of the disseminated statements.¹⁹⁴⁹ After the abovementioned analysis, for the sake of simplicity, the present Decision will refer to the "Misleading Complexity Message" to refer to one or more of the facets of the Complexity Message, that the Commission has concluded to be both objectively misleading and capable of discrediting Synthon GA.

9.3.1.1. Teva emphasised clinically irrelevant differences in GA structures

9.3.1.1.1. Background

- (1545) As described in Section 5.1, GA is a heterogeneous mixture of peptide compounds. It is "*not possible to refer to batches being 'completely identical GA in terms of both its molecular weight and polypeptides sequences and sizes'*".¹⁹⁵⁰ In other words, it is

¹⁹⁴⁶ For the sake of clarity, the present Decision concludes that a communication includes the Complexity Message when it refers to one or more of the three facets discussed in this Section.

¹⁹⁴⁷ ID 4032 Teva's Reply to the Statement of Objections, para. 1055.

¹⁹⁴⁸ Dissemination of the Complexity Message was a part of Teva's strategy to defend Copaxone in the face of emerging competing threat from the competing GA and especially Synthon GA (see Sections 9.1 and 9.3.2).

¹⁹⁴⁹ The Commission's analysis of the misleading character of information disseminated by Teva is not affected by the fact that Teva might have informed the addressee that Synthon GA had received a MA or that Teva had already raised its objections in front of the competent authorities who nevertheless decided differently, as long as it follows from the overall context of the information shared by Teva that it was capable of confusing Payers and HCPs including by inducing them in error. This will be so, for example, where Teva's message briefly acknowledges therapeutic equivalence between Copaxone and Synthon GA, but at the same time conveys extensive and detailed arguments on compositional differences without adequately discussing their therapeutic relevance (including the fact that such arguments may have already been rejected by medicines authorities, and why).

¹⁹⁵⁰ ID 906, Teva's reply to the Article 18(2) Request of 3 June 2021, pp. 39-40. See also, Assessment Report with respect to quality Mylan and Synthon's glatiramer products for the purposes of the Medicine Evaluation Board's decision on Teva's objection "*a spread can also be identified with Copaxone between batches in the various characterisation tests assessed. Such a variation in batch composition did not lead to the conclusion that one batch of Copaxone is efficacious and another batch is not*" and "*If knowledge of the precise identity of the therapeutic moiety were a fundamental*

impossible to establish that any two batches of GA are identical. This applies equally when comparing a batch of Copaxone to a Synthron GA batch as when comparing two batches of Copaxone. During the regulatory procedure for the approval of Synthron GA, Teva pointed to compositional differences between batches of Copaxone and of Synthron GA. These differences were taken into account by the MEB (as a reference competent authority). Despite this and after careful assessment, the MEB concluded that Copaxone and Synthron GA were “*therapeutically equivalent*”¹⁹⁵¹, meaning that the compositional differences pointed to by Teva were found to be clinically irrelevant because the efficacy and safety of Synthron GA was found to be similar to the efficacy and safety of Copaxone.

9.3.1.1.2. Documents and statements

- (1546) Notwithstanding the regulatory findings, Teva used a battery of statements emphasising compositional differences as a starting point to either implicitly or explicitly cast doubt on Synthron GA’s safety, efficacy and therapeutic equivalence with Copaxone. In particular, Teva claimed that physicochemical differences (such as differences in polypeptide sequences) posed a risk for patients in relation to the safety (including tolerability and immunogenicity) and efficacy of Synthron GA, thus also questioning its therapeutic equivalence with Copaxone.
- (1547) For example, in the Payer White Paper¹⁹⁵² Teva explained: {...}.¹⁹⁵³ Teva then continued to explain: {...}.¹⁹⁵⁴
- (1548) Similarly, in the presentation prepared for a meeting with FAMHP, the Belgian Federal Agency for Medicines and Health Products, on the slide {...} (emphasis added).¹⁹⁵⁵ Further, making a summary of the physicochemical differences, Teva

requirement then it would not be possible to verify that a new batch of Copaxone has the same efficacy as a batch used in clinical studies. The authorisation based on 'assumption of similarity of the active substance' that TEVA contests would therefore also apply to its own product” (emphasis added) (ID 742-79, Assessment report with respect to quality Myland and Synthron’s glatiramer products, p. 8).

¹⁹⁵¹ ID 455-2843, e.g. conclusions of the Public Assessment Report Brabio 20 mg/ml, p. 17; see also ID 742-42, p. 8.

¹⁹⁵² The Payer White Paper was primarily used as an internally approved source of information and arguments to be used in Teva’s external communication with the Payers (see Section 9.3.2.2 and Figure 32 in Recital (1678)).

¹⁹⁵³ ID 806-2, Assessing the Value of COPAXONE® in Relation to Follow-on Glatiramer Acetate Payer White Paper, 8 June 2016, p. 3. See also ID 651-7, Teva’s submission to SUKL of 24 January 2019.) Similarly, in the presentation prepared for the meeting with the Belgian FAMHP, Teva claimed: {...}. (ID 262-724, Substitution considerations for follow on glatiramer acetate products, Meeting with Federal Agency for Medicines & Health Products, Brussels, 23 January 2017, p. 3. See also ID 455-2024, The value of COPAXONE® (glatiramer acetate): Considerations when assessing the use of follow-on glatiramer acetate (FoGA), 8 September 2018, p. 42 and ID 455-855, The value of COPAXONE® (glatiramer acetate): Considerations when assessing the use of follow-on glatiramer acetate (FoGA), November 2018, p. 70). Equivalent messages are included in the documents designed for communication with the HCPs such as the KAM Objection Handler which states {...} (ID 455-2409, KAM FoGA objection handler, 7 September 2018, p. 2) and MSL Objection Handler which states {...} (ID 404-1538, COPAXONE® and the introduction of FoGA, Objection handler for MSLs, Version 2, 27 June 2017, p. 17).

¹⁹⁵⁴ ID 806-2, Assessing the Value of COPAXONE® in Relation to Follow-on Glatiramer Acetate, Payer White Paper, 8 June 2016, p. 11. See also ID 455-2210, COPAXONE® and the introduction of FoGA, Payer objection handler, 8 December 2016, pp. 16 and 20; ID 455-1452, The Complexity of COPAXONE® and Considerations for Substitution with Follow-on Glatiramer Acetate, External Expert Presentation, May 2016, p. 9.

¹⁹⁵⁵ ID 262-724, Substitution considerations for follow on glatiramer acetate products, Meeting with Federal Agency for Medicines & Health Products, Brussels, 23 January 2017, p. 19. The quote can also be found in ID 455-2304, Scientific evidence-base on COPAXONE®’s complexity and function compared

claimed that {...} (emphasis added).¹⁹⁵⁶ Finally, Teva concludes with the following statements: {...} (emphasis added).¹⁹⁵⁷

- (1549) Teva’s focus on emphasising compositional differences between Synthron GA and Copaxone is apparent in the so-called “*Payers Slide Presentation*”.¹⁹⁵⁸ {...}.¹⁹⁵⁹ {...}.¹⁹⁶⁰
- (1550) Documents designed to facilitate communication with the HCPs contain the same messages. For example, the MSL Objection Handler¹⁹⁶¹ from June 2017 provides that {...}.¹⁹⁶² These documents question Synthron GA’s safety, efficacy and therapeutic equivalence to Copaxone.
- (1551) In the same way, a so-called “*Complexity Leavepiece*”¹⁹⁶³ prepared by Teva for its sales force to leave with HCPs, warns that the {...} and that {...}.¹⁹⁶⁴ Teva’s

to FOGAs, FOGA slide deck, training material for market access team, 3 February 2016, p. 14. According to ID 660, Teva’s reply to Article 18(2) Request of 3 June 2020, p. 153, Teva stated that this presentation was prepared as a background educational material for the market access team. In the reply to Q 83 asking whether the presentation was shared with third parties, Teva replied that it was not shared with third parties, however, most of the slides of this presentation can be found in the slides in ID 262-724 which were presented to the Belgian authorities and also in the presentation given by Teva to German neurologists on 5 March 2017 - see ID 4513-96463, Copaxone, Clinical experience & future developments – attachment to ID 4513- 96462, Teva internal email dated 3 March 2017 from {...} to {...} and others; see also, ID 4513-96417, Copaxone, Clinical experience & future developments, March 2017.

¹⁹⁵⁶ Ibid, p. 27. See also the letter from Teva’s external counsel to AIFA, regarding the issuance of an MA for Copemyl and its substitutability with Copaxone 40 mg where Teva raises concerns related to long term safety, immunogenicity and efficacy of Copemyl (ID 742-10, Teva’s reply to the Article 18(2) Request of 3 June 2020).

¹⁹⁵⁷ ID 262-724, Substitution considerations for follow on glatiramer acetate products, Meeting with Federal Agency for Medicines & Health Products, Brussels, 23 January 2017, p. 57. Similarly, in the letter sent to AIFA on 3 November 2016 regarding the substitutability of Copemyl (i.e. Synthron GA) 20 mg and Copaxone, Teva stated that unlike Copaxone, with its long-term data on relative efficacy, Copemyl does not have this data and its potential outcomes in terms of safety are not certain. Teva further referred to partial elements of the GATE study without explaining the overall results of the study or the MEB’s conclusions. Further, Teva stated that there was need for more trials to determine the efficacy, safety (including immunogenicity) of Synthron GA, going expressly against the MEB’s decision (ID 742-116, Teva’s letter to AIFA of 3 November 2016).

¹⁹⁵⁸ Payer Slide Presentation is a comprehensive slide deck, a visual aid to lay out key Teva’s arguments concerning competing GA. It served as a template for the creation of the localised presentations used in Teva’s communication with the competent authorities of the Relevant Member States, (see Section 9.3.2.2 and Figure 32 in Recital (1678)). ID 455-2630, The value of COPAXONE® (glatiramer acetate): Considerations when assessing the use of follow-on glatiramer acetate (FoGA), Latest version available to the Commission dated 29 January 2019.

¹⁹⁵⁹ ID 455-2630, The value of COPAXONE® (glatiramer acetate): Considerations when assessing the use of follow-on glatiramer acetate (FoGA), Latest version available to the Commission dated 29 January 2019, pp. 21-44.

¹⁹⁶⁰ Ibid, pp. 23 and 85.

¹⁹⁶¹ The MSL Objection Handler uses a Q&A form to help Teva’s Medical Science Liasons to provide structured answers to the anticipated questions related to the Synthron GA entry (see Section 9.3.2.2 and Figure 32 in Recital (1678)). ID 266-105, COPAXONE® and the introduction of FoGA, Objection handler for MSLs, Version 4, March 2019.

¹⁹⁶² ID 404-1538, Copaxone and the introduction of FoGA, Objection handler for MSLs, 27 June 2017, Version 2, pp. 18-19.

¹⁹⁶³ The Complexity Leavepiece outlined in a succinct and simple way the main elements of Teva’s Complexity Message and had a goal to raise awareness among HCPs of the “unique” nature of Copaxone (see Section 9.3.2.2.1.8).

¹⁹⁶⁴ ID 751-427, Take a Closer Look at Copaxone, October 2018, pp. 3, 4. For similar statements also challenging safety and efficacy, see ID 455-2024, The value of COPAXONE® (glatiramer acetate): Considerations when assessing the use of follow on glatiramer acetate (FoGa), Payer Presentation, 8

message that Copaxone’s proprietary manufacturing process cannot be replicated by Synthon GA questions the latter’s capacity to be therapeutically equivalent to Copaxone. The Specialist External Expert White Paper also notes, {...}.¹⁹⁶⁵ It however fails to mention that even different batches of Copaxone cannot be considered identical.¹⁹⁶⁶ In a next step, Teva insinuates that any manufacturing differences may entail therapeutically relevant effects. For example, a promotional presentation for HCPs states that {...}¹⁹⁶⁷ which questions Synthon GA’s therapeutic equivalence with Copaxone.

9.3.1.1.3. Assessment of the objectively misleading nature of the information

- (1552) Teva’s message that compositional differences between Copaxone and Synthon GA may have clinically meaningful consequences is misleading because, as detailed in the below Sections, they contradict, explicitly or implicitly, the findings of the competent authorities that Synthon GA is safe, efficacious, and therapeutically equivalent to Copaxone. Teva’s arguments underlying its message on implications of compositional differences between Copaxone and Synthon GA had already been rejected by the competent authorities when reaching this conclusion.¹⁹⁶⁸
- (1553) The Commission notes that Teva never produced, in appropriate pharmacovigilance procedures or otherwise, any valid scientific evidence that could prove the therapeutic relevance of the differences in GA structures.
- (1554) In its communication, Teva was modulating the form of its misleading messages to make them more or less direct depending on the situation while all the time targeting Synthon GA’s safety, efficacy and therapeutic equivalence with Copaxone.
- (1555) For example, when there was the imminent danger of losing the whole market, Teva considered that the more subtle messages related to safety, efficacy and therapeutic equivalence may not be sufficient and considered that it was the time for a more direct message referring to safety of competing GAs: {...}.¹⁹⁶⁹

September 2018, p. 13 – {...}; and ID 455-1452, Considering the value of COPAXONE® in an era of Follow-on Glatiramer Acetate, May 2016 - on slide 8, Teva makes reference to the manufacturing process and mentions that changes to the manufacturing process {...}.

¹⁹⁶⁵ ID 597-41, Considering the value of COPAXONE® in an era of Follow-on Glatiramer Acetate, 6 May 2016, p. 3. The same type of messages can as well be found in other Teva’s documents, for example: ID 597-1, Considering the value of COPAXONE® in an era of Follow-on Glatiramer Acetate, 6 May 2016, p. 3. See also a similar message on p. 12: {...}; ID 806-2, Assessing the Value of COPAXONE® in Relation to Follow-on Glatiramer Acetate, Payer White Paper, 8 June 2016, p. 11 - {...}”; ID 597-33, The Complexity of COPAXONE® and Considerations for Substitution with Follow-on Glatiramer Acetate, p. 5; ID 404-337, The Complexity of Copaxone and Considerations for Substitution with Follow-on Glatiramer Acetate, 27 January 2020 contain a similar quote: {...}.

¹⁹⁶⁶ See Recital (1568).

¹⁹⁶⁷ ID 4919-27, promotional iPad presentation “*FoGA iPad - Complexity of Copaxone*”, September 2016, p. 3. (unofficial translation) Original text: {...} ID 4897, List of documents registered on Teva’s {...}. See also: ID 4919-2, promotional iPad presentation “Prezentacja iPad kampania T3 2017 (Re-approval 1)”, August 2017, pp. 28-29.

¹⁹⁶⁸ See for example, Recitals (1704), (1708) and (1719). See also ID 4513-96462, Teva internal email thread including email dated 3 March 2017 from {...} to {...} and others in which some of Teva’s employees’ share the view, that its arguments had already been {...}.

¹⁹⁶⁹ ID 404-1831, Teva internal email thread including email dated 5 January 2017 from {...} to {...}, {...}, {...}, {...}, {...}, {...}; see also ID 404-1809, Teva internal email chain dated 4-5 January 2017 between {...}, {...} and others containing the following discussions to this email; ID 404-1814 Teva internal email chain dated 4-5 January 2017 between {...}, {...} and others containing the following discussions to this email.

- (1556) Contrary to Teva’s claims¹⁹⁷⁰, Teva’s communications invoking clinically irrelevant differences were not limited to issues specifically relevant to the question whether Synthon GA and Copaxone should be automatically substitutable, but targeted more broadly the conclusions of Synthon GA’s Decentralised Procedure (that is to say, its safety, efficacy, and its therapeutic equivalence with Copaxone). As explained in Section 9.2.3.5, the Commission does not take a position concerning the messages related to automatic substitution but only concerning the misleading messages related to Synthon GA’s safety, efficacy and thus therapeutic equivalence with Copaxone, whether they were communicated in order to frustrate automatic substitution or not. The Commission notes that if Teva successfully instilled doubt as to these features, it would have necessarily also instilled doubts as to automatic substitution.
- (1557) Teva’s communications emphasising clinically irrelevant differences between Synthon GA and Copaxone and explicitly or implicitly contradicting the settled scientific findings behind the successful completion of the Decentralised Procedure for Synthon GA comprised (i) inaccurate and incomplete statements referring to Synthon GA’s physicochemical differences with Copaxone; and (ii) incorrect or incomplete claims concerning the manufacturing process for GA products. (iii) Teva was itself aware that the differences in GA structures were therapeutically irrelevant.
- 9.3.1.1.3.1. Teva’s messages on Synthon GA’s physicochemical differences with Copaxone are inaccurate and incomplete
- (1558) One of the main tenets of Teva’s Complexity Message was based on communicating that the differences between Synthon GA and Copaxone were therapeutically meaningful. Such statements were misleading as they were inaccurate, incomplete or both.
- (1559) First, Teva’s messages explicitly or implicitly suggesting that, due to physicochemical differences with Copaxone, Synthon GA could have an inferior safety and efficacy profile, and questioning its therapeutic equivalence with Copaxone, were incorrect and/or incomplete, and thus misleading.
- (1560) In the first place, the Commission recalls that the complexity and heterogeneity of a GA structure (i.e. the fact that there were certain differences in all GA structures) was recognised by the choice of Article 10(3) of Directive 2001/83 as the appropriate legal basis for Synthon’s MA application in 2014.¹⁹⁷¹ It was precisely because of these compositional differences that Synthon designed and executed the GATE study following the scientific advice received not only from the EMA but also from a number of competent national authorities.¹⁹⁷² The main purpose of the study was to

¹⁹⁷⁰ See Section 9.2.3.5.

¹⁹⁷¹ According to Article 10(3) of Directive 2001/83, the applicant may still rely on the results of pre-clinical tests and clinical trials for a reference product “[i]n cases where the medicinal product does not fall within the definition of a generic medicinal product as provided in paragraph 2(b) or where the bioequivalence cannot be demonstrated through bioavailability studies or in case of changes in the active substance(s), therapeutic indications, strength, pharmaceutical form or route of administration, vis-à-vis the reference medicinal product” provided that the application is supported with “the results of the appropriate pre-clinical tests or clinical trials”. Therefore, the applicant under Article 10(3) of Directive 2001/83 will rely in part on the results of pre-clinical tests and clinical trials for a reference product and in part on new data.

¹⁹⁷² Synthon’s approach reflected the scientific advice received in consultations with EMA and a number of competent national authorities: the UK Medicines and Healthcare products Regulatory Agency (“MHRA”), the German Federal Institute for Drugs and Medical Devices (“BfArM”), the Austrian Agency for Health and Food Safety (“AGES”), the Polish Office for Registration of Medicinal Products

establish whether the observed compositional differences had any meaningful clinical consequences compared to Copaxone, the reference medicine.

- (1561) In the second place, Teva's claims had already been rejected in the Decentralised Procedure for Synthon GA which found that it was safe, efficacious, and therapeutically equivalent to Copaxone. Teva submitted its claims (corresponding to the one in the assessed messages) to the Dutch medicines agency (MEB), as the reference competent authority with agreement of all concerned Member States in the Decentralised Procedure, as well as to the corresponding competent authorities of the concerned Member States.¹⁹⁷³ The medicines agencies participating in the Decentralised Procedure carefully assessed all relevant elements (including Teva's objections)¹⁹⁷⁴ and agreed that all concerns and arguments raised by Teva were successfully addressed by Synthon. They then unanimously agreed on the Public Assessment Report, which states that "[w]ith regard to non-clinical and clinical aspects, no relevant dissimilarities to the reference product [Copaxone] were seen".¹⁹⁷⁵ Moreover, the MEB also stated that "[n]o specific difference in efficacy or safety between the patients who were on Copaxone and later switched to Brabio [Synthon GA] and the patients who were treated with Brabio for the entire period were observed. Therefore there is no evidence against switching".¹⁹⁷⁶ In other words, the complexity of GA was recognised and accounted for in the regulatory procedures, culminating in the successful completion of the Decentralised Procedure for Synthon GA which found that any differences were therapeutically irrelevant. The Public Assessment Report specifically found "that the efficacy and safety of [Synthon GA] is similar to the efficacy and safety of [Copaxone]".¹⁹⁷⁷ The Public Assessment Report also established that the active substances in Copaxone and Synthon GA are in fact "similar" and not "dissimilar". In keeping with this, the SmPCs¹⁹⁷⁸ for both Copaxone and Synthon GA are identical, which further confirms that they are therapeutically equivalent, and that any differences between the products are therefore not therapeutically relevant.
- (1562) The significance of Copaxone and Synthon GA having the same SmPCs was recognised by Teva itself: in an internal correspondence on mechanisms to {...}, {...} simply pointed {...}.¹⁹⁷⁹ The sameness of SmPCs and its authoritative confirmation of the therapeutic equivalence between Synthon GA and Copaxone was echoed by a neurologist attending one of Teva's organised advisory board meetings on GA who noted that costs remained the only differentiating factor in prescribing behaviour and noted that {...}.¹⁹⁸⁰

("URPL) and the Spanish Agency of Medicines and Medical Devices ("AEMPS"). ID 863, Synthon's Reply to the Article 18(2) Request of 9 June 2021, pp. 2-4.

¹⁹⁷³ ID 455-2843, Public Assessment Report Brabio, pp. 3-4. In an internal email to the {...} that {...} (ID 455-1197, Teva internal email dated 16 January 2015 from {...}).

¹⁹⁷⁴ ID 455-2843, Public Assessment Report Brabio, p. 4.

¹⁹⁷⁵ Ibid, p. 17.

¹⁹⁷⁶ ID 742-172, Klinisch beoordelingsrapport Glatirameerproducten van Mylan en Synthon, p. 9.

¹⁹⁷⁷ ID 455-2843, Public Assessment Report Brabio, p. 17. See also ID 1913, Public Assessment Report Glatirameeractetaat Alvogen, p. 13.

¹⁹⁷⁸ The Summary of Product Characteristics ("SmPC") is a document approved by a competent authority as a part of the MA procedure of each medicine. It officially describes the properties and the officially approved conditions of use of a medicine. SmPC forms the basis of information for healthcare professionals on how to use the medicine safely and effectively.

¹⁹⁷⁹ ID 404-537, Teva internal email exchange dated 15 June 2018 between {...} and {...}.

¹⁹⁸⁰ ID 455-1539, Summary Report of Glatiramer Acetate in the treatment of Relapsing Forms of Multiple Sclerosis: Advisory Board Meeting, 27 October 2017, p. 14.

- (1563) In the third place, any communication by Teva suggesting that Synthron GA may not be therapeutically equivalent to Copaxone, despite the successful conclusion of the Decentralised Procedure, is misleading. Such communication may be incorrect (insofar as it contradicted settled findings by competent regulatory authorities) and/or incomplete (insofar as it failed to reconcile the statements that implied that Synthron GA was not therapeutically equivalent with Copaxone, with the corresponding settled findings of the competent authorities). Thus, it was capable of confusing its addressees.¹⁹⁸¹
- (1564) In some cases, Teva's statements directly contradicted the findings of the competent regulatory authorities. For example, in some cases, Teva explicitly claimed that {...}¹⁹⁸², while in other instances Teva claimed that active substances in Synthron GA are {...}.¹⁹⁸³ Both of these types of statements are incorrect as they contradict the findings of the MEB on Synthron GA's therapeutic equivalence with Copaxone, which the MEB had reached after assessing and rejecting Teva's arguments.
- (1565) In other instances, Teva questioned the settled finding that Synthron GA was safe, efficacious and therapeutically equivalent to Copaxone in a more indirect fashion using statements that, while not incorrect *per se*, could still lead the addressee to draw inaccurate inferences. For example¹⁹⁸⁴, Teva communicated that {...};¹⁹⁸⁵ {...} (emphasis added)¹⁹⁸⁶; {...} (emphasis added).¹⁹⁸⁷ In these statements, Teva is

¹⁹⁸¹ Similarly, in the context of the comparisons between biosimilars and their reference products, the US FDA draft guidance on promotion materials state that “[r]epresentations or suggestions that create an impression that there are clinically meaningful differences between the reference product and its biosimilar [...] are likely to be false or misleading.” (ID 2060, Food and Drug Administration, Promotional Labelling and Advertising Considerations for Prescription Biological Reference and Biosimilar Products – Questions and Answers – draft Guidance for Industry, February 2020, lines 164-174).

¹⁹⁸² ID 262-724, Substitution considerations for follow on glatiramer acetate products, Meeting with Federal Agency for Medicines & Health Products, Brussels, 23 January 2017, p. 57.

¹⁹⁸³ ID 455-2630, The value of COPAXONE® (glatiramer acetate): Considerations when assessing the use of follow-on glatiramer acetate (FoGA), Latest version available to the Commission dated 29 January 2019, p. 23.

¹⁹⁸⁴ For other examples, see Recitals (1550) and (1551).

¹⁹⁸⁵ ID 806-2, Assessing the Value of COPAXONE® in Relation to Follow-on Glatiramer Acetate, Payer White Paper, 8 June 2016, p. 11. See also ID 455-2210, COPAXONE® and the introduction of FoGA, Payer objection handler, 8 December 2016, pp. 16 and 20; ID 455-1452, The Complexity of COPAXONE® and Considerations for Substitution with Follow-on Glatiramer Acetate, External Expert Presentation, May 2016, p. 9.

¹⁹⁸⁶ ID 262-724, Substitution considerations for follow on glatiramer acetate products, Meeting with Federal Agency for Medicines & Health Products, Brussels, 23 January 2017, p. 19. The quote can also be found in ID 455-2304, Scientific evidence-base on COPAXONE®'s complexity and function compared to FOGAs, FOGA slide deck, training material for market access team, 3 February 2016. According to ID 660, Teva's reply to Article 18(2) Request of 3 June 2020, p. 153, Teva stated that this presentation was prepared as a background educational material for market access team. In the reply to Q 83 whether the presentation was shared with third parties, the reply of Teva was that it was not shared with third parties. However, most of the slides of this presentation can be found in the slides in ID 262-724 which were presented to the Belgian authorities and also in the presentation given by Teva to German neurologists on 5 March 2017, ID 4513-96463, Copaxone, Clinical experience & future developments, attachment to ID 4513-96462, Teva internal email dated 3 March 2017 from {...} to {...} and others; see also ID 4513-96417, Copaxone, Clinical experience & future developments, March 2017.

¹⁹⁸⁷ Ibid, p. 27. See also (i) the letter from Teva's external counsel to AIFA, regarding the issuance of an MA for Copemyl and its substitutability with Copaxone 40 mg where Teva raises concerns related to long term safety, immunogenicity and efficacy of Copemyl (ID 742-10, Teva's reply to the Article 18(2) Request of 3 June 2020), and (ii) ID 806-2, Assessing the Value of COPAXONE® in Relation to Follow-on Glatiramer Acetate, Payer White Paper, 8 June 2016, p. 11, already quoted in Recital (1547) above.

implying that the differences between Copaxone and Synthon GA may, for example, influence the latter's immunogenic, safety or efficacy profile, or is claiming that the outcome of these differences is unknown. Such statements are again in contradiction with the settled findings that there are no therapeutically relevant differences between Copaxone and Synthon GA, despite Teva having raised these claims before the MEB.

- (1566) Second, insofar as Teva emphasised compositional differences between Copaxone and Synthon GA, without mentioning that sameness could not be established even between Teva's own batches of Copaxone, its communication was incomplete, and thus misleading.
- (1567) Teva for example stated that {...} and it is therefore {...}.¹⁹⁸⁸ Similarly, Teva also argued that {...}¹⁹⁸⁹, suggesting that any manufacturing process different from the one used by Teva would lead to a medicinal product not therapeutically equivalent to Copaxone.
- (1568) However, the MEB confirmed that "[t]he circumstance that the production process induces variation is a known fact. After all, as Synthon also shows in its analysis of the batches of TEVA's product Copaxone, a spread can also be identified with Copaxone between batches in the various characterisation tests assessed. Such a variation in batch composition did not lead to the conclusion that one batch of Copaxone is efficacious and another batch is not".¹⁹⁹⁰ In replying to Teva's claim that the precise identity of the therapeutic moiety cannot be verified, the MEB had also found that "If knowledge of the precise identity of the therapeutic moiety were a fundamental requirement then it would not be possible to verify that a new batch of Copaxone has the same efficacy as a batch used in clinical studies. The authorisation based on 'assumption of similarity of the active substance' that TEVA contests would therefore also apply to its own product".¹⁹⁹¹
- (1569) Therefore, Teva's objections on the lack of sameness between the GA structures in Copaxone and those in competing GA products (including Synthon GA) equally apply to different batches of Teva's Copaxone, regarding which the therapeutic equivalence is not in dispute. This further confirms that the statements in question, as analysed under the first point above, are incomplete, and thus capable of confusing the addressees on Synthon GA's therapeutic equivalence with Copaxone despite the established regulatory findings to the contrary.

9.3.1.1.3.2. Teva's claims on GA's manufacturing process are inaccurate or incomplete

- (1570) Teva also questioned the soundness of the manufacturing process and related quality controls used by Synthon, suggesting that this may have an impact on Synthon GA's safety and efficacy, and consequently on its therapeutic equivalence with Copaxone.
- (1571) For example, during a telephone call with Teva's external communication advisor, {...} stated that {...} (emphasis added).¹⁹⁹² Similarly, a poster prepared for the

¹⁹⁸⁸ ID 906, Teva's reply to the Article 18(2) Request of 3 June 2021, pp. 39-40.

¹⁹⁸⁹ ID 751-427, Take a Closer Look at Copaxone, October 2018, pp. 3, 4.

¹⁹⁹⁰ ID 742-42, Assessment report with respect to quality Mylan and Synthon's glatiramer products. See also reply to Teva by {...} dated 5 March 2019 explaining in very clear terms: "{...}" (unofficial translation) (ID 3583, pp. 1-2, "{...}").

¹⁹⁹¹ ID 742-42, Assessment Report with respect to quality of Mylan and Synthon's glatiramer products, 3 November 2016, p. 8.

¹⁹⁹² ID 265-468, minutes of the call as recorded by {...} representative and not objected to by Teva's representative. {...} was the medical communications agency supporting Teva with their 2019 activities

European Committee for Treatment and Research in Multiple Sclerosis (ECTRIMS Annual Congress, October 2017, Paris) concludes: “*Synthon FOGA raises concern regarding compositional reproducibility of lots, and may indicate inadequate process robustness and lack of suitable control strategy. Overall, findings challenge the similarity of FoGA in Synthon’s EU products compared to GA in Copaxone and raise concern for standards to establish similarity of FOGAs to GA in Copaxone in general*” (emphasis added).¹⁹⁹³

- (1572) Such statements contradict the fact that a rigorous manufacturing process and effective quality controls were among the main conditions for successfully completing the Decentralised Procedure and, therefore, for Synthon GA being approved by the competent health authorities as a safe and effective medicine, therapeutically equivalent to Copaxone. Indeed, as the Public Assessment Report clearly confirmed, “*In view of the heterogeneity of the substance and the limitations of release controls the MAH has fixed the drug substance manufacturing conditions rigorously in the dossier within narrow ranges to assure consistency of the commercial product*”.¹⁹⁹⁴
- (1573) For these reasons, the statements in question are inaccurate or incomplete as they contradict the regulatory findings by competent health authorities or lead to inaccurate inferences, and are capable of inducing in error their addressees as to Synthon GA’s safety, efficacy, and therapeutic equivalence with Copaxone.

9.3.1.1.3.3. Teva was aware that differences in GA structures were not therapeutically relevant

- (1574) Teva was, or should have been, well aware that compositional differences between Copaxone and Synthon GA were therapeutically irrelevant. For example, in the draft PowerPoint presentation {...}, statements frequently included in disseminated Teva materials and emphasising observed molecular differences linking them with possible clinical effects were accompanied by critical comments by Teva’s consultant {...}, specialised in pharmaceutical advertising, which was tasked with reviewing the content of Teva’s CCP materials (see also Recital (1680)). Concerning Teva’s often repeated statement that {...} (a statement also included in later documents, with slight variations¹⁹⁹⁵), the consultant commented {...} (emphasis added).¹⁹⁹⁶ In reaction to Teva’s statement that: {...} (a statement also kept by Teva in later documents¹⁹⁹⁷), the consultant retorted: {...} (emphasis added).¹⁹⁹⁸ Finally, concerning the statement {...}, the consultant even went as far as observing that this

including complexity messaging – see ID 265-674, email dated 23 July 2019 from {...}’s Account Manager to a number of Teva correspondents.

¹⁹⁹³ ID 404-1721, poster prepared for the European Committee for Treatment and Research in Multiple Sclerosis (ECTRIMS) Annual Congress, 25-28 October 2017, Paris.

¹⁹⁹⁴ ID 455-2843, Public Assessment Report Brabio, p. 5. See also, ID 742-42, MEB’s Assessment report with respect to quality Mylan and Synthon’s glatiramer products, p. 8.

¹⁹⁹⁵ See, e.g., ID 404-337, The Complexity of Copaxone and Considerations for Substitution with Follow-on Glatiramer Acetate, 27 January 2020 containing a similar quote: {...}. See also ID 455-2024, The value of COPAXONE® (glatiramer acetate): Considerations when assessing the use of follow on glatiramer acetate (FoGa), Payer Slide Presentation, 8 September 2018, p. 13.

¹⁹⁹⁶ ID 404-848, The Complexity of Copaxone (glatiramer acetate), September 2016, p. 12.

¹⁹⁹⁷ See, e.g., ID 455-2561, Assessing the Value of COPAXONE® in Relation to Follow-on Glatiramer Acetate Payer White Paper, June 2017 – {...}.

¹⁹⁹⁸ ID 404-848, The Complexity of Copaxone (glatiramer acetate), September 2016, p. 15. Internally, Teva also shared a similar view many years prior to {...}’s comments. Indeed, in the presentation {...} prepared as a part of Teva’s internal CCP roll out (presentation dated 14 November 2014) while explaining {...} clearly states that {...} (ID 413-151, p. 8).

formulation (also reproduced in disseminated Teva documents¹⁹⁹⁹) {...} (emphasis added).²⁰⁰⁰ In relation to Teva's statement {...},²⁰⁰¹ {...} proposed to delete the highlighted text and made the comment: {...}.²⁰⁰² Notwithstanding, this quote does appear in a finalised and disseminated version of the document.²⁰⁰³

- (1575) In relation to Teva's statement {...},²⁰⁰⁴ {...} proposed to delete the highlighted text and made the comment: {...}.²⁰⁰⁵
- (1576) In relation to Teva's statement: {...},²⁰⁰⁶ {...} proposed to delete the highlighted text and made the comment: {...}.²⁰⁰⁷
- (1577) In relation to Teva's statement: {...},²⁰⁰⁸ {...} proposed to delete the highlighted text and made the comment: {...}.²⁰⁰⁹
- (1578) In relation to Teva's statement: {...},²⁰¹⁰ {...} proposed to delete the highlighted text and made the comment: {...}.²⁰¹¹
- (1579) In relation to Teva's statement: {...},²⁰¹² {...} proposed to delete the highlighted text and made the comment: {...}.²⁰¹³

¹⁹⁹⁹ See, e.g., ID 455-2561, Assessing the Value of COPAXONE® in Relation to Follow-on Glatiramer Acetate Payer White Paper, June 2017 – {...}.

²⁰⁰⁰ ID 404-848, The Complexity of COPAXONE® (glatiramer acetate), September 2016, pp. 12 and 15.

²⁰⁰¹ ID 455-1145, Assessing the Value of COPAXONE® in Relation to Follow-on Glatiramer Acetate, Payer White Paper, November 2018, p. 6.

²⁰⁰² *Ibid.*

²⁰⁰³ See, for example, ID 2229, Assessing the Value of COPAXONE® in Relation to Follow-on Glatiramer Acetate, Payer White Paper, June 2018, p. 6.

²⁰⁰⁴ ID 455-1145, Assessing the Value of COPAXONE® in Relation to Follow-on Glatiramer Acetate, Payer White Paper, November 2018, p. 13; the same substance of the message can be found for example in ID 2229, Assessing the Value of COPAXONE® in Relation to Follow-on Glatiramer Acetate, Payer White Paper, June 2018, p. 4 – {...}.

²⁰⁰⁵ ID 455-1145, Assessing the Value of COPAXONE® in Relation to Follow-on Glatiramer Acetate, Payer White Paper, November 2018, p. 13.

²⁰⁰⁶ ID 455-1145, Assessing the Value of COPAXONE® in Relation to Follow-on Glatiramer Acetate, Payer White Paper, November 2018, p. 15; the same quote can be found also for example in ID 2229, Assessing the Value of COPAXONE® in Relation to Follow-on Glatiramer Acetate, Payer White Paper, June 2018, p. 14; see also ID 751-410, Copaxone evolved campaign e-detailed implementation guide, p. 3 – {...}.

²⁰⁰⁷ ID 455-1145, Assessing the Value of COPAXONE® in Relation to Follow-on Glatiramer Acetate, Payer White Paper, November 2018, p. 15.

²⁰⁰⁸ ID 455-1145, Assessing the Value of COPAXONE® in Relation to Follow-on Glatiramer Acetate, Payer White Paper, November 2018, p. 13; the same quote can be found also for example in ID 2229, Assessing the Value of COPAXONE® in Relation to Follow-on Glatiramer Acetate, Payer White Paper, June 2018, p. 13.

²⁰⁰⁹ ID 455-1145, Assessing the Value of COPAXONE® in Relation to Follow-on Glatiramer Acetate, Payer White Paper, November 2018, p. 13.

²⁰¹⁰ ID 455-1145, Assessing the Value of COPAXONE® in Relation to Follow-on Glatiramer Acetate, Payer White Paper, November 2018, p. 24; the same quote can be found as well for example in ID 2229, Assessing the Value of COPAXONE® in Relation to Follow-on Glatiramer Acetate, Payer White Paper, June 2018, p. 21.

²⁰¹¹ ID 455-1145, Assessing the Value of COPAXONE® in Relation to Follow-on Glatiramer Acetate, Payer White Paper, November 2018, p. 24.

²⁰¹² ID 455-1145, Assessing the Value of COPAXONE® in Relation to Follow-on Glatiramer Acetate, Payer White Paper, November 2018, p. 28; the same quote can be found for example in ID 2229, Assessing the Value of COPAXONE® in Relation to Follow-on Glatiramer Acetate, Payer White Paper, June 2018, p. 24.

²⁰¹³ ID 455-1145, Assessing the Value of COPAXONE® in Relation to Follow-on Glatiramer Acetate, Payer White Paper, November 2018, p. 28.

- (1580) In a similar vein, emphasising the implications of seemingly innocuous comparisons, {...} noted that {...} was {...}.²⁰¹⁴ Teva's external communications advisor ({...}) raised similar concerns with respect to comparisons in immunogenicity between Copaxone and competing GA products, {...}.²⁰¹⁵ However, as described in more detail in Sections 9.3.2.2 and 9.4.4, despite such warnings, such misleading messages continued to dominate Teva's communication campaign.
- (1581) Similarly, in 2017 when discussing possible additional evidence against the GATE study to be submitted to AIFA (the Italian Medicines Agency responsible also for pricing and reimbursement decisions), {...} questioned the relevance of the differences between Synthon GA and Copaxone by emphasising {...}.²⁰¹⁶
- (1582) Teva consistently insisted that limited physicochemical differences have clinically meaningful consequences and could adversely affect the efficacy and safety of competing GA products although it knew that it did not have any evidence on their clinical significance. For example, {...} emphasised in May 2017 that: {...}.²⁰¹⁷ Actually, as late as in June/July 2019, Teva confirmed that {...}.²⁰¹⁸
- (1583) Teva was also well aware of the implications that Teva's unsubstantiated claims may have. For example, in an internal email of 6 November 2015 {...} expressly outlined the limits to Teva's communication following the approval of Synthon GA and warned that {...}.²⁰¹⁹ {...}.²⁰²⁰

9.3.1.1.4. Teva's messages were capable of discrediting a competing product

- (1584) By disseminating objectively misleading messages about essential characteristics of its competitor's product to HCPs and Payers, Teva was not striving to raise awareness of therapeutic and clinical characteristics of its own product. Instead, Teva's messages concerning compositional differences between Copaxone and Synthon GA aimed at instilling doubts among HCPs and Payers concerning the safety and efficacy of Synthon GA, and its therapeutic equivalence to Copaxone, directly or indirectly challenging the findings in the Decentralised Procedure based on, *inter alia*, arguments which had been rejected by MEB when granting the MA for Synthon GA. Safety and efficacy are also key parameters driving doctors' prescription decisions for individual patients, nurses' advice to patients about what medicines to ask from doctors, pharmacists' decisions about substituting Synthon

²⁰¹⁴ ID 404-1995, Teva internal email dated 25 May 2016 from {...} to {...} and others, commenting on draft slides to be used for a presentation on the Complexity Message to selected KOLs in Warsaw, p. 1. See also ID 455-3391, Teva internal email dated 12 May 2017 from {...} to {...}: {...}.

²⁰¹⁵ ID 455-1115, The value of Copaxone (glatiramer acetate): Considerations when assessing the use of follow-on glatiramer acetate (FoGA), p. 69. See also ID 455-1069, Teva internal email dated 4 December 2018 from {...} to {...} and others, with attached a version of the Payer White Paper dated 15 November 2018 with comments from {...} (p. 13) noting that mentioning of {...}.

²⁰¹⁶ ID 455-1347, Teva internal email dated 14 April 2017 from {...} to {...} and others (Teva). See also ID 404-1835, Teva internal email dated 30 July 2019 from {...} to {...} and others, expressing doubts about implications of similarities and differences in physicochemical and biological properties of Copaxone and Synthon GA.

²⁰¹⁷ ID 404-2519, Teva internal email dated 29 May 2017 from {...} to hierarchy. See also ID 404-2367, Teva internal email dated 16 August 2017 from {...} to {...}: {...}.

²⁰¹⁸ ID 413-172, Survey to inventory EU needs for a retrospective real-world database study with Copaxone, June/July 2019, p. 2. See also ID 404-367, Teva internal email dated 15 October 2018 from {...} to {...} and others on analysis of switching between Copaxone and Synthon GA in Norway confirming that {...}.

²⁰¹⁹ ID 455-3034, Teva internal email dated 6 November 2015 from {...} to {...} and others (Teva and to {...} and others ({...})).

²⁰²⁰ Ibid.

GA, as well as policy decisions concerning automatic substitution taken by Payers. As explained in Recital (1481) and Section 9.2.3.5, if Teva had genuine public health concerns (and evidence) about Synthon GA, it should have followed the procedures set out in sector-specific legislation and brought its claims to pharmacovigilance authorities. Instead, Teva was aiming to instil doubts among Payers and HCPs. Therefore, Teva's messages were capable of creating a negative perception of Synthon GA with regard to key features for its successful therapeutic and commercial uptake (i.e. creating the false impression that it was less safe or less efficacious, and not therapeutically equivalent to Copaxone). Accordingly, these messages were capable of discrediting Synthon GA with key drivers of demand, namely HCPs and Payers.²⁰²¹

9.3.1.1.5. Conclusion

(1585) In view of the above, the Commission concludes that Teva's conduct of emphasising clinically irrelevant differences in GA structures attempted to artificially differentiate Copaxone and Synthon GA and instil doubt as to the risks associated with the use of Synthon GA.²⁰²² Teva was emphasising physicochemical differences and explicitly or implicitly suggesting that they have clinically meaningful consequences in clear contradiction to the relevant regulatory findings.

(1586) Teva's Complexity Message was objectively misleading, i.e. inaccurate or incomplete and capable of confusing the addressee (including by inducing them into error) with respect to the safety and efficacy of Synthon GA and its therapeutic equivalence to Copaxone. It was also capable of creating a negative perception of Synthon GA and therefore capable of discrediting Synthon GA. It explicitly or implicitly contradicted the fact that the competent authorities found no therapeutically relevant differences between the two products, despite Teva having raised these very or at least similar claims before them, and thus established that they were therapeutically equivalent, leading to Synthon GA's SmPC being identical to that of Teva's Copaxone.

9.3.1.2. Teva implied that health risks observed in other glatiramer-related substances equally apply to Synthon GA

9.3.1.2.1. Background

(1587) When making statements about Synthon GA, whether directly or indirectly, Teva referred consistently to other, distinct glatiramer-related substances (or, in Teva's own jargon, "glatiramoids"), and the issues these other substances experienced in their development (e.g. trials) or in the clinical use.²⁰²³ Through these messages, Teva was purposefully creating the impression that risks and difficulties noted with respect to other glatiramer-related substances may equally apply to Synthon GA, despite the fact that those issues did not concern Synthon GA (or, in some instances, not even another GA but a different glatiramer-related substance) and despite the fact that, unlike any of these other substances, Synthon GA was approved in the EU (i.e. in all Relevant Member States) by the competent authorities that expressly confirmed its safety, efficacy, and therapeutic equivalence with Copaxone.

²⁰²¹ For more detail on Teva's communications targeting HCPs and Payers, see Section 9.4.1 below.

²⁰²² See to that effect Case C-179/16, *F. Hoffmann-La Roche and Others*, paragraph 89.

²⁰²³ ID 1888, A Comprehensive Review on Copemyl®, Annovazzi, P., Bertolotto, A., Brescia Morra, V. et al., *Neurol Ther* 6, 161–173 (2017), p. 2 – "Glatiramoids are a class of drugs consisting in a group of heterogenous polypeptide mixtures comprising four amino acids: L-glutamic acid, L-alanine, L-lysine, and L-tyrosine. Glatiramer acetate (GA) is the forefather of this class".

9.3.1.2.2. Documents and statements

- (1588) When discussing Synthon GA, Teva regularly contrasted experiences in the use of Copaxone to experiences in the use of another GA product called Probioglat. Probioglat is a GA injectable solution used for treatment of RRMS. It is marketed in Mexico by the Mexican company Probiomed SA and has never been assessed by any of the European competent authorities nor has it ever received an MA in any of the EU Member States (unlike Synthon GA). In addition, Probioglat’s regulatory approval obtained in Mexico did not require additional supporting scientific data (unlike the Decentralised Procedure and subsequent MAs for Synthon GA which were based on *inter alia* results of the GATE study).²⁰²⁴ According to Teva, the use of Probioglat in Mexico led to an increase in the relapse rate and in adverse effects in patients, in stark contrast with Copaxone. Teva used the references to Probioglat to emphasise the alleged risks related to the use of any GA product other than Copaxone and to draw parallels between Probioglat and Synthon GA.
- (1589) For example, Teva’s Payer White Paper states that, {...}.²⁰²⁵ Similarly, Teva’s Payer Objection Handler²⁰²⁶ indicates, {...}.²⁰²⁷ Using those statements in materials for Payers (such as the Payer White Paper) that have been created in the context of the CCP²⁰²⁸ (which was devised by Teva for the European markets) to raise issues with Synthon GA, the only competing GA in Europe, directly suggests that similar adverse effects could occur with the use of Synthon GA.
- (1590) References to Probioglat (as mentioned above, a GA product marketed in Mexico, which is not related to Synthon GA and has never been assessed by European competent authorities) also found their way to the CCP documents addressed to HCPs. For example, Teva’s Specialist External Expert White Paper²⁰²⁹ clearly links the alleged lack of real-world data on the clinical use of Synthon GA in the EU with the negative experiences in use of Probioglat in Mexico {...}.²⁰³⁰ Moreover, internal documents show that {...}.²⁰³¹
- (1591) Similarly, Teva made repeated references to Teva’s own experiences with the development of a glatiramer-related molecule named TV-5010 (Protiramer). Teva

²⁰²⁴ Ibid, p. 4. See also ID 455-2371, Price competition workshop – COPAXONE & LONQUEX, Amsterdam, 20-21 June 2017: {...}.

²⁰²⁵ ID 806-2, Assessing the Value of COPAXONE® in Relation to Follow-on Glatiramer Acetate, Payer White Paper, 8 June 2016, p. 12. Similar statements can be found on pp. 3, 10 and 11.

²⁰²⁶ The Payer Objection Handler is structured in the Q&A form in order to provide the Teva Market Access teams with an agreed line of well-structured arguments in reaction to a range of likely questions from Payers (see Section 9.3.2.2 and Figure 32 in Recital (1678)).

²⁰²⁷ ID 455-2210, COPAXONE® and the introduction of FoGA, Objection handler, 8 December 2016, p. 5. See also ID 266-105, COPAXONE® and the introduction of FoGA, Objection handler for MSLs, Version 4, March 2019, p. 13 and ID 742-113, Teva’s letter to AIFA and the Italian Minister for Health of 18 April 2017, pp. 3, 6, 7, 13, 14.

²⁰²⁸ See Section 9.3.2.2.

²⁰²⁹ The External Expert White Papers (specialist and non-specialist versions) were designed to present Teva’s position on Copaxone and competing GAs to external experts (notably neurologists, including KOLs) (see Section 9.3.2.2 and Figure 32 in Recital (1678)).

²⁰³⁰ ID 455-1421, The Complexity of COPAXONE® and Considerations for Substitution with Follow-on Glatiramer Acetate, External Expert White Paper, 6 May 2016, p. 5. Similarly, ID 455-1425, a Non-specialist External Expert White Paper hints at “significant biological differences” between FoGAs by referring to Probioglat {...} (emphasis added) - ID 455-1425, Considering the value of COPAXONE® in an era of Follow-on Glatiramer Acetate, Non-specialist External Expert White Paper, 6 May 2016, p. 3. See also ID 266-105, COPAXONE® and the introduction of FoGA, Objection handler for MSLs, Version 4, March 2019, p. 13.

²⁰³¹ ID 455-2623, Teva internal email dated 24 April 2017 from {...} to {...} and others.

developed this molecule while exploring the viability of a product to be administered once weekly. The project was terminated in pre-clinical stages due to serious adverse effects (including deaths) in rats and monkeys.²⁰³²

- (1592) Teva used the example of TV-5010 and the seriousness of the associated adverse effects to allege that even minor changes to the conditions of the manufacturing process can lead to dramatic consequences. For example, in Teva's Payer White Paper under the heading, {...}, Teva immediately noted {...}.²⁰³³ In the same way, one of the versions of Teva's Non-specialist External Expert White Paper mentions that {...}.²⁰³⁴

9.3.1.2.3. Assessment of the objectively misleading nature of the information

- (1593) Even if Teva's messaging that there were issues observed in the development and use of different glatiramer-related substance may be factually correct,²⁰³⁵ it is irrelevant for the assessment of Synthon GA. Referencing such issues in relation to Synthon GA implies that an increase in the relapse rate or the occurrence of adverse effects observed for instance with respect to Probioglat may equally affect all non-Copaxone GA products (in Teva's terms all "FoGAs") including, in particular, Synthon GA. Similarly, references to TV-5010 (also referred to as "protiramer") in the context of discussing Synthon GA imply that because Synthon cannot rely on Teva's proprietary manufacturing process, one cannot exclude the occurrence of adverse effects, even serious ones such as those described with respect to TV-5010. This was especially the case since the references to Probioglat and TV-5010 were regularly made in connection with discussions on potential risks associated with Synthon GA. These messages are objectively misleading for the reasons detailed below.

9.3.1.2.3.1. Issues connected with Probioglat and TV-5010 cannot be attributed to Synthon GA

- (1594) The Commission notes, first and foremost, that TV-5010 (also called "Protiramer"), Probioglat and Synthon GA are not equivalent compounds. Most notably, unlike TV-5010 and Probioglat, Synthon GA underwent the regulatory process for obtaining an MA before the competent authorities in the EU. In this process and based on clinical data from the GATE study, it was officially confirmed not only that Synthon GA is safe and efficacious but also therapeutically equivalent to Copaxone. The statements emphasising the risks observed in connection with Probioglat and TV-5010 cannot inform decisions on Synthon GA and its use in any reasonable way. However, Teva's messaging concerning Probioglat and TV-5010 never appropriately points to these facts.
- (1595) Unlike Synthon GA (or even Probioglat in Mexico), TV-5010 never received an MA and never even underwent the regulatory process designed to verify its safety and efficacy, as the project was discontinued during early product development. In

²⁰³² TV-5010 is a mixture of polypeptides that consist of the same amino acids, in the same defined ratio as Copaxone but with a much higher molecular weight range – see ID 906, Teva's reply to the Article 18(2) Request of 3 June 2021, p. 40.

²⁰³³ ID 806-2, Assessing the Value of COPAXONE® in Relation to Follow-on Glatiramer Acetate, Payer White Paper, 8 June 2016, p. 10. See also ID 413-628, Complexity of COPAXONE®, Medical Training: eLearning, p. 44.

²⁰³⁴ ID 404-332, Considering the value of COPAXONE® in an era of Follow-on glatiramer acetate, Non-specialist External Expert White Paper, 8 April 2016, p. 3.

²⁰³⁵ The Commission however notes that as late as 2017 there were some concerns expressed internally in Teva about validity of evidence on safety concerns related to Probioglat; {...} – see ID 455-3235, Teva internal email dated 24 April 2017 from {...} to {...} and others.

addition, contrary to what Teva implies, TV-5010 and its effects were not simply the result of “*minor changes in the manufacturing process*” but rather a deliberate and conscious experiment assessing whether a higher molecular weight of polypeptides (than that of Copaxone and Synthon GA) may lead to an increased efficacy in the treatment of MS.

- (1596) Teva knew since 1988 that there is a correlation between the molecular weight and the toxicity of GA.²⁰³⁶ TV-5010 had a molecular weight range of 11,000 to 25,000 Daltons.²⁰³⁷ By contrast, the molecular weight of both Copaxone and Synthon GA is limited to 5,000 to 9,000 Daltons, which is exactly the range that Teva identified as providing “*the best chance of providing [glatiramer acetate] that was non-toxic and active*”.²⁰³⁸ It follows that the toxicity issues associated with TV-5010 due to its higher molecular weight cannot occur with respect to Copaxone, or its therapeutic equivalent Synthon GA.

9.3.1.2.3.2. Teva was aware that comparisons of Synthon GA with Probioglat and TV-5010 were not relevant

- (1597) Teva’s own Scientific Affairs department disputed the relevance of the comparison between TV-5010 and Synthon GA. Internal Teva exchanges demonstrate that the use of the comparison with TV-5010 had been disputed already in 2014 by Teva’s then {...}, when commenting on a draft {...}.²⁰³⁹ While this document (prepared for competent authorities in charge of MA procedures) predates the successful completion of the Decentralised Procedure, it expresses the position of the {...} regarding TV-5010 even before the authorities established therapeutic equivalence between Copaxone and Synthon GA.

- (1598) Similarly, in an internal exchange on the possible use of experiences from non-EU countries before the Italian AIFA,²⁰⁴⁰ {...} questioned the validity of references to Probioglat. The internal exchange (involving also a member from Teva’s team in Mexico) expressly refers to the non-comparability between groups of patients (those treated in 2012 when only Copaxone had been available and those treated in later years when both Probioglat and Copaxone had been available) as well as to the inability to establish a clear causal link between a specific effect and the medicine used.²⁰⁴¹ However, as noted above, this knowledge did not stop Teva from drawing unwarranted inferences for Synthon GA from experiences with TV-5010 and Probioglat in a series of posterior messaging documents, such as Teva’s Payer White Paper.

- (1599) By emphasising the alleged experience with other glatiramer-related substances, Teva was implying that Synthon GA’s safety profile might be impacted in the same way. As aptly summarised in 2014 by {...} – commenting on Teva’s White Paper seeking to convince the MA authorities against granting an MA to Synthon GA – the {...}.²⁰⁴²

²⁰³⁶ ID 906, Teva’s reply to the Article 18(2) Request of 3 June 2021, p. 37.

²⁰³⁷ Ibid, p. 40.

²⁰³⁸ Ibid, pp. 37, 38 and 40.

²⁰³⁹ ID 404-2432, Teva FoGA White Paper, Copaxone and Follow-on Glatiramoids (“FoGAs”), briefing document, September 2014, comment made by {...} on 25 September 2014 at 03:53, p. 9.

²⁰⁴⁰ Teva was trying to prevent automatic substitution between Copaxone and Synthon GA in Italy. See Section 9.4.4.3.

²⁰⁴¹ ID 455-3442, Teva internal email dated 12 May 2017 from {...} to {...} and others.

²⁰⁴² ID 404-2432, Teva FoGA White Paper, Copaxone and Follow-on Glatiramoids (“FoGAs”), briefing document, September 2014, p. 9; the White Paper was prepared by Teva to be distributed to the

(1600) Referring to TV-5010 even after the successful conclusion of the Decentralised Procedure, and implying its relevance for Synthon GA, was inaccurate since Synthon GA was a duly approved medicine whose safety, efficacy, and therapeutic equivalence to Copaxone were confirmed by the competent authorities based on a unique clinical study.²⁰⁴³ In addition, these references were capable of confusing HCPs and Payers with respect to essential characteristics of Synthon GA.

(1601) Teva claimed that real-world outcomes of substituting Copaxone with Synthon GA were unknown and was making reference to Probioglat, claiming that the adverse effects increased in the years following the introduction of Probioglat, compared to before.²⁰⁴⁴ However, internal documents show that Teva was aware that it had no scientific basis for these claims related to Probioglat (let alone Synthon GA) either.²⁰⁴⁵

9.3.1.2.4. Teva's messages were capable of discrediting a competing product

(1602) Teva's messages implied that Synthon GA's safety and efficacy profile may suffer from similar deficiencies as those of Probioglat or those of TV-5010. Teva thus disseminated to HCPs and Payers objectively misleading messages about essential characteristics of its competitor's product. Teva was not striving to raise awareness of therapeutic and clinical characteristics of Copaxone but rather to instil doubts among Payers and HCPs concerning the safety and efficacy of Synthon GA or its therapeutic equivalence to Copaxone. If Teva had genuine concerns (and evidence) about Synthon GA, it should have followed the procedures set out in sector-specific legislation and brought its claims to pharmacovigilance authorities. Teva's messaging was not only objectively misleading but also capable of creating a negative perception of Synthon GA with regard to key features for its successful therapeutic and commercial uptake (i.e. creating the false impression that it was less safe or less efficacious, and not therapeutic equivalent to Copaxone). Accordingly, it was capable of discrediting Synthon GA with key drivers of demand, namely HCPs and Payers.

9.3.1.2.5. Conclusion

(1603) In view of the above, the Commission concludes that Teva's references to health risks relating to other glatiramer-related substances led to inaccurate inferences that Synthon GA, just like Probioglat and TV-5010, was plagued by a host of issues negatively affecting its safety and efficacy. These references were capable of confusing their addressees (Payers and HCPs) into perceiving Synthon GA as dangerous and even potentially lethal instead of considering it based on its own merits, in particular with respect to the specific clinical study and the regulatory

authorities in charge of granting the MA for Synthon GA. The document was reviewed by Teva employees and the comment was made by the {...}. While this document pre-dates the successful completion of the Decentralised Procedure for granting the MA to Synthon GA, the comment remains valid as Teva kept making comparisons with TV-5010 after the end of such Decentralised Procedure with the aim of instilling doubts regarding the safety and efficacy of Synthon GA and its therapeutic equivalence with Copaxone.

²⁰⁴³ See also Section 9.3.1.3.

²⁰⁴⁴ ID 455-1421, The Complexity of COPAXONE® and Considerations for Substitution with Follow-on Glatiramer Acetate, External Expert White Paper, 6 May 2016, p. 5. Similarly, ID 455-1425, a Non-specialist External Expert White Paper hints at {...} between FoGAs by referring to Probioglat {...} - ID 455-1425, Considering the value of COPAXONE® in an era of Follow-on Glatiramer Acetate, Non-specialist External Expert White Paper, 6 May 2016, p. 3. See also, ID 266-105, COPAXONE® and the introduction of FoGA, Objection handler for MSLs, Version 4, March 2019, p. 13.

²⁰⁴⁵ See Recital (1590).

findings of safety, efficacy and of therapeutic equivalence with Copaxone. These references by Teva were capable of creating an artificial differentiation between Copaxone and Synthon GA by manipulating the perception of the risks associated with the use of Synthon GA, and instilling doubt in relation to its safety, efficacy and its therapeutic equivalence with Copaxone despite the findings of the competent authorities on these issues.²⁰⁴⁶

9.3.1.3. Teva was casting doubt on the validity of the GATE study as the scientific basis for Synthon GA's marketing authorisation, even after its endorsement by the competent authorities during the Decentralised Procedure

9.3.1.3.1. Background

- (1604) The Glatiramer Acetate Clinical Trial to Assess Equivalence with Copaxone (or "GATE study") was an equivalence trial comparing Synthon GA to Copaxone. It was submitted by Synthon to MEB acting as RMS during the Decentralised Procedure. The first, double-blind part of the trial lasted 9 months and had the objective of demonstrating that the efficacy of Synthon GA was equivalent to that of Copaxone in subjects with RRMS by measuring specific brain lesions.²⁰⁴⁷ It was required to show that Synthon GA was safe, efficacious, and therapeutically equivalent to Copaxone, the reference medicine, which were the key criteria for the successful conclusion of the Decentralised Procedure in this case.
- (1605) The design of the GATE study followed the scientific advice received by Synthon in their discussions with the EMA and with a number of competent national authorities, including BfArM (the German Federal Institute for Drugs and Medical Devices), URPL (the Polish Office for Registration of Medicinal Products), and AEMPS (the Spanish Agency of Medicines and Medical Devices). As noted above, the results of the GATE study showed that differences in the GA structures do not have clinically meaningful consequences that would raise questions with respect to the therapeutic equivalence between Copaxone and Synthon GA. These results were tested and re-examined by the competent authorities during the Decentralised Procedure for Synthon GA.²⁰⁴⁸ The first part of the GATE study allowed for the conclusion that Synthon GA and Copaxone were therapeutically equivalent and established the scientific and evidentiary basis for the successful conclusion of the Decentralised Procedure for Synthon GA.
- (1606) The initial phase of the GATE study was immediately followed by a 15-month open-label extension study aimed at evaluating the efficacy, safety, and tolerability of a prolonged treatment with Synthon GA and of switching from Copaxone to Synthon GA. However, the Commission has limited its analysis to Teva's messages concerning the initial, double-blind GATE study, which was a sufficient basis for the successful completion of the Decentralised Procedure for Synthon GA and for the conclusion by the competent authorities that Copaxone and Synthon GA were therapeutically equivalent. All references to the GATE study should therefore be understood as references to the initial double-blind part of the study, unless it is expressly indicated otherwise.

²⁰⁴⁶ See to that effect Case C-179/16, *F. Hoffmann-La Roche and Others*, paragraph 89.

²⁰⁴⁷ ID 455-2843, Public Assessment Report Brabio, p. 9.

²⁰⁴⁸ *Ibid*, pp. 13 and 16.

9.3.1.3.2. Documents and statements

- (1607) Teva initiated a campaign against the GATE study immediately after the publication of its results. On 27 March 2014, Synthon made the results of the GATE study public by way of a press release. Already on 28 March 2014, Teva prepared a document called {...}. {...}²⁰⁴⁹ {...}.²⁰⁵⁰
- (1608) This general objection by Teva was consistently repeated in the CCP materials addressed to the Payers that were used after the successful conclusion of the Decentralised Procedure for Synthon GA, i.e. even after the scientific appropriateness of the study was officially confirmed by the decision of the competent authorities. For example, Teva's Payer White Paper, in its Executive Summary, clearly explains that {...}.²⁰⁵¹ Similarly, during their meeting with FAMHP, the Belgian Federal Agency for Medicines and Health Products, of 23 January 2017 Teva asserted that {...} (original emphasis) and that {...} (emphasis added).²⁰⁵² These objections are echoed in the Payer Slides of 24 January 2019 that provide that {...} and that {...} (emphasis added).²⁰⁵³
- (1609) In its criticism of the GATE study Teva emphasised alleged inconsistencies in findings and discrepancies with existing data on Copaxone in order to cast doubt on the overall trial and the conclusions reached by the regulatory authorities based on the trial's results. For example, in the letter sent to AIFA on 3 November 2016, Teva asserts that {...} (emphasis added).²⁰⁵⁴
- (1610) Similarly, in the Payer White Paper, Teva again questions the validity of the GATE study based on alleged discrepancies between the Copaxone data and its results and also takes issue with the use of MRI lesions as an appropriate endpoint for the GATE study: {...} (emphasis added).²⁰⁵⁵

²⁰⁴⁹ Clinical endpoints are perceivable as a change in the patient's conditions due to the disease. They capture how a person feels, functions or survives. Non-clinical endpoints are measuring objective effects of the disease and do not reflect how the patient actually feels. For a comparability exercise, such as the GATE study comparing Synthon GA and Copaxone, the progression of MS is better detected or monitored with instrumental (i.e. non-clinical, objective) points - see ID 2063, Minutes of the phone call with EMA experts, 21 September 2021, p. 7; ID 3388, {...} Reply to Article 18(2) Request of 9 June 2021, p. 5.

²⁰⁵⁰ ID 404-1559, Global Customer Q&A Document on the Synthon Phase III GATE Study, 28 March 2014, p. 7. See also ID 455-1425, Considering the value of COPAXONE® in an era of Follow-on Glatiramer Acetate, Non-specialist External Expert White Paper, 6 May 2016, p. 4: {...}.

²⁰⁵¹ ID 806-2, Assessing the Value of COPAXONE® in Relation to Follow-on Glatiramer Acetate, Payer White Paper, 8 June 2016, p. 3.

²⁰⁵² ID 455-2433, Substitution considerations for follow on glatiramer acetate products, Meeting with Federal Agency for Medicines & Health Products Brussels, 23 January 2017, p. 50. See also ID 455-398, Executive summary of the Expert Report "{...} which was annexed to the letter dated 1 July 2016 by Teva to the MEB, p. 7: {...}.

²⁰⁵³ ID 264-102, The value of COPAXONE® (glatiramer acetate): Considerations when assessing the use of follow-on glatiramer acetate (FoGA), Payer Presentation, 24 January 2019, p. 52. On the alleged inconsistencies in the study outcomes, see also, p. 50. See also ID 455-1427, Equivalence of Follow-On Glatiramer Acetate in Multiple Sclerosis, A Randomized Clinical Trial, Review of the GATE study, p. 4.

²⁰⁵⁴ ID 742-116, Teva's letter to AIFA of 3 November 2016, p. 3: {...}. See also ID 263-1364, Considering value of COPAXONE® in an era of Follow-on Glatiramer Acetate, External Expert Presentation, May 2016, pp. 19, 20, 21, 22.

²⁰⁵⁵ ID 806-2, Assessing the Value of COPAXONE® in Relation to Follow-on Glatiramer Acetate, Payer White Paper, 8 June 2016, p. 9. Similarly, the letter sent by Teva to AIFA and to the Ministry of Health in Italy on 18 April 2017 (ID 742-113), on p. 9 asserts: {...} (emphasis added). On inadequacy of the MRI lesions, see also Expert opinion by {...} of 4 July 2016 which was attached to Teva's letter to

(1611) Also in documents directed at HCPs, Teva repeated the claims that the GATE study was not appropriate for supporting the conclusions on Synthon GA’s safety and efficacy, and that the trial underreported safety issues. For example, in a version of the MSL Objection Handler dated 8 March 2019, Teva emphasised that {...} and explained {...}.²⁰⁵⁶ The same document alleges, {...} and that {...}.²⁰⁵⁷ The MSL Objection Handler also concludes, {...} (emphasis added).²⁰⁵⁸

9.3.1.3.3. Assessment of the objectively misleading nature of the information

(1612) Teva disseminated the message that the methodology and outcome of the GATE study were flawed, in particular because of its allegedly short duration, because of alleged underreporting of the adverse effects and because of allegedly inappropriate trial endpoints. This message was capable of creating the impression that the GATE study, as the basis for Synthon GA’s successful conclusion of the Decentralised Procedure, was seriously flawed. For example, Teva was stating that the alleged deficiencies {...} (original emphasis)²⁰⁵⁹ or even {...}.²⁰⁶⁰ In other words, Teva asserted that the GATE study could not legitimately serve as the scientific and factual basis for the conclusion on therapeutic equivalence between Synthon GA and Copaxone. This assertion called into question Synthon GA’s Decentralised Procedure that found Synthon GA to be therapeutically equivalent to Copaxone because it implied that prescribing Synthon GA, or deciding on its automatic substitution status, would lead to health risks unaccounted for in the Decentralised Procedure due to the alleged deficiencies of the study. Teva’s messages were misleading and capable of discrediting the competing products for the following reasons.

9.3.1.3.3.1. The GATE study was endorsed by the authorities

(1613) Teva’s statements directly challenged the regulatory findings of competent authorities.

(1614) First, by spreading incorrect and/or incomplete information, Teva was casting doubt on the validity of the GATE study, which, as already explained, was designed based on the scientific advice by the EMA and by a number of national competent authorities and which was endorsed by these regulatory bodies (see Section 9.3.1.3.1). The GATE study was considered appropriate by the authorities to serve as

AIFA dated 3 November 2016, p. 3 (ID 742-116, Teva’s letter to AIFA of 3 November 2016); ID 264-102, The value of COPAXONE® (glatiramer acetate): Considerations when assessing the use of follow-on glatiramer acetate (FoGA), Payer Presentation, 24 January 2019, p. 20 and ID 455-1425, Considering the value of COPAXONE® in an era of Follow-on Glatiramer Acetate, Non-specialist External Expert White Paper, 6 May 2016, p. 4.

²⁰⁵⁶ ID 266-105, COPAXONE® and the introduction of FoGA, Objection handler for MSLs, Version 4, March 2019, p. 22. See also ID 404-1538, COPAXONE® and the introduction of FoGA, Objection handler for MSLs, Version 2, 27 June 2017, p. 23.

²⁰⁵⁷ Ibid, p. 20. See also ID 404-1538, COPAXONE® and the introduction of FoGA, Objection handler for MSLs, Version 2, 27 June 2017, p. 21. Similarly, in the Non-specialist External Expert White Paper Teva asserts: “{...}” (ID 455-1425, Considering the value of COPAXONE® in an era of Follow-on Glatiramer Acetate, Non-specialist External Expert White Paper, 6 May 2016, p. 4.) The adverse effects underreporting is also alleged in the documents addressed to the Payers. For example, Payer White Paper asserts, {...} (ID 806-2, Assessing the Value of COPAXONE® in Relation to Follow-on Glatiramer Acetate, Payer White Paper, 8 June 2016, p. 9).

²⁰⁵⁸ Ibid, p. 10. See also ID 404-1538, Copaxone and the introduction of FoGA, Objection handler for MLs, Version 2, 27 June 2017, p. 10.

²⁰⁵⁹ ID 264-102, The value of Copaxone (glatiramer acetate): Considerations when assessing the use of follow-on glatiramer acetate (FoGA), Payer Presentation, 24 January 2019, p. 51.

²⁰⁶⁰ Ibid, p. 51.

a scientific basis for the successful completion of the Decentralised Procedure for Synthon GA. Challenging its validity and soundness with Payers and HCPs indirectly questioned the validity and soundness of the Decentralised Procedure itself. Teva's messages thus sowed doubt as to the safety and efficacy of Synthon GA, and as to its therapeutic equivalence with Copaxone.

- (1615) Second, Teva continued to propagate its objections about the GATE study despite the fact that these objections were known by the competent authorities yet this did not stand in the way of the successful completion of the Decentralised Procedure for Synthon GA, which found that Synthon GA was therapeutically equivalent to Copaxone. Teva's claims, essentially the same as later commonly reproduced in its communication campaign, had been assessed and unanimously rejected during numerous regulatory and court proceedings.²⁰⁶¹ For example, the Public Assessment Report for Synthon GA issued by the MEB as the RMS expressly states: {...}.²⁰⁶² Competent authorities assessed Teva's objections but decided that the efficacy and safety of Synthon GA was similar to the efficacy and safety of Copaxone based on the overall GATE study and its results. Further, Teva knew that it should not make efficacy claims on the basis of relapse rates as it is revealed from one particular comment made by a Teva employee in relation to the annual relapse rate: {...}.²⁰⁶³

9.3.1.3.3.2. MRI lesions have been validated as an appropriate end-point

- (1616) One of Teva's major challenges to the GATE study was its claim that the use of MRI lesions as the appropriate endpoint for the GATE study was flawed and that this significantly vitiated the outcome of the study.²⁰⁶⁴ In so doing, Teva selectively presented information and regularly omitted all scientific and other information confirming that MRI lesions were an appropriate endpoint.
- (1617) First, MRI lesions had been validated as a surrogate (non-clinical) endpoint for relapse rate in MS patients as early as in 2002 and this validation was also confirmed by an investigation of 31 trials involving 18,000 MS patients in 2012.²⁰⁶⁵
- (1618) Second, the fact that MRI lesions were an appropriate endpoint for a comparison, bridging trial, such as the GATE study was confirmed by competent authorities.²⁰⁶⁶

²⁰⁶¹ ID 455-2570, Teva internal email exchange dated 16 to 26 October 2015 between {...} and {...} and others, describing documents shared with EMA Coordination Group for Mutual Recognition and Decentralised Procedures in January 2015. Among these documents is the presentation "Scientific evidence-base on COPAXONE®'s complexity and function compared to FOGAs" (ID 455-2585) which covered all facets of the Complexity Message including objections on the GATE study.

²⁰⁶² ID 455-2843, Public Assessment Report Brabio, 20ml, p. 15.

²⁰⁶³ ID 404-848, The Complexity of Copaxone (glatiramer acetate), comment made by {...} on 20 September 2016 at 8:41, p. 18.

²⁰⁶⁴ The primary endpoint of the double-blind part of the GATE study was the number of T1-GdE (gadolinium-enhancing) lesions on brain magnetic resonance imaging during months 7 to 9 (PAR Brabio, 20 ml, p. 9). These readings identify new inflammatory lesions, as the GdE indicates acute breakdown of the blood-brain barrier with inflammation. The GdE is not permanent and lasts for approximately four weeks (see e.g. ID 2061, Comparative Clinical and Cost-Effectiveness of Drug Therapies for Relapsing-Remitting Multiple Sclerosis, Canadian Agency for Drugs and Technologies in Health; 2013 Oct. (CADTH Therapeutic Review, No. 1.2B.) APPENDIX 2, Validity of Outcomes.

²⁰⁶⁵ ID 3388, {...} Reply to Article 18(2) Request of 9 June 2021, p. 5 and a literature cited therein. As explained by EMA officials during an interview on 21 September 2021 "there is a difference between a trial that is designed to provide the data to demonstrate the clinical benefits of a new drug in a certain patient population and a trial which is meant to show that two drugs are comparable in terms of efficacy and safety. You may need a different set up and a much more sensitive and measurable endpoint, such as MRI, than just a setup assessing patient's improvement or side effects clinically." – See ID 2063, Minutes of the phone call with EMA experts, 21 September 2021, p. 4.

(1619) Third, Teva was aware that MRI lesions can be an appropriate endpoint for such trials. For example, in internal comments made to the draft Expert Opinion of Mr. {...} from July 2018, Teva’s {...} noted: “{...}”.²⁰⁶⁷ Teva also did not hesitate to use the same surrogate endpoint it was striving to discredit (i.e. MRI lesions) to allege that there might be issues with the efficacy of Synthon GA directly contradicting the regulatory findings: “{...}” (emphasis added).²⁰⁶⁸

9.3.1.3.3.3. Teva presented its one-sided claims on the GATE study as objective truths

(1620) Despite the fact that the GATE study was endorsed by the competent authorities, Teva criticised it by formulating detailed scientific claims by which it sought to confuse its addressees. Teva resorted to this approach in particular in its materials addressed to HCPs. If Teva had genuine doubts about Synthon GA’s therapeutic equivalence with Copaxone, it should have used the appropriate procedures for pharmacovigilance and should have brought forward new evidence (the competent regulatory authorities responsible for the Decentralised Procedure of Synthon GA had heard, assessed and unanimously rejected Teva’s objections).²⁰⁶⁹ In this context, the main goal of flooding HCPs with messages regarding alleged deficiencies of the GATE study, in contradiction to the regulatory findings that the study was methodologically sound, was to cast doubt on the validity of the GATE study as a basis for the finalisation of the Decentralised Procedure of Synthon GA which established the safety and efficacy of Synthon GA and its therapeutic equivalence to Copaxone.

(1621) For example, a presentation by Teva “*Therapie der MS*”, intended for a Nurse Meeting in Mannheim (Germany) on 19 November 2016 devotes 12 slides²⁰⁷⁰ to a detailed discussion on the GATE study, its design, subjects selection, sensitivity and

²⁰⁶⁶ On the appropriateness of the MRI lesions see e.g. ID 455-2843 Public Assessment Report Brabio, pp. 15: “*In the CHMP scientific advice it was considered that MRI measures will be acceptable to detect effect and establish equivalence of two products containing glatiramer in a shorter study duration, in case that the quality data indicate a high level of similarity. Also, the current CHMP guideline on multiple sclerosis (EMA/CHMP/771815/2011, Rev. 2) states that MRI endpoints may be sufficient for demonstrating similarity of two products in the context of biosimilar and generic applications. The concept is that for bridging purposes showing similar biological activity is sufficient irrespective of the discussion between the relationship of MRI lesions and relapses. The study was designed as recommended during scientific advice and is considered adequate to investigate similar biological activity between investigational and reference product” and “*Moreover, as the clinical study was performed for bridging purposes, showing similar biological activity was considered sufficient irrespective of the discussion between the relationship of MRI lesions and relapses*”.*

²⁰⁶⁷ ID 455-854, Expert opinion, comment made by {...}, 23 July 2018 at 19:30, p. 7. Teva’s expert services were heavily involved in drafting/commenting of the Expert Report of {...} before its submission to the Italian Council of State in the proceedings for the annulment of the Judgment of the Lazio Regional Administrative Court annulling the inclusion of Copemyl (Synthon GA) and Copaxone 20 mg in the Italian Transparency List (allowing automatic substitution between the two products). See also, ID 455-747, Characterisation and clinical aspects of non-biological complex drugs in multiple sclerosis, including glatiramoids, 14 February 2014, p. 3 and ID 404-670, Teva internal email dated 17 January 2014 from {...} to {...} and {...}.

²⁰⁶⁸ ID 266-105, COPAXONE® and the introduction of FoGA, Objection handler for MSLs, Version 4, March 2019, p. 8. The same statement is found in earlier versions of the MSL Objection Handler (see e.g. ID 404-1538, Copaxone and the introduction of FoGA, Objection handler for MSLs, Version 2, 27 June 2017, p. 8).

²⁰⁶⁹ See e.g. ID 266-105, COPAXONE® and the introduction of FoGA, Objection handler for MSLs, Version 4, March 2019, pp. 7-9 and ID 455-1425, Considering the value of COPAXONE® in an era of Follow-on Glatiramer Acetate, Non-specialist External Expert White Paper, 6 May 2016, p. 4.

²⁰⁷⁰ ID 404-2096, Therapie der MS, Nurse Meeting, Mannheim, 19 November 2016, pp. 53-64. Additional five slides are devoted to other facets of the complexity messaging.

endpoints. Speaking notes accompanying a number of slides again allude to the questionable safety and efficacy conclusions.²⁰⁷¹ Finally, the slide {...} is accompanied with the following, rather clear straightforward note:

“{...}” (emphasis added).²⁰⁷²

(1622) The level of detail used by Teva in the description of the GATE study is in stark contrast with Teva’s own assessment of the typical focus of interests of the nurses involved in the MS treatment, which is operational rather than scientific.²⁰⁷³ Teva itself characterised nurses in Germany (targeted audience of the above-mentioned scientific presentation) as “{...}” and knowing “{...}”.²⁰⁷⁴

9.3.1.3.3.4. Teva was aware of the consequences of casting doubt on the GATE study

(1623) Finally, Teva was aware that such attacks on the validity of clinical trials were highly unusual and that they were liable to affect the addressees’ perception of the risks associated with Synthon GA. As Teva’s {...} remarked in 2017 “{...}” (emphasis added).²⁰⁷⁵

(1624) The White Paper from November 2018 contains comments from the external consultant {...}’s employees which reveal that Teva knew that some of its statements that cast doubt on the validity of the GATE study were disparaging. For example, {...} proposed to delete Teva’s statement that “{...}”, and made the following comment: “{...}”.²⁰⁷⁶ The statement which {...} proposed to delete had been used by Teva previously and was also kept and re-used in later documents.²⁰⁷⁷

9.3.1.3.3.5. Teva’s claims regarding the GATE study are unfounded

(1625) In its Reply to the Statement of Objections, Teva claims that, since the Statement of Objections implicitly accepted that Teva’s criticism of the GATE extension study were lawful, it must follow that those same criticisms are also lawful when applied to the GATE study itself. Teva also interprets the Statement of Objections as finding that any and all criticism of the GATE study is automatically misleading and likens it to the Commission conducting a “*by object*” assessment of Teva’s conduct.²⁰⁷⁸ Teva claims that making a distinction between the studies removes key context of Teva’s communications (i.e. potential patient safety risks arising from automatic substitution).²⁰⁷⁹

(1626) The Commission rejects these claims.

²⁰⁷¹ Ibid pp. 60, 62, 63.

²⁰⁷² Ibid p. 64.

²⁰⁷³ Nurses hold an important position in the treatment of the MS patients. They are the ones often administering the treatment and have a significant influence on patients. They may therefore steer the choice of treatment (see e.g. ID 455-47, MS treatment decisions and positioning research, 9 April 2019, p. 6; see also ID 455-1202, TEVA European Brand Plan format, June 2013, pp. 4, 5).

²⁰⁷⁴ ID 413-95, Extra Input, 31 July 2013, p. 27.

²⁰⁷⁵ ID 455-383, Teva internal email dated 4 May 2017 from {...} to {...} and others, internal correspondence on various documents to be used in challenging AIFA’s inclusion of Copaxone and Synthon GA to the Transparency list, p.1.

²⁰⁷⁶ ID 455-1145, Assessing the Value of COPAXONE® in Relation to Follow-on Glatiramer Acetate, Payer White Paper, November 2018, p. 5.

²⁰⁷⁷ For example, it can be found in ID 264-101, Assessing the value of COPAXONE® in relation to follow-on glatiramer acetate, Payer White Paper, January 2019, pp. 19, 20.

²⁰⁷⁸ ID 4032, Teva’s Reply to the Statement of Objections, paras. 1030, 1031.

²⁰⁷⁹ ID 4032, Teva’s Reply to the Statement of Objections, para. 1036.

- (1627) First, Teva completely misconstrues the Commission’s position. The Commission does not take a position on the lawfulness of Teva’s criticism of the GATE extension study.
- (1628) Second, there is a clear distinction between the primary GATE study and its extension. The purpose of the GATE study was “[t]o evaluate [...] whether generic glatiramer acetate (hereafter generic drug) is equivalent to the originator brand glatiramer acetate (hereafter brand drug) product, as measured by imaging and clinical end points, safety, and tolerability.”²⁰⁸⁰ This was a bridging trial required by Article 10(3) of Directive 2001/83. It was designed following scientific advice from the EMA and other competent authorities (see Recital (1560)) to provide a sufficient basis for the conclusion that Synthon GA “*can be regarded as therapeutic equivalent to [Copaxone]*”²⁰⁸¹ and therefore for the successful completion of the Decentralized Procedure. In this context, both the Public Assessment Report for Synthon GA as well as other documents originating from the administrative proceedings related to the MA for Synthon GA focus on the results of the GATE study, its design and methods rather than on its follow-on extension.²⁰⁸²
- (1629) On the other hand, the purpose of the follow-on GATE extension study was different, namely, to evaluate efficacy, safety, and tolerability of prolonged treatment with Synthon GA and to evaluate efficacy, safety, and tolerability of switching from Copaxone to Synthon GA. The conclusion of the GATE extension study was that efficacy and safety of Synthon GA is maintained over two years, and that switching from Copaxone to Synthon GA is safe and well tolerated.²⁰⁸³ Thus, it was up to the

²⁰⁸⁰ ID 3604, J. Cohen, A. Belova, K. Selmaj, C. Wolf, M. P. Sormani, J. Oberyé, E. van den Tweel, R. Mulder, N. Koper, G. Voortman, F. Barkhof, Equivalence of Generic Glatiramer Acetate in Multiple Sclerosis: A Randomized Clinical Trial - Glatiramer Acetate Clinical Trial to Assess Equivalence With Copaxone (GATE) Study Group, *JAMA Neurol.* 2015 Dec;72(12):1433-41. doi: 10.1001/jamaneurol.2015.2154.

²⁰⁸¹ “‘Therapeutical equivalence’ means that the efficacy and safety of this hybrid formulation [Synthon GA] is similar to the efficacy and safety of the reference product [Copaxone]” (emphasis added). ID 455-2843, Public Assessment Report Brabio, p. 17.

²⁰⁸² See ID 455-2843, Public Assessment Report Brabio, p. 17. See also MEB’s decision on Teva’s objection notice rejecting Teva’s claims (ID 455-2197, the Decision of the Dutch Medicines Evaluation Board (EN version), pp. 8-9) from which it clearly follows that Teva’s objections with respect to the finding of therapeutic equivalence and safety and efficacy of Synthon GA were focused on the GATE study rather than on its follow-on extension. MEB also noted that “*In general it is agreed that open label data is only supportive and not pivotal evidence for efficacy and that even safety is without a placebo comparison. It does however provide some reassurance for maintenance of effect.*” (ID 742-163, *Klinisch beoordelingsrapport Glatirameerproducten van Mylan en Synthon*, p. 6).

²⁰⁸³ There is a difference between the safety, efficacy and therapeutic equivalence which have been established by the successful conclusion of the Decentralised Procedure for Synthon GA (together with the ensuing national MAs) and the long-term effects of automatic substitution. Once an MA is granted, a doctor can prescribe the medicinal product (in the case at stake, Synthon GA) for new patients, but also old patients which were treated with Copaxone can be switched by the doctor to Synthon GA. Long term effects of automatic substitution means that it is uncertain what happens when there is an automatic change of the medicine at pharmacy level, thus, without the doctor’s involvement. And the uncertainty goes both ways: what happens when the patient on Copaxone is switched to Synthon GA and what happens when a patient on Synthon GA is switched to Copaxone. For them to be credible and consistent, Teva’s messages should have thus also warned about the safety risks of switching automatically patients which were treated with Synthon GA to Copaxone. With regard to long-term use (without switching) of a medicinal product, there are no clinical trials that provide assurance for long-term use and, therefore, there is no difference between Synthon GA in this respect and other medicines. It should be assumed that safety and efficacy established by the Decentralised Procedure hold for long-term use as well unless proven otherwise. If there is evidence that there are issues related to the safety and efficacy of a medicinal product’s long-term use, pharmacovigilance rules apply.

Member States to decide whether they allow automatic substitution or not.²⁰⁸⁴ It follows that while there may have been a margin for a scientific discussion on the GATE extension study in light of the question of automatic substitution, the competent authorities already established Synthon GA's safety, efficacy and therapeutic equivalence with Copaxone based on the primary GATE study and dismissed Teva's claims and purported evidence to the contrary as shown earlier in this Section. The Commission's assessment therefore only focuses on Teva's claims implicitly or explicitly challenging these regulatory findings.

- (1630) Third, as demonstrated in Recitals (1605) et seq., it is clear that Teva devised and disseminated a battery of statements specifically criticising and questioning the scientific robustness of the primary GATE study, and its conclusions, as the basis for Synthon GA's Decentralised Procedure. Teva could have criticised only the GATE extension study to the extent that this was necessary to assess automatic substitution. However, this was not what Teva did.
- (1631) Fourth, Teva's claim that the Commission's assessment of its criticism of the GATE study likens it to a "by object" infringement is erroneous. Section 9.3.1.3 contains a detailed analysis why Teva's messages concerning the GATE study were misleading, and finds that their dissemination was capable of producing exclusionary effects (Section 9.4).
- (1632) Teva also claims that it was not unlawful to point to the inconsistencies between its data on Copaxone and the findings of the GATE study.²⁰⁸⁵ The Commission rejects this claim.
- (1633) First, the GATE study was not about Copaxone and it was never used to show any findings on Copaxone, nor did it employ the same methodology as Teva in its Copaxone studies. Teva's criticism thus generally lacks scientific rigour.
- (1634) Second, Teva has repeatedly pointed to these inconsistencies, including in proceedings before the MEB. Importantly, they were repeatedly found irrelevant for conclusions on Synthon GA: "{...}" (emphasis added).²⁰⁸⁶ These objections and alleged inconsistencies were thus already taken into account in the Decentralised Procedure and discarded as irrelevant; thus Synthon GA successfully completed the Decentralised Procedure on the basis of the primary GATE study. However, this did not prevent Teva from continuing to raise these objections with Payers and HCPs.

9.3.1.3.4. Teva's messages were capable of discrediting a competing product

- (1635) Teva's misleading messages about the GATE study created the impression that the GATE study was seriously flawed and could not legitimately serve as the basis for concluding on the therapeutic equivalence between Synthon GA and Copaxone in contradiction with the findings of the regulatory authorities that analysed and rejected Teva's claims in this respect. Teva thus disseminated objectively misleading messages about essential characteristics of its competitor's product. Teva was not striving to raise awareness of therapeutic and clinical characteristics of Copaxone but rather to instil doubts among Payers and HCPs concerning the safety and efficacy of Synthon GA or its therapeutic equivalence to Copaxone. If Teva had genuine concerns about Synthon GA, it should have followed pharmacovigilance procedures, on the basis of new evidence compared to that which the regulatory authorities had

²⁰⁸⁴ For MEB position on this aspect, see Recital (1443) and footnote 1814.

²⁰⁸⁵ ID 4032, Teva's Reply to the Statement of Objections, paras. 1037, 1038.

²⁰⁸⁶ ID 742-163, Klinisch beoordelingsrapport Glatirameerproducten van Mylan en Synthon, p. 4.

rejected. Teva's messages were not only objectively misleading but also capable of creating a negative perception of Synthron GA with regard to key features for its successful therapeutic and commercial uptake (i.e. creating the false impression that it was less safe or less efficacious, and not therapeutic equivalent to Copaxone). Accordingly, these messages were capable of discrediting Synthron GA with key drivers of demand, namely HCPs and Payers.

9.3.1.3.5. Conclusion

(1636) In view of the above, the Commission concludes that Teva's references to the alleged deficiencies of the GATE study were inaccurate or incomplete and capable of confusing their addressees (Payers and HCPs) to perceive the safety and efficacy of Synthron GA and its therapeutic equivalence to Copaxone as questionable. They were also capable of creating a negative perception of Synthron GA in relation to its key features, i.e. its safety and efficacy, and its therapeutic equivalence with Copaxone, and therefore of discrediting Synthron GA.

9.3.1.4. Teva's arguments and the Commission's assessment

9.3.1.4.1. Claims concerning the "Complexity Message"

(1637) Teva claims that the term "Complexity Message" which was used to support its campaign against automatic substitution, is used by the Commission as an umbrella term for the three types of disparaging messaging. It claims that the use of such a term allows the Commission to imply that all references to the underlying subject matter (i.e., differences between Copaxone and Synthron GA, references to other glatiramoids, and criticisms of the GATE study) are *de facto* misleading (or anticompetitive by object) with no regard for the true context, intention, and meaning behind Teva's communications in each case.²⁰⁸⁷ Teva also claims that the fact that the World Health Organisation rejected Teva's request to obtain an international non-proprietary name for GA due to its "*complex nature*" supports its arguments aimed at Synthron GA concerning the complexity of Copaxone.²⁰⁸⁸

(1638) The Commission rejects these arguments.

(1639) First, the Decision carries out a detailed assessment of the specific statements related to Copaxone's alleged complexity that are considered misleading and does not consider that all statements related to Teva's complexity messaging are problematic. As explained in Recital (1506) the Commission's objections are limited to Teva's messages implying that, due to the complexity of Copaxone, there are risks related to the safety and efficacy of Synthron GA, and/or casting doubt on the regulatory finding that the two products are therapeutically equivalent. In Sections 9.3.1.1, 9.3.1.2 and 9.3.1.3, the Commission lays out the reasoning why each of the assessed forms and expressions of Teva's Complexity Message (compositional differences, other glatiramer-related products, GATE study) is misleading.

(1640) Second, the term "*complexity*" was consistently used by Teva itself. The Commission did not make up the term "Complexity Message" nor used it as an "*umbrella term*"; on the contrary, it was precisely Teva that consistently used this term as a shorthand for the entirety of the messages which consisted in questioning Synthron GA's safety, efficacy or therapeutic equivalence with Copaxone by questioning the soundness of the GATE study as the scientific basis for these findings, insinuated that issues with

²⁰⁸⁷ ID 4032, Teva's Reply to the Statement of Objections, para.977; ID 5909, Teva's Reply to the Letter of Facts II of 17 May 2024, paras. 149, 150.

²⁰⁸⁸ ID 4032, Teva's Reply to the Statement of Objections, para. 951 (a).

other glatiramer-related molecules were also relevant for Synthon GA, and suggested that there may be therapeutically relevant differences between Copaxone and Synthon GA, in contradiction with the findings of regulatory authorities.²⁰⁸⁹ For example, in the Copaxone Brand Plan from October 2018, the Complexity Message was one of the key messages to be delivered to external stakeholders (mentioned over 30 times in the document) and, according to Teva, it meant: “{...}” (emphasis added).²⁰⁹⁰

- (1641) Third, the fact that Teva used the misleading Complexity Message to support its argument against automatic substitution is irrelevant for the reasons explained in Section 9.2.3.5. At any rate, contrary to Teva’s claim, the Complexity Message was not limited to issues concerning automatic substitution. Teva used the term and the related messages itself in its submissions to the MEB, to national authorities and HCPs before and after the successful conclusion of the Decentralised Procedure for Synthon GA, when automatic substitution was not yet an imminent threat for Teva and Teva sought to challenge the safety and efficacy of Synthon GA, and its therapeutic equivalence with Copaxone. Complexity had been Teva’s standard communication topic for years in an attempt to prepare the ground for when Synthon GA would eventually enter the market.²⁰⁹¹ For example, the document Copaxone Life Cycle Initiative created in December 2012 included 48 references to the Complexity Message comprising key messages for educating different stakeholders.²⁰⁹² Teva developed a slide deck to facilitate discussions about Copaxone’s alleged complexity with key patient and professional organisations.²⁰⁹³ An internal email from 9 October 2014 shows that communicating the complexity of GA had been {...}.²⁰⁹⁴ Similarly, a Q&A document on the GATE study from November 2014 included statements casting doubt on the safety and efficacy of Synthon GA *per se*: “{...}” (emphasis added).²⁰⁹⁵
- (1642) Despite the fact that the successful conclusion of the Decentralised Procedure leading to the approval of Synthon GA disproved all the above messages communicated by Teva, Teva abundantly repeated the same type of messages that Synthon GA is not safe, efficacious or therapeutically equivalent with Copaxone with Payers and HCPs under Teva’s “complexity” catchphrase. This is illustrated by the following examples.
- (1643) Upon the successful conclusion of the Decentralised Procedure for Synthon GA, in the presentation “Complexities of Glatiramoids – Physicochemical characterisations of glatiramoids”, Teva included the following titles: {...}. These are exactly the

²⁰⁸⁹ See Recitals (1503)-(1520) (Section 9.2.3.5).

²⁰⁹⁰ ID 263-75, Go To Market Action Plan (GTMAP), 12 October 2018, p. 26.

²⁰⁹¹ Teva’s complexity messaging pre-dates the successful conclusion of the Decentralised Procedure for Synthon GA. References to this period before the start of the disparagement abuse as established in this Decision are hereby discussed only as context. See Recitals (1503)-(1520).

²⁰⁹² ID 404-715, The Copaxone Life Cycle Initiative (LCI), December 2012 (attached to ID 404-712), pp. 5, 6: {...}.

²⁰⁹³ ID 404-715, The Copaxone Life Cycle Initiative (LCI), December 2012 (attached to ID 404-712), p. 5, 6: {...}.

²⁰⁹⁴ ID 455-1155, Teva internal email dated 9 October 2014 from {...} to {...} and others.

²⁰⁹⁵ ID 455-2325, Synthon Phase III GATE Study Teva EU MS Franchise Medical-MSL Q&A, 3 November 2014, p. 9.

elements Teva uses to disparage Synthon GA already from Phase I of the CCP and from the very beginning of the process, Teva called this “{...}”.²⁰⁹⁶

- (1644) A presentation titled “{...}” helps to further understand the significance of this term in Teva’s communications. In the document, Teva repeats the arguments related to compositional differences between Copaxone and other glatiramer-related substances, compares Copaxone with other glatiramer-related substances, and concludes that “{...}” (original emphasis).²⁰⁹⁷ Thus, the reference to the “complexity” of GA, as used by Teva, serves as a shorthand for different messages which challenge Synthon GA’s safety, efficacy, and its therapeutic equivalence with Copaxone (and thus go far beyond the arguments pertaining to automatic substitution.
- (1645) Another presentation, that Teva meant to use for “External Experts” (targeting HCPs specialised in MS in their function as prescribers but also in their function as KOLs with a view to influencing the perception of Payers and other HCPs concerning the substitution of Copaxone with Synthon GA), from May 2016 titled “*The Complexity of Copaxone and Considerations for Substitution with Follow-on Glatiramer Acetate*” (emphasis added) emphasised differences between Synthon GA and Copaxone (which had been found by the MEB as irrelevant from a therapeutic point of view) and implied that experiences from other glatiramer-related substances which were not approved in EU were relevant for the use of Synthon GA in clinical practice in the EU.²⁰⁹⁸
- (1646) The document “Copaxone evolved campaign e-detailed implementation guide”²⁰⁹⁹ of 30 June 2017 shows that the references to “complexity” were used either directly or indirectly to differentiate Copaxone from Synthon GA: “{...}”.²¹⁰⁰ A comment on this by a Teva employee which reads “{...}”²¹⁰¹ shows that Teva was attempting to disguise the connection between communications on the complexity of Copaxone and the entry of Synthon GA.
- (1647) Fourth, Teva’s claim that the WHO’s refusal to assign an INN for GA supports its messages challenging the therapeutic equivalence of Copaxone and Synthon GA is unfounded. In fact, the MEB assessed Teva’s claim and considered it irrelevant for its findings: “[t]he complex nature of the substance is well-known and forms the starting point for our assessment. Clearly the WHO did not consider it appropriate to allocate an INN name to glatiramer at that time. Nomenclature by organisations such as the WHO is dependent on the way in which a substance can be defined. Incidentally, there are BAN and USAN names for glatiramer acetate and the USP is working on a monograph for this substance”.²¹⁰² Thus the MEB pointed out that

²⁰⁹⁶ ID 404-1998, Complexities of Glatiramoids – Physicochemical characterisations of glatiramoids, Warsaw June 2016, pp. 1-2. This presentation was prepared for 9 Polish KOLs in Warsaw and it was also livestreamed for the whole EU. The origin of this presentation is explained in ID 404-1995, Teva internal email dated 25 May 2016 from {...} to {...} and others: {...}.

²⁰⁹⁷ ID 404-2001, Complexities of Glatiramoids – Biological characterisations of glatiramoids, Warsaw June 2016, p. 33.

²⁰⁹⁸ ID 455-1452, The Complexity of Copaxone and Considerations for Substitution with Follow-on Glatiramer Acetate, May 2016, pp. 8, 9; according to ID 675, {...} TPE CPX jobs, the document was first used on 23 May 2016, reapproved on 23 March 2018 and withdrawn on 28 February 2020.

²⁰⁹⁹ ID 751-328, Copaxone evolved campaign e-detailed implementation guide, 30 June 2017.

²¹⁰⁰ ID 751-328, Copaxone evolved campaign e-detailed implementation guide, 30 June 2017, p. 15.

²¹⁰¹ ID 751-328, Copaxone evolved campaign e-detailed implementation guide, 30 June 2017, comment made by {...}, p. 15.

²¹⁰² ID 742-42, Assessment Report with respect to quality Mylan and Synthon’s glatiramer products, p. 3.

there were other nomenclatures that used the name of “glatiramer acetate” such as BAN (British Approved Name) and USAN (United States Adopted Name) and the fact that the WHO did not include at that time GA in its nomenclature was not relevant for confirming Copaxone’s alleged complexity.

9.3.1.4.2. Teva’s claims that “FoGA” and “NBCD” were not coined by Teva and are not misleading

(1648) Teva claims that the terms “FoGA” and “NBCD” were not coined by Teva, are not misleading and do not artificially differentiate Copaxone from competition.²¹⁰³ Teva also claims that it sought to raise awareness of this term to facilitate discussions around the appropriate regulatory treatment of “NBCDs”, including with respect to automatic substitution, in the context of a scientific debate.²¹⁰⁴ The Commission rejects these arguments.

(1649) First, this Decision does not take issue with Teva’s usage of the terms “*FoGA*” and “*NBCD*” *per se* but, in the first place, these terms provide an overview of Teva’s overall strategy of promoting the alleged “*complexity*” of Copaxone (thereby trying to artificially differentiate it from its competitors) and, in the second place, these terms are considered misleading only in those instances where they could confuse the addressees (Payers and HCPs) as to Synthon GA’s safety, efficacy, and its therapeutic equivalence with Copaxone. As explained in Section 9.2.3.5 above, the misleading nature of such instances is not affected by whether Teva was trying to communicate about the automatic substitution between Copaxone and Synthon GA.

(1650) Second, the evidence on the Commission’s case file shows that a central part of Teva’s efforts to delay Synthon GA’s entry was indeed the introduction and promotion of the terms “FoGA” and “NBCD”.

(1651) Teva used the term “FoGA” both internally and externally, grouping together all competing GAs worldwide (although only Synthon GA secured an MA and is actually marketed in the EU). As explained in Section 9.3.1.2, by grouping these numerous different products together under one term, Teva promoted the impression that all competing GAs were one and the same product and consequently, concerns raised by any of these products would apply equally to all other “FoGAs” as well.²¹⁰⁵ The usage of the term was also designed to imply that competing GAs were materially different from, and potentially not therapeutically equivalent to, Copaxone. Thereby, as part of the CCP, Teva tried to artificially differentiate Copaxone from competing GAs, including Synthon GA. A comment on the document “Copaxone and Follow-on Glatiramoids (“FoGAs”)” suggests that the use of the term “FoGA” was seen as potentially problematic: “{...}”.²¹⁰⁶

(1652) The same document also shows that – contrary to Teva’s claim – Teva played a key role in the creation of the “NBCD” terminology and its propagation with respect to GA. Indeed, as explained above (see Recitals (1431)-(1436)), Teva fostered the development of a narrative around the so-called “Non Biologic Complex Drugs” or “NBCD”, a novel term propagated by a working group co-founded and sponsored by

²¹⁰³ ID 4032, Teva’s Reply to the Statement of Objections, para. 1338; ID 5695, Teva’s Reply to the Letter of Facts I of 9 February 2024, paras. 332, 333, 334, 335; ID 5909, Teva’s Reply to the Letter of Facts II of 17 May 2024, para. 144.

²¹⁰⁴ ID 5695, Teva’s Reply to the Letter of Facts I of 9 February 2024, para. 334.

²¹⁰⁵ See, notably, Section 9.3.1.2.

²¹⁰⁶ ID 455-705, FoGA White Paper, Copaxone and Follow-on Glatiramoids (“FoGAs”), September 2014, p. 1.

Teva and used by Teva with the aim of signalling that there was a class of chemical (i.e. non-biological) drugs whose would-be generic versions would have to undergo a more demanding, lengthy and expensive approval process than the one required for standard “non-complex” generic medicines.

(1653) Teva regularly used the concept of “NBCD” in CCP materials to imply that, due to the complexity of GA, there are compositional differences between Copaxone and Synthon GA and these differences have consequences on their therapeutic equivalence. Contrary to Teva’s assertions, Teva’s communication was not done in the context or in the spirit of a genuine scientific debate. This is because, amongst others, Teva’s communications consistently failed to acknowledge that, in relation to Synthon GA, the alleged GA complexity had been taken into account by the competent authorities²¹⁰⁷ and was not found to stand in the way of finding that Synthon GA was safe, efficacious and therapeutically equivalent to Copaxone. In spite of this, Teva’s references to “NBCDs” in the context of its disparagement campaign targeting Synthon GA (the only GA having obtained a MA in the EU other than Copaxone) explicitly or implicitly suggested that differences due to complexity may be therapeutically relevant. Therefore, the claim that Copaxone and/or Synthon GA are “NBCDs” serves as a shorthand for different messages which question the finding by the competent authorities that the two products are therapeutically equivalent (and that therefore any such differences in composition are irrelevant from a clinical point of view).

9.3.1.4.3. Teva's claim that the Commission relied on evidence pre-dating the infringement period

(1654) Teva claims that the Commission relies on allegedly irrelevant background information, including documents produced prior to the beginning of the disparagement abuse, forward-looking documents, and internal documents.²¹⁰⁸

(1655) The Commission rejects this argument for the following reasons.

(1656) First, Teva’s preparatory internal documents with a view to Synthon GA being granted a MA necessarily pre-date the conduct put in place by Teva during the infringement period, and are relevant to assess Teva’s conduct during the infringement period.²¹⁰⁹

(1657) Second, the Commission describes the development of the CCP campaign as context when referring to documents and evidence which pre-date the abuse. The evidence used by the Commission that pre-dates the end of the Decentralised Procedure for the grant of a MA to Synthon GA is not used to extend the duration of the infringement, but to interpret Teva’s communications during the infringement period and to show that Teva prepared the ground for the dissemination of its messages long before the successful conclusion of the Decentralised Procedure for Synthon GA.

(1658) Third, in some cases, the reference to the documents prepared by Teva before the end of the Decentralised Procedure for the grant of a MA to Synthon GA shows that Teva did not appropriately adapt its materials even after the successful completion of the

²¹⁰⁷ See Section 9.3.1.1.3.

²¹⁰⁸ ID 4032, Teva’s Reply to the Statement of Objections, paras. 990, 991, 992, 993; ID 5695, Teva’s Reply to the Letter of Facts I of 9 February 2024, paras. 336, 337, 338, 339

²¹⁰⁹ For a confirmation of the possibility for the Commission to use evidence before the infringement period, see judgment of 2 February 2012, *Denki Kagaku Kogyo and Denka Chemicals v Commission*, T-83/08, paragraph 188 (not appealed).

Decentralised Procedure made it plain that some messages could not be reconciled with the finding by the competent authorities that Synthon GA was safe, efficacious, and therapeutically equivalent to Copaxone.

(1659) Fourth, references to documents pre-dating the beginning of the infringement are sometimes necessary to describe the context for the dissemination of Teva's misleading messages, particularly because some of Teva's employees were recommended to pass these messages on as early as possible, so that {...}.²¹¹⁰

9.3.1.4.4. Alleged failure to take into account the Swedish MPA decision in the Commission's assessment

(1660) Teva claims that the Commission failed to take into account the Swedish MPA²¹¹¹ (Läkemedelsverket, or LV in Swedish – the Swedish Medicinal Products Agency) decision which decided to deny automatic substitution status to Synthon GA “*without any intervention of Teva*”.²¹¹² The Commission rejects these claims.

(1661) First, the Commission has taken into account the decisions of the Swedish MPA and the related judgments in its assessment. However, as explained in Section 9.2.3.5 above, the Commission's assessment does not take issue with Teva's communication concerning the topic of automatic substitution as such. This decision does not concern Member States' freedom of deciding whether Copaxone and Synthon GA should be automatically substitutable. Moreover, Teva's claim fails to take into account that in six Relevant Member States the competent authorities decided that Copaxone and Synthon GA are automatically substitutable (see Recital (260)). While there may have been some scientific uncertainty about automatic substitution,²¹¹³ this was not the case concerning the essential characteristics of the product which have already been established by the regulatory authorities: Synthon GA's safety, efficacy and therapeutic equivalence with Copaxone. The dissemination of misleading messages concerning these parameters, which are fundamental product features that have been established by competent authorities (and a condition precedent for automatic substitution), does not constitute competition on the merits.

(1662) Second, Teva's internal correspondence disproves its claim that the decision of the MPA in Sweden was achieved “*without any intervention of Teva*”. Internal correspondence shows that members of Teva Nordic staff were referring to Teva's contacts as contributing to the success in convincing the LV/MPA: “{...}” (emphasis added).²¹¹⁴ Contrary to Teva's claim, this quotation shows in unambiguous terms that Teva took steps to influence the MPA's decision in Sweden denying automatic substitution between Synthon GA and Copaxone.

²¹¹⁰ As will be shown in Recital (1829) below.

²¹¹¹ MPA stands for Medicinal Products Agency.

²¹¹² ID 4032, Teva's Reply to the Statement of Objections, paras. 468, 1020; ID 5695, Teva's Reply to the Letter of Facts I of 9 February 2024, paras. 328, 329, 330, 331.

²¹¹³ See Case C-179/16, *F. Hoffmann-La Roche and Others*, paragraphs 92 and 95 – “*Article 101(1) TFEU must be interpreted as meaning that an arrangement put in place between two undertakings marketing two competing products, which concerns the dissemination, in a context of scientific uncertainty, to the EMA, healthcare professionals and the general public of misleading information relating to adverse reactions resulting from the use of one of those products for the treatment of diseases not covered by the MA for that product, with a view to reducing the competitive pressure resulting from such use on the use of the other medicinal product, constitutes a restriction of competition ‘by object’ for the purposes of that provision.*” (emphasis added).

²¹¹⁴ ID 404-1814, Teva internal email communication including the email dated 5 January 2017 from {...} to a number of Teva staff from different departments.

(1663) In this regard, Teva claims that the Commission is wrong to infer from this statement that Teva was involved in any proceedings before the MPA and that the Commission thus “*erroneously seeks to discredit the Swedish MPA’s decisions*” to prohibit automatic substitution between Copaxone and Synthon GA in Sweden, and that this email exchange is “*a single, vague, and unsubstantiated statement from a Teva employee expressing his subjective views*”.²¹¹⁵ These arguments do not convince. First, Teva’s staff involved in these email exchanges are senior managers and employees with decision-making powers concerning Copaxone. The statement was made by the {...} and was addressed to {...}.²¹¹⁶ Second, the email is not vague but specific in its reference to Teva’s strategy in relation to LV/MPA, explaining that Teva’s strategy to target the safety of automatic substitution and to use other opportunities to influence stakeholders was successful in Sweden. The statement also details the circumstances of Teva’s contacts, which were made at the occasion of the Nordic MS symposium over the following days.²¹¹⁷

9.3.1.4.5. Teva’s claim that the Commission wrongly qualified certain statements emphasising proven benefits of Copaxone as criticism of “FoGAs”

(1664) Teva claims that the Commission’s assessment improperly treats statements emphasising the proven benefits of Copaxone (such as its “*unmatched safety and efficacy blend*”) as criticisms of “FoGAs”, while these statements were allegedly developed in response to the competitive threat from orals and interferons.²¹¹⁸

(1665) This argument misconstrues the Commission’s assessment. What the Commission challenges in the documents containing references to Copaxone’s “*unmatched safety and efficacy blend*” is the fact that, in these documents, Teva was in turn portraying Synthon GA as posing safety and efficacy risks or that it was not therapeutically equivalent to Copaxone. These are two separate issues. For example, in the “Quarterly reviews Go To Market Action Plan”²¹¹⁹, as part of Teva’s Payer Strategy, in relation to other DMTs, Teva would deliver the key message of “{...}” while in relation to Synthon GA, Teva would deliver the Complexity Message based on purported differences between Synthon GA and Copaxone: {...}.²¹²⁰ Teva’s statements were misleading because they questioned Synthon GA’s safety and efficacy and its established therapeutic equivalence with Copaxone.

9.3.1.4.6. Teva’s claims related to messages on other glatiramer-related substances

(1666) Teva claims that Teva’s communications related to the health risks posed by other glatiramer-related substances are not problematic as Teva did not expressly state that

²¹¹⁵ ID 5695, Teva’s Reply to the Letter of Facts I of 9 February 2024, paras. 327-331.

²¹¹⁶ This includes {...}, {...}, {...}, {...}, {...}, {...}, {...}; and {...}. ID 404-1814, internal email exchange dated 4-5 January 2017 between {...}, {...} and others.

²¹¹⁷ Teva’s claim on the need for the Commission to show that it influenced the MPA’s decision (ID 5695, Teva’s Reply to the Letter of Facts I of 9 February 2024, para. 330) is inapplicable as Sweden is not one of the Relevant Member States covered in this Decision. Such claims related to the Relevant Member States are generally assessed in Section 9.2.3.2.

²¹¹⁸ ID 4032, Teva’s Reply to the Statement of Objections, para. 1278.

²¹¹⁹ ID 263-2032, Pre-read – Quarterly Reviews Go To Market Action Plan (GTMAP), pp. 12-14; see also ID 263-439, 2018 EU Strategic Plan Copaxone, p. 56; ID 741-25, EU Strategic Brand Plan Copaxone – Approved and Launched Relapsing forms of MS, p. 55.

²¹²⁰ ID 263-2032, Pre-read – Quarterly Reviews Go To Market Action Plan (GTMAP), p. 14; see also ID 263-439, 2018 EU Strategic Plan Copaxone, p. 56; ID 741-25, EU Strategic Brand Plan Copaxone – Approved and Launched Relapsing forms of MS, p. 55.

“health risks observed in other glatiramer-based substances equally apply to [Synthon GA]”.²¹²¹

(1667) The Commission rejects this argument.

(1668) For a piece of information to be misleading, it does not need to be inaccurate but it can also be information “*which is in itself correct but is presented selectively or incompletely*” where, because of that manner of presentation, the disseminated information may mislead its addressees.²¹²² By making references to the health risks posed by other glatiramer-related substances in the context of discussing Synthon GA, Teva was intentionally or negligently creating the impression that risks and difficulties that had arisen with respect to these other glatiramer-related substances, which were discussed extensively in Teva’s materials as shown above²¹²³, may apply equally to Synthon GA. Since Teva’s presentations in the EU implicitly or explicitly targeted Synthon GA (as the only “FoGA” in the EU), it is clear that abundant and recurrent descriptions of observed issues with other GAs (often continuing over several pages) aimed to generally undermine confidence in non-Copaxone GA (including Synthon GA) although the evidence had nothing to do with Synthon GA because it concerned different medicines which had not been assessed by the regulatory authorities in the EU (Teva’s documents even suggest that the appropriateness of such comparisons with other GAs was disputed internally).²¹²⁴ Further, these claims apply indiscriminately to all “FoGAs” – thus, including Synthon GA – and are constantly included in the CCP materials. Since these messages on other glatiramer-related substances were not relevant for Synthon GA, there was no reason for Teva to include them systematically in CCP materials, which concerned Teva’s only competitor in Europe, Synthon, unless Teva’s objective was to imply that health risks noted by Teva in relation to other glatiramer-substances would apply to Synthon GA as well.

9.3.2. *Teva put in place effective mechanisms for disseminating the Misleading Complexity Message*

(1669) The communication of messages corresponding to or resembling those presented in Section 9.3.1 started before the launch of Synthon GA, and continued during and after the launch of Synthon GA.²¹²⁵ In view of the imminent emergence of a competing GA, in February 2014 Teva set up several scenarios, projects and planning focused on “*educating*” a number of important stakeholders (including e.g. EU MS Patient Association, local market KOLs and neurologists, etc.) on the “*complexity*” of GA or, in other words, focused on the dissemination of the Misleading Complexity Message to prevent a shift in demand to Synthon GA.²¹²⁶ For the sake of clarity, in this Section 9, the Commission only applies Article 102 TFEU to Teva’s conduct following the announcement, in April 2016, that the Decentralised Procedure for the approval of Synthon GA had been successfully concluded (thereby

²¹²¹ ID 4032, Teva’s Reply to the Statement of Objections, paras. 1022, 1023, 1024.

²¹²² Opinion of AG Saugmandsgaard Øe in *Hoffmann-La Roche*, paragraph 158. Similarly, in its *Avastin-Lucentis* case, the French NCA found that Novartis and Roche abused their collectively dominant position inter alia on the basis that Novartis made a selective and biased presentation of the results of scientific studies comparing the safety and efficacy of the use of two competing products. See Décision n° 20-D-11 du 9 septembre 2020, paras. 812 et seq.

²¹²³ See Recitals (1588)-(1601)).

²¹²⁴ See Recitals (1597)-(1599).

²¹²⁵ ID 455-269, CCP strategy, In the face of evolving FoGA competition, pp. 9-11.

²¹²⁶ ID 263-51, Copaxone Continuation Project, February 2014, pp. 8, 9.

confirming that Synthon GA’s safety, efficacy, and therapeutic equivalence with Copaxone were formally established by competent authorities).

9.3.2.1. Multiple Teva teams were responsible for the dissemination of the Misleading Complexity Message

- (1670) Several internal functions within Teva were involved in the CCP campaign, each with its own responsibilities and targets.²¹²⁷ These were (i) the Market Access team with the general, primary responsibility for Payers (regarding prices and other market access conditions for Copaxone, such as the automatic substitution status), (ii) the Key Account Manager (“KAM”) team with the general, primary responsibility for HCPs and (iii) the MSL team with the second-line responsibility for Payers (directly or with the KOLs) and HCPs. All these teams had to (and, in fact, did) receive training(s) based on the CCP materials.²¹²⁸
- (1671) As part of the CCP action plan before the launch of Synthon GA, the Market Access team was instructed {...}, the KAM team {...}, and the MSL team was initially instructed {...}.²¹²⁹ As summarised by Teva when outlining its response to the risks related to “Copaxone Generics”: {...} (emphasis added).²¹³⁰
- (1672) The CCP activities intensified during and after the launch of Synthon GA. For example, for the actions to be taken during and after the launch of Synthon GA, the KAM team was instructed to {...}. The KAMs had both (i) a proactive role – to make sales calls with HCPs highlighting the complexity of GA and (ii) a reactive role – to answer questions raised by doctors using the approved answers. KAMs also had to ensure swift post-call follow up by MSL team where necessary.²¹³¹
- (1673) In turn, the MSL team was instructed to make follow up visits to address customers’ questions resulting from the KAM’s initial contact. The MSL team were using the supplied CCP materials – External Expert White Papers and slides, GATE Study review folder and MSL Q&A.²¹³² These MSL materials included a detailed overview of all Teva’s messaging related to Synthon GA including all facets of the Misleading Complexity Message (as opposed to the succinct materials designed for KAMs).²¹³³ Since KAMs materials were not designed to answer comprehensively possible questions related to Synthon GA and since KAMs were instructed to swiftly trigger follow up contacts by the MSL team, the MSL team played an important role in the dissemination of the Misleading Complexity Message to HCPs.²¹³⁴
- (1674) As to the responsibility for the Payers, Teva’s Market Access team was instructed {...}.²¹³⁵
- (1675) The MSL team again played an important role as a second line of communication responsible for the consulted experts.²¹³⁶ Their role was to reactively educate KOLs

²¹²⁷ ID 455-2935, FoGA medical, p. 6. Teva summarised the overall CCP as a {...}.

²¹²⁸ ID 455-269, CCP strategy, In the face of evolving FoGA competition, p. 9; ID 264-1083, Copaxone Continuation Plan Germany, February 2016, pp. 1, 2; see also ID 404-1482, Teva internal email dated 4 March 2016 from {...} to {...} and others.

²¹²⁹ Ibid.

²¹³⁰ ID 455-559, GSM 2016 Top Risks – COPAXONE Generics, p. 1.

²¹³¹ ID 455-269, CCP strategy, In the face of evolving FoGA competition, pp. 10, 11, 15.

²¹³² Ibid.

²¹³³ For description of CCP materials see section 9.3.2.2.

²¹³⁴ ID 455-269, CCP strategy, In the face of evolving FoGA competition, p. 15.

²¹³⁵ Ibid, p. 10.

²¹³⁶ Consulted experts refers to MS-specialist and non-specialist experts who are consulted by Payers as part of the local decision making process (Ibid, p. 14).

in response to questions raised during discussions with the Market Access team. Teva considered that these external experts need to be “fully informed on substitution” and “ready to respond to payer questions”.²¹³⁷

- (1676) Teva’s internal communications between senior management shows that Teva was modulating the form of its misleading messages to make them more or less direct, depending on the situation while all the time targeting Synthon GA’s safety, efficacy and therapeutic equivalence with Copaxone. Teva’s internal discussions about how to pass the message clearly show that the message is about targeting the safety of the competing product, Synthon GA. The following evidence shows that when there was the imminent danger of losing the whole market, Teva considered that the more subtle messages related to safety, efficacy and therapeutic equivalence may not be sufficient and considered that it was the time to spell out clearly the message and to make direct references to the safety of Synthon GA: {...}.²¹³⁸
- (1677) Given the pan-European nature of Teva’s campaign, these statements were also informative for Teva’s conduct in the Relevant Member States. In addition, the fact that employees of Teva Pharmaceuticals Europe, which were centrally coordinating the CCP campaign, were involved in these discussions shows that Teva’s strategy and knowledge of targeting the safety of Synthon GA and the strategy used in practice was managed and coordinated centrally, and that this evidence is informative of Teva’s conduct in the Relevant Member States. Further, this email chain also contains a discussion about how Teva’s messages on differentiation should be passed. One Teva employee suggests taking a softer degree of differentiation and use other opportunities to pass Teva’s messages: {...}.²¹³⁹ In a subsequent reply, Teva’s representatives agree to {...}.²¹⁴⁰

9.3.2.2. Teva created an elaborate set of materials to disseminate the Misleading Complexity Message

- (1678) Teva developed {...}.²¹⁴¹ These materials were created before the launch of Synthon GA and were ready for use by the competent teams at its launch.²¹⁴² The Figure 42 below which was prepared by Teva at the beginning of the CCP Phase II (see Recitals (1440), (1441)) illustrates Teva’s entire campaign: Teva created different materials tailored for different audiences targeted by different Teva teams (“Teva users”).

Figure 42: CCP campaign

{...}

Source ID 455-269, CCP strategy – In face of evolving FoGA competition, p. 18.

²¹³⁷ Ibid.

²¹³⁸ ID 404-1831, Teva internal email thread including email dated 5 January 2017 from {...} to {...}, {...}, {...}; {...}, {...}, {...}; see also ID 404-1809, Teva internal email chain containing the following discussions to this email; ID 404-1814 Teva internal email chain containing the following discussions to this email.

²¹³⁹ ID 404-1814, Teva internal email communication including the email dated 5 January 2017 from {...} to {...}, {...}, {...}, {...}, {...}, {...}, {...}, {...}.

²¹⁴⁰ Ibid.

²¹⁴¹ ID 455-269, CCP strategy, In the face of evolving FoGA competition, p. 3.

²¹⁴² Ibid, pp. 9-10. The CCP strategy also reveals that Teva’s Market Access teams used {...} even before Synthon GA launch (Ibid, p. 9). Evidence on dissemination of the Misleading Complexity Message in the Relevant Member States indeed reveals that the CCP materials and messaging have been put in place before launch of Synthon GA (see Section 9.4.3); see also ID 263-52, CCP FoGA Action Plan, Phase IIb materials development and roll-out.

(1679) For the Payers (such as pricing and reimbursement bodies and insurers), Teva’s approach regarding the Misleading Complexity Message, was set out in the *Payer White Paper*, the *Payer Slide Presentation* and the *Payer Q&A* document. For the external experts (such as KOLs and MS specialist neurologists), the approach was outlined in the two *External Expert White Papers* (MS specialist and non-specialist version).²¹⁴³ The communication approach for other HCPs was contained in {...}.²¹⁴⁴

9.3.2.2.1. Overview of types of Teva’s centrally created CCP materials

(1680) In the following sub-Sections, the Commission describes in more detail the documents that were created by Teva to “educate” relevant stakeholders and that served as a basis for the dissemination of the Misleading Complexity Message with the instruction that: {...}.²¹⁴⁵ All these materials were {...}.²¹⁴⁶ The documents described below were centrally created by the CCP Taskforce²¹⁴⁷ as part of the CCP action plan and available {...} (i.e. ultimately approved by legal department and saved in a central depository of information that is vetted by Teva for use in the market).²¹⁴⁸

9.3.2.2.1.1. Payer White Paper

(1681) The Payer White Paper²¹⁴⁹ is a document laying out Teva’s key arguments concerning competing GA. According to Teva, the objective of the Payer White Paper is to demonstrate to Payers²¹⁵⁰ the continued value of Copaxone relative to competing GAs and to discourage Payers from allowing automatic substitution.²¹⁵¹

(1682) In pursuing that objective, the Payer White Paper includes all the facets of the Misleading Complexity Message analysed in Section 9.3.1: it emphasises clinically irrelevant differences in GA structures,²¹⁵² it implies that risks observed with respect

²¹⁴³ ID 263-52, CCP FoGA Action Plan, Phase IIb materials development roll-out, p. 3. According to Teva these external expert materials were created to {...} (ID 265-1367, Teva internal email dated 9 May 2016 from {...} to Teva’s medical teams).

²¹⁴⁴ ID 263-52, CCP FoGA Action Plan, Phase IIb materials development roll-out, p. 4.

²¹⁴⁵ ID 263-63, Copaxone Strategy, p. 2, ID 263-45, Plan of Action – In the face of evolving FoGA competition, 27 September 2016; ID 455-269, CCP Strategy, p. 2; ID 455-1377, CCP Strategy, 24 May 2018.

²¹⁴⁶ ID 265-1373, Teva internal email dated 17 May 2016 from Teva’s then {...}; ID 455-3520, Teva internal email dated 9 May 2016 from {...} to {...} and others.

²¹⁴⁷ Teva’s CCP taskforce comprised multidisciplinary representatives from various Teva departments dealing with Copaxone including Market Development, Medical, Market Access, Governmental Affairs, Legal, Patient Services, Regulatory, CI, Branded Biosimilars, Generics, Compliance (ID 455-801, CCP Kick-off Meeting 5 Nov 13, 18 November 2013, p. 10). On role of the CCP taskforce see Section 5.2.4.

²¹⁴⁸ ID 455-1415, email thread dated 18 May 2016 from {...} to {...} and others, reveals that the documents were uploaded on the vault. The high demand for these documents is revealed from the email thread: {...}.

²¹⁴⁹ ID 806-2, Assessing the Value of COPAXONE® in Relation to Follow-on Glatiramer Acetate, Payer White Paper, 8 June 2016; see also ID 455-2059, Assessing the Value of COPAXONE® in Relation to Follow-on Glatiramer Acetate, Payer White Paper, June 2017.

²¹⁵⁰ For communications with KOLs and HCPs, see External Expert White Paper, Section 9.3.2.2.1.4.

²¹⁵¹ ID 455-2059, Assessing the Value of COPAXONE® in Relation to Follow-on Glatiramer Acetate, Payer White Paper, June 2017, p. 22.

²¹⁵² See e.g. ID 455-1936, Assessing the Value of COPAXONE® in Relation to Follow-on Glatiramer Acetate, Payer White Paper, 15 March 2016, pp. 3, 7, 9, 10; ID 455-2574, Assessing the Value of COPAXONE® in Relation to Follow-on Glatiramer Acetate Payer White Paper, June 2017, pp. 4, 5, 11; ID 455-1145, Assessing the Value of COPAXONE® in Relation to Follow-on Glatiramer Acetate, Payer White Paper, November 2018, pp. 4, 5, 6, 12, 13, 14, 15, 25, 36, 37; ID 264-101, Assessing the

to other glatiramer-related substances equally apply to Synthon GA²¹⁵³ and questions the validity of the GATE study and its conclusions,²¹⁵⁴ all with the aim of raising doubts relating to Synthon GA's safety, efficacy, and therapeutic equivalence with Copaxone.

- (1683) The Payer White Paper was used by the Market Access teams in their communication with Payers.²¹⁵⁵ During Phase II of the Teva CCP campaign²¹⁵⁶, one of Teva's key tactics was to distribute proactively the Payer White Paper to key stakeholders.²¹⁵⁷ Moreover, Teva also used the Payer White Paper to train its Market Access staff for the discussions with Payers about "FoGAs".²¹⁵⁸ Like many other CCP materials, the document was constantly updated to take into account changes in the market.²¹⁵⁹ For example, the CCP Strategy presentation from 24 May 2016 noted that the Payer White Paper was {...} with a note that there was an update in progress.²¹⁶⁰

value of COPAXONE® in Relation to Follow-on Glatiramer Acetate, Payer White Paper, January 2019, pp. 5, 6, 12, 13, 14, 15, 16, 17.

²¹⁵³ See e.g. ID 455-1936, Assessing the Value of COPAXONE® in Relation to Follow-on Glatiramer Acetate, Payer White Paper, 15 March 2016, p. 9; ID 455-2574, Assessing the Value of COPAXONE® in Relation to Follow-on Glatiramer Acetate, Payer White Paper, September 2017, p. 22; ID 455-1145, Assessing the Value of COPAXONE® in Relation to Follow-on Glatiramer Acetate, Payer White Paper, November 2018, p. 28; ID 264-101, Assessing the value of COPAXONE® in Relation to Follow-on Glatiramer Acetate, Payer White Paper, January 2019, pp. 26, 27.

²¹⁵⁴ See e.g. ID 455-1936, Assessing the Value of COPAXONE® in Relation to Follow-on Glatiramer Acetate, Payer White Paper, 15 March 2016, pp. 7, 10; ID 455-2574, Assessing the Value of COPAXONE® in Relation to Follow-on Glatiramer Acetate, Payer White Paper, September 2017, pp. 5, 13, 15, 16; ID 455-1145, Assessing the Value of COPAXONE® in Relation to Follow-on Glatiramer Acetate, Payer White Paper, November 2018, pp. 20, 21, 22; ID 455-1936, Assessing the Value of COPAXONE® in Relation to Follow-on Glatiramer Acetate, Payer White Paper, 15 March 2016, pp. 14, 15, 16, 17, 19, 20, 22.

²¹⁵⁵ ID 455-269, CCP strategy, In the face of evolving FoGA competition, p. 18.

²¹⁵⁶ See Recitals (1438)-(1441).

²¹⁵⁷ ID 455-2880, CCP Phase II Overview, 17 November 2015, p. 22; this document is not used to establish an infringement before the Decentralised Procedure was successfully completed, but to show that Teva prepared the ground for disparagement before such event.

²¹⁵⁸ ID 455-333, Teva internal email dated 29 January 2016 from {...} to Teva's market access team; ID 264-1756, COPAXONE® Continuation Project (CCP) – Pricing & Market Access Follow-on Glatiramer Acetate (FoGA) TRAINING, 3, 4 February 2016, pp. 16, 17) The document COPAXONE® Continuation Project (CCP) – Pricing & Market Access Follow-on Glatiramer Acetate (FoGA) TRAINING shows that in order to achieve its Key Strategic Objectives such as {...}), Teva planned to use the {...}”.

²¹⁵⁹ Numerous versions of the Payer White Paper (ID 455-336, ID 455-1936, ID 265-1599, ID 265-1232, ID 455-2540, ID 455-2561, ID 455-2059, ID 455-2574, ID 455-2053, ID 455-1145, ID 264-101); ID 455-336, Assessing the Value of COPAXONE® in Relation to Follow-on Glatiramer Acetate, Payer White Paper, is marked as “Draft for legal review”; ID 455-2574, Assessing the Value of COPAXONE® in Relation to Follow-on Glatiramer Acetate, Payer White Paper, September 2017 – 15 sections are noted as updated, pp. 4, 12, 15, 18, 21, 23, 24, 28, 30; ID 455-1145, Assessing the Value of COPAXONE® in Relation to Follow-on Glatiramer Acetate, Payer White Paper, November 2018 – 4 sections are noted as updated, pp. 12, 16, 25, 27; ID 264-101, Assessing the value of COPAXONE® in Relation to Follow-on Glatiramer Acetate, Payer White Paper, January 2019 – 5 sections are noted as updated, pp. 4, 13, 17, 25, 27.

²¹⁶⁰ ID 455-269, CCP strategy, In the face of evolving FoGA competition, pp. 18, 19.

(1684) The Payer White Paper was the central document of the CCP and intended for use in all of the Relevant Member States. When necessary, for a better communication with Payers, the White Paper would be translated from English to the local language.²¹⁶¹

9.3.2.2.1.1.1. Teva's claims concerning the Payer White Paper

(1685) First, Teva claims that whilst the Payer White Paper focusses on Copaxone as a whole, its central focus is automatic substitution and the added value of Copaxone.²¹⁶² The Commission rejects this claim for the reasons explained in Section 9.2.3.5, which fully apply here as the Payer White Paper covers all three messages assessed in Section 9.3.1. Moreover, a document outlining the CCP Phase II strategy shows that the criticism on automatic substitution was to be added to the already existing messages concerning the complexity of GA: {...}.²¹⁶³

(1686) Second, Teva claims that the Commission does not demonstrate that the Payer White Paper emphasises clinically irrelevant differences in GA structures.²¹⁶⁴ The Commission rejects these claims. In particular Section 9.3.1.1 demonstrates in detail that the Payer White Paper indeed includes all facets of the Misleading Complexity Message. For example, the following message from the Payer White Paper is quoted in Recital (1547): {...}.²¹⁶⁵ Teva then continued to explain: {...} (emphasis added).²¹⁶⁶ The highlighted statements, which imply that there are potential safety issues with Synthon GA, the only GA authorised in the EU, are in direct contradiction to the findings of the competent authorities concerning the safety and efficacy of Synthon GA, and its therapeutic equivalence with Copaxone. These statements aim to discredit Synthon GA in the eyes of the Payers, in alignment with Teva's strategy to {...}.²¹⁶⁷ The misleading character of these and similar statements is assessed in Section 9.3.1.1.

(1687) Third, Teva claims that no version of the Payer White Paper implied that risks observed in other glatiramer-related substances apply equally to Synthon GA. Teva also claims that, in any event, Teva's references to Probioglat and Protiramer were ultimately removed from the Payer White Paper. Further, Teva claims that references to other glatiramer-related substances are caveated in each version of the Payer White Paper.²¹⁶⁸

(1688) The Commission rejects these arguments for the following reasons.

²¹⁶¹ For example, the Payer White Paper was translated in Italian: ID 934-114, Valutazione del valore di COPAXONE® rispetto alla versione di seconda generazione di glatiramer acetate Libro bianco per i sistemi sanitari e gli enti finanziatori 18 novembre 2016.

²¹⁶² ID 4032, Teva's Reply to the Statement of Objections, para. 1120.

²¹⁶³ ID 455-2880, CCP: agreed project scope and deliverables, November 2015, pp. 10-11, 22-23. See also ID 404-2201, A deeper understanding of the complexity of glatiramer acetate, August 2014. By way of example of messages which pre-date the successful conclusion of the Decentralised Procedure for Synthon GA and which have been repeated by Teva after such event (and which have been analysed in Section 9.3.1.1), ID 404-2201, pp. 18, 21, 33, shows that Teva suggested that compositional differences could be therapeutically relevant: {...}.

²¹⁶⁴ ID 4032, Teva's Reply to the Statement of Objections, para. 1124.

²¹⁶⁵ See footnote 1953 above.

²¹⁶⁶ ID 806-2, Assessing the Value of COPAXONE® in Relation to Follow-on Glatiramer Acetate, Payer White Paper, 8 June 2016, p. 11. See also for similar statements ID 455-2210, COPAXONE® and the introduction of FoGA; Payer objection handler, 8 December 2016, pp. 16 and 20, ID 455-1452, The Complexity of COPAXONE® and Considerations for Substitution with Follow-on Glatiramer Acetate, May 2016, p. 8.

²¹⁶⁷ ID 404-2017, Teva internal email dated 27 October 2014 from {...} to {...} and others regarding {...}.

²¹⁶⁸ ID 4032, Teva's Reply to the Statement of Objections, para. 1125.

- (1689) In the first place, references to safety and other issues with glatiramer-related substances other than Synthon GA are misleading as analysed in detail in Section 9.3.1.2. The Payer White Paper (dated 29 January 2016), to be used by Teva’s Market Access team in discussions with Payers about “FoGAs” in {...},²¹⁶⁹ states that {...} (emphasis added).²¹⁷⁰ Further, it is stated that {...} (emphasis added).²¹⁷¹ The highlighted statements directly target Synthon GA (the only “FoGA” authorised in the EU) to cast doubt on its safety and therapeutic equivalence with Copaxone once the former is launched.
- (1690) At any rate, even the version that Teva itself indicates as the finalised version of the Payer White Paper (June 2016) contains all the misleading messages relevant for the Commission’s assessment.²¹⁷² Even after Teva became aware of the successful conclusion of the Decentralised Procedure for Synthon GA, the Payer White Paper continues to suggest that the compositional differences between Copaxone and Synthon GA as well as negative experience with other glatiramer-related substances cast doubt as to the safety, efficacy and therapeutic equivalence of Synthon GA, as they {...}, mentioning {...}.²¹⁷³
- (1691) In the second place, the (partial) removal of misleading references to other glatiramer-related substances came only at a time where Teva’s campaign targeting the Payers was by and large concluded, and the relevant decisions on the grant of the MA and on automatic substitution were already taken. The Payer White Paper contained references to other glatiramer-related substances until at least 2019, which broadly coincides with the conclusion of Phase IIa of Teva’s CCP which specifically targeted Payers.²¹⁷⁴ This is implicitly confirmed by Teva’s claims that the references to Probioglat and Protiramer were removed in the version from January 2019.²¹⁷⁵
- (1692) In the third place, Teva kept referring to information concerning Glatopa, a GA supplied by Sandoz in the US, even after January 2019.
- (1693) In the fourth place, Teva’s claim that the reference to Protiramer was removed from Payer White Paper between June 2016 and November 2016 is incorrect. In the version from June 2018 the same message: {...} (emphasis added) is supported by a

²¹⁶⁹ ID 455-333, Teva internal email dated 29 January 2016 from {...} to Teva’s market access team which includes the Payer White paper from 29 January 2016 – ID 455-336, Assessing the Value of COPAXONE® in Relation to Follow-on Glatiramer Acetate Payer White Paper Draft for legal review, 29 January 2016.

²¹⁷⁰ ID 455-336, Assessing the Value of COPAXONE® in Relation to Follow-on Glatiramer Acetate Payer White Paper, 29 January 2016, p. 10, attachment to ID 455-333, Teva internal email dated 29 January 2016 from {...} to Teva’s market access which shows that the White Paper was circulated for training purposes; see also ID 806-2, Assessing the Value of Copaxone in relation to Follow-on Glatiramer Acetate, Payer White Paper, 8 June 2016, p. 12. Similar statements can be found on pp. 3, 10 and 11; see also ID 455-1145, Assessing the value of COPAXONE® in relation to follow-on glatiramer acetate, Payer White Paper, November 2018, p. 27.

²¹⁷¹ ID 455-336, Assessing the Value of COPAXONE® in Relation to Follow-on Glatiramer Acetate Payer White Paper, 29 January 2016, p. 10, attachment to ID 455-333, Teva internal email dated 29 January 2016 from {...} to Teva’s Market Access which shows that the White Paper was circulated for training purposes.

²¹⁷² ID 806-2, Assessing the Value of COPAXONE® in Relation to Follow-on Glatiramer Acetate, Payer White Paper, 8 June 2016, pp. 10, 11, 12: {...}. ID 2228, Teva’s reply to Article 18(2) request dated 13 July 2022, p. 15 indicates this version from 8 June 2016 as the final version of the Payer White Paper.

²¹⁷³ ID 806-2, Assessing the Value of COPAXONE® in Relation to Follow-on Glatiramer Acetate, Payer White Paper, 8 June 2016, p. 11.

²¹⁷⁴ ID 4032, Teva’s Reply to the Statement of Objections, para. 1125.

²¹⁷⁵ ID 4032, Teva’s Reply to the Statement of Objections, para. 1125; see also ID 263-2132, Assessing the value of COPAXONE in relation to follow-on glatiramer acetate, Payer White Paper, January 2019.

reference to Protiramer (the only difference being that this reference no longer appears in the main text but in a footnote).²¹⁷⁶

- (1694) In the fifth place, Teva’s disclaimers were added late and may in any event be inadequate to prevent doubt being cast on Synthon GA’s safety, efficacy, and therapeutic equivalence with Copaxone. Teva claims that more recent versions of the Payer White Paper state {...}.²¹⁷⁷ This disclaimer was however only included in November 2018 when the Phase IIa targeting Payers had already been going for already two years. Moreover, this disclaimer is only made in relation to Glatopa, while it does not cover the preceding sections such as {...} where the example of Probioglat in Mexico is used to cast doubt on the safety of “FoGAs”²¹⁷⁸, thus including Synthon GA.
- (1695) Further, certain Teva disclaimers are worded in a way to further aggravate the doubts as to Synthon GA instead of facilitating a more objective assessment. Teva’s Reply to the Statement of Objections²¹⁷⁹ notably refers to the following disclaimer relating to Protiramer: {...} (emphasis added).²¹⁸⁰ Although the Payer White Paper targets European Payers with messages concerning Synthon GA, the only approved “FoGA” in the EU, the highlighted statement directly contradicts the findings of competent authorities in the EU which found that the differences between Copaxone and Synthon GA **had no clinically relevant effects**. This misleading statement is further aggravated by the following sentence in the so-called disclaimer (omitted from Teva’s Reply to the Statement of Objections): {...} (emphasis added)²¹⁸¹ which reinforces the perception that there may be harmful effects in terms of safety and efficacy (and, hence, therapeutic equivalence).
- (1696) In the sixth place, it is overall questionable why Teva would include in its communications in the Relevant Member States information concerning non-EU products which are different than Synthon GA, that did not undergo the same clinical trials and other testing, and did not receive an MA (and hence are not sold) in the EU, if not to implicitly sow doubt as to Synthon GA and the findings of competent authorities. The mere inclusion in a communication of information implies that this information is relevant to the communication at hand. If such information raises doubts about safety, efficacy and therapeutic equivalence of Synthon GA with Copaxone for a stakeholder, then such information is capable of casting the seed of doubt irrespective of whether it is formally accompanied by a disclaimer.
- (1697) Fourth, Teva claims that the Payer White Paper does not constitute an illegitimate criticism of the GATE study as it focused on the results which contradicted Teva’s studies of Copaxone and, ultimately, portrayed Copaxone in a negative light. Teva claims that these allegedly legitimate questions were raised in the context of automatic substitution (not the safety and efficacy of Synthon GA *per se*) and the

²¹⁷⁶ ID 265-1104, Assessing the Value of COPAXONE® in Relation to Follow-on Glatiramer Acetate, Payer White Paper, June 2018, p. 4.

²¹⁷⁷ ID 455-1145, Assessing the Value of COPAXONE® in Relation to Follow-on Glatiramer Acetate, Payer White Paper, November 2018, p. 27.

²¹⁷⁸ {...} – See ID 455-1145, Assessing the Value of COPAXONE® in Relation to Follow-on Glatiramer Acetate, Payer White Paper, November 2018 (also referred to by Teva).

²¹⁷⁹ ID 4032, Teva’s Reply to the Statement of Objections, para. 1125.

²¹⁸⁰ ID 455-1936, Assessing the Value of COPAXONE® in Relation to Follow-on Glatiramer Acetate, Payer White Paper, 15 March 2016, p. 9; ID 806-2, Assessing the Value of COPAXONE® in Relation to Follow-on Glatiramer Acetate, Payer White Paper, 8 June 2016.

²¹⁸¹ ID 455-1936, Assessing the Value of COPAXONE® in Relation to Follow-on Glatiramer Acetate, Payer White Paper, 15 March 2016, p. 9.

document is allegedly clear that Teva brought its criticisms of the GATE study to the attention of the regulatory authorities who nevertheless approved Synthon GA.²¹⁸²

- (1698) The Commission rejects these claims. The analysis in section 9.3.1.3 shows the contrary, namely that Teva's statements questions the GATE study, and thus indirectly also the regulatory findings over Synthon GA's therapeutic equivalence with Copaxone based on the GATE study. For example, Teva's Payer White Paper states that {...} (emphasis added).²¹⁸³ Teva also questions the study, and the related regulatory findings, due to alleged inconsistencies with Copaxone data and the use of MRI lesions as the endpoint for the GATE study (as compared to the Annual Relapse Rate, or ARR, used in some of the Copaxone studies): {...} (emphasis added).²¹⁸⁴ In other words, Teva asserted that the GATE study could not legitimately serve as the basis for conclusions on Synthon GA's safety and efficacy, directly casting doubt on the scientific basis for the successful conclusion of the Decentralised Procedure for Synthon GA. Section 9.3.1.3 shows that such statements are misleading, and that Teva was aware of that, and rebuts Teva's claims concerning specific statements.

9.3.2.2.1.2. Payer Slide Presentation

- (1699) The Payer Slide Presentation was a comprehensive slide deck²¹⁸⁵, a visual aid to lay out Teva's key arguments concerning competing GA. The document, updated multiple times, covered five topics: {...}.²¹⁸⁶ While the document also covered topics specific to Copaxone (e.g. the cost effectiveness of Copaxone), it focused on communication relating to competing GA and more specifically relating to Synthon GA. For example, 23 out of 51 slides in the version of 13 October 2017 and 55 out of 85 slides in the version of 24 January 2019 contained only messages on competing GA and specifically on Synthon GA.²¹⁸⁷
- (1700) These slides together with the corresponding annexes covered all facets of the Misleading Complexity Message analysed in Section 9.3.1. The focus of the document becomes clear in its conclusions, which were exclusively devoted to the competing GA and *inter alia* repeat the Misleading Complexity Message.²¹⁸⁸
- (1701) The slide deck was used by Teva's Market Access teams in order to {...}.²¹⁸⁹ It served as a template for the creation of the localised presentations used in Teva's

²¹⁸² ID 4032, Teva's Reply to the Statement of Objections, para. 1126.

²¹⁸³ ID 806-2, Assessing the Value of COPAXONE® in Relation to Follow-on Glatiramer Acetate, Payer White Paper, 8 June 2016, p. 3.

²¹⁸⁴ ID 806-2, Payer White Paper, Assessing the Value of COPAXONE® in Relation to Follow-on Glatiramer Acetate, Payer White Paper, 8 June 2016, pp. 3 and 9.

²¹⁸⁵ For example, the version dated 13 October 2017 (ID 455-2583) consists of altogether 65 slides out of which 15 slides of appendices while the version dated 24 January 2019 (ID 264-102) consists of altogether 116 slides out of which 31 slides of appendices.

²¹⁸⁶ ID 455-2583, The value of COPAXONE® (glatiramer acetate): Considerations when assessing the use of follow-on glatiramer acetate (FoGA), Payer Presentation, 13 October 2017, p. 2.

²¹⁸⁷ Certain premises necessary for the Misleading Complexity Message (e.g. on the complex nature of GA and importance of Teva's manufacturing process) are also found on the slides not directly dealing with competing GA.

²¹⁸⁸ ID 264-102, The value of COPAXONE® (glatiramer acetate): Considerations when assessing the use of follow-on glatiramer acetate (FoGA), Payer Presentation, 24 January 2019, p. 85; ID 455-2583, The value of COPAXONE® (glatiramer acetate): Considerations when assessing the use of follow-on glatiramer acetate, Payer Presentation, October 2017, p. 50.

²¹⁸⁹ ID 455-269, CCP strategy, In the face of evolving FoGA competition, p. 23.

communication with the competent authorities of the Relevant Member States.²¹⁹⁰ According to Teva CCP Phase II plan, one of Teva’s key tactics was to use these slide decks in their contacts with stakeholders.²¹⁹¹

9.3.2.2.1.2.1. Teva’s claims concerning the Payer Slide Presentation

- (1702) Teva claims that the Payer Slide Presentation does not present any of the three limbs of the Misleading Complexity Message, and claims that this is allegedly evident from the “Conclusion” slide.²¹⁹² The Commission rejects this argument.
- (1703) First, the “Conclusion” slide itself contains a thinly veiled attempt to raise doubt as to Synthron GA’s safety, efficacy and therapeutic equivalence with Copaxone. The title {...} (emphasis added) is followed by the statement that there are {...} (emphasis added) and listing a number of precautions for physicians in case of switching patients.²¹⁹³ Most importantly, the slide does not attempt to reconcile these statements with the regulatory finding that Synthron GA is safe, efficacious and therapeutically equivalent to Copaxone. The message that this slide conveys suggests the contrary: that one needs to “carefully consider” the use of Synthron GA in view of “marked differences”. Contrary to Teva’s claim, the message is not limited to cases of automatic substitution: with the exception of two points, the rest of the slide, including its title and the boxed conclusion is not limited to cases of switching, let alone automatic substitution. Moreover, the MEB explicitly found that there were no problems with switching patients between Copaxone and Synthron GA. In keeping with this, the necessary precautions alleged by Teva are not required in either Copaxone’s or Synthron GA’s label (SmPC).
- (1704) Second, the slide deck contains other examples of misleading information as assessed in Section 9.3.1. For example, the Payer Slide presentation casts doubt on the safety and efficacy of Synthron GA: {...} (emphasis added).²¹⁹⁴ These claims had been already addressed and rejected by the MEB.²¹⁹⁵
- (1705) Further, the Payer Slide Presentation also contains a challenge to the GATE study: {...} (emphasis added)²¹⁹⁶ and {...} (emphasis added).²¹⁹⁷ Teva also claims that {...} (original emphasis).²¹⁹⁸

²¹⁹⁰ See e.g. ID 455-2433, Substitution considerations for follow on glatiramer acetate products Meeting with Federal Agency for Medicines & Health Products Brussels, 23 January 2017, presentation for the Belgian Federal Agency for Medicines and Health Products.

²¹⁹¹ ID 455-2880, CCP Phase II Overview, 17 November 2015, p. 22 – {...}.

²¹⁹² ID 4032, Teva’s Reply to the Statement of Objections, paras. 1131, 1132, 1133, 1134, 1135 and footnote 1005.

²¹⁹³ ID 264-102, The value of COPAXONE® (glatiramer acetate): Considerations when assessing the use of follow-on glatiramer acetate, Payer Presentation, October 2017, p. 85. the same idea is expressed in ID 455-2583, The value of COPAXONE® Copaxone (glatiramer acetate): Considerations when assessing the use of follow-on glatiramer acetate, Payer Presentation, October 2017, p. 50 and in ID 455-2024 The value of COPAXONE® (glatiramer acetate): Considerations when assessing the use of follow on glatiramer acetate (FoGa), Payer Presentation, 8 September 2018, p. 77.

²¹⁹⁴ ID 455-2583, The value of COPAXONE® (glatiramer acetate): Considerations when assessing the use of follow-on glatiramer acetate, Payer Presentation, October 2017, p. 12; ID 455-2024, The value of COPAXONE® (glatiramer acetate): Considerations when assessing the use of follow on glatiramer acetate (FoGa), Payer Presentation, 8 September 2018, p. 13.

²¹⁹⁵ See Section 9.3.1.1.3.

²¹⁹⁶ ID 455-2583, The value of COPAXONE® (glatiramer acetate): Considerations when assessing the use of follow-on glatiramer acetate, Payer Presentation, October 2017, p. 22; ID 264-102, The value of COPAXONE® (glatiramer acetate): Considerations when assessing the use of follow-on glatiramer acetate (FoGA), Payer Presentation, 24 January 2019, p. 52; ID 455-2024, The value of COPAXONE®

(1706) Finally, Teva's presentation also contained the misleading message that risks observed in other glatiramer-related substances equally apply to Synthon GA: {...} (emphasis added).²¹⁹⁹ Teva also points to the health dangers of introducing a competing GA: {...} (emphasis added).²²⁰⁰ Teva also claimed that {...}.²²⁰¹

9.3.2.2.1.3. Payer Objection Handler

(1707) The Payer Objection Handler was structured in a Q&A format and, in one of its first versions (dated 8 December 2016), covered 12 topics including the GATE study, immunogenicity and the use of other glatiramer-related substances outside of the EU. The purpose of the Payer Objection Handler was to provide the Teva Market Access teams with an agreed line of well-structured arguments in reaction to a range of likely questions from Payers.²²⁰² Teva's implementation guide states that: {...}.²²⁰³

(1708) The Payer Objection Handler covered all facets of the Misleading Complexity Message analysed in Section 9.3.1.²²⁰⁴ Teva emphasised clinically irrelevant differences in GA structures to cast doubt on the safety, efficacy and therapeutic equivalence of Synthon GA: {...}.²²⁰⁵ As explained in Section 9.3.1.1.3, Teva's claims had already been examined and rejected by the MEB. Teva then criticised the finding that Synthon GA was safe, efficacious and therapeutically equivalent to Copaxone by suggesting that the differences could be clinically relevant: {...}.²²⁰⁶ By emphasising the experience with GAs not commercialised or approved in the EU, Teva was also implying that risks and difficulties noted with respect to other glatiramer-related substances may equally apply to Synthon GA (contrary to the finding of the health regulatory authorities that the product is safe, efficacious and therapeutically equivalent to Copaxone): {...}.²²⁰⁷ Finally, Teva challenged the validity of the GATE study: {...}.²²⁰⁸

(glatiramer acetate): Considerations when assessing the use of follow on glatiramer acetate (FoGa), Payer Presentation, 8 September 2018, p. 50.

²¹⁹⁷ ID 455-2583, The value of COPAXONE® (glatiramer acetate): Considerations when assessing the use of follow-on glatiramer acetate, Payer Presentation, October 2017, p. 22; ID 264-102, The value of COPAXONE® (glatiramer acetate): Considerations when assessing the use of follow-on glatiramer acetate (FoGa), Payer Presentation, 24 January 2019, p. 52; ID 455-2024, The value of COPAXONE® (glatiramer acetate): Considerations when assessing the use of follow on glatiramer acetate (FoGa), Payer Presentation, 8 September 2018, p. 50.

²¹⁹⁸ ID 264-102, The value of COPAXONE® (glatiramer acetate): Considerations when assessing the use of follow-on glatiramer acetate (FoGA), Payer Presentation, 24 January 2019, p. 51; ID 455-2024, The value of COPAXONE® (glatiramer acetate): Considerations when assessing the use of follow on glatiramer acetate (FoGa), Payer Presentation, 8 September 2018, p. 49.

²¹⁹⁹ ID 455-2583, The value of COPAXONE® (glatiramer acetate): Considerations when assessing the use of follow-on glatiramer acetate, Payer Presentation, October 2017, p. 28.

²²⁰⁰ ID 455-2583, The value of COPAXONE® (glatiramer acetate): Considerations when assessing the use of follow-on glatiramer acetate, Payer Presentation, October 2017, p. 56.

²²⁰¹ ID 455-2583, The value of COPAXONE® (glatiramer acetate): Considerations when assessing the use of follow-on glatiramer acetate, Payer Presentation, October 2017, p. 29.

²²⁰² ID 934-326, ID 934-326, Copaxone and the introduction of FoGA, V5, 8 December 2016, Objection Handler. This is the only version of the Payer Objection Handler available on the Commission's file. See also ID 455-269, CCP strategy, In the face of evolving FoGA competition, p. 24.

²²⁰³ ID 751-328, Copaxone evolved campaign e-detailed implementation guide, 30 June 2017, p. 32.

²²⁰⁴ See e.g. ID 934-326, Copaxone and the introduction of FoGA, V5, 8 December 2016, Objection Handler, pp. 3, 10, 11 and 18.

²²⁰⁵ ID 934-326, Copaxone and the introduction of FoGA, 8 December 2016, Objection Handler, p. 8.

²²⁰⁶ ID 934-326, Copaxone and the introduction of FoGA, 8 December 2016, Objection Handler, pp. 14-15.

²²⁰⁷ ID 934-326, Copaxone and the introduction of FoGA, 8 December 2016, Objection Handler, p. 3.

²²⁰⁸ ID 934-326, Copaxone and the introduction of FoGA, 8 December 2016, Objection Handler, p. 10.

(1709) The document is designed for reactive use (i.e. it was meant to provide preapproved answers to possible questions raised by the Payers). It was supposed to be updated regularly so as to include any new objections raised.²²⁰⁹

9.3.2.2.1.3.1. Teva's claims concerning the Payer Objection Handler

(1710) Teva claims that the Commission's reliance on the Payer Objection Handler from December 2016 fails to show that the Misleading Complexity Message was disseminated over a 7-year period (i.e., from April 2016 to Teva's Reply to the Statement of Objections), and essentially claims that the document would have become obsolete due to the fact that Teva constantly updated such documents.²²¹⁰

(1711) The Commission rejects these arguments as they misconstrue the Commission's conclusions drawn from the Payer Objection Handler. On 18 November 2021, the Commission requested Teva to submit the Payer Objection Handler as initially approved as well as all subsequently approved versions, if any. In its response, Teva only submitted the December 2016 version as "*the latest version*" it was able to retrieve and was distributed internally, and also explained "*for completeness*" that "*a draft version, further updated, was prepared in 2017 but, to the best of Teva's knowledge, not formally approved nor circulated for use internally*".²²¹¹ Therefore, the conclusion the Commission draws is that the 2016 version is the version which could be found on Teva's central repository for use by Teva's employees and management throughout the period of the infringement.

(1712) Moreover, Teva claims that the Payer Objection Handler does not contain the three facets of the Misleading Complexity Message described above.²²¹² This claim is unfounded, for the reasons already explained in Recital (1708). Indeed, by way of further example, the Payer Objection Handler suggests that negative experience with other glatiramer-related substances is also relevant for Synthon GA (pages 3, 6, 14), implies that differences in GA structures between Copaxone and Synthon GA are therapeutically relevant (page 8, 14), and challenges the validity of the GATE study (page 10).²²¹³

9.3.2.2.1.4. External Expert White Papers (specialist and non-specialist versions)

(1713) The External Expert White Papers were designed to present Teva's position on Copaxone and competing GAs to external experts (notably specialist neurologists, including KOLs). Teva planned that the KOLs would use this information in responding to Payers' questions during local competing GA's review in the appropriate way (from Teva's perspective).²²¹⁴ Within Teva they were used by MSL teams.²²¹⁵ The External Expert White Papers were living documents being constantly edited and updated.²²¹⁶

²²⁰⁹ ID 934-326, Copaxone and the introduction of FoGA, V5, 8 December 2016, Objection Handler, p. 4

²²¹⁰ ID 4032, Teva's Reply to the Statement of Objections para. 1138 and footnote 1022.

²²¹¹ ID 1286, Teva's reply to Article 18(2) request of 17 December 2021 and 14 and 28 January 2022, p. 1.

²²¹² ID 4032, Teva's Reply to the Statement of Objections, paras. 1139, 1140, 1141, 1142.

²²¹³ ID 934-326, Copaxone and the introduction of FoGA, V5, 8 December 2016, Objection Handler, pp. 3, 4, 6, 8, 10, 11, 14, 16. See, for example, page 3: {...}. Page 8 - {...} {...}.

²²¹⁴ ID 455-269, CCP strategy, In the face of evolving FoGA competition, p. 25.

²²¹⁵ ID 455-269, CCP strategy, In the face of evolving FoGA competition, p. 18; ID 264-1083, Copaxone Continuation Plan Meeting – Update – (unofficial translation). Original text: {...} – (unofficial translation: {...}).

²²¹⁶ ID 751-163, The Complexity of COPAXONE® and Considerations for Substitution with Follow-on Glatiramer Acetate, October 2018, comments on p. 1 reveal that the document is reviewed and updated ({...}, {...}).

- (1714) The External Expert White Papers were relatively short documents²²¹⁷ but covered all three facets of the Misleading Complexity Message analysed in Section 9.3.1.²²¹⁸ In the External Expert White Papers Teva emphasised clinically irrelevant differences in GA structures and cast doubt on Synthon GA’s safety, efficacy, and therapeutic equivalence with Copaxone: {...} (emphasis added).²²¹⁹ With respect to the highlighted quote, a Teva employee raised concerns that the message may be {...}: {...}.²²²⁰
- (1715) The External Expert White Papers implied that health risks observed in other glatiramer-related substances not commercialised or approved in the EU equally apply to Synthon GA, thus raising issues related to the safety of Synthon GA: Teva also claims that {...}.²²²¹
- (1716) The External Expert White Papers also challenged the validity of the GATE study. Teva claims in the External Expert White Paper that {...}.²²²² Further, under the misleading title: “{...}”, Teva challenged the study methodology: {...}.²²²³ With this claim, Teva challenges the use of MRI lesions as appropriate endpoint for the GATE study. Teva selectively presented information and regularly omitted all scientific and other information confirming that MRI lesions are indeed an appropriate endpoint. Moreover, the MEB rejected these claims for the reasons explained in Recitals

²²¹⁷ Specialist External Expert White Paper consists of five pages including a title page and a literature (ID 455-1421, The Complexity of COPAXONE® and Considerations for Substitution with Follow-on Glatiramer Acetate, Specialist External Expert White Paper, 6 May 2016) while the Non-specialist External Expert White Paper consists of 8 pages including a title page and a literature (ID 455-1425, Considering the value of COPAXONE® in an era of Follow-on Glatiramer Acetate, Non-specialist External Expert White Paper, 6 May 2016).

²²¹⁸ See e.g. ID 455-1421, The Complexity of COPAXONE® and Considerations for Substitution with Follow-on Glatiramer Acetate, Specialist External Expert White Paper, 6 May 2016, pp. 3, 4; ID 455-1425, Considering the value of COPAXONE® in an era of Follow-on Glatiramer Acetate, Non-specialist External Expert White Paper, 6 May 2016, pp. 3, 4; ID 751-163, The Complexity of COPAXONE® and Considerations for Substitution with Follow-on Glatiramer Acetate, October 2018; ID 597-33, The Complexity of COPAXONE® and Considerations for Substitution with Follow-on Glatiramer Acetate 6 May 2016; ID 597-1, Considering the value of COPAXONE® in an era of Follow-on Glatiramer Acetate, 6 May 2016.

²²¹⁹ ID 597-33, The Complexity of COPAXONE® and Considerations for Substitution with Follow-on Glatiramer Acetate, 6 May 2016, p. 3; according to ID 675, this document in ID 597-33 was approved on 5 May 2016, reapproved on 23 March 2018, with the first used on 23 May 2016, and withdrawn on 28 February 2020; ID 597-1, Considering the value of COPAXONE® in an era of Follow-on Glatiramer Acetate, 6 May 2016, p. 3; according to ID 675, the document in ID 597-1 was approved on 5 May 2016, reapproved on 23 March 2018, with the first use on 23 May 2016 and withdrawn on 28 February 2020; for proof that these documents have been approved and uploaded on the vault, see ID 455-1415, email from {...} to {...} and others (Teva). In reply to this email, {...} says: {...}, regarding the final version on the EE White paper, see also ID 597-114, Teva’s reply to Commission Article 18(2) request dated 3 June 2020, p. 10.

²²²⁰ ID 404-332, Considering the value of COPAXONE® in an era of Follow-on Glatiramer Acetate, 8 April 2016, p. 3 comment by {...} 5 April 2016 at 16:49.

²²²¹ ID 597-33, The Complexity of COPAXONE® and Considerations for Substitution with Follow-on Glatiramer Acetate, p. 5; the same type of message can be found in ID 597-1, Considering the value of COPAXONE® in an era of Follow-on Glatiramer Acetate, 6 May 2016, p. 3 - {...}; for proof that these documents have been approved and uploaded on the vault, see ID 455-3145, Teva’s internal email dated 18 May 2016 from {...} to {...}, {...} and others.

²²²² ID 597-1, Considering the value of COPAXONE® in an era of Follow-on Glatiramer Acetate, 6 May 2016, p. 4.

²²²³ ID 597-1, Considering the value of COPAXONE® in an era of Follow-on Glatiramer Acetate, 6 May 2016, p. 4.

(1616) et seq. and the Decentralised Procedure for Synthon GA was successfully completed.²²²⁴

9.3.2.2.1.4.1. Teva's claims concerning the External Expert White Paper

(1717) Teva claims that the External Expert White Paper does not cover the three types of messages.²²²⁵ The Commission rejects these claims.

(1718) First, as mentioned in Recitals (1713), (1714)-(1717) above, the External Expert White Paper covered all the facets of the Misleading Complexity Message analysed in Section 9.3.1.²²²⁶ In any event, for Teva's communications to be considered as containing misleading information, it is not necessary for a document to cumulatively contain all three types of misleading messages as assessed in section 9.3.1. Second, the objective, or at least the potential for the External Expert White Paper to cast doubt on the safety of Synthon GA is obvious from internal comments on the previous draft versions: {...}.²²²⁷

9.3.2.2.1.5. External Expert Presentations

(1719) The External Expert Presentations are slide decks which were intended to be used in communicating with KOLs (specialists) and neurologists (non-specialists). These slides were prepared to complement the External Expert White Papers and therefore repeat the arguments made there (including the Misleading Complexity Message).²²²⁸ For example, in the External Expert Presentation from May 2016, Teva was challenging the validity of the GATE study: Teva challenges the use of MRI lesions as appropriate endpoint, even if this claim had already been rejected by the MEB: {...}.²²²⁹

²²²⁴ See also ID 742-163, Klinisch beoordelingsrapport Glatirameerproducten van Mylan en Synthon, Inzake het besluit van het College ter beoordeling van geneesmiddelen op het bezwaar van Teva, p. 3: {...} was rejected.

²²²⁵ ID 4032, Teva's Reply to the Statement of Objections, paras. 1148, 1149, 1150.

²²²⁶ For example, the External Expert White Paper casts doubt on the safety of Synthon GA and implied that health risks observed in other glatiramer -based substances apply to Synthon GA: {...}. - see ID 597-41, Considering the value of COPAXONE® in an era of Follow-on Glatiramer Acetate, 6 May 2016, p. 3; ID 597-33, "The Complexity of COPAXONE® and Considerations for Substitution with Follow-on Glatiramer Acetate", of 6 May 2016, p. 3 and ID 597-1, "Considering the value of COPAXONE® in an era of Follow-on Glatiramer Acetate", of 6 May 2016, p. 3. Further, the External Expert White Paper also casts doubt on the validity of GATE study: {...} - see ID 751-310, Considering the value of COPAXONE® in an era of Follow-on Glatiramer Acetate, October 2018, p. 4. {...} - see ID 751-310, Considering the value of COPAXONE® in an era of Follow-on Glatiramer Acetate, October 2018, p.4; ID 597-1, Considering the value of COPAXONE® in an era of Follow-on Glatiramer Acetate, 6 May 2016, p. 4

²²²⁷ ID 404-332, Considering the value of COPAXONE® in an era of Follow-on Glatiramer Acetate, 8 April 2016, p. 3 comment by {...} 5 April 2016 at 16:49.

²²²⁸ See e.g. ID 455-1452, The Complexity of COPAXONE® and Considerations for Substitution with Follow-on Glatiramer Acetate, May 2016, p. 9 (according to ID 675, {...} TPE CPX jobs, this document was approved on 5 May 2016, then reapproved on 23 March 2018, with first recorded use on 23 May 2016 and withdrawn on 28 February 2020), ID 263-1364, Considering value of COPAXONE® in an era of Follow-on Glatiramer Acetate, External Expert Presentation, May 2016, pp. 15, 19, 20 (according to ID 675, {...} TPE CPX jobs, this document was approved on 5 May 2016, then reapproved on 23 March 2018, with first recorded use on 23 May 2016 and withdrawn on 28 February 2020).

²²²⁹ ID 455-1401, Considering value of COPAXONE in an era of Follow-on Glatiramer Acetate, May 2016, p. 22; the document in ID 597-42, Considering the value of COPAXONE® in an era of Follow-on Glatiramer Acetate, June 2016, pp. 1, 15, 19-22, contains a similar presentation as the document ID 455-1401 quoted here above. One reviewer ({...}) made comments which shows that Teva was aware

9.3.2.2.1.5.1. Teva's claims concerning the External Expert Presentation

- (1720) As for other CCP materials, Teva claims that the External Expert Presentation does not cover the three facets of the Misleading Complexity Message.²²³⁰
- (1721) The Commission rejects these claims.
- (1722) First, as mentioned in Recital (1719) above, the slides have been prepared to complement the External Expert White Papers and repeat the arguments made there (including the Misleading Complexity Message). These messages have been analysed in Section 9.3.1.²²³¹ For example, Teva makes reference to Copaxone's manufacturing process and mentions that changes to the manufacturing process {...}.²²³² Further, Teva questions the validity of the GATE study by criticising the use of MRI lesions as an appropriate endpoint, stating that EMA recommends something different, even though GATE study was designed taking into account the EMA's advice (see Recital (1594 et seq): {...}).²²³³
- (1723) Second, two Teva employees criticised the content of the presentation, which is intended for KOLs and specialised MS neurologists, as problematic and "tactically sabotaging" Synthon GA: {...}.²²³⁴ This shows that, internally, Teva knew that the presentation is disparaging.

9.3.2.2.1.6. MSL Objection Handler

- (1724) Much like the Payer Objection Handler, the MSL Objection Handler used a Q&A format to provide structured answers to anticipated questions from HCPs related to Synthon GA's entry.²²³⁵ In 12 questions, it covered multiple topics including all three facets of the Misleading Complexity Message: it contained messages emphasising clinically irrelevant differences in GA structures,²²³⁶ implying that risks observed with respect to other glatiramer-related substances equally apply to Synthon GA²²³⁷

of the disparaging nature of the messages included in the presentation: {...}. Another comment made by {...} also points out to the misleading nature of the content: {...}.

²²³⁰ ID 4032, Teva's Reply to the Statement of Objections, paras. 1156, 1157, 1158.

²²³¹ See, for example, ID 455-1452, Considering the value of COPAXONE® in an era of Follow-on Glatiramer Acetate, May 2016. On slide 8, Teva makes reference to the manufacturing process and mentions that changes to the manufacturing process {...}. On slide 9 under the title {...}, Teva makes reference to other glatiramer-related substances. Further, on slide 22 of ID 455-1401, Teva questions the validity of the GATE study by criticising the use of MRI lesions as an appropriate endpoint, stating that EMA recommends something different, even though GATE study was designed with EMA advice (see Recital (1616) et seq): {...} – see ID 455-1401, Considering value of COPAXONE in an era of Follow-on Glatiramer Acetate, p. 22.

²²³² ID 455-1452, "Considering the value of COPAXONE® in an era of Follow-on Glatiramer Acetate", May 2016, p. 8.

²²³³ ID 455-1401, Considering value of COPAXONE in an era of Follow-on Glatiramer Acetate, p. 22.

²²³⁴ ID 597-42, Considering the value of COPAXONE® in an era of Follow-on Glatiramer Acetate, p. 1; one of the Teva's employees comments on the draft presentation, presentation which is the same as ID 455-1401, Considering the value of COPAXONE® in an era of Follow-on Glatiramer Acetate, the version indicated in ID 675 as being used by Teva.

²²³⁵ ID 266-105, COPAXONE® and the introduction of FoGA, Objection handler for MSLs, Version 4, March 2019.

²²³⁶ See e.g. ID 404-1538, COPAXONE® and the introduction of FoGA, Objection handler for MSLs, Version 2, 27 June 2017, p. 17. Two additional questions specific to this issue have been added in the third version of the document: {...} (ID 751-321, COPAXONE® and the introduction of FoGA, Objection handler for MSLs, Version 3, February 2019, pp. 23, 25).

²²³⁷ See e.g. ID 751-327, COPAXONE® and the introduction of FoGA, Objection handler for MSLs, 31 October 2016, pp. 5, 6, 7; ID 266-105, COPAXONE® and the introduction of FoGA, Objection handler for MSLs, Version 4, March 2019, pp. 11, 12; ID 751-321, COPAXONE® and the introduction of FoGA, Objection handler for MSLs, Version 3, February 2019, p. 11.

and questioning the validity of the GATE study and its conclusions,²²³⁸ all with the aim of raising doubts related to the safety and efficacy of Synthron GA and its therapeutic equivalence with Copaxone. For example, Teva claims that {...};²²³⁹ {...};²²⁴⁰ {...};²²⁴¹ {...}.²²⁴² The MSL Objection Handler has been regularly updated but was valid throughout the infringement period.²²⁴³

9.3.2.2.1.6.1. Teva's claims related to the MSL Objection Handler

- (1725) Teva claims that the MSL Objection Handler does not cover the three types of misleading messages.²²⁴⁴
- (1726) The Commission rejects these arguments.
- (1727) As elaborated in Recital (1724) above, the 12 issues from the MSL Objection Handler covered multiple topics including all of the facets of the Misleading Complexity Message. It emphasised clinically irrelevant differences in GA products,²²⁴⁵ it implied that risks observed with respect to specific glatiramoids

²²³⁸ See e.g. ID 404-1538, COPAXONE® and the introduction of FoGA, Objection handler for MSLs, Version 2, 27 June 2017, pp. 5-7, 13-14, 15-17, 19, 20-21 (according to ID 675, {...} TPE CPX jobs, this document was approved on 28 March 2017, reapproved on 27 December 2019, with first recorded use on 4 July 2017. This shows that the document was used and disseminated), ID 751-321, COPAXONE® and the introduction of FoGA, Objection handler for MSLs, Version 3, February 2019, pp. 5, 6, 7, 13, 14, 15, 16, 17, 19, 20, 21; ID 751-327, COPAXONE® and the introduction of FoGA, Objection handler for MSLs, 31 October 2016, pp. 5, 6, 7 (According to ID 675, {...} TPE CPX jobs, this document was approved on 18 October 2016, reapproved on 27 December 2018, with first recorded use on 1 November 2016. This shows that the document was used and disseminated); ID 751-102, COPAXONE® and the introduction of FoGA, Objection handler for MSLs, 27 June 2017, pp. 6, 8, 19 (according to ID 675, {...} TPE CPX jobs, this document was approved on 28 March 2017, reapproved on 27 December 2019, with first recorded use on 4 July 2017. This shows that the document was used and disseminated).

²²³⁹ ID 404-1538, COPAXONE® and the introduction of FoGA, Objection handler for MSLs, Version 2, 27 June 2017, p. 17.

²²⁴⁰ ID 404-1538, COPAXONE® and the introduction of FoGA, Objection handler for MSLs, Version 2, 27 June 2017, p. 6; ID 751-102, COPAXONE® and the introduction of FoGA, Objection handler for MSLs, 27 June 2017, p. 6 (according to ID 675, {...} TPE CPX jobs, this document was approved on 28 March 2017, reapproved on 27 December 2019, with first recorded use on 4 July 2017. This shows that the document was used and disseminated).

²²⁴¹ ID 404-1538, COPAXONE® and the introduction of FoGA, Objection handler for MSLs, 27 June 2017, p. 8; ID 751-102, COPAXONE® and the introduction of FoGA, Objection handler for MSLs, 27 June 2017, p. 8; see also ID 751-327, COPAXONE® and the introduction of FoGA, Objection handler for MSLs, 31 October 2016, p. 6, 7. Teva claims that use of MRI lesions as primary end point in contrast with EMA guidelines: {...}. However, Teva fails to state that the GATE study was designed based on the scientific advice from the EMA -see Recital (1614) of this Decision. And Teva also fails to mention that this claim had been already rejected by the MEB – see ID 742-163, Klinisch beoordelingsrapport Glatirameerproducten van Mylan en Synthron, Inzake het besluit van het College ter beoordeling van geneesmiddelen op het bezwaar van Teva, p. 3 and Recitals (1616) - (1619) of this Decision.

²²⁴² ID 404-1538, COPAXONE® and the introduction of FoGA, Objection handler for MSLs, Version 2, 27 June 2017, p. 19; ID 751-102, COPAXONE® and the introduction of FoGA, Objection handler for MSLs, 27 June 2017, p. 19; ID 751-327, COPAXONE® and the introduction of FoGA, Objection handler for MSLs, 31 October 2016, p. 5.

²²⁴³ ID 266-105, COPAXONE® and the introduction of FoGA, Objection handler for MSLs, Version 4, March 2019 which starts with a note: {...}.

²²⁴⁴ ID 4032, Teva's Reply to the Statement of Objections, paras. 1165, 1166, 1167.

²²⁴⁵ See e.g. ID 404-1538, COPAXONE® and the introduction of FoGA, Objection handler for MSLs, Version 2, 27 June 2017, p. 17. Two additional questions specific to this issue have been added in the third version of the document: {...} and {...} (ID 751-321, COPAXONE® and the introduction of FoGA, Objection handler for MSLs, Version 3, February 2019, pp. 23, 25).

equally apply to any competing GA (including Synthon GA)²²⁴⁶ and questioned the validity of the GATE trial and its conclusions,²²⁴⁷ all with the aim of raising doubts related to the safety and efficacy of competing GA, and specifically Synthon GA and its therapeutic equivalence with Copaxone.

(1728) These messages, which have been analysed in subchapter 9.3.1, seek to instil doubt as to Synthon GA's safety, efficacy and its therapeutic equivalence with Copaxone.

9.3.2.2.1.7. GATE Study Review

(1729) This document was exclusively devoted to discussing and criticising the GATE study. It therefore focused on only one facet of the Misleading Complexity Message by examining the design of the GATE study and its results, emphasising its alleged limitations.²²⁴⁸ It was used by the MSL team in their communications with HCPs.²²⁴⁹

9.3.2.2.1.7.1. Teva's claims concerning the GATE Study Review

(1730) Teva confirms that the GATE Study Review criticises the GATE study's "*purported secondary endpoint findings which cast doubts on the safety and efficacy of Copaxone*", but also claims that the GATE Study Review does not call into question or cast doubts over the decision to grant MA approval to Synthon GA, or its therapeutic equivalence with Copaxone.²²⁵⁰

(1731) The Commission rejects these arguments, which build on Teva's allegation that the secondary endpoint results (Annual Relapse Rate, or ARR) of the GATE study are inconsistent with studies concerning Copaxone.

(1732) First, the purpose of the GATE study was not to demonstrate the efficacy of Copaxone. Teva had raised the same argument to the MEB which retorted that {...}.²²⁵¹ Therefore, the alleged inconsistency cannot be used to support Teva's claims that the GATE study suffered from limitations, casting doubt as to the study's validity as the scientific basis for the grant of MA to Synthon GA, and instilling doubt as to Synthon GA's safety, efficacy and therapeutic equivalence with Copaxone (as assessed in Section 9.3.1.3).

(1733) Second, the GATE Study Review contains the following conclusions: {...}.²²⁵²

(1734) By using the adverb "*however*" in the last bullet of its conclusions, Teva implies that the alleged limitations were somehow at tension with the GATE study's objective to establish therapeutic equivalence between Synthon GA ("FoGA") and Copaxone ("GA"). Suggesting that there are limitations to the clinical study meant to show Synthon GA's safety and efficacy, means implying there are limitations to the safety and efficacy of Synthon GA and its therapeutic equivalence with Copaxone.

²²⁴⁶ See e.g. ID 751-327, COPAXONE® and the introduction of FoGA, Objection handler for MSLs, 31 October 2016, pp. 5, 6, 7; ID 266-105, COPAXONE® and the introduction of FoGA, Objection handler for MSLs, Version 4, March 2019, pp. 11, 12.

²²⁴⁷ See e.g. ID 404-1538, COPAXONE® and the introduction of FoGA, Objection handler for MSLs, Version 2, 27 June 2017, pp. 5-7, 13-14, 15-17, 19, 20-21.

²²⁴⁸ ID 455-1427, Equivalence of Follow-On Glatiramer Acetate in Multiple Sclerosis, A Randomized Clinical Trial, Review of the GATE study, pp. 4, 6.

²²⁴⁹ ID 455-269, CCP strategy, In the face of evolving FoGA competition, p. 18; ID 4919-25, Complexity of Copaxone, 18 August 2016; ID 4897, List of documents registered on Teva's {...}.

²²⁵⁰ ID 4032, Teva's Reply to the Statement of Objections, para 1171, 1172.

²²⁵¹ ID 742-163, Klinisch beoordelingsrapport Glatirameerproducten van Mylan en Synthon, p. 4.

²²⁵² ID 915, Equivalence of Follow-on glatiramer acetate in multiple sclerosis – a randomized clinical trial, Review of the GATE study

(1735) Third, a document prepared by specialised consultancy {...} entitled “HealthTactic Brief” suggests that the purpose of the GATE Study Review document was to influence prescriptions by neurologists by drawing their attention to the alleged limitations of the GATE study: {...} (emphasis added).²²⁵³ This said, the document contains no reference to the fact that the alleged limitations had already been rejected as irrelevant by the competent authority, the MEB.

9.3.2.2.1.8. Complexity Leavepiece

(1736) The Complexity Leavepiece is a short leavepiece that in a succinct and simple way outlines the main elements of Teva’s Misleading Complexity Message.²²⁵⁴ It has been prepared for use by KAMs in sales calls and has been consistently updated. Its goal is to raise awareness among HCPs of the allegedly unique nature of Copaxone.²²⁵⁵

9.3.2.2.1.8.1. Teva’s claims concerning the Complexity Leavepiece

(1737) Teva claims that the Complexity Leavepiece does not contain misleading messages as it does not refer to Synthon GA, other glatiramer-related substances or the GATE study, and is in any event aligned with Teva’s messaging concerning automatic substitution.²²⁵⁶

(1738) Teva’s claims do not convince. First, while it is correct that the document does not explicitly refer to Synthon GA, its purpose is precisely the same as that of other centrally created CCP materials – to influence the doctors’ perception of Synthon GA so as not to prescribe Synthon GA. Second, in line with other centrally created CCP materials, the Complexity Leavepiece emphasises that manufacturing differences (due to Teva’s proprietary processes) could {...}.²²⁵⁷ Without naming Synthon GA (which was targeted by Teva’s CCP campaign),²²⁵⁸ this message not only implies that there may be compositional differences between Copaxone and Synthon GA, but also that such differences may change the way how the medicine works in patients ({...}).²²⁵⁹ In other words, Teva contradicts the findings of competent authorities that Copaxone and Synthon GA are therapeutically equivalent. The fact that the implicit target of the Complexity Leavepiece is Synthon GA is reflected from the title {...}²²⁶⁰ which insinuates that no other alternatives are acceptable, Synthon GA being the only GA other than Copaxone authorised in the EU.

²²⁵³ ID 455-2896, {...}, Tactic Brief, 17 March 2016.

²²⁵⁴ ID 455-590, Take a Closer Look at Copaxone, May 2016, pp. 2, 3; ID 751-427, Take a Closer Look at Copaxone, October 2018, p. 4, 5. For a version of the Complexity Leavepiece adapted to specific local conditions see e.g. a version prepared in the Netherlands following an opinion of Dutch Pharmacists Organisation against the automatic substitution of GA medicines (ID 262-1785, see also Section 9.4.4.5.1).

²²⁵⁵ ID 455-269, CCP strategy, In the face of evolving FoGA competition, p. 18.

²²⁵⁶ ID 4032, Teva’s Reply to the Statement of Objections, paras. 1175-1177, ID 5695, Teva’s Reply to the Letter of Facts I of 9 February 2024, para. 370.

²²⁵⁷ ID 455-590, Take a Closer Look at Copaxone, May 2016, p. 2.

²²⁵⁸ See Section 5.2.

²²⁵⁹ ID 455-590, Take a Closer Look at Copaxone, May 2016, p. 5.

²²⁶⁰ ID 455-590, Take a Closer Look at Copaxone, May 2016, p. 2.

9.3.2.2.2. Centrally created CCP materials were transmitted to Teva's local staff for communication to stakeholders

- (1739) This Section describes how Teva's centrally created CCP materials were transmitted to its local KAM, MSL and Market Access teams for communication with stakeholders.
- (1740) The centrally created documents were uploaded in Teva's database and the teams could access them at any time; these documents were checked, approved internally by various layers of legal and regulatory checks and were updated regularly,²²⁶¹ so as to take into account new market developments. All of these documents had to be "localised" (i.e. adapted and approved for use in individual Member States)²²⁶² and the users had to track how well the materials were working so that they could be updated and improved.²²⁶³
- (1741) The competent teams used the centrally created documents either to prepare their local mirror versions or to rely on them, including on the Misleading Complexity Message formulated in them, to communicate with their local targeted addressees – Payers and HCPs. This dissemination took various forms, which are described in more detail in Section 9.4.2. In addition, Teva used the CCP documents for internal trainings organized for the members of the KAM and MSL teams. These trainings included even those CCP materials which were designed for communication with the Payers and therefore not primarily allocated for use by KAMs (such as the Payer White Paper). KAMs and MSLs were therefore acquainted with the formulations of the Misleading Complexity Message contained in such documents for Payers and could rely on these formulations in their communication with the HCPs.²²⁶⁴
- (1742) Teva argues that the Commission should not assume that the CCP materials were used at local level and that "[l]ocal teams [were] entirely autonomous in that regard: they [could], and often [did], decide not to use certain materials because they [considered] that their content was not relevant or adequate for their local situation (for instance, the Payer White Paper was not used by local teams)".²²⁶⁵ Teva also claims that the local teams were free to make even significant changes to the documents.
- (1743) However, these observations contradict the evidence on the Commission's file.
- (1744) First, as noted above (Recitals (1678), (1745)-(1746), Figure 42) all of the CCP materials have been internally classified by Teva as available and ready to use. In addition, the necessary localisation of the documents was centrally steered and

²²⁶¹ ID 455-2056, Teva internal email dated 27 June 2017 from {...} to Market Access Leadership Team Contacts and others - {...}; ID 265-1322, Teva internal email dated 15 December 2016 from {...} to Market Access Primary Contacts and others - {...}; ID 455-452, Teva internal email dated 4 October 2017 from {...} to {...} and others - {...}; ID 455-1415, Teva internal email dated 18 May 2016 from {...} to {...} and others, and related thread - {...}; ID 265-2149, Teva email dated 12 July 2019 from {...} to {...}, this email chain was further distributed to Teva MS team and Copaxone Country contacts - a Teva meeting report shows that the {...} and that a Teva employee was supposed {...}”.

²²⁶² See e.g. ID 404-2597, Copaxone FoGA Checklist – Action Plan GA 2017-2018 for the Netherlands referring to, *inter alia*, updates to the Payer White Paper and the Payer Slide Presentation and “localisation” of the Payer White Paper, Slide Presentation and Objection Handler; see also Recitals (1947), (1983).

²²⁶³ ID 455-269, CCP strategy, In the face of evolving FoGA competition, pp. 9 and 11.

²²⁶⁴ See e.g. ID 455-297, email dated 26 January 2016 from {...} to Market Access Primary Contacts and others circulating the agenda for an internal training with several topics on the Payer White Paper. According to the email, the objective of the training was {...} (emphasis added).

²²⁶⁵ ID 2228, Teva's reply to Article 18(2) Request of 13 July 2022, pp. 12-13.

controlled²²⁶⁶ and not left to the complete discretion of the local teams as Teva now claims.

- (1745) Second, the Commission’s assessment of the available evidence unequivocally confirms that the documents have been “used” by local teams and that messages formulated in the centrally created and approved CCP materials found their way to the intended addresses in the Relevant Member States (see Section 9.4.4). For example, with respect to the Payer White Paper (for which Teva now expressly claims that it “*was not used by the local teams*” the contemporary evidence on the Commission’s file confirms that for example (i) it has been translated to Italian for use before Italian Payers²²⁶⁷ or that (ii) the wording of the Misleading Complexity Message in a letter from Teva to the Polish Ministry of Health of 24 October 2016 corresponds, word for word, to the relevant parts of the Payer White Paper.²²⁶⁸ Similarly, a presentation prepared for the Belgian Federal Agency for Medicines and Health Products²²⁶⁹ is based on (both in terms of the overall content and in terms of wording of the arguments) on the Payer Slide Presentation.²²⁷⁰
- (1746) The following evidence further shows that centrally created CCP materials were meant for communication with stakeholders in one form or another:
- (a) an internal email from the {...} to a number of Teva MSL and Market Access staff, attaching links to white papers and slide decks (“scientific” and “non-scientific”) shows that the centrally created documents were meant for direct communication with stakeholders: {...}.²²⁷¹ The materials concerned were: {...}.²²⁷²
 - (b) another email confirms that MSL staff in Teva’s national (“local”) subsidiaries was meant to use and easily access centrally prepared materials from TPE: “{...} [{...}] {...},²²⁷³ {...}.²²⁷⁴
 - (c) centrally created documents were updated and used to train Teva’s Market Access local staff to disseminate Teva’s arguments concerning Synthon GA to Payers: {...}²²⁷⁵; {...}.²²⁷⁶ {...}.²²⁷⁷

²²⁶⁶ See e.g. ID 263-52, CCP FoGA Action Plan, Phase IIB materials development and roll out, p. 10 referring to a special {...} developed to {...}.

²²⁶⁷ ID 934-114, Valutazione del valore di COPAXONE® rispetto alla versione di seconda generazione di glatiramer acetate Libro bianco per i sistemi sanitari e gli enti finanziatori, 18 novembre 2016. For indication that the White Paper was translated to German as well see ID 264-1709, Copaxone Continuation Plan Gantt Chart. See also ID 264-180, Die Komplexität von COPAXNONE, 28 January 2016 and ID 264-1083, Copaxone Continuation Plan – Deutschland.

²²⁶⁸ See Recitals (2076)-(2077).

²²⁶⁹ ID 455-2433, Substitution considerations for follow on glatiramer acetate products Meeting with Federal Agency for Medicines & Health Products Brussels, 23 January 2017.

²²⁷⁰ See Recitals (1699)-(1701). For an instruction to use the KAM Objection Handler as stored on Teva’s repository in Italy see ID 404-2551, Teva internal email dated 19 April 2017 from {...} to {...} and others.

²²⁷¹ ID 455-3145, Teva internal email dated 9 May 2016 from {...} to {...}, {...} and others.

²²⁷² ID 455-3145, Teva internal email dated 9 May 2016 from {...} to {...}, {...} and others.

²²⁷³ ID 455-2597, Teva internal email dated 17 February 2017 from {...} to {...} and others.

²²⁷⁴ ID 263-1378, Understanding the COPAXONE CONTINUATION PROJECT (CCP), p. 13.

²²⁷⁵ ID 455-333, Teva internal email dated 29 January 2016 from {...} to Market Access Primary Contacts and others; see also ID 265-1322, Teva internal email 15 December 2016 from {...} to Market Access Primary Contacts and others.

²²⁷⁶ ID 265-1322, Teva internal email dated 15 December 2016 from {...} to Market Access Primary Contacts and others.

- (d) internal correspondence shows that the External Expert White paper (for “non-specialists”) was used as an internal briefing document to train them to pass on Teva’s messages concerning Copaxone and Synthon GA: {...}.”²²⁷⁸ This document shows that even if the document as such was not shared with HCPs, its purpose was to prepare KAMs on how to discuss these topics with HCPs and that the messages included in the document were meant to be passed on to HCPs.

9.3.2.3. Teva’s other arguments and the Commission’s assessment

- (1747) This section analyses Teva’s claims contesting the Commission’s finding that the Misleading Complexity Message included in the various centrally created materials were effectively disseminated.
- (1748) First, Teva claims that the Commission has adduced no or insufficient evidence to prove that Teva actually used these documents for external communications. Teva also claims that the evidence the Commission used for the internal documents dated from 2017 or earlier which actually suggests that Teva’s centrally created documents described above were not used on an ongoing basis within the Relevant Member States.²²⁷⁹ Teva claims that the purportedly misleading messages were only included in documents for internal use and not disseminated outside Teva.²²⁸⁰
- (1749) The Commission rejects these claims.
- (1750) In the first place, in relation to the centrally created documents, Sections 9.3.2.2.1 and 9.3.2.2.2 demonstrates that Teva’s centrally created documents encompassed those that were meant to be directly handed over to the persons outside Teva or used as a template for direct communication (Payer Slide Presentation, External Expert White Papers, External Expert Presentation and Complexity Leavepiece) and those that were meant to enforce capability of Teva’s teams to {...}²²⁸¹ without necessarily being handed over to the stakeholders outside Teva (Payer White Paper, Payer Objection Handler, MSL Objection Handler and GATE Study Review). However, even when the documents may have been internal in the sense that they were not meant to be handed out as such to individuals outside the company, they took a central role in communication, since, for example, they were used to train sales, medical and market access staff on the messages to be communicated, or to be actually shown or displayed during meetings or events, or provided answers for Teva’s teams on questions that might come their way. This is clearly confirmed by Teva’s strategic documents on the tactics of Teva’s campaign, which portray such documents as serving for external use, with different target audiences (HCPs, Payers, KOLs) despite the “for internal use only” marks on the documents themselves (see Figure 42).²²⁸² The local sales and medical representatives used the centrally created

²²⁷⁷ ID 455-2056, Teva internal email dated 27 June 2017 from {...} to Market Access Leadership Team Contacts and others; on information regarding updated versions of the centrally created papers see also ID 265-1322, Teva internal email dated 15 December 2016 from {...} to Market Access Primary Contacts and others; ID 455-452, Teva internal email dated 4 October 2017 from {...} to {...} and others.

²²⁷⁸ ID 751-279, Considering the value of COPAXONE® in an era of Follow-on Glatiramer Acetate, October 2018, p. 1.

²²⁷⁹ ID 4032, Teva’s Reply to the Statement of Objections, paras. 999(c), 1101, 1129; ID 5695, Teva’s Reply to the Letter of Facts I of 9 February 2024, paras. 346-352.

²²⁸⁰ ID 4032, Teva’s Reply to the Statement of Objections, paras. 1054, 1129, 1145, 1152, 1153, 1161.

²²⁸¹ ID 455-297, email dated 26 January 2016 from {...} to Market Access Primary Contacts and others circulating the agenda for an internal training with several topics on the Payer White Paper.

²²⁸² See, for example, Recital (1750).

documents either for training, to prepare their local mirror versions or to directly rely on them to communicate the messages in those documents to their local targeted addressees – Payers and HCPs.²²⁸³

- (1751) In the second place, the Commission provides detailed evidence in Section 9.4 that the messages contained in those documents have been transmitted to the respective recipients. The first versions of these internal documents were finalised in anticipation of the successful completion of the Decentralised Procedure for Synthon GA. These documents contained essentially the same messages that Teva communicated as part of their earlier campaign to influence the competent authorities not to grant the MA, and which were rejected by these authorities.²²⁸⁴ Without any appreciable changes even after the Decentralised Procedure for Synthon GA was successfully completed and Synthon GA's safety, efficacy, and therapeutic equivalence were confirmed by the competent authorities, these messages continued to be used by Teva, in order to cast doubt on these features, in contradiction with the competent authorities' findings. Teva's criticism of Synthon GA went far beyond merely criticising automatic substitution and questioned its essential characteristics on the basis of which it was authorised by the MEB. Further, Section 9.4.4 describes in detail their dissemination within the Relevant Member States. Teva's internal document which is an extract from the {...} database shows that these centrally created documents were in use until at least until 2020.²²⁸⁵

²²⁸³ See e.g. ID 404-2597, Copaxone FoGA Checklist – Action Plan GA 2017-2018 for the Netherlands referring to, *inter alia*, updates to the Payer White Paper and the Payer Slide Presentation and “localisation” of the Payer White Paper, Slide Presentation and Objection Handler; see also Recitals (1947), (1983); see also ID 455-333, Teva internal email dated 29 January 2016 from {...} to Market Access Primary Contacts and others; see also ID 265-1322, Teva internal email dated 15 December 2016 from {...} to Market Access Primary Contacts and others; ID 455-452, Teva internal email dated 4 October 2017 from {...} to {...} and others; ID 455-3145, Teva internal email dated 9 May 2016 from {...} to {...}, {...} and other; ID 404-943, Camelion action plan FoGa, 9 March 2016 – before the successful conclusion of the Decentralised Procedure for Synthon GA, Teva carefully prepares its campaign which included visits with health insurance funds to disseminate {...} which were based on {...}.

²²⁸⁴ See Recital (1439) and footnote 1802.

²²⁸⁵ ID 675, {...} TPE CPX jobs; {...} is an approval platform, designed to serve as a central repository for materials that have been approved by medical, commercial and/or legal teams (as applicable, see ID 918, Teva's reply to Article 18(2) request of 3 June 2020, p. 1). The information in the {...} database demonstrates that the CCP materials created centrally and adapted for the needs of local teams in the Relevant Member States (as referred to in Sections 9.3 and 9.4) have been used by Teva to disseminate the messages contained in these documents. Teva submitted extracts from the {...} database under the form of an excel sheet which contains information for each of the approved Teva documents (ID 4897, Teva's reply to Article 18(2) Request of 20 July 2023, extract from {...} database; ID 675, {...} TPE CPX jobs). The extract from the {...} database includes a number of data points for each of the documents, notably: the start date, the archive date, expiration date, reapproval date, cancellation date, withdrawal date, approval start date, circulation date, actual first use date, approval deadline, certification date, status, mode of dissemination, objective, planned first use date, and target audience. In response to the Commission request to explain the fields from the {...} database entitled: {...} and {...} (see ID 5187, email dated 27 October 2023 from the Commission's case team to Teva's external counsel, Teva indicated that the field {...} was {...}. Teva also explained that {...}. However, this reasoning cannot be reconciled with the fact that these {...} extracts also include dedicated data fields specifically recording the very dates of approval or reapproval. Therefore, the Commission considers that a recorded {...} indicates that the relevant document was indeed used for communication with its target audience as of the recorded date in a Relevant Member State. The documents uploaded to {...} were accessible at any time to Teva's employees and were used for direct communication or were the basis of communication with Payers and HCPs.

- (1752) Second, Teva claims that the KAM Objection Handler and MSL Objection Handler contain a list of “do’s and don’ts” which explicitly rules out the prospect that Teva implemented a strategy to cast doubt over the safety and efficacy of Synthron GA.²²⁸⁶ The Commission rejects this argument. The evidence set out in Sections 9.3.1, 9.3.2 and 9.4.4 contain abundant evidence that Teva’s messages sought precisely to cast doubt on safety and efficacy of Synthron GA and its therapeutic equivalence with Copaxone, and portray it in an ambiguous and derogatory manner. The mere existence of compliance instructions which are not implemented and respected does not exonerate Teva from its responsibility. Even if this were to be taken as an indication of Teva’s intent to compete on the merits (*quod non*), the Union Courts have highlighted that a dominant undertaking’s intention to compete on the merits, even if established, is not sufficient to prove the absence of an abuse.²²⁸⁷
- (1753) Third, Teva claims that the Commission did not show that Teva disseminated the misleading messages in the Relevant Member States because Teva’s “local” teams had allegedly considerable autonomy in national markets.²²⁸⁸ The Commission rejects this argument. In Section 9.3.2.2.2 the Decision explains in general terms how the centrally created CCP documents were adapted for use in national markets, and in section 9.4.4, the Commission demonstrates how Teva actually used these materials in each of the Relevant Member States (Belgium 9.4.4.2.; Italy 9.4.4.3.; Germany 9.4.4.4.; Netherlands 9.4.4.5.; Czechia 9.4.4.6.; Poland 9.4.4.7.; Spain 9.4.4.8). Further, in relation to the autonomy of local teams, the Commission recalls Teva’s strict instruction that {...}.²²⁸⁹
- (1754) Fifth, Teva claims that Section 9.3.2.2 relies on a small handful of quotes as evidence of abusive conduct without considering the overall message of Teva’s centrally created documents and its context, which are allegedly essential to understand whether the communication in question is (a) inaccurate or incomplete, and (b) likely to mislead or capable of misleading).²²⁹⁰
- (1755) The Commission rejects these arguments. In the first place, the entire Section 9.3.2 focuses on showing that Teva designed mechanisms, including, especially, centrally created CCP documents and workflows, to systematically formulate and disseminate the Misleading Complexity Message in its different forms and expressions. Amongst others, it shows that all the key materials identified in the Teva table summarising its CCP tactics (see Figure 42 above) contained all or at least some of facets of the Misleading Complexity Message, as assessed in Section 9.3.1. In the second place, the context in which particular statements comprising the Misleading Complexity Message are made is indeed taken into account in the assessment in Section 9.3.1. As a notable example, messages were assessed in light of the scientific or regulatory issues they were related to. This led to certain messages, for example those strictly limited to the question of automatic substitution, not being legally qualified as misleading for the purposes of this Decision. Conversely, the fact that Teva disseminated messages instilling doubt as to settled broader issues (i.e. Synthron GA’s safety, efficacy, and therapeutic equivalence with Copaxone) in the context of its commercial goal to protect its sales by avoiding automatic substitution does not

²²⁸⁶ ID 4032, Teva’s Reply to the Statement of Objections, paras. 1028, 1164, 1183

²²⁸⁷ Case C-549/10 P, *Tomra and Others v Commission*, paragraph 22.

²²⁸⁸ ID 4032, Teva’s Reply to the Statement of Objections, para. 999 d).

²²⁸⁹ ID 263-63, Copaxone Strategy, p. 2; ID 455-269, CCP Strategy, p. 2; ID 455-1377, CCP Strategy, 24 May 2018. See also Recitals (1745)-(1746) and Section 9.3.2.2.2.

²²⁹⁰ ID 4032, Teva’s Reply to the Statement of Objections, para. 1114.

exonerate Teva's conduct. It also follows that it is not necessary to show that the entire Teva document is misleading, but to show that the document in question included misleading messages (i.e. the Complexity Message, as defined above in Recital (1429)).

- (1756) Sixth, Teva claims that the Commission partially or selectively quotes statements from Teva's centrally created CCP documents, altering their meaning and thereby creating the impression that they are misleading. According to Teva, reviewing the relevant statements in full (even without the full context of the document in question) shows that they allegedly focus on automatic substitution and are not misleading.²²⁹¹
- (1757) The Commission rejects these arguments. Teva does not provide any reference to support its statement that the Commission's analysis has altered the meaning of Teva's statements in the CCP documents and created the impression that they are misleading. Further, as explained in the previous paragraph (see also Sections 9.3.1.1.3 and 9.2.3.5), as the Misleading Complexity Message concerns settled features of Synthon GA – notably safety, efficacy and its therapeutic equivalence with Copaxone – it is misleading irrespective of the specific commercial context in which Teva was using it, or the fact that the Misleading Complexity Message may also be accompanied by non-misleading messages.
- (1758) Seventh, Teva claims that the Commission inappropriately cites comments to Teva from {...} suggesting that certain statements {...} to allege that Teva knew its messaging was misleading. It is allegedly illegitimate for the Commission to portray the views of a third party communications agency as objective truth and as evidence that Teva was aware of the misleading nature of its communications.²²⁹²
- (1759) The Commission disagrees with Teva's claims. In the first place, neither the Statement of Objections nor this Decision portrays the views of {...} as an objective truth. However, the Commission objectively assessed {...}'s views as to their evidentiary value. It follows that {...}'s assessment provides credible evidence as to the nature of Teva's statements, especially considering that {...} were specialised external consultants tasked with critically reviewing Teva's promotional materials in view of rules governing advertising for pharmaceuticals, amongst others. {...}'s views as expressed to Teva constitute relevant evidence to corroborate the Commission's own assessment, because they come from a source with experience of the market and the applicable legislation. In the second place, while {...}'s views as expressed to Teva may not be attributable to Teva, they do constitute evidence that Teva had been made aware of the problematic character of its messages.
- (1760) Eighth, Teva's claims that the various CCP materials do not contain the Misleading Complexity Message was addressed in turn for each specific document type. The Commission reiterates that it is not necessary that all three facets of the Misleading Complexity Message are cumulatively present in a document for the communication to be considered as containing misleading messages.

9.3.3. Conclusion

- (1761) In the preceding Sections the Commission established that the Complexity Message was misleading as it included incorrect and/or incomplete information capable of confusing Payers and HCPs (including by inducing them into error) in relation to

²²⁹¹ ID 4032, Teva's Reply to the Statement of Objections, para. 1115; same claims are made in ID 5695, Teva's Reply to the Letter of Facts I of 9 February 2024, paras. 353-355.

²²⁹² ID 4032, Teva's Reply to the Statement of Objections, para. 1119.

Synthon GA's safety, efficacy and therapeutic equivalence to Copaxone and that it was capable of discrediting Synthon GA in the eyes of Payers and HCPs (Section 9.3.1). In addition, the Commission established that Teva had relied on dedicated teams of its staff and a range of targeted materials to communicate the Misleading Complexity Message to its intended addressees (Section 9.3.2). On this basis, the Commission concludes that the Complexity Message was objectively misleading and capable of discrediting Synthon GA. Teva's dissemination of the Misleading Complexity Message did not constitute competition on the merits.²²⁹³

9.4. Teva's Misleading Complexity Message was capable of producing exclusionary effects on the GA markets

(1762) As shown above in Section 9.3. Teva disseminated the Misleading Complexity Message to reduce the competitive pressure from Synthon GA, thereby deviating from competition on the merits. In the following sections, the Commission demonstrates that Teva's conduct was capable of producing exclusionary effects by showing that (i) the addressees of the Misleading Complexity Message – Payers and HCPs – are key drivers of demand on the pharmaceutical markets (Section 9.4.1); (ii) Teva's Misleading Complexity Message was carefully chosen to affect their decision making process (Section 9.4.2); and (iii) Teva relied on its privileged market position as the incumbent supplier of the key originator medicine during its CCP campaign (Section 9.4.3). Finally, the Commission demonstrates how Teva disseminated the Misleading Complexity Message in the Relevant Member States (Section 9.4.4).

9.4.1. Teva targeted Payers and HCPs as key drivers of demand for GA products

(1763) Teva's CCP campaign specifically targeted Payers and HCPs, which are the main drivers of demand, and thus sought to obtain the broadest possible impact from its communication campaign in which it disseminated the Misleading Complexity Message. Teva's objective was to delay and/or hinder competition from Synthon GA by way of instilling doubts as to the safety and efficacy of Synthon GA as well as its therapeutic equivalence with Copaxone, in contradiction with the findings of the competent authorities.

(1764) Teva's strategy was {...} ({...})²²⁹⁴ {...}.²²⁹⁵ {...}; {...}.²²⁹⁶ A Teva internal email containing Teva meeting notes show that in relation to the "Complexity", Teva considered important to pass the message that there is reduced efficacy/tolerability, this going against the results of the Decentralised Procedure: {...}.²²⁹⁷

(1765) By differentiating its dissemination activities both by the stage of competition with Synthon GA, and by the type of stakeholder addressed (see Section 9.3.2.1), Teva was able to optimise its outreach by focussing on actions and stakeholders which would have the most impact on demand in a given period and local situation. By disseminating the Misleading Complexity Message, Teva was striving to discourage

²²⁹³ See in relation to the concept of competition on the merits, Case C-377/20, *Servizio Elettrico Nazionale and Others*, not yet published, paragraphs 68 and 73.

²²⁹⁴ MSP = List price.

²²⁹⁵ ID 404-2581, email dated 14 June 2016, from {...} to Market Access Primary Contacts and others; ID 455-2301, COPAXONE® Continuation Project (CCP) – Pricing & Market Access Follow-on Glatiramer Acetate (FoGA) TRAINING, 3-4 February 2016, pp. 16, 17; ID 404-1316, Pricing and Market Access update with Copaxone Continuation Project (CCP), 21 March 2017.

²²⁹⁶ ID 266-117, Price competition workshop – Copaxone&Lonquex, 20-21 June 2017, p.1; See also ID 455-1982, Price competition workshop – Copaxone&Lonquex, 20-21 June 2017, p. 1.

²²⁹⁷ ID 265-2149, Teva internal email dated 12 July 2019 from {...} to {...}, this email chain was further distributed to Teva MS team and Copaxone Country contacts.

Payers from taking measures favouring price competition between Copaxone and Synthon GA (automatic substitution, clustering, tendering) (Section 9.4.1.1), and to convince HCPs to avoid prescribing and using Synthon GA for individual patients (Section 9.4.1.2). Further, Teva also tried to influence the market indirectly, by extensively using seemingly independent statements authored by KOLs to impact Payers and HCPs alike²²⁹⁸ (Section 9.4.1.3). Teva was thus seeking to protect from competition both sources of Copaxone prescriptions – treatment-naïve patients (new prescriptions by HCPs) and existing patients (product switching by HCPs, rules on automatic substitution by Payers).

9.4.1.1. Teva targeted Payers to influence demand for Synthon GA on a systemic level

- (1766) As explained above in Section 4.3, the notion of Payers in this Decision refers to health insurance companies, procurement bodies, such as hospitals and tender authorities, and Member State authorities, including bodies that can decide on, or significantly influence, various pricing or reimbursement parameters and can thus shape the demand for off-patent products such as GA on a systemic level. Their decision can impact demand either for the entire national market (for example in Italy, AIFA is the national authority involved in deciding on the substitution status at national level, i.e. whether Synthon GA can be dispensed by the pharmacists even where the prescription specifically indicates Copaxone), at regional level (e.g. tenders organised by regions in Italy and Spain) or at the level of individual healthcare organisations such as health insurance funds and hospitals.
- (1767) This Section (i) identifies Payers and their various roles, (ii) explains why Payers are a key driver of demand (alongside HCPs), and (iii) explains that Teva’s actions were implemented at national, as well as regional and local level, and sought to cover most of the relevant Payers.
- (1768) First, Payers include all actors that are in a position to influence or decide on pricing and reimbursement policies (including the substitution regime) for Copaxone and Synthon GA.
- (1769) The term Payers corresponds to the definition that Teva assigns to “payers” or “payors”²²⁹⁹ in its internal documents, which encompasses all stakeholders involved in the pricing and reimbursement process as well as those that have a role of negotiating prices or that pay or insure health care expenses. For example, in an internal document, Teva drew a non-exhaustive list of Payers in Spain. It included the Ministry of Health, the Directorate General for Pharmacy and Health Care Products (Dirección General de Farmacia y Productos Sanitarios), the National Commission for the Rational Use of Medicines (Comisión Nacional del Uso Racional de los Medicamentos), the Interministerial Price Commission for medicines (Comisión Interministerial de Precios de Medicamentos) and the health services of Spanish regions (Comunidades Autónomas).²³⁰⁰
- (1770) As a result, depending on the Member State, Payers include organisations that pay or insure health care expenses for beneficiaries, sickness funds, health and technology assessment bodies, medicine agencies, the ministry of health, hospitals, tendering

²²⁹⁸ ID 455-269, CCP strategy – In face of evolving FoGA competition, p. 25.

²²⁹⁹ A synonym for “payer” commonly used in the healthcare sector.

²³⁰⁰ ID 265-812, PVT – Ajoy meeting, 23 September 2019.

authorities and the various other bodies that may be involved in the drug pricing and reimbursement process.²³⁰¹

(1771) Second, Payers decide on key mechanisms capable of introducing price competition for Copaxone and Synthon GA at a more aggregate, systemic level, and were therefore methodically targeted by different, complementary actions by Teva.

(1772) In the first place, Payers have complementary competences with respect to shaping the demand for off-patent products such as GA. This may include determining rules on automatic substitution, setting maximum reimbursement thresholds, negotiating medicines prices, setting up reference groups (clustering) of medicines, stimulating price competition through tenders, and others. Teva's CCP strategy targeted in particular bodies in charge of clustering, automatic substitution status and tenders:

(a) **Price reference groups (clustering)**²³⁰² – the creation of a cluster (a price reference group) is a cost-containment measure introduced by pricing and reimbursement authorities. This is a system according to which when a generic or a hybrid or a biosimilar drug enters the market, the originator and the generic/hybrid/biosimilar will be placed in a cluster and the price would be lowered using various methods (for example, either by a certain percentage or the reimbursement level for the reference group, would be set at the price of the cheapest product in the group (typically a generic or equivalent product) or the reimbursement level for the reference group would be set at the level of the average of the cheapest).²³⁰³ Therefore, the introduction of clustering had a direct impact on the price of Copaxone.

(b) **Automatic substitution**²³⁰⁴ – where the competent Payer decides that Copaxone and Synthon GA are automatically substitutable, this means that pharmacists are encouraged or even obliged to dispense the cheaper version of a drug (Synthon GA) even if the original doctor's prescription was for the more expensive product (Copaxone) or did not specify a brand. Again, this will mean that the demand is expected to shift to the cheaper product (Synthon GA), with a direct impact on sales volumes and prices of the more expensive product (Copaxone). Teva's key message passed within the company was to maximise profits by engaging in price competition as late as possible and by {...} (see also Recital (1774)).²³⁰⁵ For example, an internal Teva email concerning Italy states that once Synthon GA was included on the automatic substitution list, Copaxone would have to drop the price to the level of Synthon GA. Teva

²³⁰¹ In certain Member States, Payers may be distinct divisions within organisations with broader competences related to medicines. For example, in Italy, different divisions within AIFA were responsible (i) for the Decentralised Procedure and the issuance of the Italian MA for Synthon GA and (ii) for the decisions on automatic substitution between Synthon GA and Copaxone. In such instances, this Decision addresses the misleading nature of Teva's statements inasmuch as they were meant to influence pricing and reimbursement decisions as specified in Recital (1772) below and to reach the competent divisions.

²³⁰² See e.g. Recitals (286) and ff.; see also ID 455-624, Copaxone/FoGA Update – Pricing and Market Access, 22 November 2016, where clustering/price reference groups and tenders were considered as key challenges in the following months.

²³⁰³ The system of price reference groups (clustering) differs in each Member State.

²³⁰⁴ See Section 4.3.

²³⁰⁵ ID 262-1601, Price Competition Workshop, 20-21 June 2017, Amsterdam, p. 2, attached to ID 262-1600, Teva internal email dated 7 July 2017, from {...} to {...} and others.

acknowledges that automatic substitution of Synthon GA for Copaxone in Italy left no room for negotiating Copaxone prices: {...}.²³⁰⁶

- (c) **Tendering** – Payers may also decide to organise a tender pitting Copaxone and Synthon GA against each other in a single lot. In such tenders, Copaxone enters in direct price competition with Synthon GA, leading to a decrease in prices for Copaxone and/or an impact on volumes (in case of a loss of the tender). The following quote from a Teva Price Competition Workshop highlights the potential impact that Teva considered competition for tenders could have on Copaxone’s profitability: {...}.²³⁰⁷

- (1773) As these three measures to stimulate competition rely on the assumption that the medicines that are put into direct (price) competition, have a high degree of interchangeability, Teva’s strategy was to cast doubt concerning Synthon GA’s safety, efficacy and therapeutic equivalence with Copaxone²³⁰⁸ through the dissemination of the Misleading Complexity Message (for more detail on the relevance of Teva’s messages, see Section 9.4.2).
- (1774) The following examples show that Teva’s messages followed one single objective – to defend Teva’s prices from competition from Synthon GA. The following statement concisely summarises Teva’s strategy to maximise its profits by influencing Payers to avoid price competition (which depended on Payers’ decisions as regards Synthon GA’s equivalence with Copaxone): {...} (emphasis added).²³⁰⁹ Teva’s training materials show that its CCP materials for Payers were used to soften or avoid price pressure and {...}.²³¹⁰
- (1775) In the second place, Teva’s Payer tactics systematically targeted decision-makers concerning all these three levers of stimulating price competition to Copaxone.²³¹¹
- (1776) The Payers were targeted directly by Teva’s Market Access team (normally responsible for the pricing of Copaxone) who had the role to {...} (original emphasis).²³¹² The Payers were also targeted indirectly by Teva’s MSL team who proactively approached KOLs (or “Consulted Experts”) to whom Payers would turn to ask questions and receive consultation during their decision making process.²³¹³

²³⁰⁶ ID 413-924, Teva internal email dated 27 September 2019, from {...} to {...} and others.

²³⁰⁷ ID 262-1115, Price competition workshop – COPAXONE & LONQUEX, 20-21 June 2017, p. 11; ID 455-3408, Copaxone Continuation Project, October 2017, p. 27; even in the absence of automatic substitution, Payers can still tender the two medicines together.

²³⁰⁸ Therapeutic equivalence means that the efficacy and safety of this hybrid formulation is similar to the efficacy and safety of the reference product (Copaxone). Agreement on this conclusion was reached between Member States at the end of the Decentralised Procedure for Synthon GA – see ID 455-2843, Public Assessment Report Brabio, p. 17. By casting doubt on the therapeutic equivalence of Synthon GA, Teva thus indirectly casted doubt also on its safety and efficacy.

²³⁰⁹ ID 266-117, Price competition workshop – COPAXONE & LONQUEX, 20-21 June 2017, p. 1; See also ID 455-1982, Price competition workshop – Copaxone & Lonquex, 20-21 June 2017, p. 1.

²³¹⁰ ID 455-2301, COPAXONE® Continuation Project (CCP) – Pricing & Market Access Follow-on Glatiramer Acetate (FoGA) TRAINING, 3-4 February 2016 pp. 15, 17; see also ID 404-2314, Teva’s internal email dated 31 March 2016 from {...} which contain all training materials for Market Access team.

²³¹¹ See ID 263-1255, TPE Multiple Sclerosis: 2018, February 2018, p. 43. See similar statements in ID 455-151, Brand Team MS, June 2017, Amsterdam, p. 22.

²³¹² ID 455-1696, *Copaxone Continuation Project – CCP*, June 2016, p. 8.

²³¹³ Ibid.

(1777) More specifically, an internal Teva presentation from February 2018 presents, amongst others, the various targeted Payers ({...}), planned actions ({...}), and success factors for those actions ({...}).

Figure 43: Teva’s “Payer Tactics”

{...}

Source: ID 263-1255

(1778) Teva’s tactics illustrated in Figure 43 show that Teva’s Market Access teams (in charge of maintaining Copaxone prices) were targeting sickness funds, pricing and reimbursement bodies ({...}), tendering authorities as well as HTA authorities²³¹⁴. This sought to achieve complementary, sometimes mutually reinforcing outcomes, for example to {...} (which sought to protect Copaxone’s patient base against generic-like competition from Synthon GA), and {...} (which sought to protect Copaxone prices in case it could not prevent generic-like competition from Synthon GA). The means to achieve these objectives were hinging on misleading messages seeking to to artificially differentiate between Synthon GA and Copaxone: {...}, and {...}.²³¹⁵

(1779) It follows that Teva’s campaign covered a broad array of different types of Payers in the context of various types of pricing, reimbursement and other relevant decisions that would – at a systemic, aggregate demand level – encourage and establish direct price competition between Copaxone and Synthon GA and thus imperil Copaxone’s market position.

(1780) Third, although Teva’s campaign to target Payers was designed and steered at the level of the Teva Pharmaceuticals Europe headquarters, the implementation occurred at national level, (see Section 9.4.4), reflecting the fact that the Payers’ remit is national or even narrower in scope.

(1781) Teva used the Payer White Paper to train its local Market Access teams, both before and after the launch of Synthon GA.²³¹⁶ Teva always sought to cover most, if not all, Payers that were co-shaping the demand in a given market at a systemic, aggregate level. For example, in Belgium, Teva targeted both the body in charge of automatic substitution (Agence fédérale des médicaments et des produits de santé)²³¹⁷ as well as the body determining the level of price reductions (l’Assurance soins de santé et indemnités). In Italy, Teva not only tried to influence the body deciding on automatic substitution (AIFA), but also the regional tender authorities and the regional purchasing centres.

9.4.1.2. Teva targeted HCPs to influence demand for Synthon GA at the level of individual patient prescriptions

(1782) If Teva was not successful in preventing Payers from introducing direct competition between Copaxone and Synthon GA at systemic, aggregate level the next phase of the CCP was put in motion. In this next phase, Teva would seek to discourage

²³¹⁴ Health Technology Assessment (HTA) authorities are in charge of assessing the price of the drug against its therapeutic (added) value.

²³¹⁵ ID 263-1255, TPE Multiple Sclerosis: 2018, February 2018, p. 43. See similar statements in ID 455-151, Brand Team MS, June 2017, Amsterdam, p. 22.

²³¹⁶ As explained above in Section 9.3.2.2.1.1.

²³¹⁷ Agence Fédérale des Médicaments et des Produits de Santé (AFMPS), which can also be referred to under the Dutch name Federaal Agentschap voor Geneesmiddelen en Gezondheidsproducten (FAGG) or under the English translation Federal Agency for Medicines and Health Products.

individual switching from Copaxone to Synthon GA in order to maintain Teva's patient base and protect Copaxone's revenues.

- (1783) Teva has targeted HCPs in an attempt to influence, on a large scale, the individual prescriptions of GA to patients, and thus the overall demand for GA. According to Teva, its {...} concerning HCPs served the strategic objective to {...} and included, amongst others, the use of Teva's MSL team and sales force for {...} with HCPs.²³¹⁸
- (1784) While doctors take the final decision as to which GA based medicine to prescribe, nurses also play an important role. The nurses are the ones often administering the treatment and have a significant influence on patients.²³¹⁹ They may therefore steer the choice of treatment. For example, in Germany, patients make a choice related to the treatment they will receive with the help of a nurse: {...}.²³²⁰ In Germany, {...}.²³²¹ Teva's objective was for nurses to play the role of Copaxone advocates: {...}.²³²²
- (1785) Finally, Teva sought to influence demand for GA away from Synthon GA. This is illustrated by Teva's plans concerning the launch of Synthon GA, whereby Teva's KAMs were instructed to {...},²³²³ and to {...} (emphasis added).²³²⁴
- (1786) Teva's objective to secure a broad HCP coverage in all Member States is also apparent from Copaxone Brand Plans. In these strategy documents, Teva repeatedly states its strategic imperative of retaining existing patients. It considered that to attain this objective, ensuring that {...}²³²⁵ was a critical success factor. Following its strategy, Teva contacted HCPs to convey these messages. In certain countries, this was well documented in Teva's customer relationship management ("CRM") databases such as {...}.²³²⁶ For example, during an 8-month period in Germany in 2017, Teva reported {...} contacts between members of the MSL team and HCPs

²³¹⁸ ID 263-1255, TPE Multiple Sclerosis: 2018, February 2018, p. 45.

²³¹⁹ ID 455-47, MS treatment decisions and positioning research, 9 April 2019, p. 6; see also ID 455-1202, Teva Brand Plan, June 2013, pp. 5, 6.

²³²⁰ ID 455-47, MS treatment decisions and positioning research, 9 April 2019, p. 15; see also ID 455-1202, Teva Brand Plan, June 2013, pp. 5, 6.

²³²¹ ID 455-47, MS treatment decisions and positioning research, 9 April 2019, p. 18.

²³²² ID 404-1183, email dated 6 August 2012 from {...} to {...}.

²³²³ ID 455-269, CCP strategy – In face of evolving FoGA competition, p. 10.

²³²⁴ ID 455-269, CCP strategy – In face of evolving FoGA competition, p. 10.

²³²⁵ ID 262-767, 2019 GTMAP Template – the Netherlands, p. 3. See also ID 263-54, CCP – In face of evolving FoGA competition, June 2016, pp. 13, 17: According to Teva, the KAMs were pro-actively engaging with the HCPs through sales calls where they would highlight the complexity of GA. The KAMs would re-actively engage with the HCPs when HCPs would raise questions. According to Teva, these queries were supposed to be answered with approved answers. If the approved answers were not sufficient, this would trigger the MSL to send post-call letter/email or to do a follow-up visit.

²³²⁶ According to Teva, {...} CRM ("...") is used to manage and record communication between Teva's sales representatives and MSLs, and members of the healthcare community. While the exact data that can be recorded in {...} depends on the country, typically, the following data can be recorded in all countries: (i) contact reports, including information on contact type (e.g., email, telephone or face-to-face), product name(s), contact key messages, name of sales representative or MSL, recipient name and address, country, and date and time of contact; (ii) details of HCPs, including institutions and addresses; and (iii) other information relating to HCPs. Not all of these data are recorded mandatorily and the distinction between optional and mandatory data fields may vary by country and over time. Sales representatives and MSLs are responsible for the data they record relating to contacts while managers may exercise a level of control over records and their accuracy. However, there is no built-in system mechanism requiring sales representatives and members of Teva's MSL team to record contacts. ID 1286, Teva's reply to the Article 18(2) Requests of 22 October and 18 November 2021, pp. 4-5.

concerning “*NBCD-FOGAs*” as the main message²³²⁷ (as explained in Recital (1432), “NBCD” is a term used as a means to “*educate*” the relevant stakeholders and to further the Copaxone-related business goals by enhancing Teva’s Misleading Complexity Message). This number is all the more significant considering that contacts between HCPs and MSLs only occurred in case the HCPs raised a question during an earlier contact with the Teva KAM for which the latter did not have the authority to reply.²³²⁸

- (1787) Teva claims that the Commission overlooked the fact that Teva issued internal guidelines expressly prohibiting its teams from pro-actively commenting on Synthon GA and only allowing them to respond to unsolicited questions related to Synthon GA from HCPs reactively.²³²⁹
- (1788) The Commission rejects this argument. The fact that Teva has issued such guidance as part of a compliance programme would only be relevant for the assessment to the extent it was effectively implemented. However, neither the content of Teva’s CCP materials to be used with HCPs (both external experts and others) which endemically contain misleading messages, nor the evidence of actual dissemination of these messages indicate that these instructions were systematically followed either at central level or in Teva’s national organisations. Moreover, from a competition law perspective, there is no need to prove subjective intent.²³³⁰ Therefore, even if Teva had the subjective intention to compete on the merits (*quod non*), this would not have been sufficient to prove the absence of an abuse.²³³¹
- (1789) Teva makes reference to the document “Plan of Action - In the face of evolving FoGA competition”²³³² according to which the KAM and MSL staff should not {...} and should not {...} and that Teva should {...}.²³³³ Further, the training given to sales representatives and MSLs stated: {...}.²³³⁴ Also guidelines for medical teams stated: {...}.²³³⁵
- (1790) However, Sections 9.3.1., 9.3.2., and 9.4.4.4. demonstrate that this guidance was not respected. Instead, Teva presented Synthon GA in an ambiguous and derogatory way, cast doubt on its safety, efficacy and on its therapeutic equivalence with Copaxone. The existence of such a compliance programme cannot exonerate an undertaking from liability when these guidelines are not respected.

²³²⁷ ID 404-1154, CNS MSL meeting, 04.-05.09.2017, p. 24. According to the {...} data, in the period from 2015 to May 2021 Teva’s MSLs and sales representatives made altogether {...} calls, to HCPs among which {...} were recorded as relating to “*NBCD-FoGA*”; however, in ID 404-1154, CNS MSL meeting, 04.-05.09.2017, p. 23, it is revealed that {...} medical is working since March 2017 and that there are no available numbers for the preceding period.

²³²⁸ As explained in Section 9.3.2.1; see also ID 262-1275, Plan of action – In the face of evolving FoGA competition, p. 13.

²³²⁹ ID 4032, Teva’s Reply to the Statement of Objections, paras. 1276, 1277.

²³³⁰ Case C-377/20, *Servizio Elettrico Nazionale and Others*, paragraph 62.

²³³¹ See Recital (1752) above.

²³³² ID 262-1275, Plan of Action - In the face of evolving FoGA competition.

²³³³ ID 262-1275, Plan of Action - In the face of evolving FoGA competition, p. 14.

²³³⁴ ID 455-3091, Teva internal email dated 15 April 2016 from {...} to {...} and others; ID 296, Copaxone – FOGAs Guidelines for sales representatives and commercial teams, p. 8.

²³³⁵ ID 455-2975, Copaxone – FOGAs Guidelines for medical teams, p. 9.

9.4.1.3. Teva further amplified the dissemination of the Misleading Complexity Message to Payers and HCPs by engaging Key Opinion Leaders

- (1791) Besides their role in influencing the demand through their prescriptions, some HCPs, in particular neurologists specialised in MS, also play the role of so-called Key Opinion Leaders (“KOLs”) due to their particular scientific and/or professional achievements and reputation, such as involvement in the drafting of medical guidelines. KOLs recommendations and opinions can have a particular weight both in therapeutic decisions by individual HCPs and in more systemic decisions taken by Payers.
- (1792) In Teva’s campaign, misleading messages were not only disseminated directly to targeted Payers and HCPs by Teva’s sales and MSL representatives. Using its special position in the field of MS (see Section 9.4.3), Teva engaged certain KOLs to disseminate Teva’s misleading messages, as a seemingly neutral and independent position relating to the use of Synthon GA as a substitute for Copaxone, thereby supporting and reinforcing Teva’s official message on the topic.
- (1793) First, KOLs were, owing to their status and recognition in professional healthcare circles, capable of influencing both the decision-making processes of Payers, as well as the broader public perception amongst other HCPs, concerning the therapeutic profile of Synthon GA (including its safety, efficacy, and therapeutic equivalence with Copaxone).
- (1794) Teva was aware that KOLs would be called upon by Payers to provide advice in procedures that would determine conditions of competition between Synthon GA and Copaxone.²³³⁶ Teva also counted on KOLs to influence local neurologists against the use of Synthon GA ({...}) so that neurologists would {...}.²³³⁷ Teva observed that KOLs were {...}.²³³⁸
- (1795) Teva also expected that KOL opinions would be more impactful than articles directly attributable to Teva, and therefore sought to engage KOLs for publications aligned with Teva’s interests: {...}.²³³⁹
- (1796) Second, as part of the CCP strategy, Teva anticipated that Payers would reach out to KOLs and seek their advice on specific issues related to the introduction of Synthon GA. Teva’s objective was that {...}.²³⁴⁰
- (1797) Teva’s MSL and sales teams had first {...}.²³⁴¹ A contemporaneous document dating from 2017 provides some insight into Teva’s selection criteria for {...}.²³⁴²
- (1798) The Teva MSL team was then tasked to {...} the KOLs, or {...}, in preparation for the questions addressed to them by the Payers: {...}.²³⁴³ MSLs used information

²³³⁶ ID 263-54, CCP – In face of evolving FoGA competition, p. 12; See also ID 455-269, CCP strategy – In face of evolving FoGA competition, p. 9.

²³³⁷ ID 263-52, CCP FoGA Action Plan – Phase IIB materials development roll-out, 15 March 2016, p. 3.

²³³⁸ ID 263-789, Copaxone/FoGA – P&MA outlook, European Commercial Team, 7 June 2017, pp. 34-34.

²³³⁹ ID 455-3207, Teva internal email dated 2 May 2017 from {...} to {...} and others.

²³⁴⁰ ID 404-1811, GSM Top Risks 2017 – Copaxone Generics, p. 1.

²³⁴¹ ID 455-269, CCP strategy – In face of evolving FoGA competition, p. 9.

²³⁴² ID 455-579, Copaxone – Local Brand Plan – Germany 2017-2017, p. 36.

²³⁴³ ID 263-54, CCP – In face of evolving FoGA competition, p. 12, ID 455-269, CCP strategy – In face of evolving FoGA competition, pp. 9, 14.

from EE White Papers, the EE Slides and the MSL Q&A as the basis for these contacts.²³⁴⁴

- (1799) Third, Teva strived that some KOLs align their publicly stated views with Teva's position concerning Synthon GA with the aim to mislead the authorities.
- (1800) In the first place, internal evidence shows that in many cases Teva either drafted the expert opinion for the KOLs²³⁴⁵ or commented on the draft expert opinion²³⁴⁶ before it was submitted to the relevant Payers. Teva leveraged such KOL opinions, which it influenced, trying to in turn influence Payers. Teva's extensive input aimed to ensure that the produced documents were fully aligned with Teva's CCP messages, including the Misleading Complexity Message.
- (1801) An example of Teva's involvement in influencing expert opinions or presentation is the case of {...},²³⁴⁷ to whom Teva provided materials (slides) to be used in {their} presentation at a conference in early 2018: {...}²³⁴⁸
- (1802) In the context of challenging AIFA's decision granting automatic substitution status to Synthon GA in Italy, Teva planned to task its own group of KOLs ("EE working group") with preparing publications in support of its challenge: {...}. The planned actions included: {...}.²³⁴⁹
- (1803) Similarly, when the {...} of a statutory health insurance in Germany inquired about the approval of Synthon GA and even questioned Teva's persistent complaints about the approval process and its results, {...}, one of the leading authorities in the MS field, and one of the KOLs working closely with Teva,²³⁵⁰ simply replied reiterating Teva's points on the inadequacy of the GATE study to support equivalence conclusions. {...} even pointed that GATE is a {...} which suggests false evidence: {...}.²³⁵¹ Immediately after replying, {...} forwarded the entire correspondence (a question and {their} answer) to {their} contact within Teva, while in the correspondence {...} describes {themselves} as independent: {...} (unofficial translation).²³⁵²
- (1804) In the second place, certain evidence suggests that even Teva may internally have had doubts as to the impartiality and independence of certain KOLs' opinions. A WhatsApp exchange between the {...}, and a {...} Teva, discusses Teva's

²³⁴⁴ ID 263-54, CCP – In face of evolving FoGA competition, p. 12. Also see Section 9.3.2.1.

²³⁴⁵ See e.g. Recital (1805).

²³⁴⁶ See e.g. Recitals (1950)-(1955).

²³⁴⁷ ID 2503, {...}. Teva provided materials to be used for the 12th World Congress on Controversies in Neurology (CONy), 22-25 March 2018, Warsaw, Poland, see at: <http://www.comtecmed.com/cony/2018/MS.aspx>.

²³⁴⁸ ID 404-1706, Teva internal email dated 31 January 2018 from {...} to {...}.

²³⁴⁹ ID 455-376, Teva internal email thread including email dated 24 April 2017 from {...} to {...} and others and email dated 3 May 2017 from {...} to {...} and others; ID 455-379, Teva internal email thread.

²³⁵⁰ {...} is working closely with Teva. {They} authored several studies funded by Teva; {...} was also working for Teva to design two Copaxone studies for comparison of Copaxone and FoGA – see ID 404-2595, email dated 3 July 2018 from {...} to {...} and others (Teva) and {...}; see also ID 404-2492, internal email chain dated 3 July 2018 from {...} to {...} and others; {...} is also speaker for Teva to various conferences, see ID 932, Teva's reply to Article 18(2) Request of 3 June 2020, pp. 13, 14, 15.

²³⁵¹ ID 404-1465, email dated 15 December 2016 from {...} to {...} and others (Teva) forwarding the correspondence between {...} ({...}) and {...} ({...}). Original text: "{...}"

²³⁵² ID 404-1465, email dated 15 December 2016 from {...} to {...} and others (Teva) forwarding the correspondence between {...} ({...}) and {...} ({...}).

engagement of a German KOL. In that context, the former, was a senior manager responsible for Copaxone, shared {their} personal experience from working with KOLs in the past (and in particular {...}): {...}.²³⁵³

- (1805) Teva claims that its contacts with KOLs were pursued in the interest of an {...}, and not to {...} of Synthon GA.²³⁵⁴ Teva's arguments do not convince. First, there is abundant evidence that cooperation with KOLs was part of Teva's commercial plans to defend Copaxone from competition from Synthon GA (see Section 9.4.1.3 and, as further examples, Section 9.4.4.2.2, and footnote 2355). This cooperation was thus pursued for commercial reasons, not to advance scientific exchanges. Second, the KOL statements and publications assessed in this Decision were not the result of independent research of the KOLs, but were to a significant extent influenced by Teva, and consequently faithfully mirrored Teva's positions. These expert submissions were either written by Teva (as exemplified by the following Teva quote: {...}²³⁵⁵) or Teva commented on the draft of these opinions and these comments were taken into account by the respective experts ({...} (emphasis added)).²³⁵⁶ In some cases, Teva resorted so extensively to certain KOLs that it had to carefully assess whether to further engage them: for example, in May 2017 an employee at Teva Italy suggested to avoid further engagement of {...} as {...} was {...}.²³⁵⁷
- (1806) The opinion pieces drafted or commented by Teva did not disclose links with Teva or the conflict of interest, and were also in stark contrast with Teva's internal and regulatory compliance: {...}.²³⁵⁸ For example, Teva proposed to disguise the payment to {...} for a publication as funding for a medical writer and for organizing an on-line conference with the co-authors: {...}.²³⁵⁹
- (1807) According to Teva, the Commission's assessment wrongly suggests that it was inappropriate for Teva to have sought out, and engaged, KOLs with expert scientific views that aligned with Teva's own views.²³⁶⁰ It also claims that the Commission's assessment of Teva's engaging KOLs raises the "*implausible scenario*" that leading scientific experts agreed to share invalid or misleading messages.²³⁶¹ These arguments are unfounded. The Commission does not take issue with the fact that Teva's and KOLs' views may indeed be aligned. However, submissions, interviews

²³⁵³ ID 263-435, WhatsApp conversation between {...} and {...},

²³⁵⁴ ID 4032, Teva's Reply to the Statement of Objections, paras. 1293, 1294; see also ID 5695, Teva's Reply to the Letter of Facts I of 9 February 2024, paras. 357-362

²³⁵⁵ ID 455-1054, email dated 1 July 2016 from {...}. For evidence regarding Teva's internal work to prepare these expert papers, see ID 644-363, Teva internal email of 1 July 2016 from {...} to {...} and others, pp. 1, 2: {...}; ID 644-184, Teva internal email dated 1 July 2016 from {...} to {...} and others: {...}. Although Teva argued during the proceedings that the purpose of the initial draft was to {...} (see ID 4032, Teva's Response to the Statement of Objections, para 1257(c)), the analysis of Teva's preparatory exchanges show that the focus of Teva's drafting was much more on the actual substance and exact wording of the opinion, also not to make it conflict with Teva's position in patent litigation. See ID 644-363, Teva internal email of 1 July 2016 from {...} to {...} and others, where Teva's employees also note that {...}.

²³⁵⁶ ID 455-831, Teva internal email dated 2 May 2017 from {...} to {...} and others; see also Recitals (1948); see also Recitals (1954), (2015).

²³⁵⁷ ID 455-453, Teva internal email dated 4 May 2017 from {...} to {...} and others.

²³⁵⁸ ID 455-548, Teva internal email dated 4 May 2017 from {...} to {...} and others. See also ID 455-3389, Teva internal email dated 12 May 2017 from {...} to {...}.

²³⁵⁹ ID 518-14, Teva internal email dated 8 December 2016 from {...} to {...} and others.

²³⁶⁰ ID 4032, Teva's Reply to the Statement of Objections, paras. 1010, 1011, 1012.

²³⁶¹ ID 4032, Teva's the Statement of Objections, paras. 1001, 1002, 1003, 1004, 1006, 1007, 1008, 1009; ID 5909, Teva's Reply to the Letter of Facts II of 17 May 2024, paras. 162-167

and other statements by KOLs assessed in this Decision were in one way or the other prepared in close cooperation with Teva (for example, Teva either wrote the draft text, or commented on KOL's draft statements, and KOLs relied on Teva's input - see for example Recitals (1804)). This was contrary to Teva's own rules and understanding: {...}.²³⁶² This raises issues on at least two grounds. First, by disseminating a third-party document for promotional purposes, Teva assumes the responsibility that the statement it is using is not misleading. As shown in this Section, KOL statements often closely mirrored Teva's Misleading Complexity Message. Second, Teva disseminated such KOL statements as statements of independent experts without disclosing its involvement in the preparation of such documents.²³⁶³ This shows that Teva blatantly disregarded applicable rules for collaboration with outside experts, including its own, as well as including those by EFPIA's).²³⁶⁴ Having compliance rules does not absolve a company from liability if those rules are not respected.²³⁶⁵ This deprived the addressees of Teva's communications of the possibility to make their own opinion of the credibility and scientific value of the KOLs' statements. The ultimate effect of Teva's dissemination of KOL statements prepared with Teva's involvement was to propagate Teva's Complexity Message even more effectively due to their misleading appearance of impartiality.

9.4.2. *Teva's Misleading Complexity Message was capable of influencing demand by Payers and HCPs*

- (1808) The Misleading Complexity Message was carefully calibrated to maximise the impact on the addressees – Payers and HCPs.²³⁶⁶ As described in detail in Section 9.3. and especially Section 9.3.1., it challenged the features that were essential for Synthon GA: its ability to help patients (efficacy) without compromising their health (safety) and its therapeutic equivalence with Copaxone.
- (1809) First, Teva's disparagement campaign sought to hinder and/or delay the market entry of Synthon GA by persuading Payers not to grant an automatic substitution status to Synthon GA or by not to create price reference groups²³⁶⁷ and Teva did that by spreading misleading messages related to Synthon GA's safety, efficacy and therapeutic equivalence with Copaxone.²³⁶⁸

²³⁶² ID 455-548, Teva internal email dated 4 May 2017 from {...} to {...} and others.

²³⁶³ This appears to run counter to the guidelines of EFPIA, a European industry association of originator companies, which encourage companies to include provisions regarding the obligation of the consultants to declare their affiliation to the Member Company whenever they write or speak in public about a matter that is the subject of the agreement. Although Teva is not a member of EFPIA, Teva referred to its own guidelines as being in line with EFPIA's Code of Practice (see ID 4032, Teva's Reply to the Statement of Objections, para. 1014).

²³⁶⁴ See ID 2476, "EFPIA Code of Practice", EFPIA, 2019.

²³⁶⁵ See Recital (1752).

²³⁶⁶ These stakeholders are either budget conscious in that they aim to provide value for the money spent (Payers) and/or traditionally risk aware in that they feel individually responsible for any possible worsening of their patient's health (HCPs). However, both Payers and the HCPs rely on the assumption that duly approved medicines (such as Synthon GA) are indeed safe and effective.

²³⁶⁷ For example, by creating a dedicated price reference group or tender lots comprising the two products.

²³⁶⁸ In this context, Teva argued that in view of the alleged product differences, {...} in other words, that they are not therapeutically equivalent. To strengthen its case, Teva often used opinions from external experts, which were drafted based on templates and/or information provided by Teva. (ID 262-724, Substitution considerations for follow on glatiramer acetate products, Meeting with Federal Agency for Medicines & Health Products, Brussels, 23 January 2017, p. 57. On the role of the external experts in Teva's disparagement campaign see Section 9.4.1.3). Similarly, in the presentation for the Belgian

- (1810) The question of whether two medicines are therapeutically equivalent is different from the question of whether two medicines are automatically substitutable. In fact, therapeutic equivalence between Copaxone and Synthron GA was a pre-condition for any decision on the automatic (generic-like) substitution or for a price comparison between them. This connection was, for example, made clear during the presentation made for FAMHP in Belgium where Teva explained: {...}.²³⁶⁹ In other words, when targeting Payers to avoid automatic substitution, Teva did not limit itself to argue against automatic substitution, but cast doubts on Synthron GA's safety, efficacy and therapeutic equivalence with Copaxone, in direct contradiction with the conclusions reached by the MEB who rejected these claims.
- (1811) Second, Teva's disparagement campaign sought to deter HCPs from replacing Copaxone with Synthron GA in prescriptions to new or existing individual patients. Teva tried to achieve that {...} with Synthron GA and {...}.²³⁷⁰
- (1812) Conversely, the key notion in addressing HCPs was to challenge Synthron GA's safety, efficacy and therapeutic equivalence with Copaxone. Teva's conduct was targeted against any conviction on the part of HCPs', that {...}.²³⁷¹ Any doubt with respect to the safety of a newly approved medicine, such as Synthron GA, would risk to seriously affect HCPs' perception of the risks of prescribing Synthron GA, especially in a situation where it would imply turning away from prescribing the established originator product, i.e. Copaxone. As aptly explained in the internal training materials, Teva would point to health risks in case a neurologist was open to prescribing Synthron GA instead of Copaxone: {...}.²³⁷²
- (1813) In this context, it should be noted that HCPs tend to be conservative (or "inert") about switching to a medicine other than the one they have been treating patients with in the absence of a pressing medical need. Indeed, prescribing doctors tend to prescribe the incumbent originator product²³⁷³ since they are primarily guided by considerations of therapeutic appropriateness/efficacy and safety of medicines.²³⁷⁴

Federal Agency for Medicines and health Products Teva expressly noted {...} (ID 455-2433, Substitution considerations for follow-on glatiramer acetate products, Meeting with Federal Agency for Medicines & Health Products Brussels, 23 January 2017, p. 57).

²³⁶⁹ ID 651-21, Substitution considerations for follow on glatirameracetate products Meeting with Federal Agency for Medicines & Health Products Brussels, 23 January 2017, pp. 27, 64; see also Section 9.3.1.1

²³⁷⁰ ID 263-1574, Go To Market Action Plan Copaxone, EU 2018, p. 20.

²³⁷¹ Ibid.

²³⁷² ID 404-1677, Talking Points Clift, Stand 24 November 2016, p. 8 (unofficial translation). Original text: "{...}"

²³⁷³ See Case T-321/05, *AstraZeneca v Commission*, paragraph 105: "*'inertia' is a factor which is liable to reinforce the market position of an incumbent product by creating barriers to entry or expansion for competing products newly introduced on the market.*" See also Case C-457/10 P, *AstraZeneca v Commission*, paragraph 50 where the Court concluded that "*enjoying a solid brand image and reputation, was further supported by the fact that doctors generally require time in order to learn about a new medicinal product and thus that they will hesitate to prescribe PPIs of other producers entering that market.*"

²³⁷⁴ Case C-179/16, *F. Hoffmann-La Roche and Others*, paragraph 65; see also Case C-179/16, *F. Hoffmann-La Roche and Others*, Opinion of AG SaugmandsgaardØe, paragraph 169: "*medical practitioners are particularly sensitive to safety considerations surrounding medicinal products. Where those considerations concern the off-label use of a medicine, their aversion to risk is likely to increase in accordance with the legal provisions governing medical liability in force in the Member State in question. In this instance, according to the AGCM and the Italian Government, such liability does arise in Italy and is severe under civil and criminal law. Given that specific context, the widespread communication of alarming and misleading information about the risks associated with the off-label use*

They are generally risk averse and disinclined to prescribe medicines surrounded by the type of scientific controversy concerning safety and/or efficacy that characterised Teva’s misleading messages.²³⁷⁵ For example, in Germany, Teva employees report back from their meetings with HCPs and state that: {...}.²³⁷⁶

(1814) In addition, HCPs are also unlikely to have the time or the capacity to undertake a detailed scientific assessment of the information disseminated by a dominant, disparaging undertaking. When presented with one-sided, incomplete scientific information, in particular coming directly from an established and well-reputed producer in the field, most HCPs will, in practice, not be able or willing to question, complement or correct such information.²³⁷⁷

(1815) In view of the above, the elements of the Misleading Complexity Message analysed in Sections 9.3.1.1, 9.3.1.2 and 9.3.1.3 were carefully chosen to cast doubt on the fundamental elements of the automatic substitution/pricing decision by the Payers or the treatment decision by the HCPs.

9.4.3. *Teva enjoyed a special position in its communication with the Payers and HCPs*

(1816) In addition to the content and form of the Misleading Complexity Message designed to maximise its impact on key drivers of demand for GA – Payers and HCPs (Sections 9.4.1 and 9.4.2) – it was Teva’s particularly strong and well-established position in the MS field that allowed for the successful dissemination and reception of the Misleading Complexity Message.

(1817) First, Teva enjoyed a position of unquestionable authority thanks to the success of Copaxone and Teva’s dedication to the MS field. As described in Section 5.1, Copaxone was first launched in 1999 in the UK and subsequently (in early 2000s) obtained MAs in other EU Member States through Mutual Recognition Procedures based on the UK MA. Copaxone, together with interferons, were the first disease modifying therapies for MS. The success of Copaxone made Teva one of the most important and credible participants in the scientific, medical and commercial discussions on MS treatments. In a nutshell, as noted by Teva itself, Teva was indeed seen as {...}.²³⁷⁸

(1818) Second, Copaxone’s commercial success led Teva to focus increasingly on GA in particular and the MS field in general. As described in more detail in Section 9.1, already in 2004, i.e. soon after the commercial launches of Copaxone in the EU,

of a medicinal product is inherently likely to discredit that product among doctors and stimulate demand for competing medicinal products”.

²³⁷⁵ See in this regard, judgment of the French Cour de Cassation of 18 October 2016, Chambre commerciale, N° de pourvoi: 15-10.384, which upheld that Sanofi had abused its dominant position as a result of “*a communication strategy targeting healthcare professionals (...)*” because *inter alia* “*the dissemination of negative information, or even instilling doubt about the intrinsic qualities of a medicinal product, can discredit it immediately for these professionals*”.

²³⁷⁶ ID 5161-265, Monatsbericht Januar: Region Süd, p. 3 (unofficial translation). Original text: {...}.

²³⁷⁷ Accordingly, Directive 2001/83 on the Community code relating to medicinal products for human use requires that all the information transmitted as part of the promotion of a product “*shall be accurate, up-to-date, verifiable and sufficiently complete to enable the recipient to form his or her own opinion of the therapeutic value of the medicinal product concerned.*” (Article 92(2)).

²³⁷⁸ ID 263-1255, TPE Multiple Sclerosis: 2018, February 2018, p. 14. See also ID 1151-23, Copaxone EU Go To Market Action Plan (GTMAP), 15 July 2015, p. 12: Poland Copaxone Brand Plan for 2016 listing {...} as one of the critical success factors for maintaining market access; ID 1151-36, Poland GTMAP, MS 2017, p. 3. Similarly, Spain Copaxone Brand Plan for 2017 includes {...} as a critical success factor in targeting neurologists, nurses and Payers in order to maintain and protect Copaxone patient base (ID 1151-5, Go To Market Action Plan (GTMAP) Teva Spain CNS for 2017, p. 12).

Teva put in place the Copaxone Life Cycle Initiative with a goal to communicate Teva's position on Copaxone and its alleged complexity. Teva was also one of the founding members of the NBCD Working Group, which provided a {...} for allegedly scientific and unbiased communication with the relevant stakeholders. These "education" efforts were woven into the CCP, which had as one of its main levers a broad outreach and communication campaign targeting competent authorities as well as HCPs. For example, the Copaxone Brand Plan for 2016 in Spain clearly indicates that Teva being {...} is a desired outcome of Teva's marketing activities with an estimated budget of EUR {...}.²³⁷⁹ Perception of Teva as the {...} contributes to several critical success factors such as increasing Teva's market share in both naïve patients and switch patients, transitioning from Copaxone 20 mg to Copaxone 40 mg and increasing adherence.²³⁸⁰

- (1819) The strength of Teva's message was underscored by the fact that renowned KOLs were specifically targeted by Teva and relied on to reinforce Teva's scientific points (e.g. on the "complexity" of GA). As described above in Sections 9.1 and 9.4.1.3, Teva enjoyed a particularly close relationship with leading KOLs in the MS field, even writing on their behalf opinions to be submitted to Payers, or commenting on such opinions,²³⁸¹ and made concerted efforts with some of them to guide the scientific discussion by making terms such as "FoGA" or "Non-Biological Complex Drug" mainstays.
- (1820) Conversely, Synthon was not in a position to successfully counter Teva's messaging. By the time Synthon GA was ready to enter the markets,²³⁸² Teva's strategic communication designed to protect Copaxone from competition from Synthon GA had been ongoing for over ten years. Teva started early on with its campaign, even before the Decentralised Procedure for Synthon GA was successfully completed.²³⁸³ Once doubt on the safety and efficacy of a medicinal product is sown in the minds of the Payers or HCPs, it is hard to undo the damage. This is because, as explained in Section 9.4.2 above, HCPs tend to be conservative or "inert" about switching to a medicine other than the one they have been treating patients with. Since these messages were communicated before the Decentralised Procedure for Synthon GA was finalised, HCPs were not exposed to the counterarguments of Synthon, but only to the unilateral story of the incumbent company.
- (1821) In addition, while Teva was (and still is) the largest generic company in the world, its Copaxone franchise was the flagship of its Specialty Medicines business. Teva was therefore active as an originator company and invested heavily in the marketing and

²³⁷⁹ ID 1151-46, Copaxone 40 Go To Market Action Plan (GTMAP), September 2015, Spain GTMAP for 2016, p. 12.

²³⁸⁰ Ibid. See also ID 1151-8, GTMAP MS 2017 ITALY, p. 7 including {...} among the strategic critical success factors.

²³⁸¹ See Section 9.4.1.3, Section 9.4.4.2.2, and footnote 2355.

²³⁸² Synthon started developing its version of GA in 2006, initiated the GATE study in 2011 and received the MA for the Synthon GA in 2016.

²³⁸³ ID 263-47, Copaxone Continuation Project Focus, November 2013, p. 7; ID 263-48, Copaxone Continuation Project Focus, January 2014, p. 6 and ID 263-49, Copaxone Continuation Project Focus, February 2014, p. 7; ID 263-1556, Regional Medical Go to Market Action Plan 2015, pp. 2, 3, 5, 11; ID 264-1756, COPAXONE® Continuation Project (CCP) – Pricing & Market Access Follow-on Glatiramer Acetate (FoGA) TRAINING, 3, 4 February 2016, pp. 16, 17; all these documents are not used to establish the infringement, but as context so as to show that Teva prepared its disparagement campaign before the successful conclusion of the Decentralised Procedure for Synthon GA.

detailing (i.e. individual visits to the prescribing doctors) of Copaxone.²³⁸⁴ Teva's promotional and medical activities on Copaxone have been significant, consistently accounting for over {...}% of the company's entire sales and marketing budget. Between 2016 and 2019, Copaxone was Teva's specialty medicine product which received the greatest level of sales and marketing investment from Teva.²³⁸⁵

- (1822) For example, as part of these sales and marketing activities and the CCP action plan at the launch of the GA competitors, KAMs were instructed to {...}.²³⁸⁶ KAMs were also instructed to ensure swift post-call follow up by the MSL team and the MSL team was instructed to make follow up visits to address customers' questions using supplied materials. The Market Access team was instructed {...}.²³⁸⁷ In addition, already in 2015, Teva initiated a {...} and even {...} (emphasis added).²³⁸⁸
- (1823) Conversely, Synthon and its licensee approached the GA markets based on a generic business model, with lesser importance of marketing and detailing (i.e. direct sales visits to HCPs) and instead relying on the price difference as the main factor driving market entry and expansion.²³⁸⁹ For example, in Germany in 2017, Mylan devoted to the GA 40 mg detailing altogether {...} representatives while Teva at the same time devoted 54. This significant difference in dedicated sales representatives was maintained throughout the period of the abuse.²³⁹⁰ In addition, countering Teva's messaging would be disproportionately difficult and costly for Synthon and its licensees in the Relevant Member States (Mylan/Viatrix, Alvogen and Zentiva). Once the efficacy and safety of Synthon GA's as well as its therapeutic equivalence with Copaxone was in doubt, Synthon and its partners could only hope to dispel these doubts by costly and lengthy additional trials or by allocating (including by hiring) more dedicated people to rebut Teva's messages and to explain why they were misleading. Such asymmetry of costs underlines Teva's special position and reinforces the impact of its Misleading Complexity Message.
- (1824) Therefore, Synthon, together with its partners in commercializing Synthon GA could not have successfully countered Teva's disparagement campaign with their own

²³⁸⁴ For importance of marketing (including individual visits to the prescribing doctors) for the originator companies, see Pharmaceutical Sector Inquiry, Final Report, 8 July 2009, pp. 30-32.

²³⁸⁵ ID 660, Teva's reply to the Article 18(2) Request of 3 June 2020, p. 21. See also a presentation "*Copaxone 3 x weekly launch tracker*" comparing sales/marketing activity of Teva/Copaxone in Germany with those of other originator companies – Biogen (Tecfidera, Plegidry and Avonex), Genzyme (Aubagio) and Merck (Rebif) – and concluding that "*Copaxone 40 has the highest rep coverage amongst target respondents*" (ID 263-449, Copaxone 3 x weekly launch tracker, updated 4 October 2016, p. 52).

²³⁸⁶ ID 455-269, CCP strategy – In face of evolving FoGA competition, p. 10.

²³⁸⁷ ID 455-269, CCP strategy – In face of evolving FoGA competition, p. 10.

²³⁸⁸ ID 455-2938, Teva internal email dated 28 January 2015 from {...} to {...} and others. According to Teva, a list of seven agencies was compiled and presented internally: France, Germany, Spain, Austria, Croatia, Sweden, Belgium. However, this was not the definite list since meetings were ultimately held with national regulators regarding the Synthon GA marketing authorisation applications in Spain, Croatia, Portugal, Ireland, Czechia, Hungary, Belgium and France. (ID 660, Teva's reply to the Article 18(2) Request of 3 June 2020, p. 107). See also ID 262-219, Copaxone Brand Plan Europe 2014-2017, p. 65 where Teva emphasised that {...} and {...}.

²³⁸⁹ Ibid, pp. 30-32.

²³⁹⁰ ID 3406, {...} Reply to Article 18(2) Request of 9 June 2021. While there are slight differences in the actual numbers of the FTEs (full time equivalent or FTE is a metric used to demonstrate workloads on individual tasks across various working schemes, full time, part time, etc.), Teva's data corroborate the conclusion that Teva's Copaxone's workforce was substantially larger than Mylan's (see e.g. ID 455-562, Copaxone – Local Brand Plan – Germany, 2015-2017; ID 264-908, Expertenmeeting Copaxone 40 mg/ml, 8 August 2017; ID 264-724, FoGA 2017, Germany).

messaging. As bluntly underscored internally by Teva's {...}, Teva Finland and equally applicable across all of the Relevant Member States, {...}.²³⁹¹ Similarly, Teva's German team reported in October 2016 that {...} (emphasis added).²³⁹²

(1825) Teva claims that the Commission did not account for the {...}.²³⁹³ Teva's claim is unfounded. First, Teva's claims fail to address the argument that {...} of Teva's campaign. The Commission does not dispute that the {...}. Teva's claims are however not supported by sufficient evidence to question the Commission's finding in this Section that Teva enjoyed a special position in the market {...}. Second, as the purpose and impact of Teva's CCP campaign was to {...}, it may be disproportionately difficult to dispel a doubt in the safety, efficacy, and the therapeutic equivalence of a medicine once the doubt has been sown in particular because of the HCP's abovementioned inertia. Finally, Teva's claim that a string of Payers decision granting the automatic substitution status to Synthron GA {...} is flawed. Teva's argument completely ignores the fact that Teva's Payers campaign (Phase IIa of the CCP campaign) also resulted in delays in granting the automatic substitution status to Synthron GA (for example, in Germany and Italy), and was invariably flanked by a subsequent campaign targeting individual HCPs (Phase IIb).²³⁹⁴ As this Section 9.4.3 shows, Teva also had a special position in communicating with HCPs due to its strong network of KAMs and members of the MSL team and their established relationships with HCPs. As illustrated by Teva's campaign in Germany, where Synthron GA was granted automatic substitution status early on, Phase IIb entailed massive efforts of Teva's KAM and MSL teams to protect the individual prescriptions of Copaxone by influencing HCPs.²³⁹⁵

9.4.4. *Teva's dissemination of the Misleading Complexity Message was capable of producing exclusionary effects in at least seven Member States*

9.4.4.1. Centrally developed materials for the communication of misleading messages

(1826) To protect Copaxone, Teva put in place, as part of the broader CCP, a well-structured central campaign focused on disseminating the Misleading Complexity Message (see Section 9.3.1) to the relevant stakeholders (Payers and HCPs) with a view to reducing competitive pressure from Synthron Gato (namely by hindering and/or delaying Synthron GA's market entry and uptake).

(1827) To achieve this, Teva disseminated, as described above (Section 9.3.2), the Misleading Complexity Message to Payers and HCPs including KOLs. In particular, Teva created a set of centrally approved materials to be used across Europe to "educate"²³⁹⁶ relevant stakeholders on its Misleading Complexity Message.

(1828) As noted above (Recitals (1739)-(1746)), these centrally created and approved materials were rolled-out to the Relevant Member States to support Teva's communication with Payers, KOLs and HCPs with the strict instruction that {...}.²³⁹⁷

²³⁹¹ ID 404-2367, Teva internal email dated 16 August 2017 from {...} to {...}.

²³⁹² ID 455-1432, FoGA questions- Validation, worksheet: Questions – attachment to ID 455-1429, Teva internal email from {...} to {...} and others.

²³⁹³ ID 4032, Teva's Reply to the Statement of Objections, paras. 1060, 1061, 1062; ID 5695, Teva's Reply to the Letter of Facts I of 9 February 2024, paras 363-366.

²³⁹⁴ See Recital (1441).

²³⁹⁵ See Section 9.4.4.4.2.

²³⁹⁶ ID 404-2419, CCP Plan Germany, p. 23.

²³⁹⁷ ID 263-63, Copaxone Strategy, p. 2, ID 263-45, Plan of Action – In the face of evolving FoGA competition, 27 September 2016; ID 455-269, CCP Strategy, p. 2; ID 455-1377, CCP Strategy, 24 May 2018.

For the Payers, Teva’s communication approach was included in the Payer White Paper, Payer Slide Presentation, Payer Objection Handler and Payer Q&A document. For the External Experts and neurologists, the approach was outlined in the two External Experts White Papers (MS specialist and non-specialist version) and the MSL Objection Handler. For HCPs more generally, the materials also included the Complexity Leavepiece and the GATE study review.²³⁹⁸

- (1829) These documents were shared with teams in the Relevant Member States and were used for the training of various market-facing teams in Teva – Market Access, KAM and MSL teams. These teams also used these documents in their communications with HCPs and other stakeholders, either in their original form or in a “localised” mirror image of the centrally developed material. A slide, presented by an external consultant at a Teva workshop organised for Teva’s employees²³⁹⁹ held in June 2017,²⁴⁰⁰ emphasises the importance of localisation of the CCP materials and of their timely use: {...}.²⁴⁰¹ While this is not a statement expressed by a Teva employee, it is one that was presented to Teva employees in a workshop and subsequently included in the official overall document containing all presentations during the Teva’s internal workshop from June 2017:

Figure 44: Slide entitled {...}

{...}

Source: ID 264-892, {...}, p. 85

- (1830) With regard to whether all these materials were used, the Commission’s case file includes evidence of reporting on the status of their implementation per country.²⁴⁰² According to Teva’s internal documents, all of Teva’s representatives for the 33 European markets (including the EEA markets) were reporting and updating regularly the information on Synthron GA²⁴⁰³ to Teva’s headquarters,²⁴⁰⁴ including information on the status of implementation of Teva’s materials: {...}.²⁴⁰⁵ The following Sections, set out how Teva actually used these materials in each of the Relevant Member States.
- (1831) Finally, Teva used public conferences to disseminate the Misleading Complexity Message and to increase its reach at the European level. For example, Teva was regularly represented at and prepared special materials for the European Committee

²³⁹⁸ For a detailed description of these materials, see Section 9.3.2.

²³⁹⁹ According to Teva, the price competition workshops were initiated in 2014 in preparation for the Copaxone 40 mg launch, prior to imminent Synthron GA entry (see ID 660, Teva’s reply to Article 18(2) Request of 3 June 2020, p. 53). The workshop was attended by Teva’s employees (for example {...} etc.) responsible for various EEA countries – for the list of participants to the workshop see ID 262-1601, Price Competition Workshop, 20-21 June 2017, Amsterdam, p. 2.

²⁴⁰⁰ ID 264-892, Price competition workshop – COPAXONE & LONQUEX, 20-21 June 2017, Amsterdam; {...}.

²⁴⁰¹ ID 264-892, Price competition workshop – COPAXONE & LONQUEX, June 20 – 21 2017, {...}, p. 85.

²⁴⁰² ID 455-1432, FoGA questions- Validation, worksheet: Questions – attachment to ID 455-1429, Teva internal email dated 7 October 2016 from {...} to {...} and others.

²⁴⁰³ Information on the regulatory update, pricing and reimbursement update, legal action and local legal actions taken on “FoGA”, commercial update, business intelligence update.

²⁴⁰⁴ ID 455-1429, Teva internal email chain dated 27 July – 27 September 2016 between {...}, {...} and Teva’s representatives in 33 European markets.

²⁴⁰⁵ ID 455-1432, FoGA questions- Validation, worksheet: Questions – attachment to ID 455-1429, Teva internal email dated 7 October 2016 from {...} to {...} and others; see also ID 455-1499, FoGA questions – Validation.

for Treatment and Research in MS annual congress which brings together MS specialists from across Europe.²⁴⁰⁶

9.4.4.2. Teva's dissemination of the Misleading Complexity Message in Belgium

- (1832) Synthon GA is marketed in Belgium by Mylan under the brand Glatiramyl 20 mg and Glatiramyl 40 mg. Mylan secured a marketing authorisation for Glatiramyl 20 mg on 11 May 2016.²⁴⁰⁷ Teva filed a petition for the suspension and annulment of Mylan's MA on 8 July 2016, but this was rejected on 28 September 2016.²⁴⁰⁸ The MA for Mylan's Glatiramyl 40 mg was granted to Mylan on 23 October 2017.²⁴⁰⁹ However, Mylan launched Glatiramyl (20 mg and 40 mg) on the Belgian market only in August 2021, partly because of preliminary injunctions filed by Teva.²⁴¹⁰
- (1833) In Belgium, physicians are normally encouraged to allow automatic substitution by prescribing by INN.²⁴¹¹ As explained in Recital (88), the health authorities can exclude substitution by placing an active ingredient on a "no substitution" or "no INN" list (also referred to as "NO VOS/NO SWITCH" list).²⁴¹² Further, the entry on the market of a generic triggers the creation of a cluster containing the generic and the originator.²⁴¹³ In Belgium, as explained in Recitals (419) and (537), the launch of Synthon GA would have meant a potential 44% price decrease for Copaxone. In order to hinder the entry and uptake of Synthon GA/Glatiramyl in Belgium and thus to avoid or delay the resulting price competition in Belgium from automatic substitution or creation of a cluster with Copaxone and Synthon GA (see Recital (1772)), Teva disseminated the Misleading Complexity Message primarily to the Belgian authorities (FAMHP, the Belgian Federal Agency for Medicines and Health Products and INAMI/RIZIV, the Belgian pricing and reimbursement authority), although the campaign also covered HCPs. This was mainly because there was no launch of Synthon GA until August 2021, and thus no pressing need for Teva to influence HCPs.
- (1834) Teva's document "Copaxone defence strategy" in Belgium from June 2018 reveals that for Belgium Teva had a three layer defence strategy: {...}.²⁴¹⁴ As explained above (Recital (1833)), opening the cluster meant lowering the prices for Copaxone. In the same document, as part of "preventing cluster opening", Teva indicated that the suspension be requested on the basis of non-similarity between Copaxone and Synthon GA and on the basis of the fact that {...}.²⁴¹⁵ Among the challenges to this layer of its strategy, Teva mentioned that {...}.²⁴¹⁶ An internal email exchange provides more detail on how Teva aimed to confront competition from Synthon GA

²⁴⁰⁶ See e.g. ID 404-1721, a poster prepared for the European Committee for Treatment and Research in Multiple Sclerosis Congress in Paris, October 2017 which includes elements of the Misleading Complexity Message analysed in Section 9.3.1.1.

²⁴⁰⁷ ID 455-38, Copaxone/FoGA Overview – Pricing and Market Access, 7 February 2017.

²⁴⁰⁸ ID 455-2708, Copaxone® Litigation Internal Update for week ending 11 November 2016.

²⁴⁰⁹ ID 455-440, Teva internal email dated 30 April 2018 from {...} to {...} and others.

²⁴¹⁰ ID 262-1473, 2019 AOP pre-alignment – BeLux, p. 3.

²⁴¹¹ See Recital (88) above.

²⁴¹² ID 1288, Teva's reply to Article 18(2) Request of 22 October 2021 and 18 November 2021, p. 3; See Recital (88); the FAMHP, the Belgian Federal Agency for Medicines and Health, is in charge of determining who is on the no-INN list. It is important to note that different departments of the FAMHP are in charge of MA and of deciding which product are listed on the no-INN list.

²⁴¹³ See Recital (1772).

²⁴¹⁴ ID 404-460, Copaxone defence strategy in BE, June 2018, p. 2.

²⁴¹⁵ ID 404-460, Copaxone defence strategy in BE, June 2018, p. 3.

²⁴¹⁶ ID 404-460, Copaxone defence strategy in BE, June 2018, p. 3.

in Belgium as of 2018. Amongst others, Teva planned meetings with and submissions to INAMI/RIZIV and FAMHP to prevent clustering, revision of the NO VOS/NO SWITCH list, as well as meetings with, or statements in its support from, neurologists, pharmacists and pharmacologists.²⁴¹⁷ Another strategy document shows that, in order to avoid the opening of a cluster, Teva was planning to use the claim of {...} between Copaxone and Synthron GA and that switching would be {...} and that Teva was considering delisting Copaxone and launching a duplicate (Glataxon).²⁴¹⁸

(1835) A Teva presentation²⁴¹⁹ shows that automatic substitution was, along with clustering, seen as a key risk for Copaxone in Belgium, that Teva was seeking to prevent (by influencing the Belgian authorities to include Synthron GA on the NO INN/NO SWITCH list). Some of the tactics used by Teva included raising awareness about the “specificities” of GA,²⁴²⁰ and using KOLs as advisors “to inform” INAMI/RIZIV and FAMHP.²⁴²¹

9.4.4.2.1. Dissemination of Teva’s Misleading Complexity Message to Payers in Belgium

(1836) Following the grant of the MA to Mylan in Belgium, Mylan applied for pricing and reimbursement to the Belgian authorities and Teva, accordingly, directed its disparagement actions towards the Belgian Payers (“Phase Ila” of its disparagement campaign) to prevent/delay market entry of Synthron GA by trying to influence authorities to decide against automatic substitution and clustering of Copaxone and Synthron GA/Glatiramyl. In order to achieve that, Teva used the Misleading Complexity Message as detailed below.

(1837) An internal email dated 9 August 2017 states Teva’s objectives: {...}.²⁴²² Teva wanted to maintain high prices and aimed at avoiding automatic substitution: {...}.²⁴²³ Further, the same email describes Teva’s strategy to delay clustering and, in case the clustering happened, Teva’s plans to delist Copaxone: {...}. In case Teva expressed its disagreement with the cluster to the competent authority, this would delay the cluster opening: {...}.²⁴²⁴

(1838) As indicated in the 2015 Brand Plans for Belgium, Teva’s tactics in relation to Payers was to communicate on the “complexity” of GA, including by disseminating the Misleading Complexity Message. For this purpose, Teva organised meetings with Payers, advisory boards as well as meetings with multiple stakeholders.²⁴²⁵

(1839) First, Teva systematically targeted the Belgian medicines agency, inasmuch a division of the agency was also in charge of automatic substitution status, with its campaign including the Misleading Complexity Message in order to dissuade it from granting an automatic substitution status to Synthron GA/Glatiramyl.

²⁴¹⁷ ID 455-558, Teva internal email chain including email dated 6 March 2018 from {...} to {...} and others.

²⁴¹⁸ ID 404-364, Scenario’s FoGA launch in Belgium & Impact on Copaxone, pp. 3, 4.

²⁴¹⁹ ID 455-2061, FoGA 2017, Belgium, pp. 2-8.

²⁴²⁰ ID 455-2061, FoGA 2017, Belgium, p. 7.

²⁴²¹ ID 455-2061, FoGA 2017, Belgium, p. 7.

²⁴²² ID 455-2771, Teva internal email dated 9 August 2017 from {...} to {...} and others.

²⁴²³ “Gx status” refers to the generic status. If Mylan had obtained a generic status, Copaxone and Synthron GA/Glatiramyl would have been included in the same cluster where a price reduction for generics would have been applied and thus Teva would have had to apply a higher price reduction for Copaxone.

²⁴²⁴ ID 455-2771, Teva internal email dated 9 August 2017 from {...} to {...} and others.

²⁴²⁵ ID 1135-58, Copaxone Go To Market Action Plan (GTMAP), 30 June 2015, p. 33.

- (1840) The FAMHP (Belgian Federal Agency for Medicines and Health Products) is the competent authority responsible for the quality, safety and efficacy of medicines and health products in Belgium. Apart from its role in evaluating new MA requests and pharmacovigilance tasks, FAMHP also maintains and publishes a list of products for which prescription by INN and therefore automatic substitution are not recommended (the so-called “No INN” list, see also Section 6.3.3.4.3.1).²⁴²⁶
- (1841) Teva intervened with the competent division of the FAMHP in order to persuade it to place Copaxone/GA competitors on the No INN list,²⁴²⁷ Using disparaging messages in so doing, Teva’s disparaging efforts vis-à-vis FAMHP to influence the decision-making processes in Belgium with a view to hindering Synthron GA/Glatiramyl’s entry and uptake started long before the launch of Mylan’s Glatiramyl.²⁴²⁸ On 30 March 2014, Teva delivered a presentation to the FAMHP where it conveyed the entire range of the Misleading Complexity Message described in Section 9.3.1.²⁴²⁹ Such contacts, which preceded the successful conclusion of the Decentralised Procedure for Synthron GA (thus, such contacts are not used to establish an infringement before the period of infringement began), prepared the ground for Teva’s next phase of the campaign and ensured that Teva’s position would be on the minds of the authorities.²⁴³⁰ For example, in the presentation made to the FAMHP, Teva also introduced the notions of {...} and {...} to {...} the Payers and prime them based on Teva’s commercial positions.²⁴³¹ On 23 January 2017, Teva met again²⁴³² with the FAMHP and disseminated the same range of misleading messages described in Section 9.3.1: as the document Teva used in this meeting shows, Teva sought to influence FAMHP decision on automatic substitution by using the Misleading Complexity Message: (i) emphasising clinically irrelevant differences in GA structures in order to suggest that Synthron GA was not safe, efficacious, and therapeutically equivalent to Copaxone (for example: {...});²⁴³³ (ii) making misleading presentations related to other glatiramer-related substances implying health risks for Glatiramyl²⁴³⁴ (for example: {...} suggesting that such differences

²⁴²⁶ The official name for this list is “Groupes de médicaments pour lesquels il est déconseillé de prescrire en DCI (NO DCI/NO VOS)”.

²⁴²⁷ ID 655, Teva’s reply to the Article 18(2) Request of 3 June 2021, p. 4. In a Teva internal email chain from 25 September 2017, in preparing for a meeting with FAMHP, Teva employees discuss the objectives of the meeting: {...}. In addition, in a Teva internal email from 23 February 2018 from {...}, {...} reports on Belgium that: {...} ID 455-2717, Teva internal email dated 23 February 2018 from {...} to {...}.

²⁴²⁸ Synthron applied for a MA on 30 July 2014 – see ID 863, Synthron’s Reply to the Article 18(2) Request of 9 June 2021, p. 4.

²⁴²⁹ ID 651-54, MA applications for follow on glatiramer acetate products, Federal agency for medicines and health products FAMHP, 30 March 2014, p. 11; ID 655, Teva’s reply to the Article 18(2) Request of 3 June 2021, p. 5.

²⁴³⁰ ID 455-269, CCP strategy – In face of evolving FoGA competition, p. 9.

²⁴³¹ ID 651-54, MA applications for follow on glatiramer acetate products, Federal agency for medicines and health products FAMHP, 30 March 2014.

²⁴³² In the context of its activities to prevent automatic substitution, Teva also met with the pricing and reimbursement authority, RIZIV/INAMI (which was not competent to decide on that question), and submitted a memorandum containing some facets of the Misleading Complexity Message described in Recital (1429) and emphasising clinically irrelevant differences in GA structures, for example: {...} ID 455-1845, Memorandum – Follow-on glatiramer acetate/Consequences on reimbursement level, 31 May 2016, p. 7.

²⁴³³ ID 651-21, Substitution considerations for follow on glatirameracetate products Meeting with Federal Agency for Medicines & Health Products Brussels, 23 January 2017, p. 27.

²⁴³⁴ ID 651-21, Substitution considerations for follow on glatirameracetate products Meeting with Federal Agency for Medicines & Health Products Brussels, 23 January 2017, pp. 17-47.

had {...} (original emphasis)),²⁴³⁵ amongst others, Teva was implying that adverse events concerning another glatiramer-related substance marketed in Mexico were relevant for FAMHP’s assessment of Synthon GA: {...} (original emphasis)²⁴³⁶; and (iii) casting doubt on the validity of the GATE study and its finding of therapeutic equivalence. Teva claimed, most notably, that the {...} (original emphasis).²⁴³⁷ Teva claims that {...}²⁴³⁸ and that {...}.²⁴³⁹

- (1842) Teva explained that usefulness of the MRI lesions as an applicable endpoint was {...} and thus the entire study, based on MRI lesions as an endpoint, {...}:²⁴⁴⁰ {...} (original emphasis).²⁴⁴¹
- (1843) By presenting (or implying, through comparison with other glatiramer-related substances) Synthon GA as not safe, efficacious and therapeutically equivalent with Copaxone, contrary to the findings of relevant authorities, Teva provided misleading information to the FAHMP, which questioned the basis on which the Decentralised Procedure for Synthon GA was finalised. Eventually, the FAMHP included Copaxone on the “No INN” list in 2018.²⁴⁴² This meant that, at pharmacy level, the pharmacist could not automatically substitute Copaxone with Synthon GA. This outcome was in line with the objectives of Teva’s campaign.
- (1844) Second, Teva also attempted to influence the Belgian pricing and reimbursement authority’s decision concerning price clusters for GA.
- (1845) Teva met with the Belgian pricing and reimbursement authority, RIZIV/INAMI, on 29 November 2017 with the aim {...}.²⁴⁴³
- (1846) Teva organised a meeting on 19 April 2018 with the RIZIV/INAMI to discuss the formation of the price cluster.²⁴⁴⁴ Teva’s internal email dated 30 April 2018 confirms that {...}.²⁴⁴⁵ At this occasion, Teva used a presentation which contained the Misleading Complexity Message as described in Section 9.3.1.²⁴⁴⁶ (i) Teva emphasised clinically irrelevant differences in GA structures: {...}.²⁴⁴⁷ Its conclusion, based not on a clinical study such as GATE but on a study in rats, alleges immunogenicity differences and claims that {...}²⁴⁴⁸ implying that the two products were not therapeutically equivalent; (ii) Teva falsely implied that health risks observed in other glatiramer-related substances equally apply to Synthon GA: under

²⁴³⁵ ID 651-21, Substitution considerations for follow on glatirameracetate products Meeting with Federal Agency for Medicines & Health Products Brussels, 23 January 2017, p. 19; Internally, Teva knew that this statement is disparaging; this is shown in ID 4513-96462, Teva internal email dated 3 March 2017 from {...} to {...} where in relation to this statement, a Teva employee stated: {...}.

²⁴³⁶ ID 651-21, Substitution considerations for follow on glatirameracetate products Meeting with Federal Agency for Medicines & Health Products Brussels, 23 January 2017, p. 43.

²⁴³⁷ Idem, p. 54.

²⁴³⁸ Idem, p. 54.

²⁴³⁹ Idem, p. 52.

²⁴⁴⁰ Idem pp. 52, 53; For an assessment of these claims, see in particular Recitals (1614)-(1619).

²⁴⁴¹ ID 651-21, Substitution considerations for follow on glatirameracetate products Meeting with Federal Agency for Medicines & Health Products Brussels, 23 January 2017, p. 53.

²⁴⁴² ID 655, Teva’s reply to the Article 18(2) Request of 3 June 2021, p. 4. See also ID 455-2149, Teva internal email dated 14 December 2018 from {...} to {...} and others: {...}.

²⁴⁴³ ID 404-93, Copaxone® EU Litigation Internal Update, p. 5.

²⁴⁴⁴ ID 404-93, Copaxone® EU Litigation Internal Update, p. 5.

²⁴⁴⁵ ID 455-440, Teva internal email dated 30 April 2018 from {...} to {...} and others.

²⁴⁴⁶ ID 4900, Scientific evidence-base on COPAXONE®’s complexity and comparison to Synthon EU Follow-On GA (FOGA), pp. 5, 6, 7, 12, 31, 32, 38, 39, 40.

²⁴⁴⁷ Ibid, p. 12.

²⁴⁴⁸ Ibid, pp. 12, 22 and 32.

the title {...}, Teva made references to the toxic effects of other glatiramer-related substances unrelated to Synthon GA: {...}.²⁴⁴⁹ (iii) Finally, Teva also casted doubt on the validity of the GATE study using the same message as disseminated to FAMHP (see Recital (1842)): {...} (emphasis added).²⁴⁵⁰ Teva effectively questioned the relevant authorities' finding of Synthon GA's safety, efficacy and therapeutic equivalence with Copaxone, by affirming, for example, that {...};²⁴⁵¹ and that {...} (emphasis added).²⁴⁵² Teva explained that usefulness of the MRI as an applicable endpoint was {...} and thus the entire study, based on the MRI as an endpoint, {...}: {...} (emphasis added).²⁴⁵³

- (1847) Third, in more recent years, Teva continued to pursue the strategy targeted at {...} (mostly under threat by Synthon GA) and at maintaining market access (i.e. maintaining high Copaxone prices) through its artificial differentiation campaign, as shown in its 2019, 2020 and 2021 Brand Plans.²⁴⁵⁴ The campaign included, implicitly or explicitly, the Misleading Complexity Message.
- (1848) The success of the campaign appeared to be crucial for Teva – based on its calculations from 2019, in Belgium, {...}.²⁴⁵⁵ According to 2020 Brand Plans, in case of a cluster opening with no exception,²⁴⁵⁶ there would have been {...}.²⁴⁵⁷ In case of a cluster opening with an exception granted, there would have been a {...}.²⁴⁵⁸ To avoid spill over effects in other Member States in case of a cluster opening and the ensuing price competition, Teva considered delisting Copaxone, i.e. withdrawing the product completely from the Belgian market (see section 6.3.3.4.3.1.).²⁴⁵⁹
- (1849) As part of the CCP implementation in Belgium, Teva's following Brand Plans for Belgium continue to pursue the same objectives as earlier Teva communications, including to artificially differentiate Copaxone from Synthon GA through the use of the Misleading Complexity Message. For 2019, Teva amongst others considered that it was critical for the CCP's success to communicate to Payers that Copaxone was an "NBCD" and therefore a unique medicine (implying that there was no therapeutically equivalent treatment).²⁴⁶⁰ Similarly, emphasising the differences between Copaxone

²⁴⁴⁹ Ibid, p. 6.

²⁴⁵⁰ Ibid, p. 38.

²⁴⁵¹ Ibid, p. 40.

²⁴⁵² Ibid, p. 40.

²⁴⁵³ Ibid, pp. 38, 39.

²⁴⁵⁴ The Commission requested the brand plans ('GTMAP' - Go to Market Action Plans) for each year for the period 2016-2021, however, Teva submitted only 2015 GTMAP, 2020 GTMAP, 2021 GTMAP. Teva did not provide any convincing reason why they have not submitted the Brand Plans for other years. These are commercial documents which set out proposed objectives regarding the Copaxone business for the upcoming year(s) as well as underlying assumptions on the market and its evolution. They are prepared at both European level and local level. For the rest of the years Teva submitted Annual Operating Plan ('AOP') which is a distinct document, this being a financial exercise prepared to support the budget for the upcoming year. See also ID 1062-57, 2019 AOP pre-alignment – BeLux Copaxone, 10/09/2018, p. 11; ID 1062-55, 2020 GTMAP Template – Belgium – Copaxone, p. 9; ID 1062-51, 2021 GTMAP Template Belgium – Copaxone, August 2021, p. 7; ID 262-992, 2019 GTMAP Belgium, p. 3.

²⁴⁵⁵ ID 1062-57, 2019 AOP pre-alignment – BeLux, p. 4.

²⁴⁵⁶ Meaning including Copaxone 40 mg/ml in the cluster.

²⁴⁵⁷ ID 1062-55, 2020 GTMAP Template – Belgium – Copaxone, p. 8.

²⁴⁵⁸ ID 1062-55, 2020 GTMAP Template – Belgium – Copaxone, p. 8.

²⁴⁵⁹ ID 1062-57, 2019 AOP pre-alignment – BeLux Copaxone, v.2, p. 4.

²⁴⁶⁰ ID 1062-11, 2019 AOP pre-alignment – BeLux Copaxone, 10 September 2018, p. 11; ID 1062-55, 2020 GTMAP Template – Belgium – Copaxone, p. 9; ID 262-992, 2019 GTMAP Belgium, p. 3.

and Synthon GA remained a priority in its 2020 and 2021 Brand Plans for Belgium.²⁴⁶¹

(1850) To sum up, Teva was targeting the characteristics of Synthon GA which had been a condition to the successful conclusion of its Decentralised Procedure. These characteristics were also a necessary precondition for the inclusion of Synthon GA in price clusters and for deciding on automatic substitution in Belgium. If the Payers were misled with respect to these characteristics, this was also likely to affect their decisions to include Copaxone and Synthon GA in the same price clusters and allow automatic substitution. Therefore, Teva's messages were capable of producing exclusionary effects.

9.4.4.2.2. Dissemination of Teva's Misleading Complexity Message to HCPs, including KOLs, in Belgium

(1851) Since Phase IIA²⁴⁶² of Teva's campaign was successful in Belgium, and the FAMHP ruled against automatic substitution,²⁴⁶³ Phase IIB of Teva's campaign to influence individual prescription decisions by HCPs has been less relevant, also considering that Synthon GA/Glatiramyil was not marketed until August 2021 due to, *inter alia*, a preliminary patent injunction. Phase IIB of Teva's CCP consisted in, first, "educating" the HCPs and, second, in convincing HCPs to prescribe Copaxone and not Synthon GA once the latter was launched.

(1852) As shown in the Brand Plan for Belgium from 2015, Teva planned to disseminate to HCPs information from the following promotional materials: {...}²⁴⁶⁴, which also contained the Misleading Complexity Message.

(1853) Teva was aware that Belgian neurologists, taken as a whole, were not aligned with its commercial position that Copaxone prescriptions should not be switched to Synthon GA/Glatiramyil. On 23 February 2018, Teva's {...} observed that in Belgium {...}.²⁴⁶⁵

(1854) As shown in the preceding Recital, Teva has also reached out to pharmacists, with apparent success. A Teva presentation to the Belgium Pharmacy Group²⁴⁶⁶ shows that Teva used all three facets of the Misleading Complexity Message in communicating with pharmacists. Teva emphasised clinically irrelevant differences in GA structures:²⁴⁶⁷ and casted doubt on the validity of the GATE study by, amongst others, contesting MRI lesions as a relevant primary endpoint for the study (as assessed in Recital (1616) et seq), and raising concerns due to efficacy outcomes related to the ARR endpoint (as assessed in Recital (1632)), reaching the misleading conclusion that the {...} (original emphasis).²⁴⁶⁸ In keeping with its messages to

²⁴⁶¹ ID 1062-55, 2020 GTMAP Template – Belgium – Copaxone, p. 3, and ID 1062-51, 2021 GTMAP Belgium, p. 5.

²⁴⁶² See Section 9.1.

²⁴⁶³ The Commission does not take a position on whether the outcome is lawful or not or whether this outcome was actually caused by the disparagement.

²⁴⁶⁴ ID 1062-63, Copaxone Go To Market Action Plan (GTMAP), 30 June 2015, pp. 21, 30, 33.

²⁴⁶⁵ ID 455-2717, Teva internal email dated 23 February 2018 from {...} to {...} and others.

²⁴⁶⁶ ID 455-2366, Teva internal email dated 25 April 2019 from {...} to {...}.

²⁴⁶⁷ ID 455-2381, Scientific Evidence-Base on COPAXONE® Complexity & Comparison to Synthon EU Follow-On GA (FOGA), 11 March 2019, pp. 10-31. For example, Teva claims that {...}, p. 10.

²⁴⁶⁸ ID 455-2381, Scientific Evidence-Base on COPAXONE® Complexity & Comparison to Synthon EU Follow-On GA (FOGA), 11 March 2019, p. 39.

FAMHP and RIZIV/INAMI, Teva also claimed that claimed that {...}.²⁴⁶⁹ Teva explained that usefulness of the MRI lesions as an applicable endpoint was “violated” and thus the entire study, based on the MRI as an endpoint, “invalidated”, and raising concerns {...}.²⁴⁷⁰

- (1855) Ensuring that {...}²⁴⁷¹ and communicating Copaxone’s status as “NBCD” was a critical success factor for Teva’s CCP in Belgium. The {...} was one of Teva’s three key medical projects in 2019, and was to be implemented both in face to face and in remote meetings. The implementation was planned {...}.²⁴⁷² According to the 2019 AOP and 2020 GTMAP, the imperative to retain current patients was high amongst Teva’s strategic imperatives for Belgium and one of the key medical must wins to be achieved was {...}.²⁴⁷³
- (1856) In the 2021 GTMAP, having the {...} to retain current patients, Teva similarly indicated that, in case of Synthon GA launch and depending on its timing, it should differentiate Copaxone from Synthon GA vis-a-vis HCPs. Teva identified as one of the key projects the {...} – but only in case of Synthon GA launch (which occurred in August 2021): {...}. The targeted stakeholders of this project were {...} and the channels of engagement would be face-to-face and digital meetings.²⁴⁷⁴
- (1857) Available data reveal that in the period from 2015 to May 2021 members of Teva MSL team and sales representatives made altogether {...} direct contacts (either face-to-face visits or phone calls) with {...} HCPs in Belgium related to Copaxone, GA or central nervous system products.²⁴⁷⁵ In addition, since June 2019, Teva’s sales representatives in Belgium are using an additional system for customer relationship management ({...}), which recorded altogether {...} contacts with {...} HCPs in the period from 3 June 2019 to 30 April 2021.²⁴⁷⁶ Taking into account the emphasis on the Misleading Complexity Message in the training materials prepared by Teva²⁴⁷⁷ and its Brand Plans for Belgium, it is likely that these contacts have been devoted, at least, in part to the dissemination of the Misleading Complexity Message.²⁴⁷⁸ Further, not all contacts are recorded mandatorily, and even for contacts for which documentation is mandatory there is no system in place which requires sales

²⁴⁶⁹ ID 455-2381, Scientific Evidence-Base on COPAXONE® Complexity & Comparison to Synthon EU Follow-On GA (FOGA), 11 March 2019, p. 37.

²⁴⁷⁰ ID 455-2381, Scientific Evidence-Base on COPAXONE® Complexity & Comparison to Synthon EU Follow-On GA (FOGA), 11 March 2019, pp. 37, 38, 39, 82.

²⁴⁷¹ ID 1062-11, 2019 AOP pre-alignment – BeLux Copaxone, 10 September 2018, p. 13; ID 262-992, 2019 GTMAP Belgium, p. 11.

²⁴⁷² ID 1062-11, 2019 AOP pre-alignment – BeLux Copaxone, 10 September 2018, p. 13; ID 262-992, 2019 GTMAP Belgium, p. 5.

²⁴⁷³ ID 1062-55, 2020 GTMAP Template Belgium, Copaxone, p. 9; see also ID 1062-57, 2019 AOP pre-alignment – BeLux, Copaxone, p. 11.

²⁴⁷⁴ ID 1062-51, 2021 GTMAP Belgium, pp. 5, 18, 19, 20.

²⁴⁷⁵ ID 900-11, {...} data Belgium. For scope and reliability of {...} data see footnote 2326.

²⁴⁷⁶ ID 800-50, {...} data for Belgium and ID 799, email dated 24 June 2021 from Teva’s external counsel to the European Commission.

²⁴⁷⁷ See Section 9.3.2. In particular, Teva prepared materials for the members of its MSL team (notably the External Expert White Paper for MS specialists, the GATE Study Review and the MSL Objection Handlers) and for its KAMs, (notably KAM Objection Handlers).

²⁴⁷⁸ Due to inherent limitations in the available CRM data (see footnote 2326) and due to the fact that the Commission has not independently verified the content of CRM data provided by Teva or the methodology used to reach the conclusions presented in this Recital, the exact numbers of direct contacts and of contacted HCPs are used for illustrative purposes only. The Commission cannot indeed rule out that Teva had a higher number of contacts with HCPs in Belgium than the one reported in this Recital.

representatives and members of Teva’s MSL team to record calls, as also confirmed by Teva.²⁴⁷⁹ This suggests that the actual number of contacts between Teva and HCPs in Belgium was likely higher than the number of contacts documented in the available data.

- (1858) Besides targeting HCPs in their quality of prescribers, Teva’s strategy was also to approach certain neurologists and pharmacologists in their quality as KOLs, in order to “educate” them about the “complexity” of GA, with a view to disseminating its messages more effectively to Belgian authorities, in line with Teva’s strategy.
- (1859) This plan was put in motion. An internal Teva email of 25 September 2017 shows that Teva sought to {...} a KOL in case they would be asked questions from FAMHP in the context of the decision on automatic substitution: {...}.²⁴⁸⁰
- (1860) Teva made a presentation²⁴⁸¹ to {...}²⁴⁸² in October 2017. The presentation contained all three facets of the Misleading Complexity Message : (i) Teva emphasised clinically irrelevant differences in GA structures: {...};²⁴⁸³ (ii) Teva implied that health risks observed in other glatiramer-related substances equally apply to Synthon GA: under the title claiming dissimilarity - {...},²⁴⁸⁴ Teva included a comparison table emphasising differences compared with other glatiramer-related substances;²⁴⁸⁵ (iii) Teva casted doubt on the validity of the GATE study, consistently with its presentations to FAMHP and RIZIV/INAMI (see Recitals (1842) and (1846)), claiming that {...}.²⁴⁸⁶
- (1861) It appears that Teva’s presentation was successful, as later, in February 2018, Teva was planning to request {...} for a statement concerning non-substitution of Synthon GA and Copaxone.²⁴⁸⁷
- (1862) In the context of this strategy to influence the Belgian authorities via KOLs, Teva presented a very similar slide deck²⁴⁸⁸ to another KOL, {...}, who also exercised the roles of the {...} and of the {...}. The presentation again contained the same misleading messages questioning Synthon GA’s safety, efficacy, and therapeutic equivalence with Copaxone: (i) Teva emphasised clinically irrelevant differences in GA structures claiming, amongst others, that {...}²⁴⁸⁹ and highlighting {...}²⁴⁹⁰

²⁴⁷⁹ See footnote 2326 above.

²⁴⁸⁰ ID 455-2422, Teva internal email dated 25 September 2017 from {...} to {...} and others.

²⁴⁸¹ ID 4898, Scientific evidence-base on Copaxone’s complexity and comparison to Synthon EU Follow-On GA (FOGA), pp. 12, 24, 28-30. See also ID 4896, Teva’s reply to Article 18(2) Request of 20 July 2023, p. 13 which indicates that this presentation was shown to {...} on 2 October 2017.

²⁴⁸² ID 4896, Teva’s reply to Article 18(2) Request of 20 July 2023, p. 13. According to Teva, {...}.

²⁴⁸³ ID 4898, Scientific evidence-base on Copaxone’s complexity and comparison to Synthon EU Follow-On GA (FOGA), p. 24.

²⁴⁸⁴ ID 4898, Scientific evidence-base on Copaxone’s complexity and comparison to Synthon EU Follow-On GA (FOGA), p. 12.

²⁴⁸⁵ ID 4898, Scientific evidence-base on Copaxone’s complexity and comparison to Synthon EU Follow-On GA (FOGA), p. 12.

²⁴⁸⁶ ID 4898, Scientific evidence-base on Copaxone’s complexity and comparison to Synthon EU Follow-On GA (FOGA), p. 28.

²⁴⁸⁷ ID 404-555, Teva internal email dated 23 February 2018 from {...} to {...}.

²⁴⁸⁸ ID 4899, Scientific evidence-base on COPAXONE®’s complexity and comparison to Synthon EU Follow-On GA (FOGA), pp. 5-6, 11, 15, 35-37; see also ID 4896, Teva’s reply to Article 18(2) request of 20 July 2023, p. 13 which shows that this presentation was used in a meeting with {...} on 29 November 2017.

²⁴⁸⁹ ID 4899, Scientific evidence-base on COPAXONE®’s complexity and comparison to Synthon EU Follow-On GA (FOGA), p. 11.

while claiming that the identity of the drugs cannot be demonstrated and that the verification of similarity between Synthron GA and Copaxone was not carried out.²⁴⁹¹ (ii) Teva also implied that health risks observed in other glatiramer-related substances equally apply to Synthron GA, indicating that {...}.²⁴⁹² (iii) Finally, Teva also cast doubt on the validity of the GATE study, claiming, just like in the presentation to {...}, {...} and {...}, that {...}, and that {...}.²⁴⁹³ This presentation again implicitly or explicitly contradicted the findings in the PAR that Synthron GA was safe, efficacious, and therapeutically equivalent with Copaxone.

9.4.4.2.3. Teva's arguments and the assessment by the Commission

- (1863) First, Teva claims that two documents (ID 651-54 and ID 1135-58) both pre-date the MA approval of Synthron GA.²⁴⁹⁴ In relation to this claim, the Commission would like to draw a distinction between these documents. The first document pre-dates the period of infringement and is used to show that Teva has not changed its messages, while the second document is a Brand Plan for Belgium for 2016, thus it concerns the period of infringement. ID 651-54 is not used to establish an infringement, but it is used to show that Teva was disseminating messages questioning Synthron GA's efficacy, safety, and therapeutic equivalence with Copaxone to FAMHP already before the MA grant and long before the launch of Synthron GA. Although the present Decision does not reach a conclusion on whether, at the time, these statements constituted an abuse of dominance, they show that Teva was attempting to win the agency over with its arguments even before the successful conclusion of the Decentralised Procedure for Synthron GA, and did not change its messages even in view of the PAR findings once the Decentralised Procedure was completed and despite the facts that these findings directly or indirectly belied Teva's statements.²⁴⁹⁵ With regard to ID 1135-58, the Commission notes that Teva explained that the document in question is a Teva Brand Plan for 2016 and thus informative of Teva's planned activities in 2016, the period covered by the infringement.²⁴⁹⁶
- (1864) Second, Teva claims that "*while the creation of a cluster (a price reference group) in Belgium would have implied some price decrease for Copaxone, the evidence shows that Teva was concerned that "FoGa launch [would be] harmful for company and healthcare"*".²⁴⁹⁷ The Commission rejects this claim, This piece of evidence that Teva

²⁴⁹⁰ ID 4899, Scientific evidence-base on COPAXONE®'s complexity and comparison to Synthron EU Follow-On GA (FOGA), p. 6.

²⁴⁹¹ ID 4899, Scientific evidence-base on COPAXONE®'s complexity and comparison to Synthron EU Follow-On GA (FOGA), p. 6.

²⁴⁹² Idem, p. 5.

²⁴⁹³ Idem, pp. 35 and 37.

²⁴⁹⁴ ID 4032, Teva's Reply to the Statement of Objections, para. 1196.

²⁴⁹⁵ For example, the in the presentation from 23 January 2017 Teva suggests that differences observed between Copaxone and Synthron GA had {...} (ID 651-21, Substitution considerations for follow on glatirameracetate products Meeting with Federal Agency for Medicines & Health Products Brussels, 23 January 2017, p. 19), the same is claimed in the presentation from 30 March 2014: {...} (ID 651-54, p. 54); In the presentation from 2017 Teva was implying that adverse events concerning another GA product marketed in Mexico were relevant for FAMHP assessment of Synthron GA: {...} (ID 651-21, p. 46) and the same message can be found in the 2014 presentation: on the slide titled {...}, Teva presents the Adverse Events as increased 3 fold and Relapses 7 fold (ID 651-54, p. 44); in both presentations from 2014 and 2017 Teva criticises the use of MRI as end-point (ID 651-21, pp. 52, 53) and (ID 651-54, p. 58); Teva made misleading presentations related to other glatiramer-related substances implying health risks for Glatiramyl in both presentations from 2014 (ID 651-21, pp. 13-45) and from 2017 (ID 651-54, pp. 17-47).

²⁴⁹⁶ ID 1167, Teva's reply to Commission Article 18(2) request dated 18 November 2021, p. 9.

²⁴⁹⁷ ID 4032, Teva's Reply to the Statement of Objections, para. 1198.

quoted²⁴⁹⁸ shows that Teva's main objective was to avoid price reductions which would have occurred as the result of Synthron GA entering the market in the same price cluster as Copaxone. The fact that Teva was repeatedly considering the withdrawal of Copaxone 20 mg from the market in order to avoid knock-on price effects from external reference pricing²⁴⁹⁹ shows that Teva's conduct was not driven by public health concerns, but by its interests of purely commercial nature.²⁵⁰⁰ This evidence shows, on the contrary, that in its endeavours to avoid price reductions, Teva made claims that the launch of Synthron GA would be harmful for health, as shown in Section 9.4.4.2 above.

- (1865) Third, Teva claims that it is misleading for the Commission to allege that two meetings which took place nearly three years from each other amount to Teva having systematically targeted the Belgian medicines agency.²⁵⁰¹ The Commission rejects this claim. What matters is that FAMHP, the Belgian medicines agency, was targeted with the same message despite the findings of the competent authorities dismissing the arguments put forward by Teva, both before and after the successful conclusion of the Decentralised Procedure for Synthron GA. Moreover, Teva not only approached the Belgian medicines agency as such, but targeted a KOL holding a leading function in the agency, {...}.²⁵⁰² This shows that Teva's contacts with FAMHP were subject to sophisticated and systematic preparations, despite being less frequent than, for example, Teva's visits of HCPs.
- (1866) Fourth, Teva claims that the Commission focussed on internal documents and GTMAPs (Go to Market Action Plans, or Brand Plans), and is wrong in alleging that they should be construed as proving Teva's strategy of abusive disparagement, or its implementation. Teva also claims that, without actual evidence, it cannot be inferred that objectives such as "retaining current patients" involve the use of disparaging tactics.²⁵⁰³ The Commission rejects these claims. First of all, the Brand Plans are documents which lay down the company's strategy for the future, including the strategic imperatives, the related tasks and actions to achieve the imperatives, and the allocated budget. Teva brought no evidence that the Brand Plans, which were coordinated by Teva Europe and which were adapted and implemented at national level were not to be strictly adhered to by the relevant national teams. Moreover, the same actions can be found consistently in successive annual Brand Plans and there is no indication that the actions in the previous years had not been executed. Second, the evidence on the Commission's file has to be looked at as a whole and in corroboration with the other pieces of evidence. The Brand Plans are fully consistent with Teva's strategy in Belgium to prevent or limit price competition from Synthron GA by influencing the authorities as described in Recital (1834). Furthermore, the Commission does not assume that Teva's stated objectives involve the use of disparaging tactics but demonstrates that, whatever its stated objectives may be and even if those were legitimate, Teva used disparaging messages to fulfil them.

²⁴⁹⁸ ID 404-460, Copaxone defence strategy in BE, June 2018, pp. 2-13.

²⁴⁹⁹ See Recital (689).

²⁵⁰⁰ ID 404-460, Copaxone defence strategy in BE, June 2018, p. 2 – {...}; ID 404-364, Scenario's FoGA launch in Belgium & Impact on Copaxone, p. 3; ID 455-2061, FoGA 2017, Belgium, p. 6.

²⁵⁰¹ ID 4032, Teva's Reply to the Statement of Objections, para. 1200.

²⁵⁰² See Recital (1860).

²⁵⁰³ ID 4032, Teva's Reply to the Statement of Objections, paras. 1204, 1212 the same claim in relation to the Brand Plans is made in ID 5909, Teva's Reply to the Letter of Facts II of 17 May 2024, para.146.

- (1867) Fifth, Teva claims that the Commission does not point to any evidence as to how this strategy would have been carried out before the Belgian Payers.²⁵⁰⁴ The Commission rejects this claim, as Section 9.4.4.2.1 abundantly shows that Teva was executing this strategy to the letter by communicating its misleading messages to Belgian Payers.
- (1868) Sixth, Teva claims that its documents only show that Teva was aware of the Belgian framework for generic price reductions.²⁵⁰⁵ The Commission rejects this claim. As detailed in Recital (1834), Teva’s strategy to prevent the entry on the market of Synthron GA had several prongs. Teva had various contingencies to avert or reduce price pressure in case its attempts to block Synthron GA by challenging MA approval and asserting its patents failed to entirely prevent the entry of Synthron GA: activities to influence authorities to prevent or delay the formation of a cluster, to ensure that Copaxone and Synthron GA are found non-substitutable (placed on a NO INN list), as well as possibly launching a duplicate product to safeguard the Copaxone price, or, in the extreme scenario, to delist Copaxone in Belgium with a view to avoiding knock-on effects on Copaxone prices in other Member States via price reference mechanisms.²⁵⁰⁶ Teva’s strategy documents show that Teva communicating misleading messages (concerning, for example, non-similarity, or Synthron GA being “harmful to healthcare”) was part of its strategy to influence Belgian authorities²⁵⁰⁷ not to include Synthron GA and Copaxone in a cluster or to include Synthron on No-INN list. Therefore, contrary to its claims, Teva’s strategy documents go far beyond merely showing its knowledge of the functioning of the pricing and reimbursement system in Belgium.
- (1869) With respect to its strategy documents, Teva also claims that the Commission has not shown that Teva would have carried out the plan to delist Copaxone.²⁵⁰⁸ This claim is misguided. As explained in the preceding Recital, Teva’s strategy shows that in several instances, the delisting of Copaxone was considered as a measure of last resort to protect Copaxone prices elsewhere in case of effective price competition in Belgium. This evidence contradicts Teva’s claims that its actions in Belgium were only pursuing public health interests. Further, it is irrelevant that it ultimately did not delist Copaxone. As Synthron GA was not granted automatic substitution status, Teva could maintain high prices for Copaxone, thus obviating the need to delist it.
- (1870) Finally, Teva claims that its contacts with HCPs mentioned in Recital (1857) above would “*only amount to approximately {...} contacts per HCP (i.e., an average of {...})*”.²⁵⁰⁹ This argument is flawed. This Decision shows, first, that Teva put in place an elaborate set of documents containing the misleading messages concerning Synthron GA to be communicated by Teva’s sales and medical representatives in their contacts with HCPs (such as neurologists) (see Section 9.3.2). Second, Teva strategic yearly Copaxone strategy plans for Belgium (Brand Plans/Go-To-Market-Action-Plans-GTMAPs) repeatedly show that the dissemination of the Misleading Complexity Message to HCPs was one of Teva’s main priorities. There were no indications whatsoever that the relevant actions repeatedly planned in its strategy documents, were not carried out. Third, the Commission has demonstrated that

²⁵⁰⁴ ID 4032, Teva’s Reply to the Statement of Objections, paras. 1204, 1212 the same claim in relation to the Brand Plans is made in ID 5909, Teva’s Reply to the Letter of Facts II of 17 May 2024, para.146.

²⁵⁰⁵ ID 4032, Teva’s Reply to the Statement of Objections, para.1205.

²⁵⁰⁶ ID 404-364, Scenario’s FoGA launch in Belgium & Impact on Copaxone, pp. 2-13; ID 404-460, Copaxone defence strategy in BE, June 2018, pp. 2-7.

²⁵⁰⁷ ID 404-364, Scenario’s FoGA launch in Belgium & Impact on Copaxone, p. 4.

²⁵⁰⁸ ID 4032, Teva’s Reply to the Statement of Objections, para. 1205.

²⁵⁰⁹ ID 4032, Teva’s Reply to the Statement of Objections, para. 1213.

during the Relevant Period during which Teva's CCP strategy had top priority, Teva contacted a high number of Belgian HCPs.²⁵¹⁰ Teva's claim that its promotional activities concerning HCPs did not take into account neither Teva's centrally prepared CCP documents nor the centrally agreed annual commercial plans for Copaxone in Belgium, and thus did not involve the dissemination of the Misleading Complexity Message are thus not credible. In any case, the contacts with HCPs in Belgium were less relevant in view of Teva's successful actions in relation to the authorities (FAMHP and RIZIV/INAMI).

9.4.4.2.4. Conclusion

(1871) As shown above, Teva's conduct covered most, if not all, drivers of demand for GA in Belgium. First, Teva disseminated the Misleading Complexity Message primarily to FAMHP and RIZIV/INAMI in the context of discussions on clustering and automatic substitution and the resulting price competition. Second, since Synthron GA was not marketed in Belgium until August 2021 due to, *inter alia*, a preliminary patent injunction, Teva's campaign to influence individual prescription decisions by HCPs has been less relevant. However, the dissemination of the Misleading Complexity Message to HCPs actually took place at least until 11 March 2019²⁵¹¹ and has been regularly included in Teva's Brand Plans for Belgium.

(1872) In view of the analysis made in this subsection 9.4.4.2 and in Sections 9.4.1, 9.4.2 and 9.4.3, the Commission concludes that Teva's dissemination of the Misleading Complexity Message in Belgium was capable of directly or indirectly hindering and/or delaying Synthron GA/Glatiramyl's market entry and uptake in Belgium²⁵¹² and therefore of producing exclusionary effects on the Belgian GA market. Even more, it cannot be excluded that Teva's conduct contributed to the inclusion of GA (Copaxone and Glatiramyl) on the "No INN" list.²⁵¹³ This shielded Copaxone from the competitive pressure exercised by Synthron GA/Glatiramyl.

9.4.4.3. Teva's dissemination of the Misleading Complexity Message in Italy

(1873) Synthron GA is marketed in Italy by Mylan/Viatrix in both dosages – 20 mg under the Copemyl brand and 40 mg under the Copemyltri brand. Mylan was originally granted an MA for Copemyl on 16 September 2016 (which was published in the Italian Official Journal on 6 October 2016).²⁵¹⁴ Upon Teva's notification to AIFA of an *ex parte* preliminary injunction Teva had obtained against Mylan and Synthron in July 2016 on the basis of the EP '924 patent ordering these parties to abstain from pursuing an MA for Copemyl, AIFA annulled the MA on 13 October 2016.²⁵¹⁵ After

²⁵¹⁰ In addition, since June 2019 Teva's sales representatives in Belgium are using an additional system for customer relationship management ({...}), which recorded altogether {...} contacts with {...} HCPs in the period from 3 June 2019 to 30 April 2021. ID 800-50, {...} data for Belgium and ID 799, email of 24 June 2021 from Teva's external counsel to the European Commission.

²⁵¹¹ The date when the infringement assessed in Chapter 9 ended in Belgium. See Section 12.2..

²⁵¹² Namely by influencing the demand for Synthron GA in this Relevant Member State.

²⁵¹³ ID 1326, INAMI/RIZIV's reply to Article 18(2) Request of 16 December 2021, p. 3.

²⁵¹⁴ ID 4965, Extract from the Italian Official Journal containing the (first) Italian MA for Copemyl.

²⁵¹⁵ ID 455-2708, Copaxone Litigation Internal Update for week ending 11 November 2016, p. 2; ID 4966, Extract from the Italian Official Journal containing AIFA's decision to annul the (first) Italian MA for Copemyl; ID 2644, Follow-up Submission re Copaxone, p. 117; This was done despite the fact that Article 10(6) of Directive 2001/83/EC states that conducting the studies and trials necessary to apply for a MA (as well as the consequential practical requirements) shall not be regarded as contrary to patent rights or to supplementary protection certificates.

the lifting of this preliminary injunction,²⁵¹⁶ AIFA adopted a second MA for Copemyl on 30 December 2016 (which was published in the Italian Official Journal on 9 January 2017).²⁵¹⁷ The MA for Copemyltri (i.e. for Synthon GA's 40 mg product) was granted to Mylan on 25 May 2018 (and published in the Italian Official Journal on 13 June 2018).²⁵¹⁸ Copaxone is distributed in Italy in hospital pharmacies and is procured in tenders organised by regions. Except for some regions in Italy, Copaxone is generally not dispensed in retail pharmacies.²⁵¹⁹

- (1874) In order to hinder and/or delay the market entry and uptake of Synthon GA and the resulting price competition in Italy, Teva disseminated the Misleading Complexity Message primarily to AIFA, which would decide on the automatic substitution, and to Italian tender authorities.²⁵²⁰ Moreover, as shown below, Teva's disparagement campaign also targeted HCPs.
- (1875) Following Teva's disparagement campaign, AIFA declared Copaxone 20 mg and Copemyl automatically substitutable (by including them on AIFA's so-called Transparency List) only as of 19 April 2017.²⁵²¹ After Teva challenged such decision before the competent Italian administrative courts²⁵²², Copaxone 20 mg and Copemyl were first removed from AIFA's Transparency List and then ultimately and finally re-included as of 4 March 2019.²⁵²³ Copemyltri and Copaxone 40 mg were included in AIFA's Transparency List as of 16 March 2019.²⁵²⁴

²⁵¹⁶ ID 2033, English translation of the Order of the Milan Court of 8 October 2016 lifting Teva's preliminary injunction against Mylan and Synthon.

²⁵¹⁷ ID 455-38, Copaxone/FoGA Overview – Pricing and Market Access, 7 February 2017, p. 8; ID 455-146, Brand Team MS, January 2017, p. 43; ID 455-448, Teva internal email dated 9 March 2017 from {...} to Market Access Primary Contacts list; ID 455-2693, Teva internal email dated 23 March 2017 from {...} to Market Access Primary Contacts list. ID 4967, Extract from the Italian Official Journal containing the (second) Italian MA for Copemyl.

²⁵¹⁸ ID 455-440, Teva internal email dated 30 April 2018 from {...} to {...}; ID 455-2149, Teva internal email dated 23 January 2019 from {...} to {...} and others; ID 455-2610, Teva internal email dated 28 September 2018 from {...} to {...} and others; ID 455-2683, Teva internal email dated 14 December 2018 from {...} to {...} and others. ID 4968, Extract from the Italian Official Journal containing the Italian MA for Copemyltri.

²⁵¹⁹ ID 655, Teva's reply to Article 18(2) Request of 3 June 2020, Annex Q39, p. 11.

²⁵²⁰ Teva submits that GA in Italy is predominantly administered in hospitals, and that hospital doctors are mostly required to prescribe the GA provided by the designated supplier which won the tender organised by the regions. See ID 1295-41, Teva's reply to Article 18(2) Requests of 22 October and 18 November 2021, pp. 1-2.

²⁵²¹ More precisely, after the publication of the (second) MA for Copemyl on 9 January 2017, AIFA initially decided not to include Copaxone 20 mg and Copemyl on its Transparency List. After Mylan submitted an application for the annulment of such decision, AIFA appointed an *ad hoc* working group that advised AIFA to reverse the decision. As a result, AIFA included Copaxone 20 mg and Copemyl on the Transparency List on 19 April 2017. See ID 655, Teva's reply to Article 18(2) Request of 3 June 2020, Annex Q39, pp. 11-16, and ID 906, Teva's reply to Article 18(2) Request of 3 June 2021, p. 19.

²⁵²² The present Decision does not take a position on whether Teva's administrative litigation against the Italian MA granted to Copemyl constitutes an abuse of Teva's dominant position pursuant to Article 102 TFEU.

²⁵²³ Italian administrative courts sided in first instance with Teva (with a judgment dated 6 March 2018, which AIFA complied with on the following day by amending its Transparency List and removing Copaxone 20 mg and Copemyl) and on appeal with AIFA and Mylan (with a judgment dated 22 February 2019, which AIFA complied with on 4 March 2019 by amending its Transparency List and ultimately and finally including Copaxone 20 mg and Copemyl). See ID 655, Teva's reply to Article 18(2) Request of 3 June 2020, Annex Q39, pp. 11-16 and ID 906, Teva's reply to Article 18(2) Request of 3 June 2021, p. 19.

²⁵²⁴ ID 906, Teva's reply to Article 18(2) Request of 3 June 2021, p. 19.

9.4.4.3.1. Dissemination of Teva’s Misleading Complexity Message to Payers in Italy

(1876) Teva’s disparagement campaign in Italy targeted mainly AIFA and tender authorities. Through this campaign, Teva sought to avoid a Payer decision (by AIFA or the tender authorities) declaring Copaxone and Synthon GA automatically substitutable. Such a decision was expected to lead to a faster market uptake of Synthon GA, which would, in turn, have had a direct impact on Copaxone’s prices and volumes. For example, an internal email from August 2015 warns of the expected impact on Copaxone’s price in Italy due to competition from Synthon GA: “{...}”.²⁵²⁵

9.4.4.3.1.1. AIFA

(1877) The Italian Medicines Agency (Agenzia Italiana del Farmaco, or “AIFA”) is the national authority responsible for medicines regulation and has, amongst other functions, a key role in deciding on the substitution status of medicines in Italy. It is a public body operating under the direction of the Ministry of Health.²⁵²⁶ Crucially, AIFA is responsible for deciding whether Copaxone and Copemyl/Copemyltri are substitutable at pharmacy level pursuant to Art. 7 of law decree 347/2001 (further to being included in AIFA’s Transparency List).²⁵²⁷ The inclusion of Copemyl/Copemyltri and Copaxone in AIFA’s Transparency List has also a direct and immediate effect on tenders, since – in the absence of such inclusion – Teva expected tenders to be called by Italian contracting authorities in separate lots for, respectively, Copaxone and Synthon GA.²⁵²⁸

(1878) Teva’s efforts to influence AIFA’s decision-making processes in Italy with a view to hindering and/or delaying Synthon GA’s entry and uptake started even before Copemyl had secured its MA in Italy. Already in July 2016, Teva was trying to pre-empt the possible adoption by AIFA of any decision allowing substitutability between Copaxone 20 mg and Copemyl and suggested that such decision would be illegitimate.²⁵²⁹

(1879) After Copemyl obtained its (first) MA in Italy, Teva continued to disseminate its misleading messages to AIFA in an attempt to prevent that Copaxone and Copemyl were declared automatically substitutable at pharmacy level (through their inclusion on AIFA’s Transparency List).

(1880) In particular, between November 2016 and April 2017 Teva lobbied AIFA intensely by sending it a number of letters and a presentation in which it repeatedly and

²⁵²⁵ ID 518-10, Teva internal email dated 27 August 2015 from {...} to {...} and others. According to a Teva email from January 2019, {...} – see ID 264-135, Teva internal email dated 23 January 2019 from {...} to {...}.

²⁵²⁶ ID 655, Teva’s reply to Article 18(2) Request of 3 June 20201, Annex Q39, p. 16.

²⁵²⁷ ID 655, Teva’s reply to Article 18(2) Request of 3 June 20201, Annex Q39, p. 11. Different divisions within AIFA were responsible (i) for the Decentralised Procedure and the issuance of the Italian MA for Copemyl/Copemyltri and (ii) for their inclusion on the Transparency List together with Copaxone 20 mg and 40 mg respectively. At the time of the infringement, AIFA was also assisted by two advisory committees: (i) one for scientific or technical assessments, and (ii) one for pricing and reimbursement assessments. The present Decision will consider Teva’s messages to AIFA as messages shared with a Payer in Italy inasmuch as these messages were meant to influence pricing and reimbursement decisions (including those on automatic substitution between Copaxone and Copemyl/Copemyltri).

²⁵²⁸ ID 455-1560, Teva internal emails dated 28 February 2017 on AIFA’s decision not to consider Copemyl and Copaxone 20 mg/ml automatically substitutable: “{...}”.

²⁵²⁹ ID 742-109, Teva’s letter to AIFA, 6 July 2016, pp. 2, 3. On the misleading profile of such letter, see footnote 1822 above.

systematically communicated the three facets of the Misleading Complexity Message.²⁵³⁰

- (1881) First, Teva emphasised clinically irrelevant differences in GA structures (thereby casting doubt on Synthon GA's safety and therapeutic equivalence with Copaxone) for example by submitting to AIFA that "{...}"²⁵³¹ Teva also made misleading statements regarding the safety and efficacy of Copemyl, which implicitly went against the results of the Decentralised Procedure for Synthon GA, by questioning the therapeutic equivalence between Copemyl and Copaxone: "{...}"²⁵³²
- (1882) Second, Teva also used the misleading message implying that issues with other glatiramer-related substances also applied to Copemyl. For example, Teva was referring to other medicinal products which have mixed aggregates (a graphic showing *inter alia* Natco, Probioglat and Escadra next to the graphic of Copaxone which shows no aggregates), concluding that these impurities can have an important effect on the immunogenicity of the product and on the production of an antigenic response²⁵³³, implying that this was also a risk for Copemyl (and thereby casting doubt on its safety, in contradiction with the results of the Decentralised Procedure).
- (1883) Third, Teva cast doubt on the validity of the GATE study by emphasising allegedly relevant differences between its results and pre-existing data, casting doubt on Synthon GA's efficacy and therapeutic equivalence with Copaxone and on the scientific basis for the successful conclusion of the Decentralised Procedure. For example, it suggested to AIFA that "{...}"²⁵³⁴
- (1884) To conclude, Teva disseminated all the three facets of the Misleading Complexity Message to AIFA in the context of discussions on the automatic substitution of Copaxone with Copemyl. Although Teva's position was first followed and eventually rejected by AIFA, Teva's communications to AIFA were aimed at misleading the regulator and, in view of AIFA's responsibility as regards automatic substitution, they were all the more capable of producing exclusionary effects. In fact, Teva's communications delayed the inclusion of Copemyl and Copaxone 20 mg

²⁵³⁰ ID 742-116, Teva's letter to AIFA, 3 November 2016. ID 742-13, Il valore di COPAXONE (glatiramer acetate): aspetti da considerare nella valutazione dell'uso dei follow on del glatiramer acetato, Teva's presentation sent to AIFA on 9 January 2017; ID 742-113, Teva's letter to AIFA and the Italian Minister for Health, 18 April 2017.

²⁵³¹ ID 742-116, Teva's reply to Article 18(2) Request of 3 June 2020, Annex Q39 IT 4, Teva's letter to AIFA, 3 November 2016, pp. 3-4, (unofficial translation) – "{...}". See also, for a similar message, ID 742-13, Il valore di COPAXONE (glatiramer acetate): aspetti da considerare nella valutazione dell'uso dei follow on del glatiramer acetato, Teva's presentation sent to AIFA on 9 January 2017, p. 12. The presentation was shared with AIFA in preparation of the Technical Scientific Commission ('TSC') of 18-20 January 2017 related to the inclusion of Copemyl and Copaxone 20 mg/ml on AIFA's Transparency List. See also ID 742-113, Teva's letter to AIFA and the Italian Minister for Health, 18 April 2017, pp. 3, 5, 6, 7, 8, 13, 14.

²⁵³² ID 742-116, Teva's letter to AIFA, 3 November 2016, pp. 3, 4 (unofficial translation). Original text: "{...}". See also ID 742-13, Teva's presentation sent to AIFA on 9 January 2017, p. 11, which includes a similar quote.

²⁵³³ ID 742-113, Teva's letter to AIFA and the Italian Minister for Health of 18 April 2017, p. 5 and also pp. 3, 6, 7, 8, 13, 14. See also in this regard ID 742-116, Teva's letter to AIFA of 3 November 2016, pp. 3, 4; ID 742-13, Il valore di COPAXONE (glatiramer acetate): aspetti da considerare nella valutazione dell'uso dei follow on del glatiramer acetato, Teva's presentation sent to AIFA on 9 January 2017, p. 11: "{...}" (unofficial translation). Original text: "{...}".

²⁵³⁴ ID 742-116, Teva's letter to AIFA of 3 November 2016, p. 3 (unofficial translation). Original text: "{...}".

in the Transparency List.²⁵³⁵ This resulted in a potential slower uptake of Synthon GA in Italy and artificial shielding of Copaxone from competition.

9.4.4.3.1.2. Italian tender authorities

- (1885) Teva also had interactions with the regional tender authorities and the regional purchasing centres in Italy (“Stazioni Appaltanti”, regional entities in charge of the management of the hospital tenders) and disseminated its Misleading Complexity Message while arguing against opening their tenders to price competition from Synthon GA and from tendering Copaxone and Synthon GA together. In Italy, while regions and regional purchasing centres usually follow AIFA’s Transparency List, they can, nevertheless, deviate from it and issue their own guidelines and regulations regarding the substitution of medicinal products.²⁵³⁶
- (1886) When Copemyl was launched in 2017, Teva sent letters to all the regional tender authorities and purchasing centres, arguing that Copaxone 20 mg and Copemyl should not be automatically substitutable.²⁵³⁷ These letters were aimed at explaining why, in Teva’s view, the future tenders should not be called with one single lot for both products, i.e. not be put into direct competition with one another. In a letter dated 6 April 2017, Teva included the misleading message that Copemyl is not an equivalent medicine to Copaxone by referring to AIFA’s February 2017 decision not to include the two medicines on its Transparency List and presenting it as an objective and definitive truth, thereby omitting to mention that that decision was being reviewed by AIFA itself through an *ad hoc* working group (which resulted in the inclusion of Copaxone 20 mg and Copemyl on AIFA’s Transparency List a few days after this letter).²⁵³⁸ Even when AIFA decided to include these two medicinal products on the Transparency List, thus allowing automatic substitution and triggering Teva’s judicial action for annulment against such decision, Teva still tried to influence the authorities while arguing against tendering Copaxone 20 mg and Copemyl together.²⁵³⁹
- (1887) In more recent years, Teva’s overall strategy seeking to retain existing Copaxone’s patients and to protect Copaxone price levels through its artificial differentiation campaign is shown in Teva’s 2017, 2019, 2020 and 2021 Brand Plans for Italy. Indeed, according to the 2017 Brand Plan, Teva pursued the “{...}” of (i) retaining current Copaxone patients by using “{...}” which are misleading for the reasons detailed in Sections 9.3.1 and 9.3.2.2 of this Decision and (ii) maintaining market access, i.e. maintaining Copaxone prices (by using CCP materials to “{...}” sophisticated Payers and HTA bodies²⁵⁴⁰ while arguing, amongst others, against automatic substitution).²⁵⁴¹ According to Teva, the materials used for the education

²⁵³⁵ Indeed, this conclusion is further supported by the fact that AIFA, further to Teva’s disparaging communication campaign, first ruled against the inclusion of Copaxone 20 mg and Copemyl on its Transparency List in February 2017 (see additional details in footnote 2521 above).

²⁵³⁶ See ID 655, Teva’s reply to Article 18(2) Request of 3 June 2020, Annex Q39, p. 15.

²⁵³⁷ ID 742-160, Teva’s letter to Italian tender authorities dated 6 April 2017.

²⁵³⁸ ID 742-160, Teva’s letter to Italian tender authorities dated 6 April 2017, p. 1.

²⁵³⁹ ID 742-159, Teva’s letter to Italian tender authorities in the region of Campania dated 21 July 2017. According to Teva, these letters were not sent to all the regional tender authorities and purchasing centres but only to those that were launching a new tender with one single lot. To the best of Teva’s recollection, Teva’s arguments in the letters to each authority or centre were substantially the same. Teva has therefore provided the letter to the region of Campania of 21 July 2017.

²⁵⁴⁰ For a definition of HTA bodies, see footnote 2314 above.

²⁵⁴¹ ID 1151-8, GTMAP MS 2017 Italy, pp. 2, 3.

of sophisticated Payers and HTA bodies were the Payer White Paper, the Payer Slide Presentation and the Internal Q&A document.²⁵⁴²

- (1888) Teva’s 2019, 2020 and 2021 Brand Plans for Italy confirm that, for its strategy to succeed, Teva considered it “{...}” (i) to “{...}” at national and regional level, (ii) to “{...}” Payers to “{...}” that “{...}”, (iii) to “{...}” with national health authorities (e.g. to control and manage price reduction requests by regional authorities following the launch of Copemyl/Copemyltri), and, at regional level, (iv) to “{...}” (implying that there was no therapeutically equivalent treatment).²⁵⁴³
- (1889) Moreover, Teva’s 2020 and 2021 Brand Plans for Italy show that “{...}” became important in Teva’s overall strategy, as winning tenders was “{...}”.²⁵⁴⁴ Teva also kept among its “{...}” to retain its current patient base and to maintain market access.²⁵⁴⁵

9.4.4.3.2. Dissemination of Teva’s Misleading Complexity Message to HCPs in Italy

- (1890) Teva’s disparagement conduct in Italy focused more on Payers, including tender authorities, rather than on HCPs. This is because in Italy Copaxone and Synthon GA are administered mainly in hospitals and hospital doctors are mostly required to prescribe the GA provided by the designated supplier that won the tender organised by the regions.²⁵⁴⁶ Nonetheless, Teva was also actively reaching out to Italian tender authorities to ensure that, whatever the winner of public tenders for glatiramer acetate was (even for winner-takes-all type tenders), HCPs could still prescribe Copaxone.²⁵⁴⁷
- (1891) As shown below, Teva’s disparagement campaign in Italy also targeted HCPs, first, in their function as prescribers, with a view to influencing prescription practices in the regions where hospitals would run “multiple winner” tenders, and, second, in their function as KOLs with a view to influencing the perception of Payers and other HCPs concerning the substitution of Copaxone with Synthon GA.²⁵⁴⁸
- (1892) First, communicating the Misleading Complexity Message to neurologists was one of Teva’s main tactics to influence individual prescriptions. Teva’s 2017 and 2019

²⁵⁴² ID 1151-8, GTMAP MS 2017 Italy, p. 20. For a detailed analysis of the misleading features of these documents, see Section 9.3.2.2 above.

²⁵⁴³ ID 1151-43, 2019 Italy Copaxone GTMAP, p. 3; see also ID 1151-62, 2020 GTMAP Italy Copaxone, p. 4 and ID 1151-64, 2021 GTMAP Template Italy Copaxone, p. 9.

²⁵⁴⁴ ID 1151-62, 2020 GTMAP Italy Copaxone, p. 3; see also ID 1151-64, 2021 GTMAP Template Italy Copaxone, p. 5. “{...}” means that Copaxone was tendered alone and not together with Copemyl/Copemyltri, thus avoiding Copaxone to be in competition with Copemyl/Copemyltri.

²⁵⁴⁵ ID 1151-62, 2020 GTMAP Italy Copaxone, p. 4; ID 1151-64, 2021 GTMAP Template Italy Copaxone, p. 9.

²⁵⁴⁶ ID 1171, Teva’s reply to Article 18(2) Requests of 22 October 2021 and 18 November 2021, pp. 1, 3. The only exception is that the doctor has the ability to prescribe a brand and indicate “therapeutic continuity” on the prescription, in which case the hospital pharmacy will have to dispense that product even if it did not win the tender. The neurologist must issue a written request, explaining the reasons for requesting a specific brand (for example, side effects with the other brand). In practice, Teva argues that doctors “*very rarely*” exercise this option (but, for an example, see ID 4502, Extraction of Teva’s LSMI database for Copaxone, in relation to an interaction by Teva with an Italian caregiver on 22 June 2020). During the proceedings, Teva explained that, for almost all GA tenders in Italy, the bidder offering the lowest price is the sole winner. The exception is “Accordo Quadro” (framework agreement) in which customers specify a price and all suppliers that meet this price win (qualify) and can be prescribed by doctors.

²⁵⁴⁷ ID 5070, Questions and answers in relation to an Italian tender concerning also glatiramer acetate, p. 3: “{...}” (unofficial translation). Original text: “{...}”.

²⁵⁴⁸ For Teva’s interactions with Italian KOLs, see Recitals (1805)-(1806) and footnote 2355 above.

Brand Plans for Italy show that Teva considered as a critical success factor in order to “{...}” that HCPs “{...}”.²⁵⁴⁹ The same Brand Plans show that Teva intended to attain such objective, *inter alia*, through the use of “{...}” (i.e., referring to the first type of misleading message presented in Section 9.3.1.1 above).²⁵⁵⁰ The materials used for the education by MSLs of KOLs and neurologists were the External Expert White Paper (both the version for specialists of multiple sclerosis and the one for non-specialist experts) and the External Expert slide presentations and briefing documents.²⁵⁵¹

- (1893) After AIFA approved Copemyl to be automatically substitutable to Copaxone, Teva moved on to implement Phase Iib of the CCP campaign²⁵⁵² targeting the HCPs which, through their prescriptions, could still steer demand for GA in the Italian regions that were carrying out “multiple winner”²⁵⁵³ tenders and thus potentially sourcing GA from both Teva and Mylan.
- (1894) Indeed, Teva’s records confirm that Teva’s sales and MSL representatives had numerous contacts with HCPs dedicated to the issue of “complexity” and Synthon GA. The data show that in Italy, in the period from January 2017 to May 2021, Teva’s MSLs and sales representatives registered (i) {...} direct contacts with {...} HCPs and (ii) {...} direct contacts with {...} neurology departments/clinics/pharmacies and others, all direct contacts related to *inter alia* Copaxone, GA or central nervous system products.²⁵⁵⁴ These visits were devoted, at least in part, to the dissemination of the Misleading Complexity Message.²⁵⁵⁵ There is evidence that at least {...} of such contacts were recorded by Teva as having had a key message related to “complexity” or “NBCD-FoGA” (and {...} of such contacts were registered by Teva as having received a “Positive” reaction, the latest of which in January 2020),²⁵⁵⁶ although it cannot be excluded that there were more, since there is no built-in system mechanism requiring sales representatives and members of Teva’s MSL team to record contacts, as also confirmed by Teva.²⁵⁵⁷ In any event, this is sufficient to show that Teva actually used its centrally prepared misleading messages in its contacts with HCPs in Italy.
- (1895) Teva argues that the Commission has not substantiated its “*implied allegation*” that the number of contacts made with HCPs, and in particular, the calls related to “complexity” and “NBCD-FoGA” would be particularly significant if compared to the overall number of Teva’s contacts with HCPs.²⁵⁵⁸ First, there is no need for the Commission to show that Teva’s Misleading Complexity Message was disseminated in a significant proportion of contacts with Italian HCPs during more than 4 years. It is sufficient to show that Teva has disparaged Synthon GA to HCPs in Italy, which is shown by Teva’s own records that {...} of its contacts with HCPs were dedicated to

²⁵⁴⁹ ID 1151-43 2019 Italy Copaxone GTMAP, p. 3. See also ID 1151-8, GTMAP MS 2017 Italy, p. 2.

²⁵⁵⁰ Ibid.

²⁵⁵¹ ID 1151-8, GTMAP MS 2017 Italy, p. 20.

²⁵⁵² See Section 9.1, Recitals (1438) and ff.

²⁵⁵³ Multiple-winner tender is the type of tender where there are multiple winners. See, for example, footnote 2546 above in relation to “Accordi Quadro” (framework agreements).

²⁵⁵⁴ ID 900-3, {...} data for Italy. For scope and reliability of {...} data see footnote 2326.

²⁵⁵⁵ Just like in Belgium, inherent limitations in the available CRM data apply (see footnote 2478).

²⁵⁵⁶ ID 900-3, {...} data for Italy.

²⁵⁵⁷ See footnote 2326 above.

²⁵⁵⁸ See ID 4032, Teva’s Response to the Statement of Objections, para. 1273.

the “complexity” or to “NBCD-FoGA”²⁵⁵⁹. Second, proof of Teva registering the dissemination of its Misleading Complexity Message in hundreds of cases is significant. Third, as acknowledged by the case-law of the Union courts, fixing an appreciability (*de minimis*) threshold for the purposes of determining whether a certain conduct constitutes an abuse of a dominant position is not justified, as the structure of competition on the market is already weakened by the presence of the dominant undertaking and any further weakening may constitute an abuse.²⁵⁶⁰

- (1896) For the same reason, Teva’s argument that the 2017 Brand Plan for Italy would refer to the complexity of Copaxone on “only” 3 out of 20 pages²⁵⁶¹ is irrelevant.
- (1897) More generally, Teva’s argument that the GTMAPs for Italy would not be “emphasising” any Misleading Complexity Message²⁵⁶² does not convince. Indeed, for the reasons explained in Recital (1866) above, Brand Plans are credible strategic documents which inform of Teva’s planned promotional and other activities. The evidence quoted in this Section has also abundantly shown that Teva was executing this strategy to the letter by communicating its misleading messages to HCPs in Italy. It is irrelevant whether, as argued by Teva, “communication on Copaxone complexity / FoGA” is allocated the lowest budget” in the 2019 Brand Plan.²⁵⁶³ Allocating any budget by a dominant company to disseminate misleading information is in itself capable of distorting competition and confirms that Teva’s strategy was not a purely theoretical plan. On the contrary, the dissemination of the Misleading Complexity Message to HCPs in Italy was very important to Teva.
- (1898) To conclude, while HCPs were not the main focus of Teva’s disparagement campaign in Italy, they were systematically targeted with a view to directly influencing doctors’ prescribing practices.

9.4.4.3.3. Teva’s arguments and the Commission’s assessment

9.4.4.3.3.1. Teva’s actual dissemination of disparaging messages in Italy

- (1899) During the proceedings, Teva argued that the Commission had adduced no documentary evidence that the Misleading Complexity Message was actually communicated to HCPs in Italy.²⁵⁶⁴
- (1900) At the outset, it must be noted that Teva did not deny that the Misleading Complexity Message was actually disseminated in Italy, and only tried to argue that there would be no evidence showing such dissemination.
- (1901) In any event, evidence in this respect is far from lacking.

²⁵⁵⁹ As explained in Recital (1892) above, Teva’s Brand Plans for Italy show that Teva considered as a strategic success factor that HCPs “are well aware of the complexity of GA” and that Teva intended to attain such objective, *inter alia*, through the use of “complexity messaging and materials”. For this reason, and in light of the reasons for Teva to adopt the acronyms “NBCD” and “FoGA” already indicated in Sections 9.1.1 and 9.3.1.4.2 above, it is likely that the contacts with HCPs recorded by Teva as having as key message one or both of these acronyms were devoted, at least in part, to the dissemination of the Misleading Complexity Message. This is all the more true considering the guidance prepared in the relevant CCP materials described in Section 9.3.2 for members of Teva’s MSL team (notably the External Expert White Paper for MS specialists, the GATE Study Review and the MSL Objection Handlers) and for Teva’s KAMs, (notably KAM Objection Handlers).

²⁵⁶⁰ See Case C-23/14, *Post Danmark II*, paragraphs 72-73 and the caselaw cited therein.

²⁵⁶¹ See ID 4032, Teva’s Response to the Statement of Objections, para. 1271.

²⁵⁶² See ID 4032, Teva’s Response to the Statement of Objections, para. 1271.

²⁵⁶³ See ID 4032, Teva’s Response to the Statement of Objections, para. 1271.

²⁵⁶⁴ See ID 4032, Teva’s Response to the Statement of Objections, para. 1270.

- (1902) In addition to the data extracted from Teva’s {...} platform mentioned in Recital (1894) above, the Commission’s case file includes further evidence that Teva actually disseminated the Misleading Complexity Message through promotional materials addressed to HCPs in Italy.
- (1903) For example, a presentation used by Teva during the 2018 annual meeting of the Italian Association of Neurologists confirms that Teva emphasised clinically irrelevant differences in molecular structures of Copaxone and Synthon GA and erroneously implied that they could be therapeutically relevant, thus questioning Synthon GA’s safety, efficacy, and therapeutic equivalence with Copaxone, in contradiction with the results of the Decentralised Procedure.²⁵⁶⁵ An extraction of Teva’s {...} database associated with this presentation shows that it was indeed used reactively by Teva during the annual meeting of the Italian Association of Neurologists that took place in October 2018, as it was only cancelled from Teva’s {...} platform on 26 February 2020 for purely technical reasons.²⁵⁶⁶
- (1904) Further evidence of dissemination of Teva’s Misleading Complexity Message to HCPs in Italy is a brochure prepared by Teva concerning the May 2018 publication by {...} (an employee of Teva). In the brochure, Teva was again emphasising clinically irrelevant differences in molecular structures of Copaxone and Synthon GA, thus questioning Synthon GA’s safety and efficacy, as well as its therapeutic equivalence to Copaxone.²⁵⁶⁷ Teva had submitted this brochure to AIFA prior to its use²⁵⁶⁸, and has also confirmed that “{...}”.²⁵⁶⁹ An extraction of Teva’s CRM platform related to Italy shows that (i) this brochure was the key message of {...} contacts with Italian HCPs between January and May 2019 and that (ii) for {...} of such contacts Teva recorded a “{...}” reaction by HCPs.²⁵⁷⁰ The record from the extraction of Teva’s {...} database associated with this brochure confirms that it was first used on 27 December 2018 and then reapproved on 20 October 2020.²⁵⁷¹
- (1905) All the above evidence confirms that Teva’s disparaging strategy was not a merely hypothetical plan, but was actually implemented through the dissemination of the Misleading Complexity Message also to HCPs in Italy, at least until October 2020 if not also thereafter.

9.4.4.3.3.2. The capability of Teva’s disparaging messages to mislead their addressees

- (1906) Teva also argued during the proceedings that the recipients of Teva’s messages possessed “*the requisite resources and expertise to ascertain the veracity of Teva’s communications for themselves*”, also citing the example of AIFA and the *ad hoc* working group it set up to consider automatic substitution between Copaxone and

²⁵⁶⁵ ID 4919-117, SIN 2018: Comunicazione Direzione medica_ Copaxone e FoGA, pp. 3-5, where Teva claimed – *inter alia* – that “{...}”, that “{...}”, and that “{...}” (emphasis added, unofficial translation). Original text: “{...}”, and “{...}”.

²⁵⁶⁶ ID 4897, List of documents registered on Teva’s {...}.

²⁵⁶⁷ ID 4919-119, Brochure esplicativa {...}, pp. 5-12, where Teva claimed – *inter alia* – that “{...}” (emphasis added) and that “{...}” (unofficial translation). Original text: “{...}”.

²⁵⁶⁸ ID 5149, List of materials sent by Teva for AIFA’s approval.

²⁵⁶⁹ ID 4949, email dated 2 October 2023 from Teva’s external counsel to the European Commission.

²⁵⁷⁰ ID 900-3, {...} data for Italy.

²⁵⁷¹ ID 4897, List of documents registered on Teva’s {...}. The Commission considers that Teva’s re-approval of this document its {...} platform shows that the document in question was still being used at the time and was also planned to be used subsequently

Synthon GA and which ultimately rejected Teva's arguments (a working group which would "*weigh heavily against AIFA's ability to be misled*").²⁵⁷²

- (1907) This argument does not convince and is irrelevant for the reasons already specified in Section 9.2.3.3 above.
- (1908) In addition, as to the specific case of AIFA and its *ad hoc* working group, Teva's argument is also inconsistent with Teva's own submissions before Italian courts, where Teva was calling the competence of AIFA's *ad hoc* working group into question because it did not include an expert in multiple sclerosis.²⁵⁷³

9.4.4.3.3.3. The purpose of Teva's dissemination of disparaging messages in Italy

- (1909) Teva claims that the types of communications discussed above were a way for Teva to engage in a legitimate debate with Payers around automatic substitution between Copaxone and Synthon GA without medical supervision, and were therefore a way for Teva to exercise its freedom of speech.²⁵⁷⁴
- (1910) Teva's argument cannot be accepted for the reasons explained in Sections 9.2.3.5 and 9.2.3.7 above. Indeed, Teva was targeting the characteristics of Synthon GA, which had been a condition to the successful conclusion of its Decentralised Procedure. These characteristics were also a necessary precondition for automatic substitution in Italy. If the Payers were misled with respect to these characteristics, this was also likely to affect their decision to allow automatic substitution or organize tenders for GA.
- (1911) Teva's special responsibility not to impair undistorted competition in the Italian GA market should have made it refrain from including in communications with Payers and HCPs misleading messages that are far from competition on the merits and are capable of producing an exclusionary effect.

9.4.4.3.4. Conclusion

- (1912) As shown above, Teva's conduct covered most, if not all, drivers of demand for GA in Italy. First, Teva disseminated the Misleading Complexity Message to AIFA and to Italian tender authorities, while arguing against automatic substitution and the resulting price competition. Second, Teva targeted HCPs with a view to influencing directly doctors' prescribing practices.
- (1913) In view of the analysis in this Subsection 9.4.4.3 and in Sections 9.4.1, 9.4.2 and 9.4.3, the Commission concludes that Teva's dissemination of the Misleading Complexity Message in Italy – which, as noted above, took place at least until October 2020 – was capable of hindering and/or delaying Synthon GA's market entry and uptake in Italy and therefore of producing exclusionary effects on the Italian GA market.
- (1914) Even more, it cannot be excluded that Teva's conduct in Italy contributed to delays in the inclusion of Copemyl in AIFA's Transparency List. These delays resulted in a slower uptake of Synthon GA and in the shielding of Copaxone from competition.

²⁵⁷² ID 4032, Teva's Response to the Statement of Objections, paras. 1058 and 1239.

²⁵⁷³ ID 742-95, Teva's brief of 4 June 2018 submitted to the Italian *Consiglio di Stato* for case no. 2455/2018, p. 14: "{...}" (emphasis added and unofficial translation). Original text: "{...}".

²⁵⁷⁴ See, e.g., ID 4032, Teva's Response to the Statement of Objections, paras. 1228-1229, 1232-1233, 1237, 1239 and 1242.

9.4.4.4. Teva's dissemination of the Misleading Complexity Message in Germany

- (1915) Synthon GA is marketed in Germany by Mylan under the brand Clift 20 mg and Clift 40 mg. Mylan (now Viatris) secured a MA for Clift 20 mg on 11 May 2016²⁵⁷⁵ and for Clift 40 mg on 2 November 2017.²⁵⁷⁶ Clift 20 mg and Clift 40 mg have been listed as generic versions of GA in the Lauer Taxe²⁵⁷⁷ on 1 September 2016²⁵⁷⁸ and 15 December 2017,²⁵⁷⁹ respectively. Copaxone and Clift are considered as having the same active ingredient and are therefore deemed automatically substitutable in Germany.²⁵⁸⁰
- (1916) In order to hinder and/or delay the market entry and uptake of Mylan's Clift and to avoid or delay the resulting price competition in Germany, Teva disseminated the Misleading Complexity Message to Payers and HCPs.
- (1917) Communicating "{...}" was one of Teva's strategic objectives for its Medical Affairs staff (MSL team) in Germany for 2016.²⁵⁸¹ Teva put in place "Medical Action Plan FOGA" which comprised a broad array of activities (also called "tactics").²⁵⁸² Teva's objective in Germany was to establish "{...}" with a focus on "{...}" different stakeholders: "{...}", "{...}" and "{...}"²⁵⁸³ using the centrally prepared CCP materials.²⁵⁸⁴
- (1918) More specifically, in preparation of the MA grant to Synthon GA/Clift, and its ensuing entry, Teva organised as of April 2016 trainings for its commercial management staff (such as Heads of Region), sales representatives and members of the MSL team on how to communicate messages concerning Synthon GA, based on Objection Handlers, Talking Points, etc.²⁵⁸⁵ For example, alongside with Market Access staff, members of Teva's MSL team were to disseminate the Misleading Complexity Message in meetings with Payers on the "{...}", while sales representatives would reactively communicate Teva's messages to HCPs concerning the GATE study.²⁵⁸⁶

²⁵⁷⁵ ID 404-1370, Brand Team CNS, Copaxone legal Update, 30 June 2016, p. 2; ID 455-38, Copaxone/FoGA Overview – Pricing and Market Access, 7 February 2017, p. 10; ID 455-37, CCP Update, November 2016, p. 2.

²⁵⁷⁶ ID 455-2861, Teva internal email dated 19 March 2018 from {...} to {...} and others.

²⁵⁷⁷ The Lauer Taxe contains lists of all medicine products that have an MA in Germany. Pharmacists use it to look up information on medicines (though there are other companies offering similar products). It includes information on prices and rebate contracts, as well as medical/pharmaceutical information such as side effects and drug interactions.

²⁵⁷⁸ ID 455-38, Copaxone/FoGA Overview – Pricing and Market Access, 7 February 2017, p. 8; ID 455-2610, Teva internal email dated 28 September 2018 from {...} to {...} and others.

²⁵⁷⁹ ID 455-2861, Teva internal email dated 19 March 2018 from {...} to {...} and others.

²⁵⁸⁰ It follows from § 129 (1) SGB V that drugs of the same active ingredient are substitutable. The relevant German authorities, GKV-Spitzenverband and Gemeinsamen Bundesausschuss confirmed that Copaxone and Clift are considered as having the same active ingredient. See ID 1258, GKV-Spitzenverband's Reply to Article 18(2) Request of 15 December 2021 and ID 1252, Gemeinsamen Bundesausschuss' Reply to Article 18(2) Request of 16 December 2021.

²⁵⁸¹ ID 263-2994, TPE Country visit: deep dive session, Berlin, 28 June 2017, pp. 46, 47; the execution of the MSL Medical tactical Plan is shown to be "on Track".

²⁵⁸² ID 263-2994, TPE Country visit: deep dive session, Berlin, 28 June 2017, p. 43.

²⁵⁸³ ID 404-2419, Copaxone Continuation Project, Complexity Copaxone Campaign, CCP LOC Executional Excellence Plan 2014-2015, p. 5.

²⁵⁸⁴ ID 404-2419, Copaxone Continuation Project, Complexity Copaxone Campaign, CCP LOC Executional Excellence Plan 2014-2015, pp. 17-21: introductory brochure, background, evidence dossier and slidekits.

²⁵⁸⁵ ID 264-1083, Copaxone Continuation Plan Meeting, pp. 1, 2 – "{...}".

²⁵⁸⁶ ID 263-2994, TPE Country visit: deep dive session, Berlin, 28 June 2017, p. 37.

- (1919) Teva’s strategy for Germany also comprised a “{...}” to discuss the “{...}” in several publications.²⁵⁸⁷ Such publications also involved KOLs cooperating with Teva: “{...}”.²⁵⁸⁸
- (1920) Evidence shows that Teva was internally content with the roll out of the CCP in Germany and considered that it “{...}”.²⁵⁸⁹ For example, the market access department reported that the Payer White Paper was translated into German, the marketing department reported on Objection Handlers being used and the medical affairs team’s communication strategy included the action-point “{...}”.²⁵⁹⁰ The CCP for Germany also envisaged visits by Teva’s sales team every month “{...}”.²⁵⁹¹ The CCP strategy also tasked Teva’s Medical Affairs (MSL team) with communication to health insurance providers and External Experts on the “{...}”.²⁵⁹² Teva’s internal documents show “{...}”.²⁵⁹³
- (1921) Teva maintained these “{...}”²⁵⁹⁴ throughout the period of the infringement. For example, in a 2020 Brand Plan, Teva set out to “{...}”.²⁵⁹⁵
- (1922) Importantly, Teva was well aware that its activities were (at least potentially) disparaging: when Teva Germany discussed internally whether a particular study (“{...}”, 2014)²⁵⁹⁶ should be used by its MSL team, Teva internally acknowledged that this study was useful when used with external experts such as KOLs and neurologists but that internal legal clarification was required given that, in the past, Teva had to significantly tone down a presentation on Synthon GA in Athens “{...}”.²⁵⁹⁷
- (1923) This section will examine how Teva’s campaign covered key decision makers and drivers of demand for GA in Germany – Payers and HCPs.
- 9.4.4.4.1. Dissemination of Teva’s Misleading Complexity Message to Payers in Germany
- 9.4.4.4.1.1. GKV-Spitzenverband (“GKV-SV”)
- (1924) The National Association of Statutory Health Insurance Funds (“GKV-SV”) is the central association of the statutory health insurance funds at federal level in Germany and represents their interests vis-à-vis, *inter alia*, pharmaceutical companies. It shapes the conditions for healthcare provision in Germany affecting roughly

²⁵⁸⁷ ID 263-2994, TPE Country visit: deep dive session, Berlin, 28 June 2017, pp. 51, 52.

²⁵⁸⁸ ID 264-1083, Copaxone Continuation Plan Meeting – Update, pp.1-3. Unofficial translation. Original text: “{...}”.

²⁵⁸⁹ ID 455-132, Brand Team MS February 2017, p. 30.

²⁵⁹⁰ ID 455-132, Brand Team MS February 2017, p. 30; see also ID 264-1709, Copaxone Continuation Plan Gantt Chart; ID 264-1083, Copaxone Continuation Plan Meeting

²⁵⁹¹ ID 455-132, Brand Team MS February 2017, p. 30; see also ID 264-1083, Copaxone Continuation Plan – Deutschland, notes dated 21 March 2016 for the same implementation steps; see also ID 264-1709, Copaxone Continuation Plan Gantt Chart.

²⁵⁹² ID 264-1083, Copaxone Continuation Plan – Deutschland, p. 3 (unofficial translation). Original text: “{...}”; see also ID 264-1709, Copaxone Continuation Plan Gantt Chart.

²⁵⁹³ ID 263-2994, TPE Country visit: deep dive session, Berlin, 28 June 2017, p. 44.

²⁵⁹⁴ ID 1151-24, 2020 GTMAP Template – DE markets - Copaxone, p. 4.

²⁵⁹⁵ ID 1151-24, 2020 GTMAP Template – DE markets - Copaxone, p. 4.

²⁵⁹⁶ ID 404-1514, Teva internal email communication dated 10 January 2017 from {...} to {...}. For the study in question see ID 2509, F. Towfic *et al.*, “Comparing the Biological Impact of Glatiramer Acetate with the Biological Impact of a Generic”, PloS One. 2014; 9(1): e83757.

²⁵⁹⁷ ID 404-1514, Teva internal email dated 10 January 2017 from {...} to {...}: “{...}.” (unofficial translation). Original text: “{...}.”

70 million people.²⁵⁹⁸ As a representative of Payers in Germany, the Commission considers GKV-SV to be a Payer as well.

- (1925) By its own admission, Teva had a number of interactions with the GKV-SV, the purpose of which was “to clarify which mandatory rebate would apply to Copaxone because of the launch of Mylan’s Clift in Germany”.²⁵⁹⁹ In particular, due to Mylan’s launch of Clift as a generic, a statutory rebate of 10% (pursuant to §130a Abs. 8 SGB V) would apply to Copaxone.²⁶⁰⁰
- (1926) Teva argued in the context of these discussions that Mylan’s Clift is not a generic product and that a new category should be implemented in Germany to allow for a filing of Clift as a hybrid. In trying to convince GKV-SV that hybrid applications should not be considered as generic applications (and thus not automatically substitutable), Teva put forward misleading and discrediting messages in line with the Complexity Message.
- (1927) In July 2016, Teva internally considered that its contacts with the GKV-SV “{...}”.²⁶⁰¹ Therefore, Teva would need to “{...}”.²⁶⁰²
- (1928) Evidence on the file from the same period (July-September 2016) shows that Teva communicated to the GKV-SV (at least) the misleading message raising doubt as to the validity of the GATE study, as the scientific basis for the finding that Copaxone and Synthon GA are therapeutically equivalent. Teva sent letters to GKV-SV on several instances: 29 July 2016, 7 September 2016, around 16 March 2017, 2 May 2018²⁶⁰³, and 19 March 2019. Teva also held a meeting with GKV-SV on 23 September 2016.²⁶⁰⁴
- (1929) In September 2016, Teva set up a meeting with the GKV-SV regarding “{...}”.²⁶⁰⁵ In this context, Teva argued that the conclusions of the GATE study on the efficacy and safety of Synthon GA are not valid due to, allegedly, various shortcomings of the study.²⁶⁰⁶ These messages are consistent with the content of various centrally created Teva documents for communicating the Misleading Complexity Message to Payers, such as the Payer White Paper (see section 9.3.2.2). However, the GKV-SV did not accept Teva’s arguments and considered Copaxone and Clift automatically substitutable based on Clift’s regulatory approval and therapeutic equivalence with Copaxone: “{...}”.²⁶⁰⁷ The same email exchange shows that GKV-SV’s recommendation for Teva “{...}” (Teva actually never generated such evidence, neither in Germany nor elsewhere). In reaction, Teva considered to designate the product as a solitary product, so that no automatic substitution would be possible, and to refuse to apply rebates, “{...}”.²⁶⁰⁸

²⁵⁹⁸ Approximately 90% of the population in Germany are members of statutory health insurance – see ID 2499, https://www.gkv-spitzenverband.de/english/statutory_health_insurance/statutory_health_insurance.jsp.

²⁵⁹⁹ ID 655, Teva’s reply to the Article 18(2) Request of 3 June 2021, p. 18.

²⁶⁰⁰ Ibid.

²⁶⁰¹ ID 404-389, Teva internal email dated 22 July 2016 from {...} to {...} and others.

²⁶⁰² ID 404-389, Teva internal email dated 22 July 2016 from {...} to {...}.

²⁶⁰³ The Commission could not assess the content of the documents annexed to this letter because Teva did not submit them.

²⁶⁰⁴ ID 455-539, Teva internal email dated 23 September 2016 from {...} to {...} and others.

²⁶⁰⁵ ID 455-539, Teva internal email dated 23 September 2016 from {...} to {...} and others.

²⁶⁰⁶ ID 455-539, Teva internal email dated 23 September 2016 from {...} to {...} and others: “{...}”.

²⁶⁰⁷ ID 455-539, Teva internal email dated 23 September 2016 from {...} to {...} and others.

²⁶⁰⁸ ID 455-539, Teva internal email dated 23 September 2016 from {...} to {...} and others.

- (1930) Therefore, Teva was unwilling to accept GKV-SV’s position on substitutability and the GKV-SV intended to take legal action against Teva to change Copaxone’s status from a “solitary” product to a generic product and to apply a 10% mandatory rebate.²⁶⁰⁹
- (1931) While Teva’s campaign was premised on the position that Synthron GA/Clift was not a substitute for Copaxone, Teva seems to have, however, eventually dropped its claim that Copaxone is a solitary product and agreed to the price reduction as this would, among others, “{...}”.²⁶¹⁰ Much like in the divisionals abuse, just when the German court was about to issue a judgment which would have clarified that the difference between “same” and “similar” is irrelevant, Teva withdrew the case to avoid a damaging precedent for its CCP campaign.²⁶¹¹ Teva estimated that there were {...}% chances that the Court would issue a reasoned judgment finding the two products substitutable, with detrimental effect not only on the German market but also in other jurisdictions: “{...}”.²⁶¹² In the absence of this judgment, Teva could continue its CCP campaign as described below.
- (1932) This shows that Teva was willing to incur a significant price decrease and the corresponding loss of revenue of EUR {...} annually²⁶¹³ in Germany (and to also forego the possibility of reversing the GKV-SV decision) just to avoid a court finding that Copaxone was substitutable to Synthron GA/Clift. In other words, this was the price Teva was willing to pay in order to avoid facing a judgment taking a position on the substitutability of Copaxone with Synthron GA/Clift that would be in strong contradiction to its campaign.

9.4.4.4.1.2. Statutory Health Insurance Funds

- (1933) Teva’s campaign in Germany did not only target the most important Payers’ association in Germany, GKV-SV, but also covered its members – German statutory health insurance funds. Teva sought to convince insurers not to organise tenders that would bring Copaxone in direct price competition with Clift.
- (1934) First, Teva carefully planned the campaign targeting insurance funds around the grant of the MA to Mylan’s Clift in Germany. A strategy document entitled “Camelion action plan FoGa” from March 2016 sets out an action plan to anticipate the launch of Clift in Germany in order to “{...}”.²⁶¹⁴ Teva’s “{...}” included visits by Teva’s Market Access staff to “{...}”.²⁶¹⁵ In anticipation of the grant of the MA to Clift, Teva started training German MSL and Market Access staff on the topic of “FoGA” at the end of 2015 (shortly before April 2016, when the successful completion of the Decentralised Procedure for Synthron GA was announced and,

²⁶⁰⁹ ID 404-1631, Teva internal email dated 29 May 2018, from {...} to {...} and others.

²⁶¹⁰ ID 404-1631, Teva internal email dated 29 May 2018, from {...} to {...} and others.

²⁶¹¹ Teva claims that it withdrew its legal action against the GKV-SV to avoid a legal dispute and straining the relationship with the GKV-SV and not as the Commission claims to avoid a legal judgement that Copaxone is a generic and is substitutable (ID 4032, Teva’s Reply to the Statement of Objections, para. 1284). These claims are in direct contradiction to Teva’s internal statements *in tempore non suspecto* mentioned/quoted in this paragraph, and thus lack credibility.

²⁶¹² ID 455-226, Teva internal email dated 24 November 2016, from {...} to {...} and others.

²⁶¹³ Copaxone net revenue in Germany amounted to USD {...} in 2017 (ID 1674, Teva’s reply to the Article 18(2) Request of 3 June 2020) or EUR {...}, at the average ECB exchange rate for 2017: 1.1297 USD/EUR.

²⁶¹⁴ ID 404-943, Camelion action plan FoGa, 9 March 2016, p. 6: “Projekt Charter – Camelion FoGa Abwehr”.

²⁶¹⁵ ID 404-943, Camelion action plan FoGa, 9 March 2016, p. 15.

thus, the disparagement abuse began) with a view to preparing “{...}”.²⁶¹⁶ Such visits with health insurance funds to disseminate “{...}” were based on “{...}” and started before the successful completion of the Decentralised Procedure for Synthron GA.²⁶¹⁷ The next stage, starting with the Clift MA grant, consisted in visits by members of the MSL team in order to provide “{...}”.²⁶¹⁸

- (1935) The milestones for Teva’s campaign concerning health insurers and “KVs” (*Kassenärztliche Vereinigungen* - physicians’ associations) in Germany are also set out in another document entitled “Projekt Charter FoGa / CCP” from April 2016.²⁶¹⁹ The first step, “{...}” was to be achieved by end May 2016. Once Clift received the MA, all “{...}” by end of August 2016. Teva considered “{...}” as one of the success factors.²⁶²⁰
- (1936) Second, Teva’s campaign targeting health insurance funds included the Misleading Complexity Message. Communications to German health insurance funds by Teva’s MSL team contained all three facets of the Misleading Complexity Message.²⁶²¹ In the first place, the topic of the “{...}” would point to the (therapeutically irrelevant) differences in the composition between Copaxone and Synthron GA/Clift due to differences in the production process, including by messages related to Teva’s Protiramer²⁶²² (as assessed in Recital (1594) et seq), and in the second place, the topic “FoGA” would point to the “situation world-wide”, based on examples from different glatiramer-related substances.²⁶²³ Moreover, Teva’s MSL team were also instructed to disseminate information concerning the GATE study right after the grant of the MA²⁶²⁴, in an apparent attempt to instil doubt as to the validity of the Decentralised Procedure/MA, and thus Synthron GA/Clift’s safety and efficacy as well as its therapeutic equivalence with Copaxone.²⁶²⁵ These topics closely match the content of Teva’s centrally created materials such as the Payer White Paper which included messages concerning compositional differences, other glatiramer-related substances, such as Protiramer and products marketed outside the EU, as well as the criticism of the GATE study.²⁶²⁶
- (1937) Third, Teva’s campaign, including the Misleading Complexity Message, sought to convince insurance funds to avoid introducing mechanisms such as tenders that would put Copaxone in direct price competition with Clift.
- (1938) Concerning a major German statutory health insurer, AOK, Teva observed that its messaging was instrumental in avoiding a winner-takes-all type exclusive tender for GA where price competition against Clift would be decisive.²⁶²⁷ Instead, the Payer

²⁶¹⁶ ID 404-943, Camelion action plan FoGa, 9 March 2016, p. 15.

²⁶¹⁷ ID 404-943, Camelion action plan FoGa, 9 March 2016, p. 15.

²⁶¹⁸ ID 404-943, Camelion action plan FoGa, 9 March 2016, p. 17.

²⁶¹⁹ ID 404-1863, Projekt Charter FoGa/CCP, 19 April 2016, p. 1.

²⁶²⁰ ID 404-1863, Projekt Charter FoGa/CCP, 19 April 2016, p. 1 (unofficial translation). Original text: “{...}”.

²⁶²¹ ID 404-943, Camelion action plan FoGa, 9 March 2016.

²⁶²² ID 404-943, Camelion action plan FoGa, 9 March 2016, p. 21.

²⁶²³ See Sections 9.3.1.1 and 9.3.1.2.

²⁶²⁴ ID 404-943, Camelion action plan FoGa, 9 March 2016, p. 17.

²⁶²⁵ See Section 9.3.1.3.

²⁶²⁶ See Section 9.3.1.2.

²⁶²⁷ For Teva’s perception of the varying competitive threats associated with different type of tenders, see ID 264-708. Under open house contracts, Teva’s Copaxone and Synthron GA are subject to the same price agreement (i.e. the health insurer pays the same price for both treatments). The market entry of Synthron GA has led to a net price decrease of c. 20% for Copaxone in open house contracts (see Recital (790)).

would organise an open house tender with two winners which would essentially allow Teva to maintain its Copaxone patient base with that insurer: “{...}”.²⁶²⁸

- (1939) This was not an isolated instance. For example, Teva considered that its actions concerning a tender organised by {...} constituted “{...}”.²⁶²⁹ As part of the tender process for GA, Teva had successfully opposed {...}'s initial exclusive tender concept, using “{...}”.²⁶³⁰ As a result, the “{...}”.²⁶³¹
- (1940) Given the above, despite receiving clear indications from the national statutory health insurance association (the GKV-SV) in Germany that Copaxone and Synthon GA/Clift were substitutable based on their therapeutic equivalence and that Teva would need to produce evidence to support its claims to the contrary, Teva nevertheless continued to disseminate its Misleading Complexity Message to health insurers, the majority of which are members of the GKV-SV.

9.4.4.4.1.3. Conclusion

- (1941) Against the foregoing, Teva was targeting the characteristics of Synthon GA which had been a condition to the successful conclusion of its Decentralised Procedure. These characteristics were also a necessary precondition for automatic substitution in Germany. If the Payers were misled with respect to these characteristics, this was also likely to affect their decision to allow automatic substitution or organise (exclusive) tenders for GA. Therefore, Teva's messages were capable of producing exclusionary effects.

9.4.4.4.2. Dissemination of Teva's Misleading Complexity Message to HCPs in Germany

- (1942) Given that Teva was unable to prevent the automatic substitution regime eventually imposed by the GKV-SV, it shifted its efforts in 2017 to preventing HCPs from switching from Copaxone to Synthon GA/Clift in individual patients. Teva's activities focused, in particular, on steering the public position of HCP associations on Synthon GA, on influencing the public statements of important KOLs and on systematically targeting prescribers with misleading messages to influence their prescription patterns.

9.4.4.4.2.1. Steering the position of influential HCP associations

- (1943) Teva extensively communicated with various influential German HCP associations with a view to steering their public position on Synthon GA/Clift. As described in Teva's Copaxone Continuation Plan – Projekt Charter of January 2017,²⁶³² (thus after Teva dropped its claim that Copaxone is a solitary product) Teva planned to “{...}” (emphasis added).²⁶³³
- (1944) In this context, Teva targeted members of the German federal MS association (the Deutsche Multiple Sklerose Gesellschaft Bundesverband e.V. (“DMSG")). In particular, Teva prioritised visits to DMSG members by its MSL teams and offered

²⁶²⁸ ID 404-995, Teva internal email dated 28 June 2017 from {...} to {...}.

²⁶²⁹ ID 455-1818, Teva internal email dated 30 June 2017 from {...} to {...} and others.

²⁶³⁰ ID 455-1818, Teva internal email dated 22 June 2017 from {...} to {...} and others.

²⁶³¹ ID 404-1818, Teva internal email dated 30 June 2017 from {...} to {...} and others.

²⁶³² ID 455-503, Copaxone Continuation Plan – Projekt Charter, 23 January 2017, pp. 21-23.

²⁶³³ ID 455-503, Copaxone Continuation Plan – Projekt Charter, 23 January 2017, p. 21 (unofficial translation). Original text: “{...}”.

presentation materials to “{...}”.²⁶³⁴ Teva’s “milestones” and activities to achieve this included: (i) contacts with DMSG’s board, members and regional associations; (ii) slide presentation and dispensing materials; and (iii) an “{...}” (see the explanation in the following Recital).²⁶³⁵

- (1945) The achievement of Teva’s milestones with the DMSG was reported regularly. On 23 January 2017²⁶³⁶ Teva reported that, as part of its “{...}”, out of 158 DMSG members, it contacted 85 doctors and prioritised visits since December 2016/Q1 2017 every 14 days.²⁶³⁷ In a further update on 6 February 2017, Teva reported on a visiting schedule for 74 DMSG members: Teva had “f2f” (face-to-face) meetings with more than 26 members and planned further meetings with more than 10 DMSG members.²⁶³⁸
- (1946) Teva also reported on the success rate of its “{...}”, which resulted in a success rate of 76% (i.e. 55 out of 72 DMSG external experts briefed) or 67% (i.e. 91 out of 136 DMSG external experts visited and briefed).²⁶³⁹ Teva’s successful dissemination of misleading messages to the DMSG in Germany also served as an example of best practices for other Teva subsidiaries, for example, in the Netherlands.²⁶⁴⁰
- (1947) Materials used by Teva’s MSL team during visits with DMSG members included an “{...}”.²⁶⁴¹ These centrally created Teva CCP materials, which contain misleading messages, are discussed in Sections 9.3.2.2. and 9.3.2.2.2. In addition, with a specific focus on Germany, Teva referred to the “{...}”, the “{...}”, the “{...}” and the “{...}”.²⁶⁴²

9.4.4.4.2.2. ‘Hired’ support from leading KOLs

- (1948) With the aim of influencing the public perception regarding Synthron GA/Clift, including through associations of HCPs, Teva relied on the support from a leading KOL, {...}.²⁶⁴³ At the relevant time, {...} was {...}, therefore in a position of significant influence compared to other DMSG members, or the broader neurologist community in Germany. The evidence shows that Teva “{...}”. It also shows that Teva used this statement in 2017 “{...}”.²⁶⁴⁴ Teva’s internal exchanges not only show that Teva acknowledged organising the statement/interview with {...}.²⁶⁴⁵ A draft interview of {...}²⁶⁴⁶ also indicates that the draft had come from Teva, on which {...} made some comments and changed the order of arguments. The published interview contains no acknowledgment of Teva’s involvement in this

²⁶³⁴ ID 455-503, Copaxone Continuation Plan – Projekt Charter, 9 January 2017, p. 23: “{...}” (unofficial translation). Original text: “{...}”.

²⁶³⁵ ID 455-503, Copaxone Continuation Plan – Projekt Charter, 9 January 2017, p. 24 (unofficial translation). Original text: “MSL-Besuchspan”.

²⁶³⁶ ID 455-503, Copaxone Continuation Plan – Projekt Charter, 9 January 2017, p. 24.

²⁶³⁷ ID 455-503, Copaxone Continuation Plan – Projekt Charter, 9 January 2017, p. 24.

²⁶³⁸ ID 455-503, Copaxone Continuation Plan – Projekt Charter, 9 January 2017, p. 25.

²⁶³⁹ ID 404-1154, CNS MSL meeting 04-05.09.2017, p. 25.

²⁶⁴⁰ ID 455-1312, Teva internal note dated January 2017: “{...}”, (unofficial translation).

²⁶⁴¹ ID 404-1154, CNS MSL meeting 04-05.09.2017, p. 26. ‘{...}ed’ refers to the fact that the documents have been approved internally (for a description of Teva’s {...} platform, see footnote 2285).

²⁶⁴² ID 404-1154, CNS MSL meeting 04-05.09.2017, p. 26.

²⁶⁴³ According to Teva, {...} acted as a Teva speaker during various events – see ID 660, Teva’s reply to Article 18(2) request of 3 June 2020, p. 115.

²⁶⁴⁴ ID 455-831, Teva internal email dated 2 May 2017 from {...} to {...} and others. For {...} statement/DMSG articles, see ID 455-498, {...} {...}, {...}, p. 1 and ID 455-502, {...} {...}, p. 2.

²⁶⁴⁵ ID 455-1028, Teva internal email dated 2 May 2017 from {...} to {...}.

²⁶⁴⁶ ID 264-741, {...}, draft interview with {...}.

interview. {...} received from Teva all materials available for the preparation of {their} interview.²⁶⁴⁷

- (1949) Further, a Teva email sent to {...} reveals Teva’s strategy to use “independent” third parties to pass Teva’s messages: “{...}”.²⁶⁴⁸ This was considered to be “{...}”.²⁶⁴⁹
- (1950) {...} statements, which were made at a time that Synthon GA had already successfully completed the Decentralised Procedure and Clift had already obtained its MA in Germany, closely mirror Teva’s Misleading Complexity Message from its centrally created CCP materials.²⁶⁵⁰ Notably, {...},²⁶⁵¹ implicitly raising doubts with respect to Synthon GA’s safety, efficacy, and therapeutic equivalence with Copaxone. For example, the document contains the following statement: “{...}”.²⁶⁵² While the first sentence is not controversial, the formulation of the second sentence creates the impression that Synthon GA is not therapeutically equivalent to Copaxone. This is achieved by contrasting the first sentence which acknowledges the societal importance of cheaper, therapeutically equivalent alternatives with the second sentence. That sentence starts with the adverb “however”, suggesting that this may not be the case for Copaxone and Synthon GA – the only non-Copaxone GA product authorised in the EU (to which the entire article is essentially dedicated without naming it). This impression is exacerbated by the fact that neither that sentence nor the entire article mention the fact that Synthon GA/Clift was indeed found to be a safe and effective medicinal product, and therapeutically equivalent to Copaxone. The statement also contested the validity of the GATE study and pointed to its alleged shortcomings (as the scientific basis for finding Synthon GA therapeutically equivalent to Copaxone).²⁶⁵³ On this basis, {...} concluded that at “{...}”.²⁶⁵⁴
- (1951) As Teva mentioned internally, {...} made “{...}” and Teva considered that this “{...}”²⁶⁵⁵ and that it could “{...}”²⁶⁵⁶ or “{...}”²⁶⁵⁷ Indeed, Teva was extensively using the interview with {...} in its communications with HCPs in Germany. Teva was communicating misleading messages also via dedicated newsletters for nurses. For example, Teva’s “Nurse Newsletter”, a part of Teva’s patient support programme “Aktiv mit MS”, echoes messages used in other documents, and heavily relies on the {...} interview: “{...}”.²⁶⁵⁸
- (1952) The following evidence shows how effective these statements, coming from a purportedly independent KOL, were. For example, a monthly report by Teva’s

²⁶⁴⁷ ID 455-503, Copaxone Continuation Plan – Projekt Charter, p. 22: in the slide called “{...}” (unofficial translation; original text: “{...}”), among the activities Teva planned, there is a mention of the activity “{...}” where it is mentioned that “{...}” (unofficial translation; original text: “{...}”) and the activity is marked as finished on 6 October 2016.

²⁶⁴⁸ ID 455-3112, Teva internal email dated 12 January 2017 from {...} to {...}.

²⁶⁴⁹ ID 455-3112, Teva internal email dated 12 January 2017 from {...} to {...}.

²⁶⁵⁰ Teva’s claim that the statements were limited to automatic substitution and did not question safety and efficacy *per se* (ID 4032, Teva’s Reply to the Statement of Objections, para. 1296) is unfounded as demonstrated in what follows.

²⁶⁵¹ ID 455-502, {...} (p. 2): “{...}” (unofficial translation). Original text: “{...}”.

²⁶⁵² ID 455-498, {...} p. 1: “{...}” (unofficial translation) (emphasis added). Original text: “{...}”.

²⁶⁵³ ID 455-502, {...} p. 2: “{...}” (unofficial translation). Original text: “{...}”.

²⁶⁵⁴ Ibid.

²⁶⁵⁵ ID 455-1028, Teva internal email dated 2 May 2017 from {...} to {...} and others.

²⁶⁵⁶ ID 455-1028, Teva internal email dated 2 May 2017 from {...} to {...} and others.

²⁶⁵⁷ ID 455-1028, Teva internal email dated 2 May 2017 from {...} to {...} and others.

²⁶⁵⁸ ID 5150-104, Nurse newsletter, p. 2 (Unofficial translation). Original text: “{...}”.

KAMs/sales representatives testifies that Teva used {...}²⁶⁵⁹ when asked by HCPs about Synthon GA/Clift: “{...}”.²⁶⁶⁰ This is also shown by another similar report: “{...}”.²⁶⁶¹

- (1953) Teva used another KOL, {...}, to pass on Teva’s misleading messages in Germany (see above Recitals (1803) and (1804)). Teva amplified the dissemination of the Misleading Complexity Message to Payers and HCPs by engaging {...} and the evidence on the file shows that {...} relation with Teva goes beyond a mere coincidental alignment of scientific opinions.²⁶⁶² {...} had been working closely with Teva on {...}.²⁶⁶³ {...} was also a speaker for Teva at various events.²⁶⁶⁴ In Teva’s own words, {...} is “{...}”.²⁶⁶⁵ The special relation between Teva and {...} is conspicuous from email exchanges in December 2016, showing that {...} was reporting to Teva about any inquiries {...} was receiving in relation to Synthon GA/Clift. Amongst others, a representative of an organisation advising German Health Insurance Funds reached out to {...} with questions in relation to Synthon GA to which {...} replied posing as an independent expert, while immediately forwarding {their} reply to Teva.²⁶⁶⁶ This demonstrates that Teva was able to indirectly influence unsuspecting Payers reaching out to certain KOLs in search of a neutral advice concerning their reimbursement policies for GA.
- (1954) Moreover, several of Teva’s internal documents show that the interview that {...} gave for the {...}²⁶⁶⁷ was part of activities planned by Teva and marked as a communication milestone in the Copaxone Continuation Plan as already mentioned in Recital (1919).²⁶⁶⁸ Teva considered publishing {...} as one of its tasks.²⁶⁶⁹
- (1955) {...} statements closely follow the messages developed in Teva’s CCP materials, namely implying that compositional differences in GA structures were therapeutically relevant (by arguing that GA’s effects depend on the production process, and pointing to batch variations²⁶⁷⁰), as well as criticising the GATE study on the same grounds as Teva (ARR).²⁶⁷¹ The alignment with Teva’s messages is unsurprising, as evidence shows that Teva had commented on the draft text of the

²⁶⁵⁹ See Recitals 1383-1386 of the SO.

²⁶⁶⁰ ID 5161-265, Monatsbericht Januar: Region Süd, January 2017 (Unofficial translation). Original text: “{...}”.

²⁶⁶¹ ID 5161-267, Monatsbericht Januar: Maisch Region Süd (unofficial translation). Original text: “{...}”.

²⁶⁶² ID 742-122; ID 673; ID 857; ID 742-127 show that {...} was remunerated by Teva for various services.

²⁶⁶³ For example, ID 404-2492, Teva internal email chain dated 3 July 2018 from {...} to {...} and others shows that {...} was working closely with Teva to design Copaxone studies: “{...}”.

²⁶⁶⁴ ID 932, Teva’s reply to Article 18(2) Request of 3 June 2020, pp. 13, 14, 15.

²⁶⁶⁵ ID 404-1819, Teva internal email dated 5 January 2017 from {...} to {...} and others.

²⁶⁶⁶ ID 404-1465, email communications dated 15 December 2016 from {...} (KOL) to {...} which forwards the email dated 15 December 2016 from {...} (KOL) to {...}.

²⁶⁶⁷ ID 404-1663, Stellungnahme {...} zum Thema FoGA; See also ID 404-1658, Teva internal email dated 29 August 2016 from {...} to {...} and others; see also ID 263-2994, TPE Country visit: deep dive session, Berlin 27 June 2017, p.43 where the Teva’s Medical Action plan included the publication in {...} {...} – this was considered by Teva one of its strategic projects.

²⁶⁶⁸ ID 264-1403, Projekt Charter – Copaxone Continuation Plan, 15 April 2016, p. 1, (unofficial translation). Original text: “{...}” p. 2: “{...}” (unofficial translation). Original text: : “{...}”; see also ID 264-1083, Copaxone Continuation Plan Meeting – Update, p. 2 – “{...}” (unofficial translation). Original text: “{...}”.

²⁶⁶⁹ ID 264-1709, Copaxone Continuation Plan - Gantt Chart.

²⁶⁷⁰ See Section 9.3.1.1.

²⁶⁷¹ See Recital (1634).

interview prior to its publication.²⁶⁷² The draft text, found in Teva's files, contains a comment by a Teva employee: "{...}".²⁶⁷³ And while this exact example is not reproduced in the final interview, the final text is rife with suggestions of potentially meaningful differences between Copaxone and Synthon GA. The manner in which the comment is phrased ("...") again shows that Teva internally considered this document as its own. Despite this, in the interview, the links between Teva and {...} are not disclosed. Moreover, Teva's internal documents show that the company frequently quoted {...} interview in various documents, giving the impression that they quote an independent opinion, i.e., without disclosing Teva's relationship with the expert and its possible influence over the statements.²⁶⁷⁴ In the period after the interview, a Teva manager, referring to personal experience from working with KOLs in the past and in particular {...}, observed that: "{...}".²⁶⁷⁵

9.4.4.4.2.3. Directly communicating the Misleading Complexity Message to HCPs in Germany

- (1956) Teva not only endeavoured to manipulate public perception of Synthon GA/Clift by influencing HCP associations and leveraging influenced KOL opinions, but also to directly target prescribers and pharmacists with misleading messages.
- (1957) Doctors in Germany can prescribe medicines by either referring to the INN or to the brand. In either case, pharmacists are obliged to dispense only medicines which are covered by a tender concluded with the patient's health insurance.²⁶⁷⁶ If there is no tender, pharmacists must dispense one of the four cheapest products.²⁶⁷⁷
- (1958) Doctors may exclude substitution at pharmacy level for medical reasons. If that is the case, doctors must prescribe by brand and tick the "aut-idem" box on the prescription form.²⁶⁷⁸ While it is a doctor's prerogative to tick the "aut-idem" box, health insurance funds can investigate a doctor's prescribing practice, if a doctor ticks the "aut-idem" box too often (known as a "Prüfungstelle" by the health insurance funds).²⁶⁷⁹ Pharmacists may also exclude substitution if they have medical concerns specific to a patient's situation. This decision, relying on the pharmacist's professional judgment, has to be documented on the prescription.²⁶⁸⁰
- (1959) Teva systematically communicated the Misleading Complexity Message to German neurologists, hospitals and nurses. According to the {...}²⁶⁸¹ data, in the period from

²⁶⁷² ID 264-1898, {...} Interview; see also ID 404-1482, Teva internal email dated 4 March 2016, from {...} to {...}: "{...}" (internal translation).

²⁶⁷³ ID 264-1898, draft text of {...} interview (unofficial translation). Original text: "{...}".

²⁶⁷⁴ ID 264-1504, Talking points Clift, p. 2.

²⁶⁷⁵ ID 263-435, WhatsApp conversation between {...} and {...}.

²⁶⁷⁶ See ID 1012-35, Teva's reply to the Article 18(2) Request 4 of 22 October 2021 and 18 November 2021, p. 4: In Germany, authorities organise tenders for open house contracts or, more rarely, exclusive contracts. Only products which are included in the contract, i.e., that "win" the tender (whether it is exclusive or not), will be reimbursed. Reimbursement will be at the price set in the tender. Copaxone is included in such tenders.

²⁶⁷⁷ See ID 1012-35, Teva's Reply to Article 18(2) Requests of 22 October and 18 November 2021, p. 2.

²⁶⁷⁸ ID 1012-27, Teva's Reply to Article 18(2) Requests of 22 October and 18 November 2021, p. 3. See also footnote 915.

²⁶⁷⁹ ID 1012-27, Teva's Reply to Article 18(2) Requests of 22 October and 18 November 2021, p. 3.

²⁶⁸⁰ ID 1012-27, Teva's Reply to Article 18(2) Requests of 22 October and 18 November 2021, p. 3, ID 1012-35, Teva's Reply to Article 18(2) Requests of 22 October and 18 November 2021, p. 3.

²⁶⁸¹ ID 900-2 and ID 900-8, {...} data for Germany. For scope and reliability of {...} data see footnote 2326.

March 2017 to May 2021, Teva’s MSLs²⁶⁸² and sales representatives made altogether {...} direct contacts (either face-to-face visits or phone calls) with {...} HCPs in Germany related to *inter alia* Copaxone, GA or central nervous system products.²⁶⁸³ There is evidence that, of these registered contacts, at least {...} included “*NBCD-FoGA*” as their key message.²⁶⁸⁴ During an 8-month period in Germany in 2017, Teva reported {...} MSL calls to HCPs concerning “*NBCD-FOGAs*” as the main message.²⁶⁸⁵ Reference to “*NBCD-FoGA*” as a key message of a contact with HCPs indicates that the contact likely referred, at least in part, to Synthon GA/Clift and included the Misleading Complexity Message, considering its emphasis in the training materials prepared by Teva²⁶⁸⁶ and in Teva’s strategic documents (including Brand Plans) for Germany²⁶⁸⁷, as well as the reasons for Teva to adopt the acronyms “*NBCD*” and “*FoGA*”.²⁶⁸⁸ Indeed, according to Teva, calls communicating their “*NBCD*” narrative were a tool to tackle the threat from Synthon GA: “{...}”.²⁶⁸⁹ Furthermore, it cannot be excluded that more such contacts took place, considering that contacts between HCPs and Teva’s MSL team only occurred in case the HCPs raised a question during an earlier contact with the Teva KAM for which the latter did not have the authority to reply.²⁶⁹⁰ Not all contacts are recorded mandatorily, and even for contacts for which documentation is mandatory there is no system in place which requires sales representatives and MSLs to record calls, as also confirmed by Teva.²⁶⁹¹

- (1960) In its communication with HCPs, in addition to disseminating the messages from the centrally created CCP materials (see Section 9.3.2.2) Teva used a number of documents for the German market, which reproduce the misleading messages contained in the centrally created CCP materials. In addition, Teva also included the Misleading Complexity Message in bespoke documents it produced to specifically support its campaign in Germany for doctors to tick the abovementioned “aut-idem” box when prescribing Copaxone (hereinafter, Teva’s “aut-idem campaign”). These documents will be assessed in turn below.

Teva documents reproducing misleading messages in Germany from centrally created CCP documents

Talking Points Clift

- (1961) Internal training materials entitled “Talking Points Clift” provide insight into arguments Teva’s staff was trained to use to point to the health risks that would

²⁶⁸² MSLs usually followed up once the sales representatives made their pitch to an HCP in particular to implement the “*medical strategy*” of “*communicat[ing] on the complexity of [the] glatiramer acetate structure*”. ID 404-952, MSL Tactical Plan CNS 2016 – Germany – Internal and External Events.

²⁶⁸³ In addition, in the period from January 2015 to November 2017 Teva used in Germany a different system for customer relationship management (Update 7) which reveals altogether {...} contacts with {...} HCPs. See ID 800-75 and ID 800-66 Update 7 data for Germany and ID 799, email dated 24 June 2021 from Teva’s external counsel to the European Commission.]

²⁶⁸⁴ Just like in Belgium, inherent limitations in the available CRM data apply (see footnote 2478).

²⁶⁸⁵ ID 404-1154, CNS MSL meeting 04.-05.09.2017, p. 24.

²⁶⁸⁶ See Section 9.3.2. In particular, Teva prepared materials for the members of its MSL team (notably the External Expert White Paper for MS specialists, the GATE Study Review and the MSL Objection Handlers) and for its KAMs, (notably KAM Objection Handlers).

²⁶⁸⁷ See Recitals (1917)-(1921) above.

²⁶⁸⁸ See Sections 9.1.1 and 9.3.1.4.2 above.

²⁶⁸⁹ ID 404-1154, CNS MSL meeting 04.-05.09.2017, p. 29.

²⁶⁹⁰ As explained in section 9.3.2; see also ID 262-1275, Plan of action – In the face of evolving FoGA competition, p. 13.

²⁶⁹¹ See footnote 2326 above.

supposedly arise in case a doctor was open to prescribing Clift instead of Copaxone: “{...}”.²⁶⁹² Teva’s statement claiming that Synthon GA “{...}” is incorrect and in direct contradiction to the findings of the competent authorities. The Talking Points also insinuate, in line with the misleading and discrediting messages assessed in Section 9.3.1.1, that due to GA’s complexity and manufacturing differences, the active substance is similar and not the same,²⁶⁹³ with no reference to the PAR or to the MEB’s decision which had rebutted this Teva claim and established that there were no clinically relevant differences between the products.²⁶⁹⁴ Finally, in the Talking Points, Teva also sows doubt on the validity of the GATE study by emphasising alleged limitations of the GATE study and claiming that the study did not follow EMA guidelines²⁶⁹⁵ though the study was designed based on EMA’s advice, thus questioning the scientific basis for the successful conclusion of Synthon GA’s Decentralised Procedure.²⁶⁹⁶

Glatirameracetat s.c.40 mg 3 x /Woche

- (1962) Similarly, another training slide set for communication with doctors²⁶⁹⁷ contains messages as assessed in Section 9.3.1, falsely implying that differences in GA structures may have clinically relevant effects: “{...}”; Teva further claims that “{...}”, thereby casting doubt on Synthon GA’s safety, efficacy and therapeutic equivalence with Copaxone.²⁶⁹⁸
- (1963) In the same document, Teva evoked safety and health risks posed by its own failed Protiramer pipeline project, as assessed above²⁶⁹⁹, implicitly raising concerns with Synthon GA (the only “glatiramoid” marketed in the EU) and its safety: “{...}”.²⁷⁰⁰ Teva concludes “{...}”, thereby also sowing doubts not only on Synthon GA’s safety, but also on its efficacy and therapeutic equivalence with Copaxone.²⁷⁰¹

Copaxone, Clinical experience & future developments

- (1964) Teva also communicated the Misleading Complexity Message through the trainings given to neurologists in German hospitals.²⁷⁰² For example, on 5 March 2017, Teva gave an educational workshop to German neurologists and residential neurologists.²⁷⁰³ Teva’s presentation emphasised the clinically irrelevant differences

²⁶⁹² ID 404-1677, Talking Points Clift, Stand 24.11.2016 (unofficial translation). Original text: “{...}”.

²⁶⁹³ ID 404-1677, Talking Points Clift, 24 November 2016, p. 1.

²⁶⁹⁴ See Section 9.3.1.1.3.

²⁶⁹⁵ ID 404-1677, Talking Points Clift, 24 November 2016, pp. 2, 3.

²⁶⁹⁶ See Recital (1605)).

²⁶⁹⁷ ID 4919-75, Glatirameracetat s.c.40 mg 3 x /Woche, pp. 17, 49-51, 50, 58 ; ID 4897, List of documents registered on Teva’s {...} platform - An associated excerpt from Teva’s internal database shows that the document was approved in March 2015, reapproved on 4 January 2017, with first recorded use 5 March 2015, withdrawn in February 2020; the mode of dissemination is Handover/lecture by the MSL team and the objective of the slideset is to train and present to doctors.

²⁶⁹⁸ ID 4919-75, Glatirameracetat s.c.40 mg 3 x /Woche, p. 17 (unofficial translation). Original text: “{...}” .p. 62 (unofficial translation). Original text: “{...}”.

²⁶⁹⁹ See Section 9.3.1.2.

²⁷⁰⁰ ID 4919-75, Glatirameracetat s.c.40 mg 3 x /Woche, p. 49 (unofficial translation). Original text: “{...}”.

²⁷⁰¹ ID 4919-75, Glatirameracetat s.c.40 mg 3 x /Woche, p. 49 (unofficial translation). Original text: “{...}” .p. 58 (unofficial translation). Original text: “{...}”.

²⁷⁰² ID 4513-96462, Teva internal email thread dated March 2017 including email dated 1 March 2017 from {...} to {...} and others.

²⁷⁰³ ID 4513-96462, Teva internal email thread including email dated 1 March 2017 from {...} to {...} and others; ID 4513-96462, Teva internal email thread including email dated 3 March 2017 from {...} to {...} and others contains an email exchange which revealed that the presentation given to the German

in the GA structures discussed above, suggesting possible therapeutic risks and thereby sowing doubts on Synthron GA's safety, efficacy and therapeutic equivalence with Copaxone: "{...}" (original emphasis and emphasis added).²⁷⁰⁴ In the following quote, Teva also alluded that the differences may lead to potential safety issues: "{...}". This statement was retained in the version approved for training of German HCPs and used "publicly" {...}.²⁷⁰⁵ Amongst others, this was because Teva was using arguments which, in the view of some employees of Teva's, had already been "{...}".²⁷⁰⁶ In the internal email exchange discussing this slide deck, a Teva employee asked to remove the quote on the "{...}" so as to "{...}".²⁷⁰⁷ The same internal email exchange shows that the misleading messages related to the safety and efficacy of Synthron GA are passed either directly or in a more indirect manner, (in Teva's own words, "{...}", referring to the analogy with other glatiramer-related substances in Mexico).²⁷⁰⁸

- (1965) Finally, in the conclusions, Teva even contested the similarity between Copaxone and Synthron GA: "{...}".²⁷⁰⁹ In addition, Teva casted doubt on the validity of the GATE study:²⁷¹⁰ "{...}" (emphasis added).²⁷¹¹ Based on its criticism of results related to the ARR (a claim assessed in Recitals (1610) and (1615) of this Decision), Teva claimed that there were "{...}".²⁷¹² A comment by a Teva employee made on the same slide reveals that, again, Teva was aware that these statements were misleading: "{...}".²⁷¹³

NBCD Slide Kit

- (1966) Also Teva's "NBCD Slide Kit" used by Teva's MSL team in their presentations to HCPs contains the misleading messages described in Section 9.3.1.²⁷¹⁴ Teva cast doubt on the validity of the GATE study, without reconciling these claims and inferences with the findings in MEB's PAR, notably: "{...}",²⁷¹⁵ "{...}", therefore questioning the scientific basis for the successful conclusion of the Decentralised

neurologists is the same as the one presented in Belgium during the meeting with the Medicine Agency (FAMHP).

- ²⁷⁰⁴ ID 4513-96417, Copaxone, Clinical experience & future developments, March 2017, p. 26, attachment to ID 4513-96462, Teva internal email dated 3 March 2017 from {...} to {...} and others.
- ²⁷⁰⁵ ID 4513-96462, Teva internal email thread including email dated 3 March 2017 from {...} to {...} and others.
- ²⁷⁰⁶ ID 4513-96462, Teva internal email thread including email dated 3 March 2017 from {...} to {...} and others.
- ²⁷⁰⁷ ID 4513-96462, Teva internal email thread including email dated 3 March 2017 from {...} to {...} and others.
- ²⁷⁰⁸ ID 4513-96462, Teva internal email dated 3 March 2017 from {...} to {...} and others.
- ²⁷⁰⁹ ID 4513-96417, Copaxone, Clinical experience & future developments, March 2017, p. 55.
- ²⁷¹⁰ ID 4513-96417, Copaxone, Clinical experience & future developments, March 2017, pp. 46-52. attachment to ID 4513-96462, Teva internal email dated 3 March 2017 from {...} to {...} and others.
- ²⁷¹¹ ID 4513-96417, Copaxone, Clinical experience & future developments, March 2017, attachment to ID 4513-96462, Teva internal email dated 3 March 2017 from {...} to {...} and others, p. 53.
- ²⁷¹² ID 4513-96417, Copaxone, Clinical experience & future developments, March 2017, attachment to ID 4513-96462, Teva internal email dated 3 March 2017 from {...} to {...} and others, p. 50.
- ²⁷¹³ ID 404-848, Comments summary report of The Complexity of Copaxone, comment made by {...} on 20 September 2016 at 8:41, p. 18.
- ²⁷¹⁴ ID 4919-87, NBCD Slide Kit, 17 February 2017; ID 4897, List of documents registered on Teva's {...} platform - An associated excerpt from Teva's internal database shows that the document was approved in February 2017, reappraised in December 2018, and with first recorded use on 21 February 2017
- ²⁷¹⁵ ID 4919-87, NBCD Slide Kit, 17 February 2017, pp. 5, 18, 22, 29-30 - Unofficial translation. Original text: "{...}."

Procedure for Synthon GA.²⁷¹⁶ Teva then appealed to the professional responsibility of physicians: “{...}”.²⁷¹⁷

- (1967) Various periodic reports from Teva’s sales force concerning contacts with HCPs demonstrate that the Misleading Complexity Message contained in the training documents and other materials as described above were indeed disseminated by Teva. One such report refers to the “{...}”, such as “{...}”.²⁷¹⁸ Another monthly report shows how Teva employees were instilling doubt as to Synthon GA’s (Clift’s) efficacy and the validity of the GATE study “{...}”.²⁷¹⁹
- (1968) Teva resorted to misleading messages not only in communications with doctors, but also with nurses, as exemplified by the document entitled “COPAXONE CONTINUATION PLAN PSP”.²⁷²⁰ Teva used this document to align communication on the switch from 20 mg to 40 mg and on Synthon GA’s launch towards nurses by, for example, providing Teva representatives with agreed replies to questions about Synthon GA that Teva anticipated from nurses. In the document, Teva makes sweeping, yet unfounded statements that Copaxone and Synthon GA cannot be substituted in pharmacies – this despite the fact that GKV-SV decided in favour of automatic substitution and no other German authority decided against this possibility: “{...}”.²⁷²¹ Teva also pointed to the established safety and efficacy of Copaxone, indirectly casting doubt on Synthon GA’s safety, efficacy and therapeutic equivalence with Copaxone, and creating the false impression that the scientific basis behind the successful conclusion of the Decentralised Procedure for Synthon GA (and, consequently, of its MA) is completely unknown: “{...}”.²⁷²² Since Teva itself chose to discuss Synthon GA with nurses and patients, and in view of its in-depth knowledge of Synthon GA’s features, the statement that “{...}”²⁷²³ seeks to mislead patients and nurses as to relevant facts scientifically established by competent authorities, i.e. that Synthon GA is a safe and effective medicine, therapeutically equivalent to Copaxone.

Bespoke aut-idem materials

- (1969) In view of the particular regulatory environment in Germany, one of the main strands of Teva’s misleading conduct in Germany was the information disseminated in the context of the so-called “aut-idem campaign” (as described above). In reaction to GKV-SV’s confirmation that Copaxone and Clift are automatically substitutable, Teva stated: “{...}”.²⁷²⁴ This campaign, therefore, aimed at preventing substitution from Copaxone to Clift by suggesting to prescribers that they should tick the “aut-

²⁷¹⁶ ID 4919-87, NBCD Slide Kit, 17 February 2017, p. 18 – (unofficial translation). Original text: “{...}”.

²⁷¹⁷ ID 4919-87, NBCD Slide Kit, 17 February 2017, pp. 5, 18, 22, 29-30 - Unofficial translation. Original text: “{...}”.

²⁷¹⁸ ID 4729-36, Wochenbericht (unofficial translation). The document’s meta data suggests that the weekly report was written in April 2020. Original text: “{...}”.

²⁷¹⁹ ID 5161-130, Monatsbericht September: Region Mitte – (unofficial translation). Original text: “{...}”.

²⁷²⁰ ID 4919-70, COPAXONE CONTINUATION PLAN PSP.

²⁷²¹ ID 4919-71, COPAXONE CONTINUATION PLAN PSP, p. 9 - (unofficial translation). Original text: “{...}”.

²⁷²² ID 4919-70, COPAXONE CONTINUATION PLAN PSP, p. 10 – (unofficial translation). Original text: “{...}.”; ID 4897, List of documents registered on Teva’s {...} platform – associated excerpt from Teva’s internal database shows that the document was approved on 13 July 2016, reapproved on 21 May 2018, with first recorded use on 25 July 2016, mode of dissemination – telephone conversation. It therefore shows that the “COPAXONE CONTINUATION PLAN PSP” was used and disseminated.

²⁷²³ ID 4919-71, COPAXONE CONTINUATION PLAN PSP, p. 7 – (unofficial translation). Original text: “{...}”.

²⁷²⁴ ID 455-539, Teva internal email dated 23 September 2016 from {...} to {...} and others.

idem” box on prescriptions. If prescribers ticked this “aut-idem” box, pharmacists would not be able to substitute Copaxone.²⁷²⁵

- (1970) This naturally made discussing aut-idem with neurologists (specifically, why they should prevent the substitution with Synthron GA) a priority for Teva.²⁷²⁶
- (1971) Teva’s aut-idem campaign extensively relied on artificially differentiating Copaxone from Synthron GA/Clift to prevent substitution. To that effect, Teva’s campaign was not limited to evidence specifically pertaining to the question of automatic substitution, but also comprised challenging Synthron GA’s therapeutic equivalence to Copaxone by employing the Misleading Complexity Message. In addition to seizing neurologists’ attention through purportedly neutral KOL publications in specialised journals, as described in the previous Section of this Decision, Teva was also communicating misleading messages directly to doctors with a view to convincing them to prevent substitution by ticking the “aut-idem” box. To achieve this result, Teva’s representatives could rely both on general CCP materials containing misleading messages (both centrally created and local CCP materials) as well as bespoke documents, which will be assessed below.
- (1972) First, the so-called “Elvis” handout, depicted in Figure 45 below, shows that Teva advised prescribers to tick the “aut-idem” box on prescriptions for Copaxone. This recommendation was based on the misleading message that “*nothing resembles the original*”, implying that Clift (i.e. the Elvis Presley lookalike) was a lesser version of GA and may resemble Copaxone (i.e. the real Elvis Presley), but it is not the same and, therefore, it should not be a substitute for Copaxone.

Figure 45: the “Elvis” HCP handout



Source: ID 455-503, Copaxone Continuation Plan – Projekt Charter, 6 February 2017, p.48

- (1973) Second, in a similar document for neurologists²⁷²⁷, prepared in the context of Teva’s aut-idem campaign and depicted in Figure 46 below, Teva compares Copaxone and Synthron GA by using a misleading analogy of a zebra and a horse. The image is accompanied by the message “*similar but not the same*”. Both the “Elvis” and the

²⁷²⁵ ID 455-503, Copaxone Continuation Plan – Projekt Charter, 6 February 2017, p. 46.

²⁷²⁶ ID 264-1431, Regionaltagung Südwest, 24 January 2018, p. 22.

²⁷²⁷ ID 264-1360, Regionaltagung Region Süd, 31 January 2018, p. 20; ID 39, Copaxone: Teva’s disparagement of a generic entrant, p. 4.

“Zebra” handout imply that there may be clinically relevant differences between Copaxone and Synthon GA - contrary to the established regulatory findings of therapeutic equivalence between the two products, which rejected Teva’s claims in this respect.

Figure 46: the “Zebra” HCP handout

Gesprächsleitfaden Aut-Idem



Lieber Herr Doktor, heute habe ich Ihnen eine schöne Analogie mitgebracht.....
Pferd und Zebra sehen sehr ähnlich aus, sind aber nicht gleich...



Das lässt sich auch auf Copaxone übertragen.
Wenn Sie nicht möchten, dass die Apotheke über die Therapie entscheidet, setzen Sie das Aut-Idem für alle Patienten mit Copaxone Rezept.

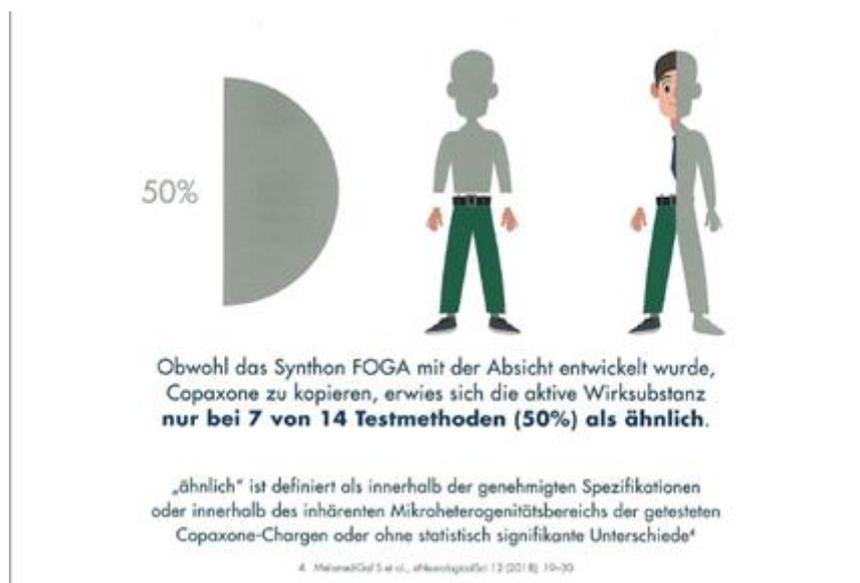


Source: ID 264-1360, Regionaltagung Region Süd, 31 January 2018

(1974) Third, another Teva handout²⁷²⁸ shown in Figure 47 below, uses a different visual method to sow doubt as to the therapeutic equivalence of Synthon GA with Copaxone. It presents on one part of the slide the message about how safe Copaxone is, and the second part of the slide shows visually the inferiority of Synthon GA.

²⁷²⁸ ID 4440, Copaxone poster (unofficial translation). Original text: “Obwohl das Synthon FOGA mit der Absicht entwickelt wurde, Copaxone zu kopieren, erwies sich die active Wirksubstanz nur bei 7 von 14 Testmethoden (50%) als ähnlich”.

Figure 47: Copaxone poster



ID 4440, Copaxone poster

(1975) In the handout, Teva states that “[a]lthough the FOGA Synthon was developed with the intention of copying Copaxone, the active ingredient was found to be similar in only 7 out of 14 test methods (50%)”. This leaves the reader with the clear impression that these differences (visually modelled as 50% of the human body) are meaningful and have clinical implications. Teva however fittingly failed to mention that the competent authorities examined these differences and found that these were not clinically relevant and that therefore Synthon GA and Copaxone were scientifically found as therapeutically equivalent despite these differences (and that Teva’s claims to the contrary were unfounded).²⁷²⁹ This Teva flyer thus, at best, represents some aleatory findings, and has been objectively designed to generate concerns about the alleged deficiencies of Synthon GA. Teva’s aut-idem campaign appears to have had an important impact on prescribing practices in Germany. While the proportion of aut-idem prescriptions varied during the period of infringement, Teva’s internal documents suggest that, by 2019, they reached around {...}% of Copaxone sales in Germany.²⁷³⁰ Importantly, the campaign was not aimed against a generalised, automatic substitution regime for the entire patient population, but at convincing prescribers to prevent pharmacists from dispensing Clift instead of Copaxone in individual patients. Therefore, the aut-idem campaign was complementary to the more general campaign aimed at German HCPs.

Communication with pharmacists

(1976) Pharmacists also formed part of Teva’s CCP plan for Germany. This is not surprising, considering that pharmacists could have an impact on the actual substitution of Copaxone with Clift. As explained earlier in this Section, where the patient’s health insurer had concluded open house tenders covering both Copaxone and Clift (which most health insurers did), pharmacists could dispense either Copaxone or Clift (if the patient’s prescription did not exclude substitution because the “aut-idem” box was ticked). Accordingly, pharmacists could in certain cases

²⁷²⁹ See, for example, Section 9.3.1.1.3.

²⁷³⁰ ID 264-1517, Copaxone: Performanceanalyse, January 2019, p. 12; see also ID 1295-7, Teva’s reply to Article 18(2) Requests of 22 October and 18 November 2021, p. 3 – according to Teva, “{...}”.

decide to dispense Clift instead of Copaxone (or vice versa). Further, pharmacists had the option to veto substitution due to pharmaceutical concerns specific to a patient's situation, even if the doctor had left the option to substitute open in the prescription (by prescribing a drug by brand without ticking the "aut-idem" box).²⁷³¹ From this perspective, in Germany, pharmacists are, after doctors, the last resort in terms of HCPs that can directly influence actual substitution of medicines.

- (1977) In particular, Teva took specific communication actions regarding pharmacies, which were aimed at informing them about the "complexity of NBCDs" to ultimately question the substitutability of Copaxone with Clift.²⁷³² Teva developed a variety of online initiatives in cooperation with the German online pharmacy portal (Deutsches Apotheken Portal, "DAP")²⁷³³ in 2016, when Synthon GA (Clift) obtained a MA in Germany. These initiatives continued in 2017 and included a "{...}", each with an estimated outreach of 25,000 participants ("all pharmacies") and online pharmacy courses on "NBCDs", which were estimated to bring on average of 1,800 participants per training.²⁷³⁴
- (1978) Teva's many articles in the DAP²⁷³⁵ regularly exposed pharmacists to various facets of Teva's Misleading Complexity Message which focused on the alleged uniqueness of Copaxone. While basing their reasoning on Teva's "NBCD" arguments, i.e. the compositional differences between Copaxone and Clift which were presented as possibly having clinical relevance, the articles stayed silent on the established therapeutic equivalence between the two products and did not explain why the alleged differences were clinically relevant. On that basis, Teva's paid-for articles ("advertorials") thus suggested that substitution would be risky. For example, in Teva's "special DAP publication for neurologists" ("*DAP Sonderdruck für*

²⁷³¹ ID 1012-35, Teva's reply to the Article 18(2) Requests of 22 October and 18 November 2021, p. 3.

²⁷³² ID 455-503, Copaxone Continuation Plan – Projekt Charter, 9 January 2017, p. 37: "{...}." (unofficial translation). Original text: "{...}."

²⁷³³ The DAP has been an established online service provider for German pharmacists for the last 10 years. It provides practical help for everyday pharmacy life, from regulatory issues relating to prescription delivery (retax avoidance) to advice on self-medication. The DAP reaches a daily audience of 20,000 pharmacies in Germany through its various media outlets, including their DAP Dialog articles. See <https://www.dap-networks.de/deutschesapothekenportal> for further information.

²⁷³⁴ ID 455-503, Copaxone Continuation Plan – Projekt Charter, 9 January 2017, p. 38.

²⁷³⁵ A selection of Teva's DAP articles are referenced in ID 264-8, Advertorials zu Copaxone, pp. 53-62: (i) "Non-Biological Complex Drugs (NBCDs) – Why substitution is to be viewed critically" (unofficial translation; original text: "Non-Biological Complex Drugs (NBCDs) – Warum ein Austausch kritisch ist") (DAP December 2016, edition 36), p. 53; (ii) "Glatirameracetat – a complex active substance" (unofficial translation; original text: "Glatirameracetat – ein komplexer Wirkstoff") [DAP reference not available], pp. 54-55; (iii) "Reinforce Adherence – Patient program for MS patients" (unofficial translation; original text: "Adherence stärken – Patientenprogramm für MS-Patienten") (October 2017, edition 41), pp. 59-60; (iv) "Substitutability: yes or no? Discussion about the therapeutic equivalence of different glatiramer preparations" (unofficial translation; original text: "Austauschbarkeit: Ja oder Nein? Diskussion zur therapeutischen Äquivalenz verschiedener Glatiramer-Präparate") (DAP April 2018, edition 44), pp. 56-57; and (v) "Glatiramer acetat – What should be considered at the pharmacy" (unofficial translation; original text: "Glatirameracetat – Was ist in der Apotheke zu beachten") [DAP reference not available], pp. 61-62. See also ID 455-503, Copaxone Continuation Plan – Projekt Charter, 9 January 2017, p. 41: "Substitutability of NBCDs viewed critically – The example of glatiramer acetat" (unofficial translation; original text: "Austauschbarkeit von NBCDs kritisch – Das Beispiel Glatirameracetat") (DAP February 2017, edition 37); ID 5150-100, DAP advertorial and ID 4897, List of documents registered on Teva's {...} platform - Associated excerpt from Teva's internal database shows that the objective of the "DAP advertorial" document was to inform pharmacists about "NBCD" and it was approved on 19 January 2017, reapproved on 23 November 2018 and with first recorded use on 23 January 2017.

Neurologen”),²⁷³⁶ Teva publicly outlined its reasoning as to why doctors’ medical discretion (“*Therapiehoheit*”) on MS therapies with GA was under threat from generics since their entry in September 2016. First, Teva’s premise in the article was that any small deviation from an individually established therapeutic treatment could result in negative consequences for patients and the success of the treatment.²⁷³⁷ Second, the article advanced the misleading notion that the so-called “NBCDs” were complex and that they were therefore not regulated from a substitution point of view.²⁷³⁸ Third, contrary to the findings of therapeutic equivalence, Teva claimed that there was a doubt as to the “comparability” of Copaxone and Clift, and therefore substitution of Copaxone should be avoided by placing an aut-idem cross on the doctors’ prescription because only this would ensure that the MS patients obtained the very treatment chosen by their treating doctor:²⁷³⁹ A DAP article originated from (or authorised by) Teva also suggested the justification to be used to dispense Copaxone:²⁷⁴⁰

²⁷³⁶ ID 455-503, Copaxone Continuation Plan – Projekt Charter, 9 January 2017, p. 43: “{...}.” (unofficial translation). Original text: “{...}.”

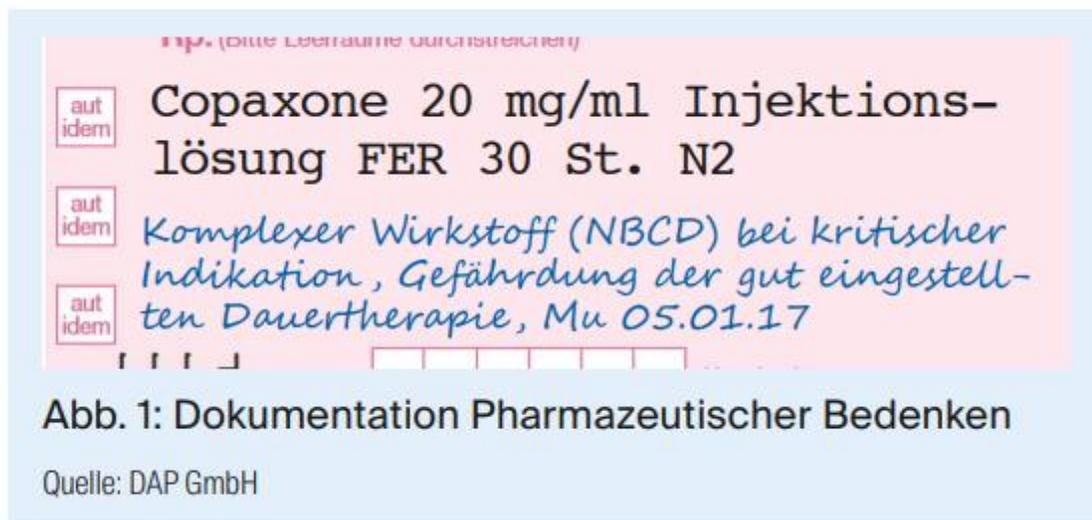
²⁷³⁷ ID 455-503, Copaxone Continuation Plan – Projekt Charter, 9 January 2017, p. 43: “*Already small deviations from an individually established therapeutic treatment could result in negative consequences for patients and the success of the treatment. In this connection the doctor’s medical discretion therefore plays a central role*” (unofficial translation). Original text: “*Schon kleine Abweichungen innerhalb eines individuell etablierten Therapieregimes können negative Auswirkungen für den Patienten und den Therapieerfolg nach sich ziehen. In diesem Zusammenhang spielt die ärztliche Therapiehoheit daher eine zentrale Rolle*“.

²⁷³⁸ ID 455-503, Copaxone Continuation Plan – Projekt Charter, 9 January 2017, p. 43: “*Because for NBCDs there is no regulatory policy regarding the practice of substitution, the pharmacy can dispense the alternative preparation instead of the original.*” (unofficial translation). Original text: “*Da es für NBCDs kein regulatorisches Konzept bezüglich der Substitutionspraxis gibt, kann in der Apotheke abstatt des Originals das Alternativpräparat abgegeben werden.*”

²⁷³⁹ ID 455-503, Copaxone Continuation Plan – Projekt Charter, 9 January 2017, p. 43: “*Despite some scientific doubts regarding the comparability of Copaxone 20mg/ml with its generic, so far they are not excluded from mutual substitution. It is therefore sensible to safeguard the prescription of Copaxone 20mg/ml by ticking the “aut-idem” box and by stating the name of the manufacturer and/or the central identification number for pharmaceuticals (PZN). Only in this way can the treating practitioner ensure that his/her MS patients will receive the chosen treatment.*” (unofficial translation). Original text: “*Trotz einiger wissenschaftlicher Zweifel bezüglich der Vergleichbarkeit von Copaxone 20mg/ml und seinem Nachahmerpräparat besteht bislang kein gegenseitiger Substitutionsausschluss. Daher ist es sinnvoll, die Verordnung von Copaxone 20mg/ml durch ein Setzen des Aut-Idem-Kreuzes sowie Nennung des Herstellers und/oder der PZN abzusichern. Nur so kann der behandelnde Arzt sicherstellen, dass seine MS-Patienten die von ihm ausgewählte Therapie erhalten.*”

²⁷⁴⁰ ID 5150-100, DAP Advertorial. The document suggests doctors to indicate the following beside the *aut idem* box: “*Complex active substance (NBCD) in critical indication, hazard to well-established long-term therapy*”. The record from the extraction of Teva’s {...} database associated with this document confirms that it was first used on 23 January 2017 and then reapproved on 23 November 2018 (see ID 4897, List of documents registered on Teva’s {...} platform). For the Commission’s conclusions based on Teva’s re-approval of this document in March 2020, see footnote 2571 above.

Figure 48: mock prescription instructing how to prevent substitution of Copaxone with Synthon GA



Source: ID 5150-100, DAP Advertorial.

- (1979) Teva also published certain surveys through the DAP allegedly showing that the majority of pharmacy staff is against substitutability of GA, clearly attempting to accentuate the perception it was creating with the Misleading Complexity Message.²⁷⁴¹
- (1980) Teva created a template for a flyer on “*aut-idem substitution of non-biological complex drugs*” for distribution to pharmacies via email.²⁷⁴² The stated objective of distributing this flyer was to spread information to pharmacists about so-called “{...}”.²⁷⁴³ Therefore, Teva misled pharmacists about the non-existence of a standardised regulatory path (while there is a special procedure under Article 10(3) of Directive 2001/83 for hybrid medicines which applied to Synthon GA) while asking them to think carefully about the substitution. The document contains links to the NBCD group materials and to the DAP training which provides background information (for DAP materials, see above Recitals (1977)-(1978)). An associated excerpt from Teva’s internal database shows that the document was approved on 17 May 2018, with first recorded use on 24 May 2018 and reapproved on 24 March 2020.²⁷⁴⁴ This shows that the flyer was used and disseminated.

9.4.4.4.3. Teva’s arguments and the Commission’s assessment

- (1981) Teva claims that the Commission’s argument that, by providing information about Copaxone’s safety and efficacy, Teva implied that Synthon GA is not safe and effective is unfounded. Teva refers to the 2020 Brand Plan for Germany mentioned in Recital (1921) above and identifying the following strategic objectives: “{...}”. According to Teva, the Commission ignored statements which provide further context that Teva’s communications were legitimate and were not designed to

²⁷⁴¹ ID 455-503, Copaxone Continuation Plan – Projekt Charter, 9 January 2017, p. 40: “{...}” (unofficial translation). Original text: “{...}”.

²⁷⁴² ID 4919-100, email to pharmacies - (unofficial translation). Original text: “{...}”.

²⁷⁴³ ID 4919-100, email to pharmacies - (unofficial translation). Original text: “{...}”.

²⁷⁴⁴ ID 4897, List of documents registered on Teva’s {...} platform. For the Commission’s conclusions based on Teva’s re-approval of this document in March 2020, see footnote 2571 above.

disparage other treatments (including Synthron GA).²⁷⁴⁵ The Commission rejects these arguments. Section 9.4.4.4.2 contains ample references and evidence of the actual documents that Teva prepared and used for its communications with HCPs (as planned, among others, in the Brand Plan mentioned by Teva), and that contain the Misleading Complexity Message.

- (1982) Teva claims that the Commission’s interpretation of the quote “{...}” (see Recital (1920) above) is flawed as it allegedly relates to “*positive messages about aspects of Copaxone (i.e., its complexity, safety, and efficacy)*” and not misleading messages about Synthron GA.²⁷⁴⁶ This argument is flawed. The above quote makes it clear that the communication with 450 External Experts was to be based on the centrally prepared Payer White Paper.²⁷⁴⁷ The Payer White Paper precisely contains the Misleading Complexity Message related to Synthron GA’s safety and efficacy, as well as its therapeutic equivalence with Copaxone (as shown in Section 9.3.2.2.1.1). Besides, the same document shows that this task was 10% completed, thereby further confirming that the plan of disseminating the messages contained in the Payer White Paper in Germany was being implemented.
- (1983) Teva claims that the Commission is wrong in claiming that Teva pointed to health risks associated with the prescription of Clift in its internal training material “Talking Points Clift” (see Recital (1961) above) and that the same document also includes a paragraph where Teva contrasted Copaxone’s safety and efficacy with the “*unknown efficacy or side effect profile [of Clift] in practice*” (emphasis in Teva’s quote).²⁷⁴⁸ Further, Teva claims that the Talking Points Clift focused on the alleged advantages of Copaxone, including its 40 mg dosage and its patient support programme, and that there is allegedly no evidence that this document was circulated to Teva’s KAM or MSL staff.²⁷⁴⁹ In addition, Teva claims that the Talking Points Clift focus on Copaxone’s “*proven medical safety record*”, whose promotion by Teva allegedly amounts to competition on the merits in relation to an aspect of non-price competition.²⁷⁵⁰ Lastly, Teva claims that the same reasoning applies to Teva’s messages concerning automatic substitution between Copaxone and Clift, which allegedly amount to competition on the merits also because “*the District Court Hamburg rejected the notion that the GATE Study would support such substitution*”.²⁷⁵¹ The Commission rejects these arguments. First, the very quote Teva refers to instils doubt as to the safety and efficacy of Clift, as it incorrectly suggests that its efficacy or side effects are “*unknown*” and deliberately obscures the fact that Clift and Copaxone were found to be therapeutically equivalent, i.e. having equivalent efficacy and safety. Second, the document Talking Points Clift is uploaded on Teva’s {...} platform, and available at any time (its target group being the salesforce).²⁷⁵² Lastly, Teva’s argument that the Talking Points Clift focus on allegedly legitimate aspects of non-price competition and on automatic substitution is misguided, for the simple reason that the fact that Teva’s documents also relate to other aspects, such as the 40 mg dosage, do not change the legal qualification of

²⁷⁴⁵ ID 4032, Teva’s Reply to the Statement of Objections, para. 1278 (b) (i).

²⁷⁴⁶ ID 4032, Teva’s Reply to the Statement of Objections, para. 1278 (b) (ii).

²⁷⁴⁷ ID 264-1709, Copaxone Continuation Plan - Gantt Chart.

²⁷⁴⁸ ID 4032, Teva’s Reply to the Statement of Objections, para. 1278 (b) (iii).

²⁷⁴⁹ ID 4032, Teva’s Reply to the Statement of Objections, para. 1278 (b) (iii).

²⁷⁵⁰ ID 4032, Teva’s Reply to the Statement of Objections, para. 1278 (c).

²⁷⁵¹ ID 4032, Teva’s Reply to the Statement of Objections, para. 1278 (c).

²⁷⁵² ID 597-76, Talking Points Clift, 9 September 2016; for updated version, see ID 264-1500, Talking points Clift 6 February 2017.

misleading statements related to Synthron GA's safety, efficacy, and therapeutic equivalence with Copaxone (see Section 9.2.3.5 above). Further, Teva's argument related to the statements of the District Court Hamburg, is addressed in Recital (1987) below.

- (1984) Teva claims that it is illegitimate for the Commission to rely on documents pre-dating the infringement.²⁷⁵³ The Commission recalls it only presents documents previous to the beginning of the disparagement abuse as mere context and to show that Teva did not appropriately adapt its materials even after the competent authorities had found that Synthron GA was safe, efficacious and therapeutically equivalent to Copaxone (see Section 9.3.1.4.3 above).
- (1985) Teva claims that the communication with the German Payers was not misleading or disparaging because it conveyed messages related to automatic substitution and were based on (allegedly) objective supporting evidence and relevant context.²⁷⁵⁴ The Commission rejects these arguments. Section 9.4.4.4.1 provides abundant examples of misleading messages in Teva's communication, casting doubt on the very basic features of Synthron GA – its safety, efficacy and therapeutic equivalence with Copaxone. Further, Teva's communication, implying the inferiority of Synthron GA, was not based on any supporting evidence and for this reason GKV-SV requested Teva "*to generate data showing that CLIFT is clinically less efficacious and/or less safe as Copaxone 20mg*"²⁷⁵⁵ for its claims to be followed. Teva has never provided such data. Lastly, Section 9.2.3.5 explains the reasons why the fact that Teva's messages related also to automatic substitution is not sufficient for them not to be considered misleading when including misleading information on Synthron GA's safety, efficacy, and therapeutic equivalence with Copaxone.
- (1986) Teva claims that its communications to German Payers (related to the "*uniqueness of Copaxone*") and differences in the composition between Copaxone and Synthron GA including by reference to Teva's experience with Protiramer) "*did not specifically address any particular FoGAs, but were aimed at the general education on the complexity of GA (in relation to which Teva's experience with Protiramer is relevant)*".²⁷⁵⁶ This argument is flawed. First, Teva's communications are misleading precisely because the arguments related to other GA or even more remotely related substances such as Protiramer are irrelevant to understand the characteristics of Synthron GA. This is confirmed by Teva's own statements (see, for example, Recitals (1591)-(1599)). Second, Teva's claim that these arguments did not specifically target Synthron GA is incorrect. These arguments are consistently used in Teva's CCP materials which were created for Teva's European markets and which share the primary objective to defend Copaxone from Synthron GA. Synthron GA has been the only GA product competing with Copaxone across the EU and therefore any messages disseminated in the EU which emphasise risks associated with GA other than Copaxone are just thinly veiled attempts to disparage Synthron GA.
- (1987) Teva argues that the Commission's claim that Teva instructed its MSL team to disseminate information concerning the GATE study right after the grant of the MA, in an apparent attempt to instil doubt as to the validity of the MA, and thus Synthron

²⁷⁵³ ID 4032, Teva's Reply to the Statement of Objections, para. 1280, referring to "*Camelion action plan FoGa*" of 9 March 2016, the "*Big Ideas Copaxone*" document of 30 January 2014, 1232 or the "*Copaxone Continuation Project*" of 25 November 2014.

²⁷⁵⁴ ID 4032, Teva's Reply to the Statement of Objections, para. 1285.

²⁷⁵⁵ ID 455-539, Teva internal email dated 23 September 2016 from {...} to {...} and others.

²⁷⁵⁶ ID 4032, Teva's Reply to the Statement of Objections, para. 1286 (a).

GA/Clift’s safety and efficacy as well as its therapeutic equivalence with Copaxone is flawed and misleading. Teva claims that its criticisms do not relate to the safety and/or efficacy of Synthon GA *per se*. Teva also claims its legitimate questions around the limitations of the GATE study in Germany were confirmed by the German District Court Mannheim and District Court Hamburg.²⁷⁵⁷ The Commission rejects these arguments. First, Sections 9.4.4.4.1 and 9.4.4.4.2 describe numerous communications which criticise the GATE study and directly question its main findings. Second, of the two German court cases cited by Teva, one – the case in front of the Hamburg Court – indeed shortly addresses alleged shortcomings of the GATE extension study related to the specific issue of automatic substitution. The Hamburg Court does, however, not call into question the general findings related to the safety and efficacy of Synthon GA and its therapeutic equivalence with Copaxone. Moreover, the “*statement of the Court*” in question, as quoted by Teva,²⁷⁵⁸ consists in an extract from the hearing protocol of the District Court Hamburg of 23 November 2016 and not from a decision on substance.²⁷⁵⁹ In fact, none of the two court cases raised by Teva in support of its claim were decisions on substance.²⁷⁶⁰ Teva’s claim that the courts vindicated its claims related to these issues is thus entirely unfounded. Finally, as described in Recital (1931) Teva withdrew the case pending before the Hamburg Court to avoid a negative decision: “{...}”.²⁷⁶¹

- (1988) Teva claims that the Commission’s assessment of its communications with the GKV-SV is flawed as it is based on a single Teva internal email reporting the GKV-SV meeting, which was thus “*hearsay at most*”. In Teva’s view, Teva did not question the safety and efficacy *per se* and only argued the implications of automatic substitution. Teva claims that its questioning of certain aspects of the GATE study was limited to “*duration and missing PROs etc.*”.²⁷⁶² These arguments do not convince. First, the said internal report carries high evidentiary value, as it was drafted (i) on the day of the meeting with the GKV-SV, (ii) by a meeting participant, (iii) to inform Teva’s (European-wide) senior management and legal team of the outcome of the discussion with the GKV-SV. Second, as to Teva’s claim that it did not question the GATE study *per se* but only the “*duration, missing PROs etc.*”, it is not necessary that Teva questions the GATE study *per se* for its communication to be qualified as misleading. By questioning the parameters of the GATE study, Teva questioned the validity of the outcomes of this study, and thereby the scientific soundness of the GATE study itself as the basis for the finding that Synthon GA is safe, efficacious, and therapeutically equivalent to Copaxone. The GATE study was

²⁷⁵⁷ ID 4032, Teva’s Reply to the Statement of Objections, para. 1286 (b).

²⁷⁵⁸ In footnote 1242 of its Reply to the Statement of Objections (ID 4032), Teva quotes the District Court Hamburg as follows: “*Furthermore, the board is of the opinion that the Gate study does not substantiate the advertised statement resulting from the press release. In the Board’s opinion, the safety of switching from a current therapy is not sufficiently documented by the Gate study*”. Note that, while the District Court Hamburg refers to the “Gate study”, the safety of switching between Copaxone and Synthon GA was not the subject of the GATE study, but of the GATE extension study.

²⁷⁵⁹ ID 4107, Annex 8.16 to Teva’s Reply to the Statement of Objections, p. 3. Teva withdrew its claim in the hearing and there was no final decision on the substance of the case.

²⁷⁶⁰ The decision of the Mannheim District Court was made in a preliminary proceedings. Due to “urgency” (“*Dringlichkeit*”), the Mannheim court adopted a decision without making any statements on the decision-making rationale (“*Entscheidungsgründe*”), see ID 4106, Annex 8.15 to Teva’s Reply to the Statement of Objections, pp. 2-6.

²⁷⁶¹ ID 455-226, Teva internal email dated 23 November 2016, from {...} to Copaxone enforcement, and others; PRO – patient-reported outcome.

²⁷⁶² ID 4032, Teva’s Reply to the Statement of Objections, para. 1287; PRO stands for Patient-reported outcomes.

carried out to show that Synthon GA is equivalent to Copaxone in safety and efficacy. Even if Teva “only” questioned the abovementioned features of the study, this would still have been capable of casting doubt on its results as a whole and therefore on Synthon GA’s safety, efficacy and therapeutic equivalence with Copaxone. The evidence on the exchange with GVK-SV shows that Teva’s ultimate goal was to sow doubt about these features to artificially differentiate Copaxone from Synthon GA. Third, the fact that Teva challenged the safety and efficacy of Synthon GA is also corroborated by GKV-SV requesting Teva to prove their claim, and “{...}”.²⁷⁶³ Finally, the above described messages are consistent with the content of the Payer White Paper, a centrally created CCP material designed precisely with a view to develop arguments for Teva’s communications with Payers such as the GKV-SV (see Section 9.3.2.2).

- (1989) Teva claims that the Commission misrepresents the evidence because the alleged dissemination of information about “NBCDs”, the GATE study, Copaxone’s long-term experience, and Copaxone’s long-term data allegedly falls within the scope of “*innocuous*” education of Payers and physician associations about the pharmaceutical product based on valid and objective facts. Teva also claims that its plans to defend against Synthon GA are not *de facto* abusive taking into account how aggressively Synthon GA/Clift was positioning itself in Germany, even allegedly violating laws of fair competition.²⁷⁶⁴ The Commission rejects these arguments. First, Teva’s communication is not based on “valid and objective” facts as it is revealed by GKV-SV’s request to submit data to prove Teva’s claims, which Teva never provided. Secondly, the Commission does not object to Teva promoting its product, but objects to it “defending” itself against competitors through means not consistent with competition on the merits. Notably, for the reasons explained above, Teva disparaged Synthon GA, by disseminating misleading information to key drivers of demand on Synthon GA’s safety, efficacy and thus its therapeutic equivalence with Copaxone, in contradiction with the findings of the regulatory authorities. The {...} data was provided by Teva of confronting Synthon GA was not reactive, as it falsely portrays. Section 9.1. shows Teva’s detailed and systematic preparations of its communication campaign targeting competing GAs in Europe which started many years before Synthon GA could actually enter the market and try to compete with Copaxone.
- (1990) Teva claims that its attempts to convince Payers to launch open house contracts rather than exclusive tenders in Germany were legitimate. Teva claims that open house contracts do not prevent the use of Synthon GA or otherwise curb its uptake.²⁷⁶⁵ The Commission rejects these arguments as irrelevant. The Commission does not dispute the legitimacy of Teva’s contacts with the Payers *per se*, but rather the misleading information used in this context to influence their decisions on automatic substitution (without which exclusive tenders would not be possible). First, Teva’s campaign failed to reconcile Teva’s statement on “complexity” and similarity with the regulatory findings that Copaxone and Synthon GA are therapeutically equivalent, thus artificially differentiating the two products. Teva’s communications to Payers, such as German insurers, was based on the messages developed in the Payer White Paper and other Payer materials (see Section 9.3.2.2).

²⁷⁶³ ID 455-539, Teva internal email dated 23 September 2016 from {...} to {...} and others.

²⁷⁶⁴ ID 4032, Teva’s Reply to the Statement of Objections, para. 1289.

²⁷⁶⁵ ID 4032, Teva’s Reply to the Statement of Objections, paras. 1290, 1291.

Internal documents show that Teva used “{...}”²⁷⁶⁶ to convince German health insurer {...} to not launch an exclusive tender. Teva used the Misleading Complexity Message to convince German health insurers to publish open tenders instead of winner-takes-all type tenders (“{...}”²⁷⁶⁷). Second, replacing exclusive tenders with open-house tenders significantly reduced competition between GAs. As a result of such artificial differentiation, and as Teva’s statement above illustrates, many German insurers have foregone the benefits of exclusive, winner-takes-all type tenders based on price competition between the two GA products. Instead, they opted for open-house tenders, which essentially avoid automatic substitution. Teva’s senior management for Germany acknowledged this by stating that “{...}”²⁷⁶⁸. As a result, Teva could maintain its Copaxone patient base with the relevant insurers and the price level for GA did not drop as drastically as was to be expected with exclusive winner-takes-all type tenders.

- (1991) Teva contests the Commission’s interpretation of the statement related to the cooperation with {...} (see Recital (1954)), claiming that Teva’s managers were upset with the cooperation and expressed hope and expectation that {...} would work on and revise the provided materials.²⁷⁶⁹ Teva’s claim is not supported by facts. On a preliminary note, as shown in Recital (1953), Teva had a close relation with {...} and considered {them} to be a “{...}”²⁷⁷⁰. The quote does not show that a Teva manager was upset with {...} copying Teva’s “{...}”, or that it expected a different working arrangement. In fact {...} simply informed another {...} of {their} experience of working with KOLs (including {...}). The {...} then went to express {their} doubt, or lack of conviction, that {...} would change {their} statement: “{...}”²⁷⁷¹. Teva claims the fact that {...} publicly endorsed Teva’s arguments means that {they} agreed with Teva’s message against automatic substitution and that Teva’s own belief in the soundness of its scientific arguments and communication strategy was reinforced, and that a KOL would not jeopardise his reputation by supporting an untenable medical position.²⁷⁷² Teva also claims that it cannot be held accountable for the statements made by an independent expert and even if the statements can be attributed to Teva, they would fall within the scope of legitimate conduct.²⁷⁷³ These arguments do not convince. First, as explained in Recital (1807), the Commission does not take issue with the fact itself that Teva’s and KOLs’ views are aligned, but objects to the manifest lack of transparency concerning the specific circumstances of the creation of {...} opinion piece. As shown in Recitals (1948) to (1950), the statements in the {...} {...} were developed with Teva, and were based on materials provided to {...} by Teva. However, not only did {...} statement itself not disclose {their} links with Teva, but Teva itself used and disseminated it as a statement of an independent expert in its many communications with various stakeholders without disclosing Teva’s involvement in its creation. This deprived the addressees of Teva’s communications of the

²⁷⁶⁶ ID 455-1818, Teva internal email dated 22 June 2017 from {...} to {...} and others.

²⁷⁶⁷ ID 404-995, Teva internal email dated 28 June 2017 from {...} to {...}, see Recital (1938).

²⁷⁶⁸ ID 455-539, Teva internal email dated 23 September 2016 from {...} to {...} and others

²⁷⁶⁹ ID 4032, Teva’s Reply to the Statement of Objections, para.1294.

²⁷⁷⁰ ID 404-1819, Teva internal email dated 5 January 2017 from {...} to {...} and others.

²⁷⁷¹ ID 263-435, WhatsApp conversation between {...} and {...}.

²⁷⁷² ID 4032, Teva’s Reply to the Statement of Objections, para. 1295.

²⁷⁷³ ID 4032, Teva’s Reply to the Statement of Objections, para. 1296.

possibility to make their own opinion of the credibility and scientific value of the views of a leading KOL in the field of MS, such as {...}.²⁷⁷⁴

- (1992) Teva claims that the messages were limited to the issue of automatic substitution and that the Commission has not demonstrated that any of the KOL opinions were misleading and therefore it was legitimate for it to use them for communications with Payers and HCPs.²⁷⁷⁵ The Commission rejects this argument. As stated in Recital (1800), Teva’s extensive input to these opinion pieces aimed to ensure that the produced documents were fully aligned with Teva’s CCP messages, including the Misleading Complexity Message. First, it follows from an internal Teva email that, under its own internal rules regarding publications compliance, Teva should not contribute to an independent publication.²⁷⁷⁶
- (1993) Second, to add more detail to the assessment of {...} interview in Recital (1955) and the finding that {their} statements follow the same line of arguments as those in Teva’s CCP campaign, the Commission observes that (i) it emphasises clinically irrelevant differences in GA structures: “{...}”²⁷⁷⁷; (ii) it criticises the GATE study without reconciling its claims with the findings of the MEB and without mentioning that all these claims have been assessed and rejected by the MEB: “{...}”.²⁷⁷⁸
- (1994) Third, in relation to {...} statement on the topic of Synthon GA, labelled as the “first follow-on medicine”²⁷⁷⁹ (in line with Teva’s own terminology), Recital (1948) explains how the statement implicitly denies the therapeutic equivalence between Copaxone and Synthon GA. In keeping with this, the document also emphasises that, due to GA’s “complexity” and other factors, it is necessary to prove equivalence through studies regarding the so-called clinical parameters such as relapse reduction, influence on disability progression and MRI markers.²⁷⁸⁰ However, it conveniently omits to mention that Synthon submitted the clinical studies as required by competent authorities and Synthon GA had on that basis been found to be safe, efficacious, and therapeutically equivalent to Copaxone. The document also criticises the alleged shortcomings of the GATE study (see Recital (1950) above) in line with the arguments from Teva’s own communications.²⁷⁸¹
- (1995) Teva contests the Commission’s findings in Recital (1944) et seq. concerning the dissemination of misleading messages to members of DMSG, as the communications were allegedly limited to automatic substitution.²⁷⁸² This argument is unfounded. In the abovementioned Recital, the Commission shows that Teva’s communication with DMSG members was based on the messages included in the Payer White Paper, and the slide deck as described and assessed in section 9.3.2.2. These documents contain misleading messages concerning broader issues, notably Synthon GA’s safety,

²⁷⁷⁴ For the same reasons, also Teva’s claim that the Commission is wrong to insinuate that Teva influenced opinions of professional associations such as DMSG or KKNMS, or that statements of these associations could somehow be attributed to Teva, is unfounded. ID 4032, Teva’s Reply to the Statement of Objections, para. 1302.

²⁷⁷⁵ ID 5695, Teva’s Reply to the Letter of Facts I of 9 February 2024, para. 362. ID 4032, Teva’s Reply to the Statement of Objections, para. 1296.

²⁷⁷⁶ ID 455-548, Teva internal email dated 4 May 2017 from {...} to {...} and others: “{...}”.

²⁷⁷⁷ 404-1663, {...} (unofficial translation) - Original text: “{...}”.

²⁷⁷⁸ 404-1663, {...} (unofficial translation) - Original text: “{...}”.

²⁷⁷⁹ ID 455-2654, {...} (unofficial translation). Original text: “{...}”.

²⁷⁸⁰ ID 455-2654, {...}.

²⁷⁸¹ ID 455-2654, {...} (unofficial translation). Original text: “{...}”.

²⁷⁸² ID 4032, Teva’s Reply to the Statement of Objections, para. 1302.

efficacy and therapeutic equivalence with Copaxone and thus go beyond the specific question of automatic substitution.

- (1996) Teva claims that the Commission should not rely on the {...} data, qualifying the statistics as referring to an allegedly “*hypothetical*” number of interactions with HCPs and “*misleading*”.²⁷⁸³ Teva claims that key message “NBCD-FoGA” is insufficient to ascertain the content of the communication, and to assume that it cast doubt as to the safety and efficacy of Synthron GA (as opposed to Teva’s messages on automatic substitution). Teva also claims that the Commission disregarded the fact that KAMs were explicitly instructed to proactively only talk about Copaxone’s benefits and complexity, and that the number of MSL communications concerning Synthron GA was very limited.²⁷⁸⁴ The Commission rejects these arguments. First, the Commission’s conclusion that Teva disseminated misleading information to discredit Synthron GA/Clift with German HCPs is based on the assessment of multiple elements, whereby {...} statistics complement qualitative evidence showing the dissemination of the Misleading Complexity Message to HCPs (centrally created CCP materials, training materials for communication with German doctors²⁷⁸⁵, etc.). Second, Teva does not explain why it refers to the number of interactions with HCPs as “hypothetical”. The {...} data was provided by Teva and generated by Teva employees recording their contacts with HCPs. Not all contacts are recorded mandatorily, and even for contacts for which documentation is mandatory there is no system in place which requires sales representatives and MSLs to record calls. This suggests that the actual number of contacts in which misleading information was disseminated is likely to be higher than the number of contacts documented in the {...} data. Moreover, Teva’s own documents suggest that it was relying on {...} data in monitoring MSL calls to neurologists in the CCP campaign (see, for example, Recital (1959)). Third, concerning the meetings for which the key message “NBCD-FoGA” was recorded in {...}, such as the MSL calls to neurologists, the Commission relies not only on the {...} data, but in particular on the content of Teva’s CCP materials that Teva’s staff were to use in such communications (see, for example, Figure 42). Teva’s internal documents show that {...}.²⁷⁸⁶ There was in fact a total of {...} registered contacts with “NBCD-FoGA” as key message. It is important to note that for many contacts the key message was not registered. It is therefore very well possible that more calls with the key message “NBCD-FoGA” have taken place.²⁷⁸⁷ Fourth, the Commission did take into account Teva’s instructions that KAMs could not proactively engage in certain messages (see, for example, the same Recital (1959)). However, the Commission also takes into account the evidence of the actual messages for Teva’s communication with HCPs (whether proactive or reactive, whether by KAMs or by Teva’s MSL team, irrespective of how the messages are formally entitled). Such actual evidence takes precedence over Teva’s formal instructions. Fifth, Teva’s claim that the number of reactive MSL contacts with HCPs is very limited and amounts to a total of {...} calls in the period from 2015 to May 2021 only strengthens the likelihood that the {...} data suffers from underreporting of such contacts. This becomes particularly obvious in view of Teva’s contemporaneous reports based on {...} according to which no less than {...} MSL contacts concerning “NBCD/FoGA” took place during an 8-month period in 2017,

²⁷⁸³ ID 4032, Teva’s Reply to the Statement of Objections, para. 1305.

²⁷⁸⁴ ID 4032, Teva’s Reply to the Statement of Objections, para. 1306.

²⁷⁸⁵ See Recitals (1961) to (1964).

²⁷⁸⁶ ID 404-1154, CNS MSL meeting 04.-05.09.2017, p. 29.

²⁷⁸⁷ See Teva’s comments in ID 4032, Teva’s Reply to the Statement of Objections, para. 1306.

that is to say almost {...} per month. If the {...} data were correct, the remaining {...} calls (out of the total of {...}) would be spread over a period of 69 months, i.e. {...} every second month, which does not appear plausible.

- (1997) Teva claims that the Commission’s assessment of its aut-idem campaign is not supported by evidence of misleading messaging, or of its impact on HCPs’ prescribing practices in Germany (as, in Teva’s view, the reasons which prompted doctors to tick the aut-idem box which could be legitimate – for instance, to ensure that patients continue to benefit from Teva’s Patient Support Programme - PSP).²⁷⁸⁸ More generally, Teva claims that the Commission failed to demonstrate the harmful nature of Teva’s aut-idem campaign.²⁷⁸⁹ These claims are unfounded. First, the Commission’s assessment shows that Teva deployed misleading messages in the context of the aut-idem campaign. In addition to Teva’s standard CCP materials for HCPs, containing the Misleading Complexity Message intended for the same HCP population, Teva also developed specific aut-idem materials based on messages which also disparage Synthon GA by casting doubts on its safety, efficacy, and therapeutic equivalence with Copaxone (see Recital (1969) et seq). Amongst others, Teva published a document “{...}”²⁷⁹⁰, which suggests that it is medically necessary to tick the aut-idem box to avoid the use of Synthon GA/Clift. The fact that such statements were baseless was confirmed by a German court, which forbade Teva from using such statement as it did not provide any studies in its support.²⁷⁹¹ Second, the Commission’s assessment shows that Teva’s disparagement campaign was capable of producing exclusionary effects to the detriment of Synthon GA. Both the statistics showing high aut-idem use in German HCPs and the low uptake of Synthon GA compared to other Relevant Member States with a comparable timeline of entry are consistent with, and corroborate the finding that Teva’s campaign was capable of producing exclusionary effects (also taking into account that discussing aut-idem with every neurologist was a top priority for Teva at least in some regions in Germany²⁷⁹²). The Commission is however under no legal obligation to show that these effects can be exclusively attributed to Teva’s disparagement conduct. Third, it is also questionable whether ensuring access to the PSP is a “legitimate” reason for an aut-idem prescription, as claimed by Teva. This possibility to tick the aut-idem box on a prescription is foreseen for medical-therapeutic reasons only and not to give patients access to additional benefits which they might otherwise miss out on.
- (1998) Teva claims that the SO evidence shows that aut-idem prescriptions for Copaxone ({...}%) or Synthon GA ({...}%) were not high compared to other first-line DMTs ({...}%).²⁷⁹³ This argument does not convince. First, Teva itself has observed a significant increase in aut-idem prescriptions compared to Copaxone prescriptions without aut-idem.²⁷⁹⁴ Moreover, the fact that the aut-idem prescriptions render as

²⁷⁸⁸ ID 4032, Teva’s Reply to the Statement of Objections, paras. 1307-1309, 1311.

²⁷⁸⁹ ID 4032, Teva’s Reply to the Statement of Objections, para. 1310.

²⁷⁹⁰ ID 4919-98, Aut Idem Dossier DAP (unofficial translation). Original text: “{...}”. According to ID 4897, List of documents registered on Teva’s {...} platform, this document was approved on 8 February 2018, first used on 21 February 2018, reapproved on 21 December 2019; The advertisement *Warum das Aut-idem Kreuz aus medizinischer Sicht notwendig ist* against generic switching at the pharmacy level was published on 26 June 2018 on a portal for German prescribers (www.deutschesarztportal.de) – see ID 39, Copaxone: Teva’s disparagement of a generic entrant, p. 15, example 12.

²⁷⁹¹ ID 264-715, Teva’s internal email dated 29 August 2019 from {...} to {...} - “{...}”.

²⁷⁹² ID 264-1431, Regionaltagung Südwest, 24 January 2018, p. 22.

²⁷⁹³ ID 4032, Teva’s Reply to the Statement of Objections, paras. 1309, 1310.

²⁷⁹⁴ ID 264-1517, Copaxone: Performanceanalyse, January 2019, p. 12; see also Recital (1975).

much as a quarter of the German market incontestable for Synthon GA/Clift is not insignificant. Second, the Commission's assessment does not depend on the success of similar aut-idem campaigns for products outside the scope of this investigation. Moreover, Rebif, Extavia, Avonex and Betaferon are all biological drugs and can thus not be readily compared with Copaxone or Synthon GA. This means that comparing the aut-idem rate for biologic drugs with the aut-idem rate of Copaxone has limited (if any) evidentiary value.

- (1999) Lastly, Teva claims that its publications in the DAP were not disparaging, as they allegedly were limited to automatic substitution and do not suggest that Synthon GA/Clift might have any adverse effects.²⁷⁹⁵ The Commission rejects this argument based on its assessment in Recital (1978) which shows that, amongst others, Teva pointed to "{...}"²⁷⁹⁶ Teva failed to reconcile this statement with the finding of therapeutic equivalence of the two products by competent authorities, or to disclose that the "scientific doubts" were generated by Teva's own activities to instil doubt into the validity of the GATE study.

9.4.4.4.4. Conclusion

- (2000) As shown above, Teva's conduct covered most, if not all, drivers of demand for GA in Germany. First, Teva disseminated the Misleading Complexity Message to the GKV-SV, the most important Payers' association in Germany, as well as to its members, the German statutory health insurance funds, either directly or by influencing the public perception with the help of KOLs, in communications criticising the possibility of automatic substitution of Copaxone with Synthon GA/Clift and the resulting price competition. Despite receiving clear indications from the GKV-SV that Copaxone and Synthon GA/Clift were substitutable based on their therapeutic equivalence, Teva nevertheless continued to disseminate the Misleading Complexity Message to both the insurance funds (members of the GKV-SV), and HCPs with the aim of delaying the market uptake of Synthon GA/Clift. Second, Teva targeted HCPs with a view to influencing directly doctors' prescribing practices or pharmacists' dispensing practices.
- (2001) In view of the analysis made in this Subsection 9.4.4.4 and in Sections 9.4.1, 9.4.2 and 9.4.3, the Commission concludes that Teva's dissemination of the Misleading Complexity Message in Germany was capable of directly or indirectly hindering and/or delaying Synthon GA's market entry and uptake in Germany and therefore of producing exclusionary effects on the German GA market.

9.4.4.5. Teva's dissemination of the Misleading Complexity Message in the Netherlands

- (2002) Synthon GA is marketed in the Netherlands by Mylan under the brand Glatirameeracetaat 20 mg and Glatirameeracetaat 40 mg. Mylan secured an MA for Glatirameeracetaat 20 mg on 10 May 2016²⁷⁹⁷ and for Glatirameeracetaat 40 mg on 3 October 2017.²⁷⁹⁸ Mylan launched both versions of Glatirameeracetaat Mylan (20 mg and 40 mg) at the same time – in January 2018.

²⁷⁹⁵ ID 4032, Teva's Reply to the Statement of Objections, paras. 1312, 1313.

²⁷⁹⁶ ID 455-503, Copaxone Continuation Plan – Projekt Charter, 9 January 2017, p. 43 (see footnote 2739).

²⁷⁹⁷ ID 413-1, Update- BT, October 2016; ID 404-1370, Brand Team CNS, Copaxone Legal Update, 30 June 2016.

²⁷⁹⁸ ID 455-2497, Teva internal email dated 6 October 2017 from {...} to {...}.

- (2003) The Netherlands played an important role in the authorisation of Synthron GA as it was the RMS (Reference Member State) and the Dutch Medicines Evaluation Board (MEB) assessed Synthron GA and granted the MA on 10 May 2016.
- (2004) Teva disseminated the Misleading Complexity Message both to the Payers – Royal Dutch Pharmacists Association (Koninklijke Nederlandse Maatschappij ter bevordering der Pharmacie, “KNMP”) and specific major insurance companies – and to HCPs (including KOLs). Teva had the goal of hindering market entry and uptake of Mylan’s Glatirameeracetaat and delaying the resulting competitive pressure to the detriment of the costs incurred by the Dutch healthcare system. For example, as Teva’s {...} stated internally, the aim of the Copaxone communication plan was to “{...}”.²⁷⁹⁹
- (2005) Teva recognised that “{...}”²⁸⁰⁰ and focused on (i) “{...}”; (ii) “{...}” and (iii) “{...}”.²⁸⁰¹
- (2006) These strategic objectives were elaborated on Teva’s “Action Plan GA 2017-2018” in a comprehensive and very detailed checklist setting out the ongoing, planned and completed tasks with various external (and internal) stakeholders.²⁸⁰² Regarding external stakeholders, the same document included sending out letters and organising meetings with the Dutch Pharmacists Organisation KNMP, challenging tender proposals by health insurances (e.g. by sending letters, organising visits, soliciting KOLs’ support, updating and localising relevant CCP materials), organising an advisory board for KOLs on the topic of complexity, among others.²⁸⁰³ According to the Action Plan, the phases of the Copaxone process in the Netherlands were: 1) Phase 1 – Court challenge to Synthron GA’s MA; 2) Phase 2 – sending a letter to KNMP on automatic substitution between Copaxone and Synthron GA²⁸⁰⁴; 3) Phase 3 – preventing automatic substitution / influencing the PKR code (if Copaxone and Synthron GA are in the same PKR code, it means that they are substitutable); 4) Phase 4 – influencing Payers.²⁸⁰⁵
- (2007) In September 2017, draft internal meeting notes and Q&As from Teva’s CNS team indicate that these initiatives were being implemented at local level and that a plan to counter Synthron GA’s projected market entry in December 2017 “{...}”.²⁸⁰⁶

9.4.4.5.1. Dissemination of Teva’s Misleading Complexity Message to Payers in the Netherlands

- (2008) In the Netherlands, most prescriptions are written by reference to the INN. Therefore, it is for the pharmacists to decide which product in such a category should be

²⁷⁹⁹ ID 404-2017, Teva internal email dated 27 October 2014 from {...} to {...} and others regarding “*Afspraken tactics plan CPX 20*” (unofficial translation). Original text: “{...}”.

²⁸⁰⁰ ID 404-1702, Teva internal email dated 30 September 2014 from {...} to {...}, and others regarding “*CCP – NL Project Team*” (unofficial translation). Original text: “{...}”.

²⁸⁰¹ ID 404-1704, Copaxone Continuation Project (CCP), Complexity Copaxone Campaign, CCP LOC Executional Excellence Plan 2014-2015, The Netherlands, p. 8, attached to ID 404-1702, Teva internal email dated 30 September 2014 from {...} to {...}.

²⁸⁰² ID 404-2597, Checklist Copaxone FoGA 040717; ID 404-2527, Checklist Copaxone FoGA 090517 attachment to ID 404-2525, Teva internal email dated 9 May 2017 from {...} to {...} and others.

²⁸⁰³ ID 404-2597, Checklist Copaxone FoGA 040717; ID 404-2527, Checklist Copaxone FoGA 090517 attachment to ID 404-2525, Teva internal email dated 9 May 2017 from {...} to {...} and others.

²⁸⁰⁴ ID 262-1100, Phases in the Future CPX process, p. 1: “{...}”. Concerning the letter initiating Teva’s exchanges with KNMP, see Recital (2011) et seq.

²⁸⁰⁵ ID 262-1100, Phases in the Future CPX process.

²⁸⁰⁶ ID 404-1462, minutes dated 1 September 2017 regarding “{...}” (unofficial translation). Original text: “{...}”.

dispensed. Pharmacists typically follow their professional guidelines, including those relating to the substitution of medicines issued by KNMP and take into account the reimbursement policy of the patient's insurer (as reflected in the insurer's "preference policy"). Therefore, by way of its general substitution guidelines, KNMP exercises systemic influence on the uptake of medicines in the Netherlands (much like the insurers). As noted internally by Teva's {...}, "{...}"²⁸⁰⁷ Recognizing their importance, Teva's disparagement campaign targeted both KNMP as well as the individual major insurance companies.

9.4.4.5.1.1. KNMP

- (2009) KNMP, the Royal Dutch Pharmacists Association, is an association of Dutch pharmacists which, amongst others, issues non-binding recommendations on automatic substitution. Teva targeted KNMP in order to influence its substitution guidelines so as to limit or prevent substitution between Copaxone and Synthon GA/Glatirameeracetaat. In order to convince KNMP that Copaxone and Synthon GA/Glatirameeracetaat are not substitutable and to include a warning about Synthon GA/Glatirameeracetaat in the substitution guidelines for pharmacists, Teva disseminated the Misleading Complexity Message.
- (2010) First, Teva organised a meeting with KNMP in March 2017.
- (2011) Ahead of the meeting, on 20 February 2017, Teva sent a letter to KNMP emphasising the substance of its Misleading Complexity Message and the importance of Teva's manufacturing process.²⁸⁰⁸ In the letter, Teva, went beyond criticising automatic substitution and, by alluding more broadly to safety risks posed by Synthon GA, contained some of the regularly deployed misleading messages.²⁸⁰⁹ The letter, amongst others, insinuated that compositional differences between Synthon GA and Copaxone (due to differences in their manufacturing) were meaningful²⁸¹⁰ and may have therapeutic consequences: "{...}"²⁸¹¹ The letter thus implicitly negates the finding of therapeutic equivalence between the two products by the competent authority. If the KNMP had doubts about Synthon's safety, efficacy and thus therapeutic equivalence with Copaxone as established by the competent authority, it would be highly unlikely to issue a positive recommendation on Synthon GA's substitution status, as these characteristics are a condition precedent for granting this status. Teva also challenged the legality of the MA itself²⁸¹², despite the fact that its legal actions have been invariably rejected.²⁸¹³ Based, amongst other, on these arguments, Teva claimed that Synthon GA/Glatirameeracetaat – while having received an MA (following a hybrid application) – could not be perceived as a generic version of Copaxone and, hence, should not be substitutable with Copaxone.²⁸¹⁴
- (2012) These messages were repeated during the meeting with KNMP held on 28 March 2017. The presentation by Teva's {...} made a detailed comparison

²⁸⁰⁷ ID 455-2878, Teva internal email dated 2 February 2017 from {...} to {...} (unofficial translation). Original text: "{...}"

²⁸⁰⁸ ID 404-1512, letter dated 20 February 2017 from {...} (Teva) to {...}.

²⁸⁰⁹ ID 404-1512, letter dated 20 February 2017 from {...} (Teva) to {...}, pp. 2, 3, 8, 13.

²⁸¹⁰ For MEB's rejection of this point, see Section 9.3.1.1.3.

²⁸¹¹ ID 404-1512, letter dated 20 February 2017 from {...} (Teva) to {...}, p. 2 (unofficial translation). Original text: "{...}"

²⁸¹² ID 404-1512, letter dated 20 February 2017 from {...} (Teva) to {...}, p. 13.

²⁸¹³ See Recital (152).

²⁸¹⁴ ID 404-1512, letter dated 20 February 2017 from {...} (Teva) to {...}.

between Copaxone and Synthon GA striving to emphasise their differences.²⁸¹⁵ The presentation contains some facets of the Misleading Complexity Message. Amongst others, Teva again emphasised clinically irrelevant differences in GA structures, insinuating that the differences between Copaxone and Synthon GA/Glatirameeracetaat may be therapeutically relevant and thereby questioning Synthon GA's safety, efficacy, and therapeutic equivalence with Copaxone: "{...}" (original emphasis).²⁸¹⁶ Teva's arguments also relied on irrelevant and misleading comparisons with glatiramer-related substances other than Synthon GA (and not marketed in the EU). For example, an entire slide entitled "{...}" is dedicated to the morphology analysis using Atomic Force Microscopy (AFM). The slide points to AFM differences between Copaxone and glatiramer-related substances other than Synthon GAs, implying immunogenic risks (see title), in an attempt to extrapolate that these also apply to Synthon GA, to which the entire presentation was dedicated. However, not only is the analysis of other glatiramer-related substances irrelevant to draw any consequences concerning Synthon GA, but the AFM imaging of Synthon GA also confirmed that its morphology was similar to Copaxone's.²⁸¹⁷ In keeping with this, Teva made further conjectures that health risks observed in other glatiramer-related substances equally apply to Synthon GA, thus questioning its safety and therapeutic equivalence with Copaxone. For example, Teva alluded to possible therapeutic effects due to compositional differences between Copaxone and other glatiramer-related substances referring to "{...}" and to the experience with Probioglat in Mexico: "{...}" (original emphasis).²⁸¹⁸ For the reasons explained in Section 9.3.1.2, such analogies are misleading.

- (2013) Following the meeting between Teva and KNMP on 28 March 2017, KNMP requested Teva to set out its position on whether or not substitution should be recommended.²⁸¹⁹ Teva's submission to KNMP of 10 April 2017 entitled "{...}"²⁸²⁰ In the submission, Teva emphasised that the intended effect and safety profile depended heavily on the controlled manufacturing process and that a different manufacturing process may lead to relevant differences in safety and efficacy, thus implying that such relevant differences also characterised Synthon GA/Glatirameeracetaat. Teva also implied that health risks observed in other glatiramer-related substances equally apply to Synthon GA/Glatirameeracetaat. In relation to potential risks to patient safety, tolerability and efficacy, Teva made reference to Probioglat and alleged that the Mexican market experienced seven-fold increases in neurological recesses after the introduction of Probioglat.²⁸²¹ For the assessment of the misleading nature of these claims, see Sections 9.3.1.1 and 9.3.1.2, respectively.

²⁸¹⁵ ID 4032, Teva's Reply to the Statement of Objections, para. 1328.

²⁸¹⁶ ID 404-1764, Substitution considerations for Follow-on Glatiramer Acetate products (FOGAs), meeting KNMP, 28 March 2017, pp. 18-20. See also a similar message on p. 12: "{...}" (emphasis added).

²⁸¹⁷ ID 404-1764, Substitution considerations for Follow-on Glatiramer Acetate products (FOGAs), meeting KNMP, 28 March 2017, p. 20.

²⁸¹⁸ ID 404-1764, Substitution considerations for Follow-on Glatiramer Acetate products (FOGAs), meeting KNMP, 28 March 2017, p. 26.

²⁸¹⁹ ID 404-1886, email dated 10 April 2017 from {...} to {...} regarding "{...}"

²⁸²⁰ ID 404-1886, email dated 10 April 2017 from {...} to {...} attachment entitled "10042017memoKNMP_ComplexiteitGAenImmunogeniciteit_NL" (unofficial translation). Original text: "{...}"

²⁸²¹ ID 404-2072, memo KNMP, attachment to ID 404-2065, email dated 10 April 2017 from {...} to {...}, pp. 1, 2, 3.

- (2014) In these representations to KNMP, Teva thus repeatedly questioned the findings of safety, efficacy and therapeutic equivalence of Synthron GA which are a necessary pre-condition for automatic substitution, despite the fact that the competent authorities, led by the Dutch MEB, had already rejected these claims by Teva.
- (2015) Ultimately, the KNMP took a position aligned with Teva's. In October 2017, the {...} of KNMP informed Teva's {...} that the draft non-binding position statement on biologicals/biosimilars essentially excluded automatic substitution between Copaxone and Synthron GA.²⁸²²
- (2016) Teva claims that KNMP's position regarding automatic substitution was not the consequence of the dissemination of misleading information.²⁸²³ The Commission does not take a position on whether the KNMP's position advising that automatic substitution be excluded was the result of Teva's misleading messages (for a rebuttal of Teva's claims relating to misleading nature of the messages, see Recitals (2042)-(2046)). The Commission however notes that the position statement, which was subsequently published²⁸²⁴, included a newly-added separate section on "*follow-on NBCD's*", which closely reflects the main elements of Teva's Misleading Complexity Message: it refers to GA as an example of "follow-on NBCD", states that GA cannot be characterised by analytical methods, and claims that differences in the manufacturing process may have therapeutically relevant effects, including undesirable immunogenicity. This is confirmed by the fact that Teva's {...} boasted internally that "{...}"²⁸²⁵.
- (2017) After its publication, Teva relied on the non-binding KNMP position statement to further its messages to the health insurers and HCPs. For example, a direct reference to the KNMP position statement was included in the Dutch localised version of Teva's Complexity Leavepiece approved on 28 November 2017 and the accompanying internal training material.²⁸²⁶ The training material also reveals that Teva used the KNMP position statement to roll out additional waves of dissemination of its Misleading Complexity Message: "{...}"²⁸²⁷.
- (2018) However, in using the KNMP statement as a seemingly neutral position in support of its campaign against automatic substitution, Teva did not disclose its involvement in KNMP's process in issuing this statement. In addition to its communications with KNMP which contained the Misleading Complexity Message (described in Recitals (2011)-(2013)), Teva was also involved in the finalisation of KNMP's statement. {...} "{...}"²⁸²⁸ None of this information was revealed to the public by Teva.

²⁸²² ID 404-2059, email dated 27 October 2017 from {...} to {...}.

²⁸²³ ID 4032, Teva's Reply to the Statement of Objections, para. 1328.

²⁸²⁴ ID 1934, KNMP-standpunt biosimilars en follow-on non-biological complex drugs (NBCDs).

²⁸²⁵ ID 404-2059, Teva internal email dated 27 Oktober 2017 from {...} to {...} and others.

²⁸²⁶ ID 262-1785, Copaxone onder de loep, p. 4 and ID 262-1732, Possible neurologists' questions about the "{...}" HCP leaflet (unofficial translation) - Mogelijke vragen neurologen over de "{...}" HCP folder, 13 December 2017. A reference to the KNMP's opinion is included in the internal training materials for Czechia and Poland as well (ID 455-2349, Copaxone Price Competition Workshop with PL and CZ Team, 4 December 2017). It is also noteworthy that Teva relied on the KNMP's position on substitution while arguing that its communication campaign towards the authorities competent for the substitution was justified (see ID 1866, Teva's spontaneous submission of 25 May 2022, p. 5).

²⁸²⁷ ID 262-1732, Possible neurologists' questions about the "{...}" HCP leaflet (unofficial translation) - Mogelijke vragen neurologen over de "{...}" HCP folder, 13 december 2017, (unofficial translation), p. 1: "{...}." See also ID 651-25, Teva's reply to Article 18(2) Request of 3 June 2020, letter sent to Menzis on 4 April, p. 6.

²⁸²⁸ ID 404-595, Teva internal email dated 22 May 2017 sent by {...} to {themselves}.

9.4.4.5.1.2. Health insurers

(2019) As explained above (see Recital (592)), “preference policy” or “preferential policy” refers to preferential rates that health insurers can negotiate with pharmaceutical companies for one or several drugs of an active substance. When a health insurer has entered into a preference policy for an active substance with one or several pharmaceutical companies, then patients insured with that health insurer will only receive the medicines covered by the preferential rates from a pharmacist. This means that patients may have to change the treatment that they are on because their insurer introduced a new preference policy. The medicines affected by a preference policy therefore need to be automatically substitutable with each other. Through a preference policy, a health insurer can therefore exclude one or more products with the same active substance from reimbursement to the patient while reimbursing at least one product with that same INN.²⁸²⁹ If a prescriber insists on the use of a specific, excluded product by a specific individual patient for reasons of medical need, by law, that patient will receive reimbursement of that product despite the general exclusion by his insurer. Where a branded product is prescribed, the pharmacist is not allowed to dispense another product – even if it contains the same INN – without the doctor’s approval.²⁸³⁰ It therefore depends mostly on the preference policy of the insurer which medicine a patient receives and there is no separate legal framework for automatic substitution in the Netherlands.²⁸³¹ Ultimately, preference policies and automatic substitution lead to the same result, which is that patients receive a generic or generic-like alternative in the pharmacy instead of the originator medicine.

9.4.4.5.1.2.1. Teva targeted the main health insurers and disseminated the Misleading Complexity Message to them

- (2020) The main insurers in the Netherlands are VGZ, Achmea/Zilveren Kruis, CZ, and Menzis. Together, they represent over 80 % of the market. ONZV and its subcontractor Zorg & Zekerheid are also important insurers in the Netherlands.²⁸³²
- (2021) Teva sought to influence the Dutch health insurers’ preference policy, requesting initially not to apply the preference policy to the existing patients and later, requesting to terminate the preference for GA.²⁸³³
- (2022) Teva approached the main Dutch health insurers such as Menzis, CZ, VGZ, Zilveren Kruis, ONVZ and its subcontractor Zorg & Zekerheid in the period February 2018 – March 2019.
- (2023) Teva conveyed the Misleading Complexity Message to these Payers via its Market Access teams either in written submissions or in face-to-face meetings (based on the messages elaborated in Payer White Paper²⁸³⁴). For example, Teva was alluding to alleged risks with Synthon GA/Glatirameeracetaat related to immunogenicity and therefore safety and efficacy. Teva’s efforts were initially successful, as health insurers delayed the application of the preference policy to existing patients, as Teva

²⁸²⁹ See Article 2.8.1(a) Healthcare Insurance Decree (“Besluit zorgverzekering”) – see ID 655, Teva’s reply to the Article 18(2) Request of 3 June 2021, p. 21.

²⁸³⁰ ID 655, Teva’s reply to the Article 18(2) Request of 3 June 2021, p. 21.

²⁸³¹ ID 655, Teva’s reply to the Article 18(2) Request of 3 June 2021, p. 21.

²⁸³² ID 655, Teva’s reply to the Article 18(2) Request of 3 June 2021, p. 25.

²⁸³³ For example: ID 3584, email dated 27 February 2019 from {...} to {...}. See also ID 404-1637, Teva internal email dated 21 February 2018 from {...} to {...}, analysed in Recital (2026) below.

²⁸³⁴ See Figure 42.

requested. Teva even brought an action for annulment against CZ's preference policy but lost the case in December 2019. The legal proceedings against CZ were considered by Teva as a "test case" for possible proceedings against other Dutch health insurers.

- (2024) In a series of letters sent to Menzis, CZ, VGZ, Zilveren Kruis, ONVZ and to Zorg & Zekerheid, Teva again conveyed the Misleading Complexity Message.²⁸³⁵ Teva emphasised clinically irrelevant differences in GA structures and claimed that, due to the production process, it is not possible for another manufacturer to make exactly the same active ingredient with the same therapeutic characteristics.²⁸³⁶ Further, it claimed that, since the safety and efficacy of GA depends on the manufacturing process, any differences in the manufacturing process may result in differences in safety and efficacy.²⁸³⁷ Teva went further to state that GA has problems related to immunogenicity: "{...}".²⁸³⁸ Teva's statements thus implicitly contest therapeutic equivalence between Synthon GA/Glatirameeracetaat and Copaxone and thus contradict the findings by competent authorities (which had rejected Teva's claims).
- (2025) The aforementioned messages in Teva's main submissions to insurers were further compounded by more detailed messages in a scientific annex, meant to present the scientific position as advocated by Teva, and in which it repeated its Misleading Complexity Message contesting the safety, efficacy and therapeutic equivalence of

²⁸³⁵ ID 651-25, Teva's reply to the Article 18(2) Request of 3 June 2020, letter sent to Menzis on 4 April 2018; ID 651-45, Teva's reply to the Article 18(2) Request of 3 June 2020, letter sent to CZ on 21 June 2018; ID 651-31, Teva's reply to the Article 18(2) Request of 3 June 2020, letter sent to Zilveren Kruis on 5 February 2018 and ID 651-32, Teva's reply to the Article 18(2) Request of 3 June 2020, letter sent to Zilveren Kruis on 21 August 2018; ID 1062-35, Teva's reply to the Article 18(2) Request of 18 November 2021, letter sent to Zilveren Kruis 10 December 2018; ID 651-9, Teva's reply to the Article 18(2) Request of 3 June 2020, letter sent to ONVZ on 21 June 2018; ID 651-50, Teva's reply to the Article 18(2) Request of 3 June 2020, letter sent to Zorg and Zekerheid on 10 July 2018.

²⁸³⁶ ID 651-25, Teva's reply to the Article 18(2) Request of 3 June 2020, letter sent to Menzis on 4 April 2018, p. 4: "{...}"; ID 651-19, Teva's reply to the Article 18(2) Request of 3 June 2020, letter sent to VGZ on 6 December 2018, p. 5; ID 651-45, Teva's reply to the Article 18(2) Request of 3 June 2020, letter sent to CZ on 21 June 2018, p. 4; ID 651-43, Teva's reply to the Article 18(2) Request of 3 June 2020, letter sent to CZ on 6 December 2018, p. 5; ID 651-9, Teva's reply to the Article 18(2) Request of 3 June 2020, letter sent to ONVZ on 21 June 2018, p. 3; ID 651-60, Teva's reply to the Article 18(2) Request of 3 June 2020, letter sent to Menzis on 6 December 2018, p. 5; ID 651-50, Teva's reply to the Article 18(2) Request of 3 June 2020, letter sent to Zorg en Zekerheid on 10 July 2018, p. 5; ID 651-32, Teva's reply to the Article 18(2) Request of 3 June 2020, letter sent to Zilveren Kruis on 21 August 2018, p. 2; ID 1062-35, Teva's reply to the Article 18(2) Request of 3 June 2020, letter sent to Zilveren Kruis 10 December 2018, p. 5.

²⁸³⁷ ID 651-63, Teva's reply to the Article 18(2) Request of 3 June 2020, letter sent to Menzis on 8 May 2018, p. 1: "{...}" (unofficial translation).; ID 651-19, Teva's reply to the Article 18(2) Request of 3 June 2020, letter sent to VGZ on 6 December 2018, p. 4.

²⁸³⁸ ID 651-25, Teva's reply to the Article 18(2) Request of 3 June 2020, letter sent to Menzis on 4 April 2018, p. 5 (unofficial translation). Original text: "{...}"; ID 651-45, Teva's reply to the Article 18(2) Request of 3 June 2020, letter sent to CZ on 21 June 2018, p. 5; ID 651-31, Teva's reply to the Article 18(2) Request of 3 June 2020, letter sent to Zilveren Kruis on 5 February 2018, pp. 11,12; ID 1062-35, Teva's reply to the Article 18(2) Request of 18 November 2021, letter sent to Zilveren Kruis 10 December 2018, p. 3; ID 651-9, Teva's reply to the Article 18(2) Request of 3 June 2020, letter sent to ONVZ on 21 June 2018, p. 4; ID 651-50, Teva's reply to the Article 18(2) Request of 3 June 2020, letter sent to Zorg en Zekerheid on 10 July 2018, pp. 3,4,5,6,7,12; ID 651-60, Teva's reply to the Article 18(2) Request of 3 June 2020, letter sent to Menzis on 6 December 2018, p. 5.

Synthon GA. The scientific annex to the letter includes Teva's Misleading Complexity Message: "{...}"²⁸³⁹ (see above, Section 9.3.1.1).

9.4.4.5.1.2.2. Teva's arguments were capable of misleading Payers

- (2026) Teva managed to protect its existing patient base from competition from Synthon GA through preference policies for several months, even if some Dutch health insurers were initially in favour of entering preference policies for GA. For example, Teva's {...} confirmed the effectiveness of Teva's messages in February 2018: "{...}" (emphasis added).²⁸⁴⁰ As explained in Recital (2016) above, the statement by KNMP used by Teva with the insurer in question closely reflects the main elements of Teva's Misleading Complexity Message.
- (2027) In April 2018, the insurer {...} claimed that {...}. In spite of this, {...} took precautionary measures and, following Teva's suggestion, for the first six months, {...} preference policy for GA only applied to new patients, and not to existing patients (that were already treated with Copaxone).²⁸⁴¹ This meant that MS patients, who were insured with {...} and were prescribed GA for the first time after implementation of the preference policy, received Synthon GA from their pharmacist. Patients who were already treated with Copaxone before implementation of the preference policy could continue treatment with Copaxone for a further six months, to allow patients and physicians to prepare for the change from Copaxone to Synthon GA ("...").²⁸⁴² Later, in March 2019, {...} argued that {...}.²⁸⁴³
- (2028) Finally, {...} also observed that {...}: "...".²⁸⁴⁴ {...} concluded that "...".²⁸⁴⁵
- (2029) Other insurers also followed {...} path of applying the preference policy only to new patients for several months, but in the end rejected Teva's request to remove the preference policy.
- (2030) Once the health insurers applied the preference policy to all patients, Teva went as far as launching legal action against a Dutch insurer, CZ, as a "test case" to reverse the introduction of the preference policy. The action was dismissed in December 2019. The Court of Appeals in 's-Hertogenbosch held that the fact that these medicines are not completely identical (at the level of the molecular chains) does not

²⁸³⁹ ID 651-25, Teva's reply to the Article 18(2) Request of 3 June 2020, letter sent to Menzis on 4 April 2018, p. 13 (unofficial translation). Original text: "{...}."; ID 651-45, Teva's reply to the Article 18(2) Request of 3 June 2020, letter sent to CZ on 21 June 2018, pp. 12-13; ID 651-31, Teva's reply to the Article 18(2) Request of 3 June 2020, letter sent to Zilveren Kruis on 5 February 2018, pp. 11-12; ID 651-32, Teva's reply to the Article 18(2) Request of 3 June 2020, letter sent to Zilveren Kruis on 21 August 2018, p. 13; ID 651-9, Teva's reply to the Article 18(2) Request of 3 June 2020, letter sent to ONVZ on 21 June 2018, p. 12; ID 651-50, Teva's reply to the Article 18(2) Request of 3 June 2020, letter sent to Zorg & Zekerheid on 10 July 2018, pp. 3-7, 12; ID 651-63, Teva's reply to the Article 18(2) Request of 3 June 2020, letter sent to Menzis on 8 May 2018, p. 1; ID 651-19, Teva's reply to the Article 18(2) Request of 3 June 2020, letter sent to VGZ on 6 December 2018, p. 4; ID 1940, Synthon's reply to the Article 18(2) Request of 11 February 2022, letter sent by Teva's external counsel to VGZ on 13 February 2019, pp. 8-9.

²⁸⁴⁰ ID 404-1637, Teva internal email dated 21 February 2018 from {...} to {...}.

²⁸⁴¹ ID 404-2130, email dated 4 April 2018 from {...} {...} to {...} (Teva): "{...}" (unofficial translation).

²⁸⁴² ID 404-2130, email dated 4 April 2018 from {...} {...} to {...} (Teva).

²⁸⁴³ ID 3583, letter from {...} to Teva's legal representative, {...}, dated 5 March 2019 attached to ID 3584 email dated 5 March 2019 from {...} {...} to {...} and others (Teva). The letter also clarified that {...}.

²⁸⁴⁴ ID 3583, letter from {...} to Teva's legal representative, {...}, dated 5 March 2019, p. 3.

²⁸⁴⁵ ID 3583, letter from {...} to Teva dated 5 March 2019, p. 3 (unofficial translation). Original text: "{...}".

alter the fact that they both have GA as the active ingredient and that CZ did not infringe the law by applying the preference policy to GA.²⁸⁴⁶

- (2031) With the dissemination of the Misleading Complexity Message to these Payers, Teva was targeting the characteristics of Synthon GA which had been a condition to the successful conclusion of its Decentralised Procedure. These characteristics were also a necessary precondition for automatic substitution and preference policies in the Netherlands. If the Payers were misled with respect to these characteristics, this was also likely to affect their decision to allow automatic substitution or organise preference policies for GA, or to delay a decision of these Payers to this effect, which protected its existing patient population from Synthon GA for several months. In reaction to Teva's messaging, the insurer {...}, {...}, initially limited its preference policy to new patients only, effectively shielding Copaxone's existing patients from competition with Synthon GA/Glatirameeracetaat.

9.4.4.5.2. Dissemination of Teva's Misleading Complexity Message to HCPs in the Netherlands

- (2032) In Teva's Brand Plans for the Netherlands, "*CCP complexity*" was seen as a critical success factor in achieving Teva's strategic imperatives of (i) maintaining its status as first line choice for naïve patients and (ii) retaining current patients. In particular, the 2019 Brand Plan highlighted it was critical for Teva to "{...}"²⁸⁴⁷
- (2033) Teva prepared and used the presentation "Substitution considerations for Follow-on Glatiramer Acetate products (FoGAs)"²⁸⁴⁸ which was destined for selected External Experts, Payers and patient organisations. The document presents the alleged complexity of Copaxone/GA and consequent substitution considerations²⁸⁴⁹ without reconciling these claims and inferences with the findings in MEB's PAR: the presentation emphasizes clinically irrelevant differences in the GA structures, referring to product differences between Copaxone and Synthon GA "{...}", as well as drawing irrelevant and misleading inferences between characteristics and experiences with other glatiramer-related substances and those of Synthon GA.²⁸⁵⁰
- (2034) In its communication with HCPs, Teva also purposefully used the terms "*NBCD*" and "*FoGA*" (see Sections 9.1.1 and 9.3.1.4.2) relying on the fact that both of them imply the non-generic nature of Synthon GA to raise concerns with switching individual patients. As explained by Teva's legal department, it is possible to

²⁸⁴⁶ ID 3547, Arrest van Gerechtshof 's-Hertogenbosch van 10 december 2019, *Teva Nederland B.V. tegen Centrale Zorgverzekeraars Groep, Zorgverzekeraar U.A. en Mylan B.V.*, zaaknummer 200.259.953/01, NL:GHSHE:2019:4471.

²⁸⁴⁷ ID 1151-70, AOP 2019 CPX Netherlands, p. 50.

²⁸⁴⁸ ID 4919-45, Substitution considerations for Follow-on Glatiramer Acetate products (FoGAs). ID 4897, List of documents registered on Teva's {...} platform, the associated excerpt from Teva's internal database shows that the document was approved on 24 April 2017, with first recorded use on 8 May 2017 and reapproved on 20 September 2020. This shows that the document "Substitution considerations for Follow-on Glatiramer Acetate products" was used and disseminated. For the Commission's conclusions based on Teva's re-approval of this document in September 2020, see footnote 2571 above.

²⁸⁴⁹ ID 4897, List of documents registered on Teva's {...} platform.

²⁸⁵⁰ ID 4919-45, Substitution considerations for Follow-on Glatiramer Acetate products (FoGAs), p. 18-26. According to {...} data submitted by Teva, this document was approved on 5 May 2017, with registered first-time use on 8 May 2017.

“{...}”.²⁸⁵¹ A presentation named “{...}” from June 2018 indicates that a letter “{...}” should have been sent to all HCPs.²⁸⁵²

- (2035) In March 2018, Teva prepared a letter to neurologists which, contrary to Teva’s claims²⁸⁵³, included the Misleading Complexity Message.²⁸⁵⁴ The letter, which is dedicated to Synthon GA without naming it, as the only other approved GA in the Netherlands, included standard Teva messaging deployed in the Netherlands. It essentially claims that the safety and efficacy of Copaxone is determined by the manufacturing process. Consequently, any change in the process would allegedly have a direct impact on the quality of the product, as well as on its efficacy and safety.²⁸⁵⁵ This leads the reader to the wrong conclusion that due to the manufacturing differences, Synthon GA does not have equivalent safety and efficacy to Copaxone. As in its other materials, Teva fails to reconcile these statements with the finding that the two products are therapeutically equivalent as confirmed by the competent authority. And as shown in Section 9.3.1.1.3.3, Teva was well aware that references to compositional differences between Copaxone and Synthon GA, as alluded to in this letter, were therapeutically irrelevant, and even “disparaging”. Further, Teva referred to KNMP’s position, which Teva had influenced (see Recital (2009)) and which mirrors Teva’s messaging. Amongst others, it alludes to potential immunogenicity issues, possibly resulting in an inferior therapeutic effect.²⁸⁵⁶ All these claims are misleading and contradict the finding by the competent authority that Synthon GA is safe, efficacious, and therapeutically equivalent to Copaxone. The MEB also rejected Teva’s claims implying that the differences in the manufacturing process are therapeutically significant.
- (2036) Teva planned to send this letter via email²⁸⁵⁷ and as hard copies to neurologists during face-to-face meetings or otherwise.²⁸⁵⁸ Evidence shows that, contrary to Teva’s claims²⁸⁵⁹, the letter was indeed sent to neurologists.²⁸⁶⁰

2851 ID 404-1793, Teva internal email dated 6 November 2017 from {...} to {...} and {...} regarding “{...}” (unofficial translation). Original text: “{...}”.

2852 ID 262-555, Update CPX NL, June 2018.

2853 ID 4032, Teva’s Reply to the Statement of Objections, paras. 1340, 1341.

2854 ID 455-3536, email chain dated February-March 2018 between {...} and others; ID 262-1781, Teva’s signed letters for distribution to neurologists; see also ID 1935, letter sent by Teva to neurologists in Netherlands, February 2018; see also ID 4919-60, NL/CPX/18/0003 Teva’s signed letters for distribution to neurologists. According to Teva’s {...} database (ID 4897, List of documents registered on Teva’s {...} platform), this is a promotional letter which was approved on 7 February 2018, was first used on 15 February 2017 and was withdrawn on 2 January 2020.

2855 ID 455-3537, letter to neurologists NBCD, attachment to ID 455-3536, email chain dated February-March 2018 between {...} and others. “{...}” (unofficial translation). Original text: “{...}”; ID 262-1781, Teva signed letters for distribution to neurologists, p. 1; ID 1935, letter sent by Teva to neurologists in Netherlands, February 2018, ID 4919-60, NL/CPX/18/0003 Teva’s signed letters for distribution to neurologists. According to Teva’s {...} database; According to Teva’s {...} database (ID 4897, List of documents registered on Teva’s {...} platform), this is a promotional letter which was approved on 7 February 2018, was first used on 15 February 2017 and was withdrawn on 2 January 2020.

2856 ID 455-3537, letter to neurologists NBCD, attachment to ID 455-3536, email chain dated February-March 2018 between {...}. “{...}” (unofficial translation). Original text: “{...}”.

2857 ID 455-3536, Teva internal email dated 16 February 2018 from {...} to {...} and others: “{...}” (unofficial translation). Original text: “{...}”.

2858 ID 455-3536, Teva internal email dated 8 March 2018 from {...} to {...} and others: “{...}” (unofficial translation) – “{...}”.

2859 See ID 4032, Teva’s Reply to the Statement of Objections, para. 1339.

2860 ID 262-1781, Teva’s signed letters for distribution to neurologists; see also ID 1935, letter sent by Teva to neurologists in Netherlands, February 2018; see also ID 4919-60, NL/CPX/18/0003 Teva’s signed

- (2037) Teva was also reaching out to individual neurologists by email to inform them about its opposition to a preference policy for GA (thus automatic substitution between Copaxone and Synthon GA/Glatirameeracetat). For example, in an email to a Dutch neurologist Teva’s {...} notes: “{...}.”²⁸⁶¹ Relatedly, Teva’s internal correspondence shows that a separate letter covering the same topic (i.e. Teva’s opposition to preference policies by Dutch insurers) was prepared for circulation to the HCPs.²⁸⁶² The letter is another example of how Teva was able to capitalise on its activities to influence KNMP and rely on the resulting statement in also convincing HCPs, including KOLs.
- (2038) According to the {...} data, in the period from 2015 to 2020 Teva’s MSL and sales representatives made altogether {...} direct contacts (either face-to-face visits or phone calls) to HCPs with {...} HCPs in the Netherlands related to *inter alia* Copaxone, GA or central nervous system products.²⁸⁶³ These visits were devoted, at least in part, to the dissemination of the Misleading Complexity Message.²⁸⁶⁴ There is evidence of at least {...} calls that concerned the topics of “{...}” or “{...}”²⁸⁶⁵, although it cannot be excluded that there were more, since there is no built-in system mechanism requiring sales representatives and members of Teva’s MSL team to record contacts, as also confirmed by Teva.²⁸⁶⁶ In any event, this is sufficient to show that Teva actually used its centrally prepared misleading messages in its contacts with HCPs in the Netherlands.

9.4.4.5.3. Teva’s arguments and the Commission’s assessment

- (2039) Teva claims that the Commission has relied upon a wide range of “contextual” evidence dating prior to the MA approval of Synthon GA 20 mg in April 2016. According to Teva, this gives the “*misleading*” impression that such evidence forms part of the abusive conduct.²⁸⁶⁷ Teva’s claim is unfounded for the reasons explained in Section 9.3.1.4.3 above.
- (2040) Teva further claims that the Commission’s findings twist the meaning and context of statements in Teva’s internal documents to create the impression that Teva sought to counter Mylan’s projected market entry in the Netherlands with the Misleading Complexity Message. According to Teva, the cited evidence does not support the

letters for distribution to neurologists. According to Teva’s {...} database (ID 4897, List of documents registered on Teva’s {...} platform), this is a promotional letter which was approved on 7 February 2018, was first used on 15 February 2017 and was withdrawn on 2 January 2020.

²⁸⁶¹ ID 404-1024, email dated 23 August 2018 from {...} to {...} (unofficial translation). Original text: “{...}”. See also ID 404-1049, email dated 17 July 2018 from {...} to neurologists from an association of the Dutch hospitals – {...}.

²⁸⁶² ID 404-1026, Teva’s prepared letter for circulation to HCPs.

²⁸⁶³ ID 900-1, {...} data for Netherlands and 900-22, {...} data for Netherlands. For scope and reliability of {...} data, see Recital (1786) of this Decision and footnote 2326 of this Decision.

²⁸⁶⁴ Just like in Belgium, inherent limitations in the available CRM data apply (see footnote 2478).

²⁸⁶⁵ As explained in Recital (2032) above, Teva’s Brand Plans for the Netherlands show that Teva considered “{...}” a critical success factor and that it was critical for Teva to “{...}”. For this reason, and in light of the reasons for Teva to adopt the acronyms “*NBCD*” and “*FoGA*” already indicated in Sections 9.1.1 and 9.3.1.4.2 above, it is likely that the contacts with HCPs recorded by Teva as having as key message one or both of these acronyms were devoted, at least in part, to the dissemination of the Misleading Complexity Message. This is all the more true considering the guidance prepared in the relevant CCP materials described in Section 9.3.2 for members of Teva’s MSL team (notably the External Expert White Paper for MS specialists, the GATE Study Review and the MSL Objection Handlers) and for Teva’s KAMs, (notably KAM Objection Handlers).

²⁸⁶⁶ See footnote 2326 above.

²⁸⁶⁷ ID 4032, Teva’s Reply to the Statement of Objections, para. 1316.

Commission’s findings, but only shows Teva prepared a plan in response to Synthon GA’s possible launch in the Netherlands. Teva also claims that compliance guidelines indicated not to actively talk about Teva’s competitors and to rely on Copaxone’s own strengths.²⁸⁶⁸ The Commission rejects these arguments. First, elements of Teva’s CCP strategy, described in more detail in Recitals (1436)-(1441) and Sections 5.2.3.3 and 5.2.3.4 merely provide a broader context for the Commission’s assessment of Teva’s dissemination of the Misleading Complexity Message during the period of infringement. Second, Teva does not explain how the Commission has allegedly “twisted” the meaning of the statements and how it should interpret the statement made by Teva’s {...} according to which the aim of the Copaxone communication plan was to “{...}”.²⁸⁶⁹ Third, in relation to the existence of so-called compliance guidelines, see the Commission’s assessment in Recital (1790).

- (2041) Teva claims that the Commission has used allegedly irrelevant statements from third parties as evidence of Teva’s stance on automatic substitution. According to Teva, the statement from health insurer {...} that {...} (see Recital (2028)) is “*pure speculation from {...}*” and does not take into account that the letter in question focussed on Teva’s concerns related to automatic substitution. Teva claims that the Commission’s evidence does not show that any of Teva’s communications were misleading.²⁸⁷⁰ This argument is misguided. Teva wrongly makes this point with respect to the finding described in Recital (2028) of this Decision²⁸⁷¹ which shows that Teva’s campaign {...} – and relate to {...} observation that {...}. However, Teva fails to refer to the Commission’s findings described in Recitals (2020)-(2025)²⁸⁷² which assess the content of Teva’s communications with Dutch insurers including {...} and find that it contained the Misleading Complexity Message.
- (2042) Teva claims that its communication with KNMP and healthcare insurers was consistent with its campaign to discourage automatic substitution and was conveyed in the context of decision-making processes on the status of automatic substitution and reimbursement, where Teva was invited or anyway entitled to make submissions.²⁸⁷³ The Commission rejects these arguments. As shown in Recitals (2011)-(2013), Teva’s communication with KNMP contained misleading messages questioning Synthon GA’s safety, efficacy, and therapeutic equivalence with Copaxone, which goes beyond the mere issue of automatic substitution and question the successful conclusion of the Decentralised Procedure for Synthon GA (see also Section 9.2.3.5).
- (2043) Teva also claims that “*the mention of the potential immunogenicity risk to patients*” in relation to automatic substitution “*does not qualify as part of the so-called ‘Complexity Message’. [...] the suggestion that the term ‘FoGA’ is somehow misleading, and Teva used this term to artificially differentiate or protect Copaxone from competition, is misplaced*”.²⁸⁷⁴ This argument is unfounded. Section 9.3.1.1, explains why Teva’s suggestion that compositional differences between Copaxone and Synthon GA would lead to immunogenicity risks is misleading. Teva’s

²⁸⁶⁸ ID 4032, Teva’s Reply to the Statement of Objections, para. 1317.

²⁸⁶⁹ ID 404-2017, Teva internal email dated 27 October 2014 from {...} to {...} and others regarding “*Afspraken tactics plan CPX 20*” (unofficial translation): “{...}”.

²⁸⁷⁰ ID 4032, Teva’s Reply to the Statement of Objections, para. 1318.

²⁸⁷¹ Teva’s claims refer to this finding as it was included in Recital 1432 of the Statement of Objections.

²⁸⁷² These findings were made available to Teva in Recitals 1424-1429 of the Statement of Objections.

²⁸⁷³ ID 4032, Teva’s Reply to the Statement of Objections, paras. 1321,1322, 1323 (a), (b), (c).

²⁸⁷⁴ ID 4032, Teva’s Reply to the Statement of Objections, paras. 1323 (c) and 1332.

allegations of immunogenicity risks challenge the finding of therapeutic equivalence between Synthron GA and Copaxone. Moreover, the MEB expressly rejected Teva's claims that there were clinically relevant compositional differences between Synthron GA and Copaxone. Such messaging was thus in line with Teva's strategy to prevent automatic substitution by using misleading messages, therefore preventing (price) competition from Synthron GA.²⁸⁷⁵

- (2044) Teva claims that the internal exchanges concerning KNMP's draft position statement are irrelevant, as they allegedly do not show that Teva's communications were misleading. Teva further claims that Teva is justified in relying on KNMP's expert position to confirm its campaign on automatic substitution with regards to HCPs and healthcare insurers as Teva has allegedly always relied on public and official sources as evidence.²⁸⁷⁶ The Commission rejects these arguments. First, the internal email exchange in question (see Recital (2015)) is used to demonstrate that Teva's misleading messages were capable of influencing Payers; in this example, Teva's manager was boasting about the success of Teva's disparagement campaign. Second, as explained in Recitals (2017)-(2018), Teva was subsequently extensively using the KNMP statement in its campaign against preference policies without disclosing its significant involvement in its preparation²⁸⁷⁷, therefore not allowing the targeted stakeholders to create their view on the independent and objective nature of the document.²⁸⁷⁸
- (2045) Teva argues that, in its materials, it repeatedly noted that Synthron GA is safe and effective for the general population, which set the tone for the whole presentation for KNMP.²⁸⁷⁹ Teva's argument does not convince. As Figure 37 of Teva's Reply to the Statement of Objections shows, while Teva stated that "*the MEB considers the FOGAs safe and effective for the general population for the treatment of RRMS patients*"²⁸⁸⁰, Teva implicitly challenged this statement on the very same slide by failing to clearly acknowledge the key finding of the MEB procedure in this context - that the safety and efficacy of Synthron GA were found to be equivalent to those of Copaxone. This is all the more confusing to the reader as Teva also states that the MEB "{...}", and that Synthron GA was authorised under the hybrid procedure - which Teva "{...}"²⁸⁸¹ Teva does mention, on the subsequent slide (Figure 39 of Teva's Reply to the Statement of Objections), a "*therapeutic equivalence study*" and that "*the safety and efficacy of the FOGAs at population level is comparable to that of Copaxone*" (original emphasis). However, these statements are also incomplete and misleading. The MEB's finding that Synthron GA was therapeutically equivalent to Copaxone did not further qualify that this only applied "at population level",

²⁸⁷⁵ See Recital (2008) et seq.

²⁸⁷⁶ ID 4032, Teva's Reply to the Statement of Objections, paras. 1323 (d) (e).

²⁸⁷⁷ As also acknowledged in ID 4032, Teva's Reply to the Statement of Objections, for example para. 1328; see further ID 404-595, Teva internal email dated 22 May 2017 sent by {...} to {themselves}.

²⁸⁷⁸ ID 4032, Teva's Reply to the Statement of Objections, para. 1328 - "*The KNMP, as a sophisticated and independent professional organization, was provided with factual and substantiated elements, which it further shared with relevant stakeholders to reach its own expert position on the matter*".

²⁸⁷⁹ ID 4032, Teva's Reply to the Statement of Objections, paras. 1324-1328, Figures 36-39 of the Reply to the Statement of Objections.

²⁸⁸⁰ ID 4032, Teva's Reply to the Statement of Objections, paras. 1324-1328, Figures 36-39 of the Reply to the Statement of Objections.

²⁸⁸¹ In addition, Teva's argument cannot be reconciled with the fact that the presentation also contains inaccurate information as it states that "{...}", omitting to state that in Germany the product was automatically substitutable, and giving only the example of Sweden and Italy. ID 651-40, Teva's presentation to KNMP of 28 March 2017, p. 9 (unofficial translation) - Original text: "{...}".

which implies that there may be issues with individual patients or with switching. On the contrary, in the PAR, MEB explicitly found that “*based on all data presented, ... [Synthon GA] can be regarded as therapeutic equivalent to the reference product*” and held that there “[n]o specific difference in efficacy or safety between the patients who were on Copaxone and later switched to Brabio [Synthon GA] and the patients who were treated with Brabio for the entire period were observed. Therefore there is no evidence against switching”.²⁸⁸² Moreover, in these slides Teva refers to Synthon GA as “FoGAs” (in plural). The very same term, FoGAs, is also used in the more detailed slide deck that Teva presented at the same meeting²⁸⁸³, which emphasises, in an extensive way, the differences and negative experiences with other glatiramer-related substances. Using the same term in slide decks presented at the same meeting is capable of falsely inducing the addressees into believing that the issues experienced with other glatiramer-related substances would also apply to Synthon GA. Against the foregoing, the Commission considers that this slide not only fails to exonerate Teva, but is in itself yet another example of incomplete information capable of misleading its addressees.

- (2046) Teva also claims that it is misleading for the Commission to allege that a letter, a meeting, and a memo (sent at KNMP’s request) together constitute a full-fledged disparagement campaign targeting KNMP. It also claims that no blame can be put on Teva for providing a memo at KNMP’s explicit request.²⁸⁸⁴ These arguments are misguided. First, Section 9.4.4.5.1.1 above already explained that the documents Teva shared with KNMP systematically and repeatedly contained the Misleading Complexity Message. Teva fails to explain its term “full-fledged campaign” or how it is relevant for the legal qualification of its conduct. Second, this Decision is not concerned with the question whether or not contacts were (exclusively) initiated by Teva, but with whether, in such contacts, Teva was disseminating misleading information on Synthon GA’s essential characteristics.
- (2047) Similarly, Teva claims that its contacts with Dutch health insurers Menzis, CZ, VGZ, Zilveren Kruis, ONVZ, and its subcontractor Zorg & Zekerheid, did not constitute a “full-fledged ‘disparagement campaign target[ing ...] the individual major insurance companies’”.²⁸⁸⁵ This claim is misguided. Teva itself admits that it contacted each of these five insurers from three to eight times, totalling 26 contacts concerning the communications assessed in this Decision. Again, it is not clear why an individual addressee of misleading information²⁸⁸⁶ ought to be targeted more than three to eight times for the conduct to be considered abusive.
- (2048) Teva claims that with respect to the contents of the letters, the Commission mischaracterises the contents of these interactions and does not properly explain why they were considered misleading.²⁸⁸⁷ The Commission rejects this argument. The Commission first recalls that the aim of the Copaxone communication plan in the

²⁸⁸² See Recital (1443). Similarly, the Summary Public Assessment Report states that “[p]atients can switch from Copaxone to Brabio [Synthon GA] without problems” (Recital (1509)).

²⁸⁸³ ID 404-1764, Substitution considerations for Follow-on Glatiramer Acetate products (FOGAs), meeting KNMP, 28 March 2017, pp. 18-26. See also ID 4032, Teva’s Reply to the Statement of Objections, para. 1325.

²⁸⁸⁴ ID 4032, Teva’s Reply to the Statement of Objections, paras. 1324-1328.

²⁸⁸⁵ ID 4032, Teva’s Reply to the Statement of Objections, paras. 1330, 1331.

²⁸⁸⁶ The content of these communications is assessed in Recitals (2020)-(2028).

²⁸⁸⁷ ID 4032, Teva’s Reply to the Statement of Objections, para. 1332.

Netherlands was to “{...}”.²⁸⁸⁸ The Commission identifies the misleading messages in Recitals (2023) - (2025) and points to the assessment of the misleading nature of such messages in Section 9.3.1.

- (2049) Teva claims that its communications in the Netherlands were not based on the Payer White Paper, and that the Commission has provided insufficient evidence to show that Teva’s centrally created CCP materials were actually used in communication.²⁸⁸⁹ The Commission rejects these arguments. As explained in Recitals (1678)-(1679)(1680) and (1739)-(1746), the centrally created documents were uploaded in Teva’s database and the teams could access them at any time. These documents were checked, approved internally by various layers of legal and regulatory checks and were updated regularly, so as to take into account new market developments. All of these documents had to be “{...}” (i.e. adapted and approved for use in individual Member States) and the users had to track how well the materials were working so that they could be updated and improved. In that regard, Teva’s “{...}”²⁸⁹⁰ shows that the centrally created documents were indeed updated in the Netherlands. There were *inter alia*, updates to the Payer White Paper and the Payer Slide Presentation and “{...}” of the Payer White Paper, Slide Presentation and Objection Handler. Finally, the messages that Teva communicated to Dutch Payers closely mirror the content of the Payer White Paper.
- (2050) Teva claims that its communications only concerned automatic substitution and neither misled nor confused the Dutch Payers. In Teva’s view, it is also incorrect for the Commission to assume that the delays to the application of the insurers’ preference policies were due to Teva’s correspondence with them and not due to the position of KNMP (which Teva claims was not unduly influenced by it) and wider discussions in the scientific community.²⁸⁹¹ The Commission rejects these arguments. First, it is long settled case law that the Commission does not have to demonstrate actual anticompetitive effects for the conduct to be found in violation of Article 102 TFEU.²⁸⁹² Second, the Commission shows that Teva tried to influence the Payers’ decisions on the application of the preference policy both through direct communication of misleading information (Recitals (2020)-(2025)) and indirectly by communicating misleading information to influence the KNMP position (Recitals (2009)-(2017)). In that regard, Teva’s argument actually acknowledges the importance for Teva of influencing KNMP’s position in view of its importance for Dutch health insurers. Third, while the insurers did ultimately adopt preference policies for both new and existing patients despite Teva’s campaign, which included the Misleading Complexity Message, this does not affect the conclusion that the messages were capable of misleading the insurers to reduce the commercial pressure on Copaxone. Recitals (2011)-(2015) as well as (2026)-(2029) show that Teva’s disparagement to Payers was capable of producing exclusionary effects. Indeed,

²⁸⁸⁸ ID 404-2017, Teva internal email dated 27 October 2014 from {...} to {...} and others regarding “*Afspraken tactics plan CPX 20*” (unofficial translation): “{...}”.

²⁸⁸⁹ ID 4032, Teva’s Reply to the Statement of Objections, para. 1333.

²⁸⁹⁰ ID 404-2597, Checklist Copaxone FoGA 040717; ID 404-2527, Checklist Copaxone FoGA 090517 attachment to ID 404-2525, Teva internal email dated 9 May 2017 from {...} to {...} and others; ID 404-2597, Copaxone FoGA Checklist – Action Plan GA 2017-2018 for the Netherlands referring to, *inter alia*, updates to the Payer White Paper and the Payer Slide Presentation and “{...}” of the Payer White Paper, Slide Presentation and Objection Handler; ID 262-1753, Checklist Copaxone FoGA, 21022018.

²⁸⁹¹ ID 4032, Teva’s Reply to the Statement of Objections, paras. 1334-1335.

²⁸⁹² See Sections 8.2 and 9.2.1.

Teva was targeting the characteristics of Synthon GA, which were a condition to the successful conclusion of its Decentralised Procedure. These characteristics were also a necessary precondition for automatic substitution (and therefore for preference policies), so that questioning them also questioned the basis for preference policies in the Netherlands. If the Payers were misled with respect to these characteristics, this was also likely to affect their decision to enter preference policies. Therefore, Teva's messages were capable of producing exclusionary effects. For example, the insurer {...}, which was {...}, initially limited its preference policy to new patients only pursuant to Teva's misleading messages, effectively shielding Copaxone's existing patients from competition with Synthon GA.

(2051) Teva claims that the Commission should not have relied on the 2019 GTMAP strategy document, as it cannot be interpreted as containing instructions to the commercial and medical teams, and is not a summary of actual activities. According to Teva, neither the quoted document as a whole, nor the cited extract (“{...}”) relate to the Complexity Message.²⁸⁹³ The Commission rejects these arguments. First, concerning the status and evidentiary value of Teva's GTMAP document, the Commission refers to its assessment in Recital (1866). Second, in addition to analysing the GTMAP, the Commission's assessment also takes into account Teva's strategy as described in Sections 5.2.3, 5.2.4, 9.3.2, 9.4.1.2 and 9.4.3, which lay down Teva's strategy and tactics, and, finally, on {...} data and other internal evidence showing that Teva disseminated the Misleading Complexity Messages to HCPs in the Netherlands (see, for example, Recitals (2035)-(2037)).

9.4.4.5.4. Conclusion

(2052) As shown above, Teva's conduct covered most, if not all, drivers of demand for GA in Netherlands. First, Teva disseminated the Misleading Complexity Message to KNMP, to health insurers (e.g. VGZ, Achmea/Zilveren Kruis, CZ, and Menzis, ONZV and its subcontractor Zorg & Zekerheid). Second, Teva targeted HCPs with a view to influencing directly doctors' prescribing practices.

(2053) In view of the analysis in this subsection 9.4.4.5 and in Sections 9.4.1, 9.4.2 and 9.4.3, the Commission concludes that Teva's dissemination of the Misleading Complexity Message in the Netherlands was capable of directly or indirectly hindering and/or delaying Synthon GA/Glatirameeracetaat's market entry and uptake in the Netherlands and therefore of producing exclusionary effects on the Dutch GA market. Even more, it cannot be excluded that Teva's conduct in the Netherlands contributed to delays in the application of the preference policy in relation to existent patients. These delays allowed Teva to protect its existing patient population from Synthon GA/Glatirameeracetaat for several months, resulting in a slower uptake of Synthon GA/Glatirameeracetaat and delayed price competition.

9.4.4.6. Teva's dissemination of the Misleading Complexity Message in Czechia

(2054) Due to preliminary injunctions requested by Teva, the entry of Synthon GA in Czechia has been severely delayed.²⁸⁹⁴ Zentiva has been ready to launch Synthon GA on the Czech market for some time and obtained in September 2021 a pricing and

²⁸⁹³ ID 4032, Teva's Reply to the Statement of Objections, para. 1337.

²⁸⁹⁴ ID 1664, {...} Reply to Article 18(2) Request of 11 February 2022, p. 3; ID 2161, Teva's Reply to Article 18(2) Request of 13 July 2022; see Recital (741); see also Recital (1396).

reimbursement decision from the Czech authorities in preparation for the future launch of the product under the brand name “Remurel”.²⁸⁹⁵

- (2055) In order to hinder and/or delay the market entry and uptake of Synthon GA and its uptake in Czechia,²⁸⁹⁶ Teva disseminated the Misleading Complexity Message to Payers (e.g. SUKL) and HCPs.
- (2056) Teva’s communication campaign in Czechia started long before the successful conclusion of the Decentralised Procedure for Synthon GA.²⁸⁹⁷ For example, already in September 2014 Teva organised and funded a “{...}” in Prague in order for the Payers and HCPs to acquire an “{...}”.²⁸⁹⁸
- (2057) Teva consistently pursued the strategic imperatives of being the first choice DMT and of maintaining market access by implementing the CCP and by spreading the Misleading Complexity Message.²⁸⁹⁹ As shown in the 2016 Brand Plan for Czechia, Teva planned to implement the strategy of communicating “{...}” by relying on the materials such as the expert slide decks, the “{...}” as well as by way of scientific meetings including the “{...}” and the Annual Copaxone symposium.²⁹⁰⁰ Similarly, the 2020 Brand Plan for Czechia includes “{...}” as one of the critical success factors in reaching the strategic imperative of maintaining the status as the first choice for newly diagnosed patients.²⁹⁰¹
- (2058) One of Teva’s CCP materials, the Czech language leavepiece on “Complexity of Copaxone” dated 18 August 2016 claims that only Teva’s patented manufacturing process may ensure Copaxone’s structure and biological activity and emphasised the meaning of “{...}”: “{...}”.²⁹⁰² Although the leavepiece does not specifically refer to Synthon GA, it was issued as part of the CCP campaign tactics to prepare for the entry of Synthon GA.²⁹⁰³ The leavepiece, which implicitly targets Synthon GA, insinuates that the compositional differences (resulting from “complexity of Copaxone” and the ensuing difference in production processes) could have therapeutically relevant effects. The wording of the leavepiece thus implicitly contradicts the fact that Synthon GA and Copaxone had already been found to be

²⁸⁹⁵ ID 1664, {...} Answer to the Article 18(2) Request of 11 February 2022, p. 4.

²⁸⁹⁶ For example, in an email from January 2019, the {...} reports that Alvogen (now Zentiva) has submitted the pricing and reimbursement application for Remurel with a proposed price reduction of 30%, and concludes, “{...}.” (ID 455-2921, Teva internal email dated 23 January 2019 from {...} to {...} and others.

²⁸⁹⁷ Such evidence which preceded the successful conclusion of the Decentralised Procedure for Synthon GA is not used to establish an infringement but to show that Teva prepared the ground for the dissemination of its messages analysed in Section 9.3.1. before the infringement period started.

²⁸⁹⁸ ID 455-213, Glatiramoids Educational Meeting, Viewpoints on characterisation and clinical aspects of glatiramoids, 26 September 2014, p. 4.

²⁸⁹⁹ ID 1151-37, Czechia GTMAP for 2019, p. 3; ID 1151-16, Czechia GTMAP for 2020, p. 4; ID 1151-69, 2021 GTMAP Czech republic Copaxone, p. 6; ID 1151-12, 2022 GTMAP Czech Republic Copaxone, p. 4. The Commission requested the brand plans (‘GTMAP’ – Go to Market Action Plans) for each year for the period 2016-2021. However, Teva did not deliver brand plans for 2017 and 2018. GTMAPs are commercial documents, which set out proposed objectives regarding the Copaxone business for the upcoming year(s) as well as underlying assumptions on the market and its evolution. They are prepared at both European level and local level.

²⁹⁰⁰ ID 1151-66, Czechia GTMAP for 2016, p. 11.

²⁹⁰¹ ID 1151-16, Czechia GTMAP for 2020, p. 4.

²⁹⁰² ID 4919-25, Complexity of Copaxone, 18 August 2016 (unofficial translation). Original text: “{...}”.

²⁹⁰³ See Figure 42, CCP strategy and ID 455-269, In face of evolving FoGA competition, p. 18.

therapeutically equivalent through the successful conclusion of Synthon GA's Decentralised Procedure.²⁹⁰⁴

- (2059) Teva was particularly concerned with the effects that Synthon GA pricing and reimbursement status would have on Copaxone.²⁹⁰⁵ The Copaxone Brand Plan for Czechia for 2019 therefore continues to include communication on Copaxone's "{...}" by emphasising "{...}" as a success factor critical for market access.²⁹⁰⁶
- (2060) In this context, in the period from January to April 2019, Teva intervened in the SUKL's procedure,²⁹⁰⁷ which concerned Alvogen's request for a reimbursement assessment of Synthon GA (Remurel 40 mg and Remurel 20 mg). In several written submissions, Teva objected to Synthon GA being assessed as the first similar medicine in the reference group, which would have an immediate pricing impact on Copaxone. In addition to the procedural arguments, relating to Teva's participation in the proceedings and Teva's warning about possible infringement of Teva's patents,²⁹⁰⁸ the submissions also include facets of the Misleading Complexity Message. More specifically, Teva emphasises the "complexity" of GA and the fact that Synthon GA is approved as a medicine with a "similar" rather than the "same" active ingredient, thus questioning Synthon GA's established therapeutic equivalence with Copaxone in contradiction with the successful conclusion of the Decentralised Procedure for Synthon GA.²⁹⁰⁹
- (2061) Also with respect to HCPs, Teva's local Brand Plans reveal the importance of its communication campaign. The Copaxone Brand Plan for Czechia for 2016 sets the objective that "{...}" as a desired outcome with respect to doctors to be achieved through various CCP activities. These activities included implementing and updating CCP materials and communicating to HCPs in Czechia on the complexity of the GA structure by way of scientific and clinical MS expert education materials as well as thorough scientific meetings.²⁹¹⁰ The Copaxone Brand Plan for 2019 expressly mentions explanation of Complexity to "{...}" as a "{...}" (original emphasis).²⁹¹¹
- (2062) In this context, the Commission notes that available data show that in the period from 2015 to May 2021 Teva's MSL and KAMs/sales representatives made altogether {...} direct contacts (either face-to-face visits or phone calls) with {...} HCPs in Czechia related to Copaxone, GA or central nervous system products.²⁹¹² Taking into account the emphasis on the Misleading Complexity Message in the training

²⁹⁰⁴ According to ID 4897, List of documents registered on Teva's {...}, the associated excerpt from Teva's internal database shows that that the document was approved on 5 August 2016, reapproved on 18 August 2017, with first recorded use on 29 August 2016. For the Commission's conclusions based on Teva's re-approval of this document in August 2017, see footnote 2571 above.

²⁹⁰⁵ ID 1151-12, 2022 GTMAP Czech Republic Copaxone, p. 6 lists "{...}" among Key Market Landscape Characteristics for 2022. See also key threats in the SWAT analysis on p. 8.

²⁹⁰⁶ ID 1151-37, Czechia GTMAP for 2019, pp. 3-4.

²⁹⁰⁷ The SUKL is responsible for the pricing of drugs (both out-patient and hospital only drugs) and for the reimbursement of out-patient drugs.

²⁹⁰⁸ In its paragraph 4, Teva's letter of 24 January 2019 mentions CZ/EP patent no. 2 630 962, CZ/EP patent č. 2 949 335 and CZ/EP patent č. 3 199 172 (ID 651-7, Teva's submission to SUKL of 24 January 2019, pp. 2-3).

²⁹⁰⁹ ID 651-7, Teva's submission to SUKL of 24 January 2019, pp. 10-11; ID 651-64, Teva's submission to SUKL of 7 March 2019, pp. 6-7; ID 651-48, Teva's submission to SUKL of 15 March 2019, pp. 4-5; ID 651-14, Teva's submission to SUKL of 17 April 2019, p. 5.

²⁹¹⁰ ID 1151-66, Czechia GTMAP for 2016, p. 11.

²⁹¹¹ ID 1151-37, Czechia GTMAP for 2019, pp. 3-4.

²⁹¹² ID 900-7, and ID 900-23, {...} data Czechia. For scope and reliability of {...} data see footnote 2326.

materials prepared by Teva²⁹¹³ and in Teva's Brand Plans for Czechia, it is likely that these contacts have been devoted, at least in part, to the dissemination of the Misleading Complexity Message.²⁹¹⁴ Further, not all contacts are recorded mandatorily, and even for contacts for which documentation is mandatory there is no system in place which requires sales representatives and members of Teva's MSL team to record contacts, as also confirmed by Teva.²⁹¹⁵ This suggests that the actual number of contacts between Teva and HCPs in Czechia is likely higher than the number of contacts documented in the available data.

9.4.4.6.1. Teva's arguments and the Commission's assessment

- (2063) Teva claims that the Commission erroneously considers that the conference "Glatiramoids Educational Meeting" (see Recital (2056)), which pre-dates the period of infringement, sought to hinder and/or delay the market entry and uptake of Synthon GA or contained misleading information.²⁹¹⁶ The Commission rejects these arguments. As noted in Section 9.3.1.4.3, the evidence used by the Commission that pre-dates the period of infringement shows that Teva prepared the ground for dissemination of its messages long before the successful conclusion of the Decentralised Procedure for Synthon GA. In addition, the conference materials prepared by Teva before the end of the Decentralised Procedure for the grant of a MA to Synthon GA shows that Teva did not appropriately adapt its materials even after the successful completion of such Decentralised Procedure made it plain that some messages could not be reconciled with the finding by the competent authorities that Synthon GA was safe, efficacious, and therapeutically equivalent to Copaxone. For example, a presentation by Teva's {...} contains, amongst others, a slide where Teva compares Copaxone with other glatiramer-related substances, and poses the question: "{...}".²⁹¹⁷ Teva states that "{...}" and that "{...}" (emphasis added).²⁹¹⁸
- (2064) Concerning the 2019 GTMAP, Teva essentially claims that the document does not constitute evidence of a disparagement strategy, as its focus on the "complexity" of Copaxone did not involve misleading messages.²⁹¹⁹ The Commission rejects this argument. The Copaxone Brand Plan for Czechia for 2019 includes plans to communicate on Copaxone's "complexity" by emphasising "*COPAXONE's status as a NBCD*" as a critical success factor (see Recital (2059)). For the reasons already explained²⁹²⁰, Teva's communication on Copaxone's "complexity" is closely tied to the dissemination of the Misleading Complexity Message, as also reflected by Teva's CCP communication materials as described in Section 9.3.2.2.
- (2065) Teva claims that its concerns with the impact that pricing and reimbursement status of Synthon GA could have on Copaxone were normal and legitimate.²⁹²¹ This is not disputed. This Decision does not take issue with Teva's intervening before the

²⁹¹³ See Section 9.3.2. In particular, Teva prepared materials for the members of its MSL team (notably the External Expert White Paper for MS specialists, the GATE Study Review and the MSL Objection Handlers) and for its KAMs, (notably KAM Objection Handlers).

²⁹¹⁴ Just like in Belgium, inherent limitations in the available CRM data apply (see footnote 2478).

²⁹¹⁵ See footnote 2326 above.

²⁹¹⁶ ID 4032, Teva's Reply to the Statement of Objections, paras. 1346, 1347, 1348.

²⁹¹⁷ ID 455-54, Glatiramoids Educational Meeting, Biological characterisations of glatiramoids, {...}, (this is a {...} approved presentation) – CZ/CPX/14/0054, p. 15.

²⁹¹⁸ ID 455-54, Glatiramoids Educational Meeting, Biological characterisations of glatiramoids, {...}, (this is a {...} approved presentation) – CZ/CPX/14/0054, p.29.

²⁹¹⁹ ID 4032, Teva's Reply to the Statement of Objections, para. 1349.

²⁹²⁰ See Recitals (1539)-(1541) and (1637) et seq.

²⁹²¹ ID 4032, Teva's Reply to the Statement of Objections, para. 1350.

pricing and reimbursement bodies, but only with Teva's messages that, whether in the context of discussing automatic substitution or not, directly contradict the settled findings by Member States' medicines authorities concerning Synthon GA's safety, efficacy and therapeutic equivalence with Copaxone, which had already assessed and rejected Teva's concerns.²⁹²²

- (2066) Indeed, Teva was targeting the characteristics of Synthon GA which had been a condition to the successful conclusion of its Decentralised Procedure. These characteristics were also a necessary precondition for the assessment of Synthon GA as first similar medicine to Copaxone in the reference group and for automatic substitution in Czechia. If the Payers were misled with respect to these characteristics, this was also likely to affect their decision to consider Synthon GA a similar medicine to Copaxone and allow automatic substitution. Therefore, Teva's messages were capable of producing exclusionary effects.
- (2067) Teva claims that its letters to SUKL did not contain misleading messages and were fully consistent with its messaging on automatic substitution.²⁹²³ This claim is unfounded. For example, Teva's letter to SUKL dated 24 January 2019, contains the standard narrative constituting Teva's Misleading Complexity Message. Teva points out the (alleged) complexity of GA, the compositional differences in view of proprietary production processes, and claims that such differences may lead to different immunogenic effects.²⁹²⁴ Teva's letter then turns to an extensive critique of the GATE study containing misleading messages (concerning MRI as the primary end point, the result related to ARR, etc.).²⁹²⁵ Consistently with other disparaging materials, Teva's letter thus challenges the finding by competent authorities that Synthon GA is safe, efficacious, and therapeutically equivalent to Copaxone.²⁹²⁶
- (2068) Teva claims that the Commission failed to demonstrate that Teva's communications with HCPs in Czechia were misleading, and that the GTMAPs cannot be used as evidence of dissemination of misleading messages. Teva also claims that the Commission should rely on the GTMAP for 2016 only as context and not as evidence of alleged abusive conduct, as it was created in 2015 and thus pre-dates the period of infringement.²⁹²⁷ These arguments do not convince. First, concerning the general evidentiary value of GTMAPs, the Commission explains in Recital (1866) why such Brand Plans are credible strategic documents which inform of Teva's planned promotional and other activities. Specifically, the Copaxone Brand Plan for Czechia for 2016 sets the objective that "{...}" as a desired outcome of various CCP activities. These activities included implementing and updating CCP materials and communicating to HCPs in the Czech Republic on the "complexity" of GA. Also the 2019 Brand Plan expressly planned the communication of the Misleading Complexity Message to "{...}" as a "{...}"; as already pointed out in Recital (2064), this message is closely tied to the dissemination of misleading messages. Second, with regard to the fact that the GTMAP for 2016 was drafted in 2015, the Commission points to the fact that it reflects the actions which needed to be taken in

²⁹²² See Section 9.2.3.5.

²⁹²³ ID 4032, Teva's Reply to the Statement of Objections, paras. 1351, 1352.

²⁹²⁴ ID 651-7, Teva's submission to SUKL of 24 January 2019, pp. 9-10. Such claims are assessed in Section 9.3.1.1.

²⁹²⁵ ID 651-7, Teva's submission to SUKL of 24 January 2019, pp. 10-12. Such claims are assessed in Section 9.3.1.2.

²⁹²⁶ For arguments concerning Teva's claims that its messages were made to persuade the Payers and HCPs not to allow automatic substitution between Copaxone and Synthon GA, see Section 9.2.3.5 above.

²⁹²⁷ ID 4032, Teva's Reply to the Statement of Objections, paras. 1354-1358.

2016, thus within the period of infringement, and the evidence in the Commission’s case file does not indicate that Teva desisted from or changed its plans.

(2069) Teva claims that (i) the Commission has failed to prove the dissemination of misleading messages to HCPs in Czechia, also considering that {...} data has (allegedly) limited or no evidentiary value, (ii) that the average number of contacts with an HCP in Czechia is limited ({...} per year), and (iii) that pointing to training materials is insufficient to prove that such contacts were likely to have been devoted at least in part to the dissemination of the Misleading Complexity Message.²⁹²⁸ The Commission rejects these arguments. First, the only conclusion the Commission draws from the {...} data summarised in Recital (2062) above is that Teva staff were contacting HCPs in Czechia to promote Copaxone. Taking into account the emphasis on the Misleading Complexity Message in the training materials prepared by Teva²⁹²⁹ and concluded that it is likely that the contacts that Teva’s employees had with HCPs visits followed Teva’s strategic plans and have thus been devoted at least in part to the dissemination of the Misleading Complexity Message. As shown in the 2016 Brand Plan for Czechia, Teva planned to implement the strategy of communicating “{...}” by relying on the materials such as the expert slide decks, the MSL Slide Decks and briefing documents as well as by way of scientific meetings including the “{...}” and the Annual Copaxone symposium. Second, a Teva internal document shows that Teva’s local staff in Czechia “{...}.”²⁹³⁰ They were reporting (and updating regularly) on Synthon GA to Teva’s headquarters, including information on the status of implementation of Teva’s materials. The document also reveals that by October 2016 the majority of the CCP materials had been implemented in Czechia.²⁹³¹ Third, the Commission points to Recital (1996) which explains the limitations of {...} data (including possible under-reporting).

9.4.4.6.2. Conclusion

(2070) As shown above, Teva’s conduct covered most, if not all, drivers of demand for GA in Czechia. First, Teva disseminated the Misleading Complexity Message primarily to SUKL in communications criticising Synthon GA’s reimbursement status that would result in price competition. Second, since the entry of Synthon GA in Czechia has been severely delayed due to preliminary injunctions requested by Teva,²⁹³² Teva’s campaign to influence individual prescription decisions by HCPs has been less relevant. However, dissemination of the Misleading Complexity Message to HCPs is regularly included in Teva’s Brand Plans for Czechia.

(2071) In view of the analysis made in this subsection 9.4.4.6 and in Sections 9.4.1, 9.4.2 and 9.4.3, the Commission concludes that Teva’s dissemination of the Misleading Complexity Message in Czechia was capable of directly or indirectly hindering and/or delaying Synthon GA’s market entry and uptake in Czechia and therefore of producing exclusionary effects on the Czech GA market.

²⁹²⁸ ID 4032, Teva’s Reply to the Statement of Objections, paras. 1359, 1360.

²⁹²⁹ The centrally created and approved materials were rolled-out to the Member States to support Teva’s communication with Payers, KOLs and HCPs with the strict instruction that “{...}”. See section 9.3.2.2.

²⁹³⁰ ID 455-1432, FoGA questions- Validation, worksheet: Questions,

²⁹³¹ ID 455-1432, FoGA questions- Validation, worksheet: Questions - attachment to ID 455-1429, Teva internal email from {...} to {...} and others. For implementation of centrally created CCP materials see Section 9.3.2.2.2.

²⁹³² For detailed description of the delay see Recital (741).

9.4.4.7. Teva's dissemination of the Misleading Complexity Message in Poland

- (2072) Synthon has entered a licensing agreement with Alvogen to commercialise Synthon GA in Poland.²⁹³³ Alvogen launched Synthon GA 20 mg in January 2017 under the brand name Remurel. The 40 mg version of Remurel was launched in July 2018.
- (2073) In order to hinder the market entry and uptake of Synthon GA/Remurel and to avoid or delay the resulting price competition, in Poland Teva disseminated the Misleading Complexity Message primarily to Payers (Polish Ministry of Health and tendering bodies), although the campaign also covered HCPs. For example, in the 2016 Copaxone Brand Plan, Teva noted that the expected launch of Remurel and fixing its reimbursement status would immediately entail a price reduction of 25%.²⁹³⁴
- (2074) Teva's communication campaign under the CCP umbrella started before Synthon GA/Remurel's entry. The Copaxone Brand Plan for 2016 lists CCP as one of the strategic projects for 2016 and its key tactics comprised various CCP actions including the education of stakeholders on the "complexity" of Copaxone and driving discussions on regulatory pathways.²⁹³⁵ Teva consistently pursued the strategic imperatives of retaining the existing patients and of maintaining market access (that is to say, pricing and reimbursement conditions) by implementing the CCP and by spreading the Misleading Complexity Message.²⁹³⁶

9.4.4.7.1. Teva's dissemination of the Misleading Complexity Message to Payers in Poland

- (2075) In light of the expected market entry of Synthon GA/Remurel in 2017, one of Teva's key planned activities was targeting "{...}" with the messages contained in the relevant CCP materials.²⁹³⁷ CCP's objective was to "{...}".²⁹³⁸ The goal (or as Teva calls it a "{...}") was "{...}"²⁹³⁹ by means of a broad variety of CCP activities, including CCP materials for the education of sophisticated Payers and HTA bodies (the Payer White paper, the Payer Slide presentation and the "{...}"), External Expert White Papers, External Experts Presentation and "{...}" as well as EU CCP taskforce meetings.²⁹⁴⁰
- (2076) In its submission of 24 October 2016 to the Polish Ministry of Health, Teva strived to mitigate the impact of Synthon GA's entry by challenging the possibility of automatic substitution between Copaxone and Remurel.²⁹⁴¹ Teva's arguments

²⁹³³ In April 2020, the Czech generic company Zentiva acquired the right to license Synthon GA in Poland.
²⁹³⁴ ID 1151-23, Poland GTMAP for 2016, p. 8. The Commission requested the Brand Plans ('GTMAP' – Go to Market Action Plans) for each year for the period 2016-2021. However, Teva did not submit Brand Plans for 2018, 2019 and 2020; ID 455-1432, FoGA questions- Validation, worksheet: Questions - attachment to ID 455-1429, Teva internal email from {...} to {...} and others.

²⁹³⁵ ID 1151-23, Poland GTMAP for 2016, pp. 10, 17, 18 and 24. See also ID 1151-36, Poland GTMAP for 2017, p. 15.

²⁹³⁶ ID 1151-36, Poland GTMAP for 2017, pp. 2-3; ID 1151-15, Poland GTMAP for 2021, p. 6; ID 1151-60, Poland GTMAP for 2022, p. 7.

²⁹³⁷ ID 1151-36, Poland GTMAP for 2017, p. 2.

²⁹³⁸ 1151-23, Poland GTMAP for 2016, p. 10.

²⁹³⁹ ID 1151-36, Poland GTMAP for 2017, p. 3.

²⁹⁴⁰ ID 1151-36, Poland GTMAP for 2017, p. 13.

²⁹⁴¹ In Poland, prices for reimbursable drugs are regulated by the National Health Fund (Narodowy Fundusz Zdrowia). The pricing and reimbursement status of a drug is determined in a single process and declared in an administrative decision by the Ministry of Health. For both the official and the effective price, the basis for discussions with the Ministry of Health is the therapeutic program to which Copaxone belongs. The therapeutic program describes the indication for which drugs should be used.

submitted to the Ministry of Health included the Misleading Complexity Message and, in particular, Teva emphasised clinically irrelevant differences in GA structures and raised doubts about the validity of the GATE study.²⁹⁴² For example, Teva argued that “{...}”.²⁹⁴³ It thus implicitly challenged the finding that Synthon GA and Copaxone were therapeutically equivalent.

- (2077) The Commission notes that these arguments used in the letter of 24 October 2016 correspond, word for word, to the relevant parts of the Payer White Paper: “{...}” and “{...}”.²⁹⁴⁴ This confirms once more that the centrally drafted Payer White Paper was indeed heavily used and relied on for Teva’s external communication with Payers at local level, including in Poland.²⁹⁴⁵
- (2078) Teva considered winning the tenders in Poland “{...}” as the “{...}” (original emphasis).²⁹⁴⁶ After the launch of Synthon GA/Remurel, Alvogen could still not participate in all tenders for GA drugs in Poland because some tenders specified Copaxone as the only option for existing Copaxone patients.²⁹⁴⁷ Teva’s internal documents suggest that Teva contacted tendering bodies to argue against the substitution of Copaxone with Synthon GA/Remurel for patients that were already treated with Copaxone.²⁹⁴⁸
- (2079) A Teva internal email from 21 February 2017 shows that the legal strategy in relation to tenders was to reply to the letter from the Ministry of Health which focussed on “{...}”.²⁹⁴⁹ In this context, on 2 March 2017, Teva sent a letter to the Polish Ministry of Health disputing the letter that had been sent by the Ministry to hospitals on 6 December 2016. In that letter, the Ministry explained the framework for the procurement of medicines and opted for single tenders for medicines containing GA as opposed to separate tenders for Copaxone and Synthon GA. In order to maintain the possibility of separating the tenders for Copaxone and for Synthon GA (and thus avoid price competition), Teva particularly emphasised the clinically irrelevant differences in GA structures.²⁹⁵⁰ For example, in the summary of its letter, Teva explains that “{...}”.²⁹⁵¹ Again, Teva’s statement is in direct contradiction with the finding by the competent authorities that Synthon GA and Copaxone are therapeutically equivalent.
- (2080) Teva was targeting the characteristics of Synthon GA, which had been a condition to the successful conclusion of its Decentralised Procedure. These characteristics were also a necessary precondition for automatic substitution in Poland. If the Payers were misled with respect to these characteristics, this was also likely to affect their

Copaxone’s therapeutic program includes most first-line DMTs, including interferons and orals. For more details, see Section 6.3.3.4.2.3.

²⁹⁴² ID 651-62, Teva’s letter to the Ministry of Health of 24 October 2016, pp. 4-7.

²⁹⁴³ Ibid, p. 5. For analysis of misleading character of these messages, see Section 9.3.1.1 and Section 9.3.1.3.

²⁹⁴⁴ Payer White Paper, Executive Summary (ID 806-2, Assessing the Value of COPAXONE® in Relation to Follow-on Glatiramer Acetate, Payer White Paper, 8 June 2016, p. 3).

²⁹⁴⁵ See also Section 9.3.2 and Section 9.4.4.1.

²⁹⁴⁶ ID 1151-15, Poland GTMAP for 2021, p. 10. See also ID 1151-60, Poland GTMAP for 2022, p. 13 with a reference to the central tender for GA.

²⁹⁴⁷ ID 1664, {...} Reply to the Article 18(2) Request of 11 February 2022, p. 6.

²⁹⁴⁸ ID 404-93, Copaxone EU Litigation Update, week 31 August 2018, p. 10.

²⁹⁴⁹ ID 266-90, Teva’s internal email dated 21 February 2017 from {...} to {...}; see also ID 265-844, COPAXONE®/GA tenders, 5 April 2017, p. 16: “{...}”.

²⁹⁵⁰ ID 651-71, Teva’s letter to the Ministry of Health of 2 March 2017, pp. 1, 4, 6.

²⁹⁵¹ Ibid, p. 1: “{...}”.

decision to allow automatic substitution or organise tenders for GA Therefore, Teva's messages were capable of producing exclusionary effects.

9.4.4.7.2. Teva's dissemination of the Misleading Complexity Messages to HCPs in Poland

- (2081) The objective that HCPs (neurologists) become “{...}”²⁹⁵² was listed as one of the critical success factors in the strategic goal of maintaining and protecting Copaxone's existing patient population in Poland. Activities planned for achieving this goal included HCP promotional efforts by way of “{...}”, “{...}”, the incorporation of “{...}”. Medical activities included medical education, “{...}” on complexity and competing GA topics during scientific meetings and congresses as well as “{...}”.²⁹⁵³
- (2082) Similarly, the strategic imperative of maintaining Copaxone's status as a first line option for new RRMS patients rested on, *inter alia*, marketing driven communication of the “complexity” of GA with the aim of neurologists choosing Copaxone instead of Synthon GA (including by speaker trainings, live streaming sessions and sponsored lectures).²⁹⁵⁴ In addition, the Copaxone Brand Plan for Poland for 2016 set that “{...}” as a physicians' desired behaviour to be achieved by various “medical” CCP activities. The plan required both marketing (KAMs) and medical team (MSLs) to communicate on the “complexity” of the GA structure (speaker training after MS Management conference), livestreaming session after the launch of Synthon GA, sponsored lecture during local conferences), included the use of scientific and clinical MS expert educational materials (slide decks, MSL decks and briefing documents, reprints on “FoGAs/NBCDs”), speaker trainings, lectures during local workshops with HCPs and medical information on “FoGAs” and “NBCDs”.²⁹⁵⁵
- (2083) An internal email exchange from May 2016 shows that the Presentation on “Complexities of Glatiramoids” from June 2016²⁹⁵⁶ was targeting selected Polish KOLs as well as a wider group of HCPs: “{...}”.²⁹⁵⁷ One of Teva's presentations in the conference, “Complexities of Glatiramoids – Biological characterisations of glatiramoids” contains the Misleading Complexity Message and makes direct references to “{...}” of “{...}”, not only failing to acknowledge the finding of therapeutic equivalence between Synthon GA and Copaxone, but also contradicting it: “{...}” (original emphasis and emphasis added).²⁹⁵⁸ “{...}” (original emphasis).²⁹⁵⁹ The other Teva presentation at the conference “Complexity of Copaxone - Physicochemical and Functional characterisation” concludes that “{...}”,²⁹⁶⁰ again going against the findings of the competent regulatory authorities on Synthon GA.

²⁹⁵² ID 1151-36, Poland GTMAP for 2017, p. 3.

²⁹⁵³ ID 1151-36, Poland GTMAP for 2017, pp. 3 and 11.

²⁹⁵⁴ ID 1151-23, Poland GTMAP for 2016, pp. 12 and 17.

²⁹⁵⁵ Ibid, p. 18.

²⁹⁵⁶ ID 404-2001, Complexities of Glatiramoids – Biological characterisations of glatiramoids, Warsaw June 2016.

²⁹⁵⁷ ID 404-1995, Teva internal email dated 4 May 2016 from {...} to {...}, p. 4.

²⁹⁵⁸ D 404-2001, Complexities of Glatiramoids – Biological characterisations of glatiramoids, Warsaw June 2016, p. 33.

²⁹⁵⁹ ID 404-2001, Complexities of Glatiramoids – Biological characterisations of glatiramoids, Warsaw June 2016, p. 35.

²⁹⁶⁰ ID 404-1998, Complexity of Copaxone - Physicochemical and Functional characterisation, Warsaw, June 2016, p. 37.

- (2084) An email update from December 2016 related to Synthon GA shows that Teva’s KAM and MSL teams were using centrally created CCP materials: “{...}”.²⁹⁶¹ Teva used a promotional leavepiece (leaflet) in Polish in which Teva explained the meaning of “complexity” of Copaxone: “{...}”.²⁹⁶² The misleading message that differences from the manufacturing process may be therapeutically significant, thus questioning Synthon GA’s therapeutic equivalence with Copaxone, is assessed in Section 9.3.1.1.
- (2085) Teva created an electronic version of the leaflet containing the same message to be shown to HCPs on a tablet.²⁹⁶³ Again, Teva *disseminated* information concerning Copaxone’s alleged hidden complexity to Polish HCPs and put into question the therapeutic equivalence of Synthon GA and the soundness of its manufacturing process.
- (2086) On 27 March 2017, Teva organised an advisory board meeting in Poland dedicated to the entry of Synthon GA/Remurel and the implications this entry may have on the clinical practice (especially prescription behaviour and substitution). Among others, topics discussed included “{...}”, “{...}”, etc.²⁹⁶⁴. A Teva internal email shows that Teva planned to talk about the idea that “{...}” and the fact that the quality of GA is determined by the process: “{...}”.²⁹⁶⁵ This is a standard component of Teva’s Misleading Complexity Message which, as the other Teva messages assessed in this Section, implies that Synthon GA is not therapeutically equivalent to Copaxone. Another document reveals that Teva would typically follow up an advisory board with a range of activities: “{...}”.²⁹⁶⁶
- (2087) A Teva internal email from 24 September 2018 shows that the proactive communication of the Complexity Message to Polish HCPs continued to be a priority for Teva: “{...}”.²⁹⁶⁷
- (2088) In this context, “{...}”.²⁹⁶⁸ The strategy would be implemented primarily by way of face-to-face meetings with the neurologists and MS specialists supported with mailing and access to Neurologybytes.com.²⁹⁶⁹
- (2089) According to the {...} data, in the period from 2015 to May 2021 Teva’s MSL and sales representatives (KAMs) made altogether {...} direct contacts (either face-to-face visits or phone calls) with {...} HCPs in Poland related to *inter alia* Copaxone, GA or central nervous system products.²⁹⁷⁰ There is evidence of at least {...} of these

²⁹⁶¹ ID 404-884, Teva internal email dated 9 December 2016 from {...} to {...} and others.

²⁹⁶² ID 4919-26, promotional leavepiece (leaflet) “*FoGA ulotka - zapoznaj się bliżej z Copaxone*” September 2016, p. 6, ID 4919-38, promotional presentation “{...}”, April 2017, p. 8 (unofficial translation). Original text: “{...}”. According to ID 4897, List of documents registered on Teva’s {...}, the document was approved on 18 August 2016, reapproved on 8 August 2017. For the Commission’s conclusions based on Teva’s re-approval of this document in August 2017, see footnote 2571 above.

²⁹⁶³ ID 4919-27, promotional iPad presentation “*FoGA iPad - Complexity of Copaxone*”, September 2016, p. 3. Also, ID 4919-2, Promotional iPad presentation “*Prezentacja iPad kampania T3 2017 (Re-approval I)*”, August 2017, pp. 28-29.

²⁹⁶⁴ ID 644-144, Advisory Board Copaxone Agenda, 27 March 2017.

²⁹⁶⁵ ID 455-3412, Teva internal email dated 27 March 2017 from {...} to {...}.

²⁹⁶⁶ ID 455-2359, Teva internal email dated 24 September 2018 from {...} to {...}.

²⁹⁶⁷ ID 455-2359, Teva internal email dated 24 September 2018 from {...} to {...}.

²⁹⁶⁸ ID 1151-15, Poland GTMAP for 2021, pp. 9-10. See also ID 1151-60, Poland GTMAP for 2022, p. 11.

²⁹⁶⁹ ID 1151-15, Poland GTMAP for 2021, p. 11.

²⁹⁷⁰ ID 900-9 and ID 900-12 {...} data for Poland. For scope and reliability of {...} data see footnote 2326. Just like in Belgium, inherent limitations in the available CRM data apply (see footnote 2478).

sales contacts concerned “*NBCD-FoGA*”.²⁹⁷¹ Taking into account the emphasis on the Misleading Complexity Message in the training materials prepared by Teva²⁹⁷² and in the Brand Plans for Poland²⁹⁷³, and the reasons for Teva to adopt the acronyms “*NBCD*” and “*FoGA*”²⁹⁷⁴, it is likely that these contacts were devoted, at least in part, to the dissemination of the Misleading Complexity Message. Further, it cannot be excluded that there were more contacts, since there is no built-in system requiring sales representatives and members of Teva’s MSL teams to record contacts as also confirmed by Teva.²⁹⁷⁵ Not all contacts are recorded mandatorily, and even for contacts for which documentation is mandatory there is no system in place which requires sales representatives and members of the MSL team to record them.

9.4.4.7.3. Teva’s arguments and the Commission’s assessment

- (2090) Teva notes that the abovementioned Brand Plan for 2016²⁹⁷⁶ dated 15 July 2015, pre-dates the period of infringement. Therefore, in Teva’s view, it can be used as background only not as part of the alleged abuse.²⁹⁷⁷ The Commission rejects this claim for the same reasons as explained in Recital (2068).
- (2091) In relation to the 2016 GTMAP, Teva claims that the Commission is wrong to find that Teva’s communications with Payers and HCPs in Poland were pursued in order to hinder the market entry and uptake of Synthon GA and to avoid or delay the resulting price competition, and the reference to an anticipated price reduction of 25 % due to Synthon GA is (allegedly) not causally linked to Teva’s disparagement campaign. Teva also claims that the existence of discussions on Copaxone’s “complexity” cannot stand as evidence of a disparaging strategy.²⁹⁷⁸ These arguments do not convince. First, the Commission’s finding is consistent with the broader finding of Teva’s pan-European CCP strategy to counter competition from Synthon GA, of which the disparagement campaign was an important part.²⁹⁷⁹ The reference to the 25 % price reduction due to Synthon GA as mentioned in the 2016 Copaxone Brand Plan for Poland therefore only complements the overall description, and provides a specific example of what was at stake for Teva in Poland. Second, for the reasons already explained²⁹⁸⁰, Teva’s communication on Copaxone’s “complexity” is closely tied to the dissemination of the Misleading Complexity Message, as explained in the analysis of Teva’s CCP communication materials in Section 9.3.2.2.
- (2092) Teva argues that the two letters it addressed to the Polish Ministry of Health only relate to the issue of automatic substitution.²⁹⁸¹ This claim is unfounded, for the reasons explained in Recitals (2076)-(2077). The fact that the communication is

²⁹⁷¹ *Ibid.*

²⁹⁷² See Section 9.3.2. In particular, Teva prepared materials for the members of its MSL team (notably the External Expert White Paper for MS specialists, the GATE Study Review and the MSL Objection Handlers) and for its KAMs, (notably KAM Objection Handlers).

²⁹⁷³ As explained in Recital (2081) above, Teva’s Brand Plans for Poland show that Teva indicated that the fact that HCPs (neurologists) become “{...}” was one of the critical success factors in the strategic goal of maintaining and protecting Copaxone’s existing patient population in Poland.

²⁹⁷⁴ See Sections 9.1.1 and 9.3.1.4.2 above.

²⁹⁷⁵ See footnote 2326.

²⁹⁷⁶ ID 1151-23, Poland GTMAP for 2016.

²⁹⁷⁷ ID 4032, Teva’s Reply to the Statement of Objections, para. 1362.

²⁹⁷⁸ ID 4032, Teva’s Reply to the Statement of Objections, paras. 1364-1365.

²⁹⁷⁹ See Section 9.1.

²⁹⁸⁰ See Recitals (1539)-(1541) and (1637) et seq.

²⁹⁸¹ ID 4032, Teva’s Reply to the Statement of Objections, paras. 1370-1372.

made in the context of discussion on the automatic substitution does not exonerate the misleading statements included in the communication, for the reasons explained in Section 9.2.3.5.²⁹⁸²

- (2093) Teva claims that its second letter to the Polish Ministry of Health, dated 2 March 2017, inviting the Ministry to amend the letter it had sent to the Opole Hospital, was limited to arguments concerning automatic substitution and contests that Teva emphasised the clinically irrelevant differences in GA structures.²⁹⁸³ The Commission rejects these arguments. Teva does not explain how a misleading statement contradicting the finding of therapeutic equivalence between Synthon GA and Copaxone (e.g. “{...}”²⁹⁸⁴) becomes less misleading if the letter also discusses some other topics.
- (2094) Teva claims that the Commission misread the document "Copaxone EU Litigation Update", dated 31 August 2018 to support the finding that Teva contacted tendering bodies to argue against the substitution between Copaxone and Synthon GA in existing patients. Teva argues that the statement “*tenders for GA should be called in a way which allows patients to continue their treatment on Copaxone*” can only be understood as Teva advocating that patients already treated on Copaxone kept the possibility, in case needed, to maintain access to their current treatment.²⁹⁸⁵ The Commission rejects these arguments. Regardless of whether it was about existing patients or not, the quotes demonstrate that in such contacts Teva spread misleading messages which were going against the results of the Decentralised Procedure for Synthon GA. For example, contrary to the finding of therapeutic equivalence between Copaxone and Synthon GA, in the summary of its letter, Teva insinuates that the compositional differences may result in safety (immunological) and efficacy issues: “{...}”.²⁹⁸⁶
- (2095) Teva claims that the Commission fails to demonstrate the existence of Teva's communications with the Polish tendering bodies.²⁹⁸⁷ The Commission rejects this argument. First, the evidence in Recital (2079) confirms the existence of such contacts, as well as their content. Second, the Commission also relies on other evidence, such as Teva Brand Plans that suggest the same.²⁹⁸⁸ Furthermore, an internal email contains Teva's strategy in relation to tenders: to “{...}”.²⁹⁸⁹
- (2096) Teva claims that the Commission fails to demonstrate that Teva's communications with HCPs in Poland were misleading. Teva claims that the Commission is wrong to rely on GTMAPs, as they cannot be interpreted as instructions to the commercial and medical teams as such, or as a summary of actual activities, and the Commission does not show that the contents of the GTMAPs were actually implemented.²⁹⁹⁰ The Commission rejects these arguments.

²⁹⁸² See Section 9.3.1.1.4.

²⁹⁸³ ID 4032, Teva's Reply to the Statement of Objections, paras. 1373, 1374.

²⁹⁸⁴ Ibid, p. 1 (unofficial translation). Original text: “{...}”.

²⁹⁸⁵ ID 4032, Teva's Reply to the Statement of Objections, paras. 1376, 1377.

²⁹⁸⁶ See Recital (2079).

²⁹⁸⁷ ID 4032, Teva's Reply to the Statement of Objections, paras. 1379, 1380.

²⁹⁸⁸ ID 1151-23, Poland GTMAP for 2016, p. 12; ID 1151-36, Poland GTMAP for 2017, pp. 3, 13.

²⁹⁸⁹ ID 266-90, Teva's internal email dated 21 February 2017 from {...} to {...}; see also ID 265-844, COPAXONE@GA tenders, 5 April 2017, p. 16 (as quoted in footnote 2949).

²⁹⁹⁰ ID 4032, Teva's Reply to the Statement of Objections, paras. 1383, 1384, 1385.

- (2097) First, concerning evidentiary value of GTMAPs/Brand Plans, the Commission explains in Recital (1866) why they are credible strategic documents which inform of 24 October 2016 to the Polish Ministry Teva’s planned promotional and other activities.
- (2098) Second, the Commission’s assessment also relies on overall evidence on Teva’s strategy as explained in Sections 5.2.3, 5.2.4, 9.3.1, 9.3.2, 9.4.1.2, and 9.4.3, which detail Teva’s overall CCP strategy, and the communication campaign as its important component part (including an analysis of the misleading messages and its dissemination). Teva put in place, as part of the broader CCP strategy, a well-structured central communication campaign that aimed at disseminating the Misleading Complexity Message to the relevant stakeholders (Payers and HCPs) with a view to reducing competitive pressure from Synthon GA. To achieve this, Teva disseminated, as described above (Section 9.3.2), the Misleading Complexity Message to Payers and HCPs including KOLs. In particular, Teva created a set of centrally approved materials to be used across Europe to “educate” relevant stakeholders on its Misleading Complexity Message. These centrally created and approved materials were rolled-out to the Member States to support Teva’s communication with Payers, KOLs and HCPs with the strict instruction that “{...}” (see Recital (1828)). For Payers, Teva’s communication approach was included in the Payer White Paper, Payer Slide Presentation, Payer Objection Handler and Payer Q&A document. For KOLs and specialist neurologists, the approach was outlined in the two External Experts White Papers (MS specialist and non-specialist version) and the MSL objection handler. For other HCPs, the materials in addition included the Complexity of Copaxone and the GATE study review; and the Complexity and experience leavepiece. These documents were shared with teams in the Relevant Member States and were used for the training of various market-facing teams in Teva – Market Access, KAM and MSL teams. These teams also used these documents in their communications with HCPs and other stakeholders, either in their original form or in a “localised” mirror image of the centrally developed material. A slide, presented by an external consultant at a Teva workshop organised for Teva’s employees held in June 2017, emphasises the importance of localisation of the CCP materials and of their timely use: “{...}.”²⁹⁹¹
- (2099) Finally, Teva representatives were reporting and updating regularly the information concerning Synthon GA to the headquarters, including information on the status of implementation of Teva’s materials: “{...}”. A Teva internal document shows that, in Poland, all the materials have been implemented at that point in time when it was created.²⁹⁹²
- (2100) Teva essentially claims that the GTMAPs, including Teva’s efforts to protect Copaxone, do not go beyond the scope of competition on the merits, that they contain no evidence raising doubt as to the safety and efficacy of Synthon GA, but rather communicate the benefits of Copaxone in competing with other, non-GA DMTs.²⁹⁹³ The Commission rejects these claims. First, while it is normally legitimate for a company to anticipate the entry on the market of its competitors, the means to achieve this need to constitute competition on the merits. Second, GTMAPs show Teva’s plans to communicate on Copaxone’s “complexity”. For the reasons already

²⁹⁹¹ See Recital (1829).

²⁹⁹² ID 455-1432, FoGA questions- Validation, worksheet: Questions - attachment to ID 455-1429 Teva internal email dated 7 October 2016 from {...} to {...}.

²⁹⁹³ ID 4032, Teva’s Reply to the Statement of Objections, para. 1387.

explained²⁹⁹⁴, Teva’s communication on Copaxone’s “complexity” is closely tied to the dissemination of the Misleading Complexity Message, as also reflected by Teva’s CCP communication materials as described in Section 9.3.2.2. Finally, the fact that GTMAPs/Brand Plans also references to other topics does not exonerate Teva’s conduct in relation to Synthon GA.

- (2101) Teva claims that the advisory board did not serve to disseminate the Misleading Complexity Message, and aimed to gather HCPs’ views on issues such as substitution.²⁹⁹⁵ The Commission rejects these arguments. As explained in Recital (158), Teva sometimes organised “advisory boards”, where HCPs and KOLs were paid to attend and to (supposedly) advise Teva on commercial issues concerning Copaxone, that Teva in turn used as an opportunity to influence the way these HCPs and KOLs perceived Synthon GA.²⁹⁹⁶ As shown in Recital (2086), Teva used such events to communicate its message on the “{...}” of Copaxone, about the message that “{...}” (which would allegedly impact the quality of GA medicinal product, implying that Synthon GA is not therapeutically equivalent to Copaxone),²⁹⁹⁷ about other glatiramer-related substances and about the GATE study – corresponding to the three facets of the Misleading Complexity Message, regularly reoccurring in Teva’s communications.
- (2102) Teva claims that the Commission (i) has failed to prove the dissemination of misleading message to HCPs in Poland, also considering that {...} data has limited or no evidentiary value, (ii) that the average number of contacts with an HCP in Poland recorded in {...} is limited ({...} per year), and (iii) that pointing to training materials is insufficient to prove that such contacts were used to communicate misleading messages.²⁹⁹⁸ The Commission rejects these arguments, for the reasons explained in Recital (2069).

9.4.4.7.4. Conclusion

- (2103) As shown above, Teva’s conduct covered most, if not all, drivers of demand for GA in Poland. First, Teva disseminated the Misleading Complexity Message primarily to the Polish Ministry of Health and the competent tendering bodies in communications criticising automatic substitution and single procurements covering both Copaxone and Synthon GA, and the resulting price competition. Second, Teva’s campaign to influence individual prescription decisions by HCPs has been conducted by way of individual visits and organised meetings (including advisory boards).
- (2104) In view of the analysis made in this Subsection 9.4.4.7 and in Sections 9.4.1, 9.4.2 and 9.4.3, the Commission concludes that Teva’s dissemination of the Misleading Complexity Message in Poland was capable of directly or indirectly hindering and/or delaying Synthon GA’s market entry and uptake in Poland and therefore of producing exclusionary effects on the Polish GA market. Even more, it cannot be excluded that Teva’s conduct in Poland contributed to delaying the uptake of Synthon GA, since Alvogen could still not participate in all tenders for GA medicines because some tenders specified Copaxone as the only option for existing Copaxone patients.

²⁹⁹⁴ See Recitals (1539)-(1541) and (1637) et seq.

²⁹⁹⁵ ID 4032, Teva’s Reply to the Statement of Objections, paras. 1388, 1389.

²⁹⁹⁶ ID 455-837, Teva internal email dated 1 October 2014 from {...} to {...} and others; Teva internal email dated 9 October 2014 from {...} to {...} and others. For specific advisory boards see e.g. Recital (1435), or Recital (2086).

²⁹⁹⁷ ID 455-3412, Teva internal email dated 27 March 2017 from {...} to {...}.

²⁹⁹⁸ ID 4032, Teva’s Reply to the Statement of Objections, paras. 1390, 1391.

9.4.4.8. Teva's dissemination of the Misleading Complexity Message in Spain

- (2105) Synthon has entered a licensing agreement with Mylan (now Viartis) to commercialise Synthon GA in Spain. Mylan launched the 20 mg version of Synthon GA in February 2017 under the brand name Glatiramero Mylan. Mylan launched the 40 mg version of Glatiramero Mylan in June 2018.²⁹⁹⁹
- (2106) In order to hinder market entry and uptake of Synthon GA/Glatiramero Mylan and to avoid or delay the resulting price competition in Spain, Teva disseminated the Misleading Complexity Message to Payers and HCPs. For example, in the Copaxone Brand Plan for 2016, Teva estimated that the entry of Synthon GA would lead to an immediate price reduction of 20%.³⁰⁰⁰ Similarly, the Annual Operating Plan for 2016 estimates that the launch of Synthon GA 40 mg in May 2018 (termed as the “{...}”, which in fact materialised only a month later than in Teva's scenario) would lead to a “{...}”.³⁰⁰¹
- (2107) Teva's communication campaign under the CCP umbrella started before Synthon GA's entry in Spain. Already on 23 October 2014, during a meeting organised in order to “{...}”, Teva delivered a presentation which, *inter alia*, outlined the alleged complexity of “NBCDs”, the alleged failure of the regulatory pathways to appropriately account for this complexity, the issues occurring with Teva's own Protiramer project and Teva's position on what type of trial (including e.g. duration, endpoints, etc.) would be required to establish therapeutic equivalence between two GA products.³⁰⁰²
- (2108) The Copaxone Brand Plan for Spain for 2016 indicates that the “{...}” is one of the strategic projects for 2016³⁰⁰³ and that Teva should work towards “{...}”.³⁰⁰⁴ In order to achieve this, Teva planned to organise regional meetings in Madrid, Andalusia, Cataluña and Levante for the hospital pharmacists³⁰⁰⁵ and to discuss, *inter alia*, “{...}”. Planned speakers included KOLs, experts from {...}, as well as legal and regulatory experts.³⁰⁰⁶
- (2109) In anticipation of Synthon GA's entry in Spain in 2017, Teva planned to focus its CCP activities on those regional Payers and hospital Payers where there was a “{...}”.³⁰⁰⁷ In this context, by its letter of 12 May 2017 Teva asked AEMPS to take the appropriate legal steps to make sure that Synthon GA is not substitutable to Copaxone without the express approval of the prescribing physician. In this letter, Teva emphasised the (clinically irrelevant) structural differences between Copaxone and Synthon GA, thus questioning their therapeutic equivalence. Teva also noted that it was actually the manufacturing process that determined the safety and efficacy of these medicines, implying thus that Synthon GA's (different) manufacturing process cannot ensure the same results, and thus casting doubt on its safety, efficacy and therapeutic equivalence with Copaxone. Teva also argued that available regulatory

²⁹⁹⁹ ID 404-2134, Copaxone EU Litigation Internal Update, p. 6.

³⁰⁰⁰ ID 1151-46, Spain GTMAP for 2016, p. 4.

³⁰⁰¹ ID 1151-30, Spain AOP for 2018, p. 15.

³⁰⁰² ID 644-142, Teva's reply to the Article 18(2) Request of 3 June 2020, Presentations for the advisory board meeting of 23 October 2014.

³⁰⁰³ ID 1151-46, Spain GTMAP for 2016, p. 18.

³⁰⁰⁴ *Ibid*, p. 16.

³⁰⁰⁵ Copaxone and Synthon GA are only authorised for hospital use and are dispensed by hospital pharmacies (see Recital (89)).

³⁰⁰⁶ ID 1151-46, Spain GTMAP for 2016, p. 16.

³⁰⁰⁷ ID 1151-5, Spain GTMAP for 2017, p. 17. See also ID 1151-30, Spain AOP for 2018, p. 26.

pathways did not appropriately account for these differences and concluded that “{...}”.³⁰⁰⁸

- (2110) In addition, Teva focused on the pricing and reimbursement process for Synthron GA and on opposing the creation of a single reference group including both Copaxone and Synthron GA.³⁰⁰⁹ In its contacts with the authorities, Teva repeated arguments regarding the differences between Copaxone and Synthron GA, implying a lack of therapeutic equivalence in contradiction to the findings of the competent authorities. For example, in a letter dated 16 October 2017 to the Ministry of Health/DGCF, Teva explained that the results of new studies show “{...}” between Copaxone and Synthron GA and “{...}” about the immunogenicity of Synthron GA and about the reproducibility of its batches (i.e. of the consistency of its manufacturing process).³⁰¹⁰
- (2111) With respect to hospitals, Teva’s action plan stated the following objectives “{...}”,³⁰¹¹ “{...}”.³⁰¹²
- (2112) Also with respect to HCPs, Teva included all the facets of the Misleading Complexity Message in the presentation prepared and communicated to them.³⁰¹³ The objective of the presentation was to “[e]xplain the value of copaxone vs FoGAs”.³⁰¹⁴ Teva emphasised clinically irrelevant differences in GA structures and implied that differences between Copaxone and other glatiramer-related substances were relevant for Synthron GA, without reconciling this with the finding of therapeutic equivalence between the two products: “{...}”.³⁰¹⁵ Teva implied that health risks observed in other glatiramer-related substances equally apply to Synthron GA³⁰¹⁶: “{...}”.³⁰¹⁷ Teva also casted doubt about the validity of the GATE study claiming that there are inconsistencies in its results³⁰¹⁸: “{...}”³⁰¹⁹ and challenging the use of MRI as an appropriate end-point: “{...}”.³⁰²⁰
- (2113) Teva also prepared and used the document entitled “Analysis of the scientific evidence of COPAXONE and FoGA” to inform neurologists about the main

³⁰⁰⁸ ID 651-33, Teva’s letter to the Spanish Agency for Medicines and Medical Devices of 12 May 2017, pp. 3-7.

³⁰⁰⁹ See e.g. ID 455-3169, Teva internal email dated 6 January 2019 from {...} to {...} and others: “{...}”. See also, ID 455-3158, Teva internal email dated 25 November 2017 from {...} to {...}.

³⁰¹⁰ ID 910-49, Teva’s letter to the Spanish Ministry of Health of 16 October 2017, pp. 4-5.

³⁰¹¹ ID 4729-305, REUNIÓN CICLO EQUIPO MARKET ACCES/KAM, Granada, 10-13 December 2019, p. 39 – “{...}”.

³⁰¹² ID 4729-305, REUNIÓN CICLO EQUIPO MARKET ACCES/KAM, Granada, 10-13 December 2019, p. 41 – “{...}”.

³⁰¹³ ID 4919-32, Considering the value of COPAXONE® in an era of Follow-on Glatiramer Acetate, External Expert White Paper Non-Specialist, 6 May 2016, pp. 3, 4, 5; According to ID 4897, List of documents registered on Teva’s {...} platform, the document above was approved on 27 October 2016, with first recorded use on 15 November 2016 and reapproved on 2 September 2018.

³⁰¹⁴ ID 4897, List of documents registered on Teva’s {...} platform.

³⁰¹⁵ ID 4919-32, Considering the value of COPAXONE® in an era of Follow-on Glatiramer Acetate, External Expert White Paper Non-Specialist, 6 May 2016, p. 4.

³⁰¹⁶ Such claims are assessed in section 9.3.1.2.

³⁰¹⁷ ID 4919-32, Considering the value of COPAXONE® in an era of Follow-on Glatiramer Acetate, External Expert White Paper Non-Specialist, 6 May 2016, p. 4.

³⁰¹⁸ Such claims are assessed in Section 9.3.1.3.

³⁰¹⁹ ID 4919-32, Considering the value of COPAXONE® in an era of Follow-on Glatiramer Acetate, External Expert White Paper Non-Specialist, 6 May 2016, p. 5.

³⁰²⁰ ID 4919-32, Considering the value of COPAXONE® in an era of Follow-on Glatiramer Acetate, External Expert White Paper Non-Specialist, 6 May 2016, p. 5.

differences between Copaxone and Synthon GA.³⁰²¹ Teva emphasised clinically irrelevant differences in GA structures, thus casting doubt on Synthon GA's therapeutic equivalence with Copaxone: "{...}".³⁰²² Teva also challenged the GATE study: "{...}".³⁰²³

- (2114) Teva's Brand Plans for Spain for 2018, 2019, 2020 and 2021 include references to the implementation of CCP activities or to the dissemination of the Misleading Complexity Message (e.g. HCPs being "{...}") in support of a number of key tactics and strategic imperatives of Teva.³⁰²⁴ The Brand Plan for 2019 establishes a separate strategic imperative of "{...}" with the expansion of the CCP as one of the critical success factors.³⁰²⁵ In this context, the Copaxone Brand Plan for 2019 includes "{...}" as a key marketing project. According to Teva's plan, HCPs (neurologists, primary care professionals and pharmacies) were to be targeted with summaries of relevant articles outlining biological and chemical characteristics of Copaxone and Synthon GA.³⁰²⁶
- (2115) The Copaxone Brand Plan for 2020 sets "{...}"³⁰²⁷ while according to the Copaxone Brand Plan for 2021 "{...}" was one of Teva's key activities in 2021.³⁰²⁸ In this context, Teva recognised that the "{...}"³⁰²⁹
- (2116) According to the {...} data, in the period from 2015 to May 2021, Teva's MSL and sales representatives made altogether {...} direct contacts (either face-to-face visits or phone calls) with {...} HCPs in Spain labelled as *inter alia* Copaxone, GA or central nervous system products.³⁰³⁰ In addition, before December 2018, Teva used a different system for customer relationship management ({...}) in Spain, which recorded altogether {...} contacts with {...} HCPs in the period from 7 January 2015 to 12 December 2018.³⁰³¹ Taking into account the emphasis on the Misleading Complexity Message in the training materials prepared by Teva³⁰³² and in the Brand Plans for Spain, it is likely that these contacts were devoted, at least in part, to the dissemination of the Misleading Complexity Message.³⁰³³ Further, not all contacts are recorded mandatorily, and even for contacts for which documentation is mandatory there is no system in place which requires sales representatives and

³⁰²¹ ID 4969-5, Análisis de la evidencia científica de COPAXONE® y FoGA; According to ID 4897, List of documents registered on Teva's {...} platform, this document was approved on 14 November 2018 and reapproved on 20 September 2020 and with first recorded use on 3 December 2018. For the Commission's conclusions based on Teva's re-approval of this document in September 2020, see footnote 2571 above.

³⁰²² ID 4969-5, Análisis de la evidencia científica de COPAXONE® y FoGA, p. 10: "{...}".

³⁰²³ ID 4969-5, Análisis de la evidencia científica de COPAXONE® y FoGA, p. 12.

³⁰²⁴ See e.g. ID 1151-30, Spain AOP for 2018, p. 22; ID 1151-1, Spain GTMAP for 2019, p. 3; ID 1151-65, Spain GTMAP for 2020, p. 5.; ID 1151-49, Spain GTMAP for 2021, p. 6.

³⁰²⁵ ID 1151-1, Spain GTMAP for 2019, p. 3. Other critical success factors include a successful launch of the single dose disposable device and a development of the duplicate strategy.

³⁰²⁶ ID 1151-1, Spain GTMAP for 2019, p. 6.

³⁰²⁷ ID 1151-65, Spain GTMAP for 2020, p. 6. See also, ID 1151-49, Spain GTMAP for 2021, p. 10.

³⁰²⁸ ID 1151-49, Spain GTMAP for 2021, p. 5.

³⁰²⁹ Ibid, p. 9. For the analysis of the misleading character of Teva's assertions regarding Synthon GA manufacturing process, see e.g. Recital 9.3.1.1.3.2 and ff.

³⁰³⁰ ID 900-6 and ID 900-13, {...} data for Spain. For scope and reliability of {...} data see footnote 2326.

³⁰³¹ ID 800-10, {...} data for Spain and ID 799, email dated 24 June 2021 from Teva's external counsel to the European Commission.

³⁰³² See Section 9.3.2. In particular, Teva prepared materials for the members of its MSL team (notably the External Expert White Paper for MS specialists, the GATE Study Review and the MSL Objection Handlers) and for its KAMs, (notably KAM Objection Handlers).

³⁰³³ Just like in Belgium, inherent limitations in the available CRM data apply (see footnote 2478).

members of the MSL team to record calls, as also confirmed by Teva.³⁰³⁴ This suggests that the actual number of contacts between Teva and HCPs in Spain was likely higher than the number of contacts documented in the available data.

9.4.4.8.1. Teva's arguments and the Commission's assessment

- (2117) Teva claims that the Brand Plan for 2016 pre-dates the MA approval of Synthon GA in April 2016, and cannot be evidence for the alleged disparagement abuse.³⁰³⁵ The Commission rejects this argument, for the reasons already explained in Recital (2068).
- (2118) Teva claims that its statements are consistent with Teva criticising automatic substitution and that Commission's interpretation of its statements is erroneous and creates the impression that Teva's communication campaign in Spain was disparaging of Synthon GA. For example, the statement that Teva should work towards "{...}", does allegedly not disparage Synthon GA. These claims are misguided. Teva misconstrues the Commission statements and presents them in an incomplete manner. The above statements were used in the context of describing Teva's objectives in the context of its "{...}" – and not in the assessment of Teva's misleading messages disseminated in the framework of that campaign (see Recital (2108)). The campaign was to be pursued with, amongst others, regional meetings with KOLs and various experts to discuss "{...}". The Commission's assessment shows that, in pursuit of its objective to prevent automatic substitution in Spain, Teva sought to artificially differentiate Synthon GA from Copaxone by spreading its Misleading Complexity Message as assessed, for example, in Recitals (2109)-(2113).
- (2119) Teva claims that it sought to inform its recipients of the potential patient safety risks related to automatic substitution between different GA products, and that its communication was consistent with that. Teva also claims that it only interacted with the AEMPS regarding automatic substitution in a single letter dated 12 May 2017 in which it requested measures to prevent automatic substitution between Copaxone and Synthon GA.³⁰³⁶ The Commission rejects these arguments. First, as shown in Section 9.1 and Recitals (2106)-(2108), Teva's strategy had nothing to do with patients' safety, but was driven by pure economic reasons to avoid competition and keep high profits. Second, potential safety and efficacy issues should be addressed before competent pharmacovigilance bodies, and it is not up to the incumbent undertaking to "sow doubts" among Payers and HCPs in relation to a competing product. Third, the Commission does not take a position on whether or not the products should be found to be automatically substitutable in any given Member State. However, Teva's attempt to influence such decisions cannot be based on conduct that deviates from competition on the merits, such as Teva's misleading messages which sought to instil doubt as to Synthon GA's safety, efficacy, and therapeutic equivalence with Copaxone (as a condition precedent for any decision on automatic substitution).
- (2120) Teva claims that its letter to the AEMPS did not discredit the safety and efficacy of Synthon GA, but only underlined the need to avoid back and forth switching of patients between Copaxone and Synthon GA.³⁰³⁷ This argument is unfounded. First, Teva's letter contained statements challenging Synthon GA's therapeutic

³⁰³⁴ See footnote 2326 above.

³⁰³⁵ ID 4032, Teva's Reply to the Statement of Objections, para. 1396.

³⁰³⁶ ID 4032, Teva's Reply to the Statement of Objections, paras. 1397, 1398.

³⁰³⁷ ID 4032, Teva's Reply to the Statement of Objections, paras. 1400, 1401.

equivalence with Copaxone. For example, in its letter to the AEMPS Teva explicitly states that the therapeutic activity and the clinical effects depend to a large extent on the robustness of the manufacturing process, and also hinted to possible immunogenic effects.³⁰³⁸ Second, Teva had no evidence to support its stated concerns for patients' health. As noted in Recital (1514), Teva's own staff observed that it did not "{...}".³⁰³⁹ Third, Teva was well aware, or should have been aware, that compositional differences between Copaxone and Synthon GA were therapeutically irrelevant (see Section 9.3.1.1.3.3). Fourth, at any rate, Teva's internal documents show that Teva's main aim was to influence AEMPS against automatic substitution by raising issues related to the safety of Synthon GA and in particular due to (assumed) differences in safety/immunogenicity: "{...}".³⁰⁴⁰ The same message that Synthon GA posed health and safety risks is revealed in another Teva's internal message: "{...}".³⁰⁴¹ Both Teva internal and external advisors found such statements to be problematic³⁰⁴², and even disparaging.³⁰⁴³ Indeed, they are in direct contradiction with the successful conclusion of the Decentralised procedure for Synthon GA.

- (2121) Thus, Teva was targeting the characteristics of Synthon GA which had been a condition to the successful conclusion of its Decentralised Procedure. These characteristics were also a necessary precondition for Synthon GA's inclusion in a price reference group with Copaxone and for deciding on automatic substitution in Spain. If the Payers were misled with respect to these characteristics, this was also likely to affect their decision to include Synthon GA in a price reference group with Copaxone and to allow automatic substitution, or organise tenders for GA. Therefore, Teva's messages were capable of producing exclusionary effects.
- (2122) Teva claims that even the AEMPS acknowledged that regulatory procedures had been appeal-intensive and involved interactions with both laboratories.³⁰⁴⁴ Teva's claim is misguided. In fact, as explained by the AEMPS in its reply to the Commission, the AEMPS was referring to {...}.³⁰⁴⁵
- (2123) Teva claims that neither its letter to the Spanish Ministry of Health dated 16 October 2017 nor the two internal emails also mentioned in the same Recital (2110) did disparage Synthon GA.³⁰⁴⁶ Teva also claims that its statements were based on a peer-reviewed scientific publication and thus referring to evidence that was relevant for the on-going debate around potential patient safety risks arising from automatic substitution.³⁰⁴⁷ These arguments are unfounded. First, that Recital points to misleading messages in the letter that raise doubt as to Synthon GA's therapeutic equivalence with Copaxone. Second, the article to which Teva refers was actually authored by Teva's staff, served to support Teva's statements that quite directly contested the finding of therapeutic equivalence between Synthon GA and

³⁰³⁸ ID 651-33, Teva's letter to the Spanish Agency for Medicines and Medical Devices of 12 May 2017, p. 6.

³⁰³⁹ ID 404-2519, Teva internal email dated 29 May 2017 from {...} to hierarchy. See also ID 404-2367, Teva internal email dated 16 August 2017 from {...} to {...}: "{...}" (emphasis added).

³⁰⁴⁰ ID 404-912, Teva's internal email dated 22 September 2016 from {...} to {...}.

³⁰⁴¹ ID 404-2091, FoGA and P&R table.

³⁰⁴² See footnotes 2017 and 3039.

³⁰⁴³ See Section 9.3.1.1.3.3.

³⁰⁴⁴ ID 4032, Teva's Reply to the Statement of Objections, para. 1403.

³⁰⁴⁵ ID 4032, Teva's Reply to the Statement of Objections, para. 1403 and footnote 1428.

³⁰⁴⁶ ID 4032, Teva's Reply to the Statement of Objections, para. 1404.

³⁰⁴⁷ ID 4032, Teva's Reply to the Statement of Objections, para. 1405.

Copaxone: “{...}”³⁰⁴⁸ Further, Teva claimed that “{...}”³⁰⁴⁹ The differences were well known – they have been raised by Teva before the MEB, they have been taken into account by the MEB in its assessment and were rejected as unfounded by the MEB.³⁰⁵⁰ Teva failed to reconcile its claims with the findings of the MEB and continued to allude to purely theoretical safety risks without bringing adequate evidence.³⁰⁵¹ Third, the two emails Teva refers to and which are mentioned in the same Recital do not contain misleading messages as such but demonstrate that, contrary to Teva’s claims,³⁰⁵² the ultimate reasons behind Teva’s conduct were not related to patients’ health, but to restricting competition from Synthon GA. “{...}”³⁰⁵³ “{...}”³⁰⁵⁴

- (2124) Teva claims that the presentation mentioned in Recital (2107) pre-dates the period of infringement and should be used as context only and that, in any event, it does not contain misleading information.³⁰⁵⁵ Teva’s claims does not convince for the reasons explained in Section 9.3.1.4.3 above.
- (2125) Teva (i) claims that the Commission has failed to demonstrate that its communications with HCPs in Spain were misleading, (ii) claims that the evidence of its interactions with HCP is lacking³⁰⁵⁶, (iii) contests the Commission’s reliance on GTMAPs³⁰⁵⁷ and on {...} data, (pointing to an average of roughly {...} per HCP per year).³⁰⁵⁸ First, concerning the general evidentiary value of GTMAPs, the Commission explains in Recital (1866) why such Brand Plans are credible strategic documents which inform of Teva’s planned promotional and other activities. Moreover, the Commission’s assessment is based on the entirety of the available evidence, which can provide a broader context for the interpretation of GTMAPs/Brand Plans.³⁰⁵⁹ Finally, concerning {...} data, the Commission’s assessment in Recital (1996) applies as appropriate.
- (2126) Finally, Teva claims (i) that the references to Synthon GA in Teva’s materials reflect Teva’s allegedly legitimate efforts to protect the sales of Copaxone³⁰⁶⁰, (ii) that GTMAPs for Spain as such do not raise doubts as to the safety and efficacy of Synthon GA but show that Teva tried (allegedly) to communicate the benefits of Copaxone and differentiate it from non-GA first-line DMTs.³⁰⁶¹ The Commission rejects these arguments. First, the GTMAPs do contain evidence of Teva’s plan to disseminate misleading messages as illustrated in Recitals (2114) and (2115) which shows that Teva’s communication on “complexity” served to differentiate Copaxone

3048 ID 910-49, Teva’s reply to the Article 18(2) Request of 3 June 2021, pp. 4-5 (unofficial translation). Original text: “{...}”.

3049 ID 910-49, Teva’s reply to the Article 18(2) Request of 3 June 2021, pp. 4-5 (unofficial translation). Original text: “{...}”.

3050 See Section 9.3.1.1.3.

3051 See, for example, Recital (2120).

3052 ID 4032, Teva’s Reply to the Statement of Objections, para. 1405.

3053 Recital 1475 of the SO, and footnote 1691 of the SO; ID 455-3169, Teva internal email dated 6 January 2019 from {...} to {...} dated 6 January 2019.).

3054 ID 455-3158, Teva internal email dated 25 November 2017 from {...} to {...} dated 25 November 2017.).

3055 ID 4032, Teva’s Reply to the Statement of Objections, para. 1408.

3056 ID 4032, Teva’s Reply to the Statement of Objections, para. 1409.

3057 ID 4032, Teva’s Reply to the Statement of Objections, para. 1410.

3058 ID 4032, Teva’s Reply to the Statement of Objections, para. 1411.

3059 See, for example, Recital (2098).

3060 ID 4032, Teva’s Reply to the Statement of Objections, para. 1412.

3061 ID 4032, Teva’s Reply to the Statement of Objections, para. 1413.

from Synthon GA and was a commercial must win. This corresponds to Teva's standard "differentiation" narrative sowing doubts as to the therapeutic equivalence of the two GA products. Moreover, Teva's Copaxone Brand Plan for 2021 again points to the need for (artificial) differentiation and the use of the Complexity Leavepiece as described, for example, in Recital (2084), which contains misleading messages. For the remaining arguments, the reasons explained in Recital (2100) apply.

9.4.4.8.2. Conclusion

- (2127) As shown above, Teva's conduct covered most, if not all, drivers of demand for GA in Spain. First, Teva disseminated the Misleading Complexity Message primarily to AEMPS as well as the regional and hospital Payers in communications criticising the possibility of introducing automatic substitution and the creation of a single reference group including both Copaxone and Synthon GA. Second, dissemination of the Misleading Complexity Message to HCPs took place by way of individual visits and it was regularly included in Teva's Brand Plans for Spain.
- (2128) In view of the analysis made in this Subsection 9.4.4.8 and in Sections 9.4.1, 9.4.2 and 9.4.3, the Commission concludes that Teva's dissemination of the Misleading Complexity Message in Spain was capable of directly or indirectly hindering and/or delaying Synthon GA's market entry and uptake in Spain and therefore of producing exclusionary effects on the Spanish GA market.

9.4.5. Conclusion

- (2129) The Commission concludes that Teva's conduct was capable of producing exclusionary effects because (i) Teva targeted Payers and HCPs as key drivers of demand on the markets for GA (Section 9.4.1); (ii) Teva disseminated the Misleading Complexity Message capable of influencing Payers' and HCPs' decision-making and prescription behaviour (Section 9.4.2); (iii) in disseminating the Misleading Complexity Message, Teva relied on its special position on the market (Section 9.4.3) and (iv) the dissemination of the Misleading Complexity Message to Payers and HCPs had significant coverage in the Relevant Member States (Section 9.4.4.). Teva's dissemination of the Misleading Complexity Message therefore amounted to an anticompetitive disparagement campaign against Synthon GA.

9.5. Teva's conduct has no objective justification

- (2130) As shown above, Teva's conduct does not seek to disseminate in a balanced manner objective scientific knowledge. As a part of the CCP,³⁰⁶² the dissemination of Teva's Misleading Complexity Message (see Section 9.3.1), had the sole goal of avoiding the market erosion of Copaxone by hindering and/or delaying Synthon GA's market entry and uptake in the Relevant Member States.
- (2131) The purpose of Teva's communication campaign was twofold, seeking to prevent: (i) the generalised (generic-like) substitution of Copaxone,³⁰⁶³ and (ii) the switching of individual patients from Copaxone to Synthon GA³⁰⁶⁴ and, to achieve this purpose,

³⁰⁶² See Section 5.2.

³⁰⁶³ A decision on automatic substitution would have meant that it would have been possible to substitute Copaxone with Synthon GA at pharmacy level, which would have translated in a loss of market shares for Teva. A decision to include Synthon GA and Copaxone in the same reimbursement group would likely have had an impact on the price of Copaxone because Synthon GA would have competed with Copaxone in tenders.

³⁰⁶⁴ See Section 9.3.2

Teva communicated misleading messages related to the safety, efficacy of Synthron GA and its therapeutic equivalence with Copaxone. Already in 2013, Teva set as key objectives for the CCP (including its communication arm) to “{...}”.³⁰⁶⁵ A note to the presentation on “*EU CCP Strategy*” in 2017 makes the connection between the CCP efforts and the purpose of reducing the competitive pressure in rather unambiguous terms: “{...}” (emphasis added).³⁰⁶⁶

- (2132) Teva’s {...} made the connection between the Misleading Complexity Message and the purpose of reducing the competitive pressure in rather unambiguous terms in an internal email of 15 June 2018, when {they} included “{...}” as the most prominent among actions that Teva was “{...}”.³⁰⁶⁷
- (2133) Teva states that “*the issues raised by Teva specifically concerned repeated substitution without medical supervision between Copaxone and FoGAs, for which there was no data and which could have given rise to safety issues for patients*”.³⁰⁶⁸ Teva further argues that “*Teva was not trying to challenge issues that had been settled by the MA grant*” and that “*it did not challenge the safety and efficacy of FoGA per se*”.³⁰⁶⁹ In support of its arguments Teva relies on (i) detailed explanations concerning the “complexity” of Copaxone, the differences in GA structures and their possible impact on clinical results; (ii) experiences observed with respect to other glatiramer-related substances (including Teva’s own Protiramer) and (iii) alleged deficiencies in the GATE study.
- (2134) Teva’s arguments do not convince. First, as explained in this Decision, the Commission’s analysis is focused solely on the parts of Teva’s Misleading Complexity Message which directly question and contradict the findings of the competent authorities embodied in the successful completion of the Decentralised Procedure: that Synthron GA is safe and efficacious and therapeutically equivalent with Copaxone.³⁰⁷⁰ A type of information that the Commission found as objectively misleading is, for example, Teva’s claim that “{...}”³⁰⁷¹ which goes against basic findings of the competent authorities that Synthron GA “*can be regarded as therapeutic equivalent to the reference product. ‘Therapeutical equivalence’ means that the efficacy and safety of this hybrid formulation is similar to the efficacy and safety of the reference product Agreement on this conclusion was reached between Member States*”.³⁰⁷² The fact that these and similar statements were made in the context of the discussions on automatic substitution does not change their misleading character. Conversely the Commission’s analysis of the Misleading Complexity Message does not encompass Teva’s statements concerning whether specific conditions for automatic substitution have been met in a particular Member State or

³⁰⁶⁵ ID 455-796, Copaxone® Continuation Taskforce EU Kick-off meeting, 5 November 2013, p. 9.

³⁰⁶⁶ ID 455-823, Presentation by Teva’s {...} of March 2017, p. 9.

³⁰⁶⁷ ID 404-537, Teva internal email chain dated 15 June 2017 between {...} and {...}, Other actions “{...}” that Teva’s {...} included in the email were (in what appears to be a decreasing order of prominence): (i) batch analysis; (ii) legal: challenging MAs, patent enforcement, unfair competition cases and (iii) the SDD (single dose device) and duplicate.

³⁰⁶⁸ ID 1866, Teva’s spontaneous submission of 25 May 2022, p. 3.

³⁰⁶⁹ Ibid, p. 15.

³⁰⁷⁰ See Section 9.3.1

³⁰⁷¹ ID 262-724, Substitution considerations for follow on glatiramer acetate products, Meeting with Federal Agency for Medicines & Health Products, Brussels, 23 January 2017, p. 57; See also ID 651-21, Substitution considerations for follow on glatirameracetate products Meeting with Federal Agency for Medicines & Health Products Brussels, 23 January 2017.

³⁰⁷² ID 455-2843, Public Assessment Report Brabio, p. 17.

Teva's statements regarding the alleged lack of evidentiary basis for allowing automatic substitution (e.g. Teva's critique of the GATE extension study).

- (2135) Second, Teva's submission includes a number of inconsistencies with the evidence available on the file or with Teva's previous submissions. For example, Teva alleged that the focus of its communication campaign was the GATE extension study and strives to explain Teva's position thereon. However, this contradicts the ample evidence clearly demonstrating that Teva's Misleading Complexity Message targeted the soundness of the first, double-blind part of the study and the validity of conclusions based on this part of the GATE study, most notably, the conclusion on therapeutic equivalence and the safety and efficacy of Synthron GA.³⁰⁷³
- (2136) In addition, Teva explains that its concerns and its communication with the health care authorities were informed by "*Teva's experience that changes in the composition of GA could result in possibly immune-mediated safety issues*". Teva now paints a picture of the safety issues observed with TV-5010³⁰⁷⁴ being of unknown origin but possibly related to the immunogenicity of the compound, of Protiramer's "*manufacturing process [being] only marginally different from that of Copaxone*" and of, therefore "*Teva [having] reason to have serious concerns that differences between GA products might impact its immunogenic properties*". Teva claims that "[a]lthough the results [of investigations seeking to establish that Protiramer's issues were immune-mediated] were not conclusive (and Teva still does not know the exact reason for these responses, despite various investigations), the fact that Teva initially thought that these issues were related to GA's immunogenic properties shows that there were genuine concerns that even small changes in the manufacturing process of GA might give rise to immunogenicity issues" (emphasis added).³⁰⁷⁵
- (2137) However, these arguments by Teva contradict the evidence available on the Commission's file as well as other submissions by Teva. In the first place, TV-5010 and its effects were not simply a result of "*marginal*" differences in the manufacturing process, but rather of a deliberate and conscious experiment assessing whether higher molecular weight of polypeptides (than that of Copaxone and Synthron GA) may lead to an increased efficacy in treatment of the MS (see Recital (1595)). In the second place, toxicity issues associated with TV-5010 due to its higher molecular weight cannot occur with respect to Copaxone, or its therapeutic equivalent Synthron GA, because of the fixed range of the molecular weight. As explained in Recital (1596), Teva knew since 1988 that there is a correlation between the molecular weight and the toxicity.³⁰⁷⁶ TV-5010 had a molecular weight range of 11,000 to 25,000 Daltons.³⁰⁷⁷ By contrast, the molecular weight of both Copaxone and Synthron GA is limited to 5,000 to 9,000 Daltons, which is exactly the range that Teva identified as providing "*the best chance of providing [glatiramer acetate] that was non-toxic and active*".³⁰⁷⁸ Finally, the references to TV-5010 had been

³⁰⁷³ See Section 9.3.1.3.

³⁰⁷⁴ For an explanation of what TV-5010 (also referred to as Protiramer) is, see Section 9.3.1.2 above.

³⁰⁷⁵ ID 1866, Teva's spontaneous submission of 25 May 2022, pp. 8, 9, 11.

³⁰⁷⁶ ID 906, Teva's reply to the Article 18(2) Request of 3 June 2021, p. 37.

³⁰⁷⁷ Ibid, p. 40.

³⁰⁷⁸ Ibid, pp. 37, 38 and 40.

questioned already in 2014 by Teva’s then {...} who confirmed that: “{...}” (emphasis added).³⁰⁷⁹

- (2138) Third, Teva explains that the communication campaign concerning Synthon GA was driven by concerns regarding “*uncontrolled back-and-forth substitution*” and possible safety issues that could result from automatic substitution with Copaxone “*without physician’s supervision*”.³⁰⁸⁰ This cannot be accepted for the following reasons.
- (2139) In the first place, Teva’s claim contradicts extensive evidence on the commercial nature of Teva’s disparagement campaign, which was implemented to protect Copaxone revenues and reduce the competitive pressure from Synthon GA (see Section 9.1). For example, Teva’s Strategic Brand Plan for 2016, the year of Synthon GA’s entry, clearly states that the ultimate objective of Teva’s communications with Payers (via Teva’s Market Access teams) was not to raise genuine health issues, but to protect the price of Copaxone: “{...}” (emphasis added).³⁰⁸¹ Internal documents also revealed that the real objective behind Teva’s participation in the alleged “{...}” was to “{...}”.³⁰⁸²
- (2140) In the second place, this Decision explains that Teva’s Misleading Complexity Message was targeting Synthon GA’s safety, efficacy and therapeutic equivalence with Copaxone, which were a condition to the successful conclusion of its Decentralised Procedure and had been the subject-matter of findings made by the competent authorities – even when Teva’s message was purportedly targeting automatic substitution (“*uncontrolled back-and-forth substitution*” in Teva’s language). These characteristics of safety, efficacy and therapeutic equivalence were also a necessary precondition for automatic substitution. If the Payers were misled with respect to these characteristics, this was also likely to affect their decision to allow automatic substitution, or organize tenders for GA. In the third place, Teva’s claim also contradicts evidence showing that Teva was aware or should have been aware of the misleading nature of its statements.³⁰⁸³ In addition, these arguments by Teva fail to explain the extensive disparagement efforts focused on the physicians that are not in charge of the decisions regarding automatic substitution. In addition, it is not clear how Teva’s disparagement campaign targeting HCPs may alleviate Teva’s concerns regarding “*uncontrolled*” substitution and substitution “*without physician’s supervision*” when it is the HCPs who are indeed tasked to provide the level of control that Teva pleads for.
- (2141) Fourth, Teva’s communication campaign went against Teva’s own guidance, as confirmed by Teva’s instructions for KAM and MSL staff not to “{...}”, not to “{...}” and instead “{...}”.³⁰⁸⁴

³⁰⁷⁹ ID 404-2432, Teva FoGA White Paper, Copaxone and Follow-on Glatiramoids (“FoGAs”), briefing document, p. 9.

³⁰⁸⁰ ID 1866, Teva’s spontaneous submission of 25 May 2022, pp. 6-7.

³⁰⁸¹ ID 455-2276, COPAXONE® EU STRATEGIC BRAND PLAN, 29 March 2016, pp. 33, 34.

³⁰⁸² ID 404-2017, Teva internal email dated 27 October 2014 from {...} to {...} and others regarding “*Afspraken tactics plan CPX 20*” (unofficial translation). Original text: “{...}”.

³⁰⁸³ For example, as late as in June 2019, Teva’s {...} confirmed that “{...}” and that “{...}” (ID 455-3357, Teva internal email of 7 June 2019 from {...} to the members of Teva’s medical team). See also other evidence quoted in the Recitals (1582) and (1583).

³⁰⁸⁴ See Recital (1789) above and the evidence cited therein, including ID 262-1275, Plan of Action - In the face of evolving FoGA competition, pp. 13, 14.

(2142) Finally, even if one would accept (*quod non*) Teva's arguments that its communication campaign disseminating the Misleading Complexity Message had been made in the interest of public health, it is long settled case-law that it is not for the dominant firm (such as Teva) to venture into protecting public health against alleged risks from competitor products (such as Synthon GA).³⁰⁸⁵ The Court of Justice expressly recalled this principle specifically in the context of actions of disparagement concerning medicinal products.³⁰⁸⁶ Teva did not follow proper pharmacovigilance procedures to challenge these findings before the competent authorities, instead targeting HCPs and Payers. Moreover, Teva never submitted any evidence that would corroborate its claims concerning health and safety issues related to Synthon GA. In light of the above, the Commission concludes that Teva's disparagement campaign against Synthon GA had no objective justification.

9.6. Conclusion: Teva's conduct constitutes an abuse of its dominant position

(2143) Based on the analysis in the preceding Sections, the Commission finds that Teva's Complexity Message included objectively misleading information, i.e. inaccurate or incomplete information capable of confusing Payers and HCPs (including by inducing them in error), that was capable of discrediting Synthon GA (Section 9.3.1); and that Teva put in place effective mechanisms for the dissemination of the Misleading Complexity Message to Payers and HCPs in the Relevant Member States (Section 9.3.2).

(2144) The Commission also established that Teva's conduct was capable of producing exclusionary effects because (i) Teva targeted Payers and HCPs as key drivers of demand on the markets for GA (Section 9.4.1); (ii) the Misleading Complexity Message was capable of influencing their decision-making and prescription behaviour (Section 9.4.2); (iii) in disseminating the Misleading Complexity Message, Teva relied on its special position on the market (Section 9.4.3) and because (iv) dissemination of the Misleading Complexity Message to Payers and HCPs had significant coverage in the Relevant Member States (Section 9.4.4.). Finally, the Commission established that there was no objective justification for Teva's communication campaign disparaging Synthon GA (Section 9.5).

(2145) In view of the foregoing, the Commission has reached the conclusion that Teva's conduct does not constitute competition on the merits and has the capability to produce exclusionary effects without being objectively justified. Such conduct amounts to an abuse of Teva's dominant position in the relevant markets for GA in Belgium, Czechia, Germany, Italy, the Netherlands, Poland and Spain by means of an elaborate disparagement campaign against Synthon GA.

³⁰⁸⁵ See Case T-30/89, *Hilti v Commission*, paragraphs 115-119. Applicable legal rules also make it clear that pharmacovigilance is the responsibility of a MA holder (such as Synthon or Mylan) rather than of its closest competitors. See. e.g. Article 21 and ff of Regulation (EC) No 726/2004 of the European Parliament and of the Council of 31 March 2004 laying down Community procedures for the authorisation and supervision of medicinal products for human and veterinary use and establishing a European Medicines Agency (OJ L 136, 30.4.2004, p. 1-33) and Article 104 and ff. of Directive 2001/83/EC of the European Parliament and of the Council of 6 November 2001 on the Community code relating to medicinal products for human use (OJ L 311 28.11.2001, p. 67).

³⁰⁸⁶ See Case C-179/16, *F. Hoffmann-La Roche and Others*, paragraph 91.

10. EFFECTS ON TRADE

10.1. Principles

- (2146) Article 102 of the Treaty prohibits as incompatible with the internal market an abuse of a dominant position “*in so far as it may affect trade between Member States*”.
- (2147) The effect on trade criterion consists of three elements.³⁰⁸⁷
- (2148) First, “*trade between Member States*” must be affected. The concept of trade is not limited to traditional exchanges of goods and services across borders, but covers all cross-border economic activity. It also encompasses practices affecting the competitive structure of the internal market by eliminating or threatening to eliminate a competitor operating within the territory of the European Union.³⁰⁸⁸
- (2149) Second, a practice must be “*capable of having an effect*” on trade between Member States.³⁰⁸⁹ In other words, it must be foreseeable with a sufficient degree of probability on the basis of a set of objective factors of law or fact that the practice in question has an influence, direct or indirect, actual or potential, on the pattern of trade between Member States.³⁰⁹⁰ Where a dominant undertaking engages in exclusionary conduct in more than one Member State, such conduct is normally, by its very nature, capable of affecting trade between Member States.³⁰⁹¹
- (2150) Third, the effect on trade between Member States must be “*appreciable*”. This is assessed primarily with reference to the position of an undertaking on a relevant product market.³⁰⁹² The stronger the position of an undertaking, the more likely it is that the effect on trade between Member States of a practice will be appreciable.³⁰⁹³

10.2. Application to the present case

- (2151) In the present case, Teva’s behaviour had an effect on trade.
- (2152) The first abuse is exclusionary in nature in that it was capable of excluding (or at least delaying) generic-like competition in the market concerned and in certain instances actually did produce such effects. The prolonged legal uncertainty due to Teva’s conduct was in itself capable of preventing or delaying the market entry of Synthron GA in the entire EEA. These effects became even more pronounced where, based on the patents that Teva shielded from timely and effective legal review, Teva launched warning letters and infringement actions, which in a number of cases led to the granting of preliminary injunctions. For example, by obtaining a preliminary injunction based on process patents in Czechia, Teva’s actions caused an effective shutdown of the production of the active pharmaceutical ingredient (API), and thus

³⁰⁸⁷ Guidelines on the effect on trade concept contained in Articles 81 and 82 of the Treaty, OJ C 101, 27.4.2004, p. 81, point 18.

³⁰⁸⁸ Joined Cases 6/73 and 7/73 *Istituto Chemioterapico Italiano and Commercial Solvents Corporation v Commission*, EU:C:1974:18, paragraphs 32-33; Joined Cases T-24/93 and others, *Compagnie Maritime Belge v Commission*, EU:T:1996:139, paragraph 203.

³⁰⁸⁹ Case C-322/81, *Michelin v Commission*, paragraph 104; Judgement of the Court of 23 April 1991, *Höfner and Elser*, C-41/90, EU:C:1991:161, paragraph 32; and Judgement of the Court of First Instance of 7 October 1999, *Irish Sugar v Commission*, T-288/97, EU:T:1999:246, paragraph 170.

³⁰⁹⁰ Judgment of the Court of Justice of 9 July 1969, *Voelk*, C-5/69, EU:C:1969:35, paragraph 5/7.

³⁰⁹¹ Guidelines on the effect on trade concept contained in Articles 81 and 82 of the Treaty, OJ C 101, 27.4.2004, p. 81, paragraph 75.

³⁰⁹² Case C-5/69, *Voelk*, paragraph 5/7.

³⁰⁹³ Judgment of the Court of First Instance (Second Chamber) of 1 April 1993, *BPB Industries Plc and British Gypsum Ltd v Commission*, T-65/89, EU:T:1993:31, paragraph 138.

disrupted Synthon's supply chains for the production and supply of Synthon GA for the entire EEA (see Recital (143)).

- (2153) By preventing, or at least delaying, Synthon GA's entry and expansion on the market, Teva affected the economic activities in which its competitor was engaged. Teva's practice thus had an effect both on trade and on the competitive structure.
- (2154) The second abuse is also exclusionary in nature as Teva's campaign was capable of excluding competition by dissuading healthcare organisations and professionals from switching prescriptions from Copaxone to Synthon GA. Teva's campaign covered the entire EEA and was implemented at the level of individual Member States as set out above in Section 9.3.2 and Section 9.4.4. It sought to influence individual prescriptions of GA on a sufficiently large scale by not only targeting HCPs, but also other actors influencing the demand for Copaxone, such as insurance funds, pricing and reimbursement authorities and other healthcare organisations. By instilling doubt in relation to Synthon GA's safety, efficacy and its therapeutic equivalence with Copaxone, Teva's conduct was capable of impacting doctors' decisions to switch patients from Copaxone to competing GA.
- (2155) As such, Teva's campaign was capable of affecting demand for Synthon GA in the Relevant Member States and thus had an impact on trade between Member States.
- (2156) Moreover, due to external reference pricing rules, hindering market entry or expansion in one Member State may affect prices in other Member States. Price cuts for the originator medicine that result from generic-like price competition often lead to price cuts in other Member States which use the prices in the other Member States as a benchmark. Delaying market entry in one Member State therefore has broader effects on the price level for GA across Europe and leads to an additional effect on trade between Member States. Teva, as dominant undertaking, engaged in these two exclusionary conducts (misuse of divisional patents and exclusionary disparagement) in at least seven Member States – Belgium, Czechia, Germany, Italy, the Netherlands, Poland and Spain. Such abuses are by their very nature capable of affecting trade between Member States.³⁰⁹⁴
- (2157) Finally, in view of Teva's strong position in the Relevant Member States where it was selling Copaxone, the potential impact on trade can be said to be appreciable.

11. SINGLE AND CONTINUOUS INFRINGEMENT

11.1. Principles

- (2158) The concept of a single and continuous infringement relates to a series of actions which form part of an overall plan because their identical objective distorts competition within the internal market.
- (2159) For the purposes of characterising various instances of conduct as a single and continuous infringement, it is not necessary to ascertain whether they present a link of complementarity, in the sense that each of them is intended to deal with one or more consequences of the normal pattern of competition, and, through interaction, contribute to the attainment of the set of anticompetitive effects desired by those responsible, within the framework of a global plan having a single objective. By contrast, the condition relating to a single objective requires that it be ascertained

³⁰⁹⁴ Guidelines on the effect on trade concept contained in Articles 81 and 82 of the Treaty, OJ C 101, 27.4.2004, p. 81, point 75.

whether there are any elements characterising the various instances of conduct forming part of the infringement which are capable of indicating that the instances of conduct do not form part of an “overall plan” as a result of their identical object distorting the normal pattern of competition within the internal market. In that regard, it is necessary to take into account any circumstance such as the period of application, the content (including the methods used) and, correlatively, the objective of the various actions in question.³⁰⁹⁵

11.2. Application to the present case

(2160) For the reasons set out in Chapters 6 to 9, the following conducts constitute, each of them separately, infringements of Article 102 TFEU:

- Teva’s misuse of divisional patents; and
- Teva’s exclusionary disparagement.

(2161) For the reasons set out in the following Recitals, the Commission further concludes that these different forms of conduct described in Chapters 8 and 9 together constitute a single and continuous infringement of Article 102 TFEU.

(2162) First, both forms of conduct described in Chapters 8 and 9 **pursue an identical objective**, namely to protect or strengthen Teva’s dominant position on the GA market and thus to protect its revenues derived from Copaxone, by hindering and/or delaying market entry of competing GA on the market and eliminating price competition. As noted with respect to the misuse of divisional patents, Teva’s divisional strategy served to “{...}”³⁰⁹⁶ and was part of Teva’s “{...}”³⁰⁹⁷ for Copaxone. It was designed to prolong the exclusivity of Copaxone artificially. Similarly, as regards the disparagement abuse, as Teva’s {...} stated internally, the aim of the Copaxone communication plan was to “{...}”³⁰⁹⁸. Both of Teva’s abuses were included in the “{...}”³⁰⁹⁹ part of the CCP. They were orchestrated with a high degree of centralisation and coordination by the CCP legal team in coordination with the regulatory team, all within the CCP Taskforce.³¹⁰⁰ Therefore, the two separate infringements described in Chapters 8 and 9 form together a single and continuous infringement joined by a common, overall plan in pursuit of a single anticompetitive aim.

(2163) Second, the different actions undertaken by Teva **were complements** to protect and strengthen Teva’s dominant position on the GA market and thus its revenues derived from Copaxone, by hindering and/or delaying market entry of competing GA on the market and eliminating price competition.³¹⁰¹ In that respect, the Commission

³⁰⁹⁵ Judgment of the Court (Fourth Chamber) of 19 December 2013, *Siemens AG and Others v European Commission*, Joined Cases C-239/11 P, C-489/11 P and C-498/11 P, EU:C:2013:866, paragraphs 247-248.

³⁰⁹⁶ ID 455-1784, Teva internal email dated 24 June 2012 from {...} to {...} and others, concerning “Copaxone defence europe”, p. 1.

³⁰⁹⁷ ID 455-2502, Teva internal email dated 14 April 2016 from {...} to {...}, p. 1.

³⁰⁹⁸ ID 404-2017, Teva internal email dated 27 October 2014 from {...} to {...} and others regarding “*Afspraken tactics plan CPX 20*” (unofficial translation). Original text: “{...}”.

³⁰⁹⁹ See Recital (123).

³¹⁰⁰ CCP Taskforce was set up in 2013 and comprised of multidisciplinary representatives from various Teva departments dealing with Copaxone, including Market Development, Medical LCI, Market Access, Governmental Affairs, Legal, Patient Services, Regulatory, CI, Branded Biosimilars, Generics, Compliance, see ID 455-801, Copaxone Continuation Taskforce EU – Kick-off meeting, 5 November 2013, p. 10. See also Section 5.2.4.

³¹⁰¹ For overview of complementarity of various CCP activities see Section 5.2.4.1 and Section 5.2.5.

considered the following elements. The strategy to file and enforce divisional patents as well as the comprehensive campaign to disseminate misleading information were included among the main pillars of the CCP³¹⁰² and were instrumental to attain the CCP objectives (i.e. to protect Copaxone's market position) on two levels. In the first place, the repeated cycles of filing, enforcing and withdrawing several parent and divisional patents before the EPO were designed to prevent market entry of competing GA by obstructing and delaying the legal review of the validity of Copaxone's patent protection and artificially prolonging legal uncertainty. In the second place, once the market entry nevertheless became imminent or actually took place, the elaborate disparagement campaign aimed at hindering and/or delaying Synthon GA's uptake on the EU markets by misleadingly casting doubts on the essential characteristics of Synthon GA – its safety, efficacy and therapeutic equivalence with Copaxone.

12. DURATION OF THE INFRINGEMENTS

12.1. First abuse: misuse of divisional patents

- (2164) The infringement described in Chapter 8 started in all the Relevant Member States on 3 February 2015, when Teva withdrew the approval for the text of its process patent EP '703 (the parent patent in the process patent family).
- (2165) Teva argues that the fact that the patent filings are not problematic from a competition law perspective is implicitly acknowledged by taking the first withdrawal (that of EP '703) as a starting point of the infringement. According to Teva, had the filings genuinely raised competition issues, the starting point of the abuse would be the filing of the first divisional, EP '528, in January 2010.³¹⁰³ However, the fact that the infringement started with the first withdrawal does not mean Teva's staggered patent filings are not problematic. To the contrary, as demonstrated in Section 8.3.1, Teva's comprehensive patenting behaviour consisted of a combination of staggered filings and strategic withdrawals of patents before a reasoned decision on their validity could be reached. It is precisely because Teva's conduct is assessed in its entirety that the first withdrawal is considered as the starting point of the infringement. The first withdrawal was therefore the tipping point of Teva's conduct. Had Teva not withdrawn the patent, the divisionals game, as assessed in this Decision, would not have taken shape. Therefore, the Commission considered that the infringement started when both constituent elements of the conduct were in place: with the first withdrawal. This Decision does not take a position on whether Teva's staggered filing of divisional patent applications could in itself constitute an infringement of Teva's dominant position pursuant to Article 102 TFEU.
- (2166) The infringement in Belgium, Czechia, Germany and Spain ended on 7 February 2024 when the TBA effectively revoked EP '962 and EP '172, the last of Teva's divisional patents remaining in those Relevant Member States (see Section 8.3.2.1). The infringement in Italy ended on 31 December 2021 and in Poland on 31 December 2022 on the last day of Teva holding a dominant position on the GA markets in Italy and Poland, respectively (see Section 7.3). The infringement in the

³¹⁰² Teva repeatedly referred to "pillars of the CCP", although the exact delimitation and number of these varied, see ID 263-26, COPAXONE®/ FoGA, Overview Pricing and Market Access, 15 February 2017, p. 3; ID 455-473, EU COPAXONE Continuation Project Strategy, March 2017, p. 9.

³¹⁰³ ID 4032, Teva's Reply to the Statement of Objections, para. 786.

Netherlands ended on 4 April 2017 when the deadline for the national validation of EP ‘335 lapsed. Teva did not validate EP ‘335 in the Netherlands and had previously withdrawn the Dutch designation of the dosage divisional EP ‘962 on 26 January 2017. As a consequence, Teva did not hold any patents in the Netherlands (see Recitals (1405)-(1409)).

- (2167) Teva argues that the conduct constituting misuse of divisional patents “*however [it] is envisaged, [...] necessarily stopped a long time ago*”.³¹⁰⁴ In this context Teva maintains that (i) filings of divisional patents as well as Teva’s actions in enforcing and defending them were legitimate and cannot be considered as being part of an abuse and that (ii) the last withdrawal by Teva of a patent dates back to February 2017.³¹⁰⁵ Teva’s arguments do not convince.
- (2168) First, the Commission recalls that it is well-established case-law of the Court of Justice that exercising patent rights is not exempt from the application of competition law and may amount to abusive conduct within the meaning of Article 102 TFEU.³¹⁰⁶ The Commission has also demonstrated that Teva was not simply exercising its intellectual property rights but rather engaged in an elaborate misuse of divisional patents (see Section 8.3).
- (2169) Second and as demonstrated above, based on the evidence in the Commission’s file, Teva’s conduct constituting the misuse of the patent system, consisted of a comprehensive strategy combining staggered patent filings and repeated strategic withdrawals obstructing the effective legal review of these patents and prolonging legal uncertainty concerning their validity. It is the combination of filings and withdrawals that was capable of hindering and/or delaying market entry and uptake of competing GAs on the market and eliminating price competition. Accordingly, Teva’s claim to assess the patent filings and withdrawals separately cannot be accepted (see Sections 8.3.1 and 8.3.2).
- (2170) In addition, the developments regarding a preliminary injunction in Germany illustrate why it would be incorrect to refer to the moment of the last withdrawal as the end date of the infringement. As detailed above (see Recital (1373)(1373)), Teva first requested a preliminary injunction based on the EP ‘335 from the Regional Court in Munich on 6 December 2017, which request was finally rejected by the Higher Regional court in Munich on 4 April 2018 *inter alia*, due to essential similarity between EP ‘335 and EP ‘749. However, as soon as the OD upheld EP ‘335 in the opposition proceedings, which was made possible by an absence of a reasoned revocation decision on EP ‘749 due to Teva’s withdrawal,³¹⁰⁷ Teva moved again to enforce the patent against Synthon GA and obtained a preliminary injunction based on EP ‘335 from the Regional Court in Düsseldorf on 14 June 2019.³¹⁰⁸ It follows that while the withdrawal of EP ‘749 occurred in

³¹⁰⁴ ID 4032, Teva’s Reply to the Statement of Objections, para. 1436.

³¹⁰⁵ ID 4032, Teva’s Reply to the Statement of Objections, paras. 1433-1435.

³¹⁰⁶ Judgment of the Court of Justice of 31 October 1974, *Centrafarm BV and Adriaan de Peijper v Sterling Drug Inc*, C-15/74, EU:C:1974:114, paragraphs 7-9. Judgment of the Court of Justice of 29 April 2004, *IMS Health*, C-418/01, EU:C:2004:257, paragraph 35; C-170-13, *Huawei Technologies*, paragraph 47.

³¹⁰⁷ The confirmation of EP ‘335 in the opposition proceedings should be contrasted with OD’s decisions on EP ‘962 and EP ‘172 where the OD benefited from the earlier reasoned revocation decision on EP ‘335. Following a formal revocation of EP ‘335, which occurred only after the competent court in Germany ordered Teva to abstain from withdrawing the approval of the text of EP ‘335, EP ‘962 and EP ‘172 were immediately revoked by the OD, unlike in all previous cases (see Section 8.3.3.5).

³¹⁰⁸ On 30 September 2020, after the revocation of EP ‘335 by the TBA (owing to another injunction preventing Teva from withdrawing the EP ‘335 patent), Teva simply waived the preliminary injunction

February 2017, Teva was able to continue to enforce its patents in the dosage family, beyond such date, which in turn served to exclude competing GAs from the market.

- (2171) Based on the evidence in the Commission’s file, Teva actively defended its two remaining dosage divisionals (EP ‘962 and EP ‘172) until the final TBA decision confirming their invalidity. Teva also maintained their validity in the relevant Member States by payment of the relevant fees until that final TBA decision. Teva thus ensured that it “{...}”³¹⁰⁹ until 7 February 2024. This date should be therefore taken as the last date of the first abuse in all of the Relevant Member States, except for the Netherlands, Italy and Poland where specific circumstances warrant the conclusion that the infringement ended earlier (see Recital (2164)).

12.2. Second abuse: exclusionary disparagement

- (2172) The infringement described in Chapter 9 started in all the Relevant Member States on 12 April 2016, the date on which the successful conclusion of the Decentralised Procedure for the approval of Synthon GA was publicly announced. In the Decentralised Procedure it was established that Synthon GA was safe and efficacious and therapeutically equivalent to Copaxone. At least from this date, it was clear that Teva’s claims before the authority responsible for the Decentralised Procedure had been rejected, that Synthon GA’s safety, efficacy and therapeutic equivalence had been established by the competent authority, and that the Misleading Complexity Message contradicted these findings (see Section 9.3.1).
- (2173) As to the end date of the infringement, the Commission’s file includes evidence on the use of centrally created CCP documents at least until 2020.³¹¹⁰ Furthermore, the Misleading Complexity Message was referred to in Teva’s brand plans at least until 2021 and in this period (i.e. at least until 2021) Teva’s staff (Market Access, MSL and KAM teams) had a high number of direct contacts with Payers and HCPs across the Relevant Member States, a number of which was directly linked to the competing GAs (in Teva’s terminology “FoGAs” – effectively only Synthon GA).³¹¹¹ The Commission also notes that Teva never implemented any corrective measures with respect to the dissemination of its Misleading Complexity Message.
- (2174) However, the Commission takes a conservative approach and concludes that the infringement in a Relevant Member States ended on the date of the last available evidence of dissemination of the disparaging message in each individual Relevant Member State, based on the records in Teva’s central database (called {...}) related to the approval and use of Teva’s communication materials. Accordingly, the Commission concludes that the infringement ended on 8 August 2017 in Poland,³¹¹² on 18 August 2017 in Czechia,³¹¹³ on 11 March 2019 in Belgium,³¹¹⁴ on 24 March

issued by the Regional Court in Düsseldorf and did not request further preliminary injunctions based on two other dosage patents (EP ‘962 and EP ‘172).

³¹⁰⁹ ID 404-2555, Teva internal email dated 16 March 2016 from {...} to {...} and others, p. 1.

³¹¹⁰ See Section 9.3.2.2.2.

³¹¹¹ See Section 9.4.4.

³¹¹² The excerpt from Teva’s internal database shows that Teva’s promotional leavepiece (leaflet) and presentation including the Misleading Complexity Message were used and disseminated and reapproved on 8 August 2017 (ID 4919-26, FoGA ulotka - zapoznaj się bliżej z Copaxone, September 2016; ID 4919-38, Prezentacja Copaxone – ‘Skomplikowana cząsteczka – nieskomplikowana terapia’, April 2017 and ID 4897, List of documents registered on Teva’s {...}).

³¹¹³ The excerpt from Teva’s internal database shows that a Leaflet (leavepiece) “Complexity of Copaxone” including the Misleading Complexity Message was used and disseminated and that it was reapproved on 18 August 2017 in Czechia (ID 4919-25, Complexity of Copaxone, 18 August 2016 and ID 4897, List of documents registered on Teva’s {...}).

2020 in Germany,³¹¹⁵ on 20 September 2020 in Spain,³¹¹⁶ and on 20 October 2020 in Italy.³¹¹⁷ The infringement in the Netherlands ended on 31 December 2018, the last day of Teva holding a dominant position on the GA market in the Netherlands.³¹¹⁸

12.3. Duration of the single and continuous infringement

- (2175) The start date of the single and continuous infringement is 3 February 2015. This is because since that date, Teva: (i) has been found to hold a dominant position in the GA market in the Relevant Member States; and (ii) has been engaged in the single and continuous infringement via the misuse of divisional patents.
- (2176) The single and continuous infringement in Belgium, Czechia, Germany and Spain ended on 7 February 2024 when the TBA effectively revoked EP ‘962 and EP ‘172. The single and continuous infringement in the Netherlands ended on 31 December 2018, in Italy on 31 December 2021 and in Poland on 31 December 2022, the last day Teva has been found to hold a dominant position on the GA markets in the Netherlands, Italy and Poland respectively.
- (2177) The Commission therefore concludes that the duration of the single and continuous infringement is 3292 days in Belgium, Czechia, Germany and Spain, 1428 days in the Netherlands, 2524 days in Italy and 2889 days in Poland.

13. ADDRESSEES

13.1. Principles

- (2178) Article 102 of the TFEU is addressed to undertakings. The concept of an undertaking refers to any entity engaged in an economic activity, regardless of its legal status and the way in which it is financed.³¹¹⁹ The term “undertaking” must also be understood as designating an economic unit even if in law that economic unit consists of several persons, natural or legal.³¹²⁰
- (2179) When such an economic entity infringes the competition rules, it falls, according to the principle of personal responsibility, to that entity to answer for that infringement.³¹²¹ However, the infringement of competition law must be imputed unequivocally to one or more legal person on whom fines may be imposed. It is also

³¹¹⁴ Presentation to the Belgium Pharmacy Group including the Misleading Complexity Message, ID 455-2381, Scientific Evidence-Base on COPAXONE® Complexity & Comparison to Synthron EU Follow-On GA (FOGA), 11 March 2019.

³¹¹⁵ The excerpt from Teva’s internal database shows that a template for a flyer on substitution of “NBCDs” for distribution to pharmacies including the Misleading Complexity Message was used and disseminated and that it was reapproved on 24 March 2020 in Germany (ID 4919-100, email to pharmacies and ID 4897, List of documents registered on Teva’s {...}).

³¹¹⁶ The excerpt from Teva’s internal database shows that a document “*Análisis de la evidencia científica de COPAXONE® y FoGA*” including the Misleading Complexity Message was used and disseminated and that it was reapproved on 20 September 2020 in Spain (ID 4969-5, *Análisis de la evidencia científica de COPAXONE® y FoGA* and ID 4897, List of documents registered on Teva’s {...}).

³¹¹⁷ The excerpt from Teva’s internal database shows that a brochure prepared by Teva including the Misleading Complexity Message was used and disseminated and that it was reapproved on 20 October 2020 in Italy (ID 4919-119, *Brochure esplicativa* {...} and ID 4897, List of documents registered on Teva’s {...}).

³¹¹⁸ The evidence reveal that Teva continued to disseminate the Misleading Complexity Message in the Netherlands even past this date (see Section 9.4.4.5).

³¹¹⁹ Judgment of the Court (First Chamber) of 20 January 2011, *General Química SA and Others v European Commission*, C-90/09 P, EU:C:2011:21, paragraph 34.

³¹²⁰ Case C-90/09 P, *General Química and Others v Commission*, paragraph 35.

³¹²¹ Case C-90/09 P, *General Química and Others v Commission*, paragraph 36.

necessary that the decision establishing the infringement indicates in which capacity the legal persons are called on to answer the allegations.³¹²²

- (2180) The conduct of a subsidiary may be imputed to the parent company even if the parent company does not participate directly in the infringement when the parent company and the subsidiary form a “single economic entity”, that is to say a single “undertaking” within the meaning of Articles 101 and 102 of the TFEU, because, in such a case, the parent company exercises a decisive influence over the subsidiary which has participated in the infringement.³¹²³ A parent company that owns 100% (or almost 100%) of a subsidiary has the ability to exercise decisive influence over such subsidiary. In such a case, there exists a rebuttable presumption that the parent company also in fact exercises that control without the need for the Commission to adduce further evidence on the actual exercise of control (the parental liability presumption).³¹²⁴ The parent company can then be held jointly and severally liable for the payment of the fine imposed on its subsidiary, unless the parent company, which has the burden of rebutting that presumption, adduces sufficient evidence to show that its subsidiary acts independently on the market.³¹²⁵

13.2. Application to the present case

- (2181) The infringement in this case should be imputed to Teva Pharmaceuticals Europe B.V. because it directly engaged in the conduct that resulted in the infringement (see Chapters 8 and 9).
- (2182) In light of the {...} by Teva Pharmaceutical Industries Ltd of Teva Pharmaceuticals Europe B.V., the Commission presumes that Teva Pharmaceutical Industries Ltd exercised a decisive influence over the commercial policy of Teva Pharmaceuticals Europe B.V. Teva Pharmaceutical Industries Ltd has not provided any evidence to rebut that presumption. Moreover, senior managers of Teva Pharmaceutical Industries Ltd gave direct instructions to put in place a strategy to defend Copaxone in Europe³¹²⁶, and/or were directly involved in decisions concerning the implementation and monitoring of the conduct, such as the divisionals game.³¹²⁷
- (2183) The Commission therefore considers that Teva Pharmaceutical Industries Ltd and Teva Pharmaceuticals Europe B.V. infringed Article 102 TFEU and, consequently, the infringements mentioned in Chapter 8 and Chapter 9 of this Decision should be imputed to these legal persons. They should therefore be the addressees of this Decision.

14. TEVA’S CLAIMS RELATED TO RIGHTS OF DEFENCE

- (2184) Teva claims that the Commission has failed to respect Teva’s rights of defence, essentially by not providing full and timely access to minutes of all the contacts between the Commission and third parties, notably the complainants.

³¹²² Judgment of the Court (Third Chamber) of 10 September 2009, *Akzo Nobel NV and Others v Commission of the European Communities*, C-97/08 P, EU:C:2009:536, paragraph 57.

³¹²³ Case C-90/09 P, *General Química and Others v Commission*, paragraphs 37-38

³¹²⁴ Case C-90/09 P, *General Química and Others v Commission*, paragraphs 39-40.

³¹²⁵ Case C-90/09 P, *General Química and Others v Commission*, paragraph 40.

³¹²⁶ See, for example, Recital (119).

³¹²⁷ See, for example, Recitals (1211) and (1212).

14.1. Teva’s claim that the Commission failed to provide minutes of all contacts between the Commission and the complainants

- (2185) In its Reply to the Statement of Objections, Teva referred to a number of potential contacts between the Commission and the complainants for which minutes had not been provided in the initial access to file accompanying the Statement of Objections. Teva also argued that it was unclear if and when additional contacts with third parties took place.
- (2186) Upon review, the Commission confirmed that certain minutes of contacts as well as a limited number of email exchanges with the complainants’ external counsel were not included in the initial access to file granted to Teva.
- (2187) The Commission immediately identified additional contacts and emails between the Commission and the complainants that were missing from the initial access to file, going beyond the list of potential contacts identified by Teva. The Commission registered on the case file the missing emails and, based on contemporaneous internal notes as well as input from the complainants, retrieved or reconstituted minutes for those contacts that may qualify as interviews within the meaning of Article 19 of Regulation 1/2003. The Commission also produced minutes for certain contacts that do not constitute interviews within the meaning of Article 19 of Regulation 1/2003, because the Commission merely invited the complainants to provide certain information. The Commission obtained the complainants’ agreement on these draft minutes.³¹²⁸
- (2188) As a result of this exercise, the Commission granted Teva supplemental access to file on 19 July 2023 (the “Supplemental Access to File”), which included agreed minutes for 24 contacts between the case team and the complainants or their external counsel as well as some email exchanges that had not been included in the initial access to file granted to Teva in October 2022.
- (2189) Teva provided its written observations on the documents included in the Supplemental Access to File on 9 November 2023,³¹²⁹ as well as in its reply to the Letter of Facts of 9 February 2024.³¹³⁰ In its submissions, Teva maintained that its rights of defence were breached on the grounds that (i) not all records of contacts with the complainants had been provided to Teva,³¹³¹ (ii) the agreed minutes postdate the contacts by up to 6 years and cannot represent an accurate record of the information discussed,³¹³² and (iii) some of the agreed minutes are too vague to serve as complete records of the discussion³¹³³.
- (2190) The Commission replied to and rejected Teva’s request for further access to file on 5 July 2024.³¹³⁴ Teva replied on 19 July 2024, reiterating its earlier access to file

³¹²⁸ The Commission’s actions to verify and, where necessary, address the alleged shortcomings of the initial access to file are explained in detail in Section 2 of the Commission letter sent to Teva on 5 July 2024 (see ID 5942).

³¹²⁹ ID 5192, Teva’s Observations on the Supplemental Access to File.

³¹³⁰ ID 5695, Teva’s Reply to the Letter of Facts I of 9 February 2024. Teva was also granted access to file following the Letter of Facts II. Teva did not provide observations on the Supplemental Access to File (nor made any procedural claims) in its reply to the Letter of Facts II.

³¹³¹ ID 5192, Teva’s Observations on the Supplemental Access to File, paras. 118-120, 126; ID 5940, Teva’s letter of 19 July 2024, paras. 57-59.

³¹³² ID 5192, Teva’s Observations on the Supplemental Access to File, para. 60; ID 5940, Teva’s letter of 19 July 2024, para. 2.

³¹³³ ID 5192, Teva’s Observations on the Supplemental Access to File, paras. 68-69.

³¹³⁴ ID 5942, Letter to Teva on Access to File request, 5 July 2024.

request and requesting access to records of additional (alleged) contacts.³¹³⁵ The Commission replied to Teva's additional claims and requests on 2 September 2024.³¹³⁶ Teva submitted further arguments on 16 September 2024³¹³⁷ and the Commission replied on 20 September 2024.³¹³⁸ Lastly, Teva indicated on 25 September 2024 that it considered that the Commission had not adequately addressed "*the central points raised in its prior correspondence*".³¹³⁹

14.1.1. *Teva's claim that it has not received access to all records of contacts with the complainants*

- (2191) Teva claims that there still appear to be contemporaneous correspondence and records of meetings with the complainants that the Commission has not provided to Teva. According to Teva, first, there is no written record around the organisation of 12 contacts for which agreed minutes have been provided to Teva.³¹⁴⁰ Second, there are indicia pointing to the existence of 39 meetings for which no agreed minutes have been provided³¹⁴¹. Third, Teva also requested access to correspondence between the Commission and the complainants concerning the preparation of agreed minutes.³¹⁴² These claims are unfounded for the reasons set out below.
- (2192) First, the Commission explained in its letter of 5 July 2024 that Teva's request to receive allegedly missing correspondence around the organisation of certain contacts with the complainants is unfounded. Teva has received access to all email exchanges with the Complainants' (or their external counsel) registered on the case file (except discussions on confidentiality). Whereas unsolicited calls with the complainants' external counsel indeed took place with a view to request additional information or clarifications, there has been no organisational email correspondence to that end. In any event, the Commission recalls that, according to the case law, "*the possibility of drawing a distinction between documents relevant to the investigation and those which are not and, consequently, the possibility of excluding the latter from the investigation file remains essential in order to prevent the Commission from being exposed to an excessive procedural burden*", provided that this does not prevent the Court from verifying that the Commission complied with its recording obligations under Article 19 of Regulation 1/2003.³¹⁴³
- (2193) Second, concerning the allegedly missing 39 minutes, the Commission explained in its letters of 5 July 2024 and 2 September 2024 that Teva's request for additional access is not warranted because each of the related contacts either (i) did not take place or (ii) was not an interview within the meaning of Article 19 of Regulation 1/2003, as they were purely administrative and/or procedural.³¹⁴⁴ In this respect, the

³¹³⁵ ID 5940, Teva's letter of 19 July 2024.

³¹³⁶ ID 5947, Second Letter to Teva on Access to File request, 2 September 2024.

³¹³⁷ ID 5957, Teva's response to the Commission's letter of 2 September 2024.

³¹³⁸ ID 5970, Email exchange between Teva's external counsel and the Commission.

³¹³⁹ ID 5970, Email exchange between Teva's external counsel and the Commission.

³¹⁴⁰ ID 5192, Teva's Observations on the Supplemental Access to File, paras. 118-120.

³¹⁴¹ ID 5940, Teva's letter of 19 July 2024, paras. 13, 57-59 and Annex 1.

³¹⁴² ID 5192, Teva's Observations on the Supplemental Access to File, para. 154, first indent letter (a), and second indent.

³¹⁴³ Judgment of 25 October 2023, *Bulgarian Energy Holding and Others v Commission*, T-136/19, EU:T:2023:669, paragraph 1171.

³¹⁴⁴ ID 5942, Letter to Teva on Access to File request, 5 July 2024, paras. 33-34, 42-54; ID 5947, Second Letter to Teva on Access to File request, 2 September 2024, paras. 20-25, 28-68. Teva also initially argued that it had not received agreed minutes for a contact between the Commission and the complainants on 8 January 2020 (see ID 5192, Teva's observations on the supplemental access to file,

Court of Justice held that “a distinction must be drawn on the basis of the subject matter of the interviews carried out by the Commission, and that only those seeking to collect information relating to the subject matter of a Commission investigation fall within the scope of Article 19(1) of Regulation No 1/2003 and, therefore, the obligation to record”.³¹⁴⁵

- (2194) Teva challenges the distinction between interviews within the meaning of Article 19 of Regulation 1/2003 and other contacts which do not qualify as interviews (and that, therefore, do not trigger the recording obligations stemming from that provision).³¹⁴⁶
- (2195) However, in the first place, the *Intermarché* judgment, confirms that a distinction must be drawn on the basis of whether an interview is seeking to collect information relating to the subject matter of an investigation, and that the obligation to record an interview only applies where this is the case.³¹⁴⁷ The Court of Justice explicitly confirmed that the recording obligation enshrined in Article 19 of Regulation 1/2003 does not apply to exchanges in which the Commission is not collecting information, or seeking to collect information, relating to the subject matter of an investigation. That distinction between interviews and other oral exchanges between the Commission and third parties follows from an established line of case law.³¹⁴⁸ It is also consistent with the wording of Article 19 of Regulation 1/2003, which indicates that “the Commission may interview any natural or legal person who consents to be interviewed for the purpose of collecting information relating to the subject-matter of an investigation” (emphasis added). Teva has not clarified on which legal basis it would be entitled to be provided with records of contacts between the Commission and third parties that do not qualify as an interview under that provision.
- (2196) Third, the Commission explained in its letter of 5 July 2024 that Teva’s request to receive access to exchanges concerning the preparation of the agreed minutes is unfounded. In addition to the minutes of the relevant contacts, the Commission granted Teva access to non-confidential versions of the email exchanges between the Commission and the complainants’ external counsel to establish a list of potential contacts, as well as the input provided by the latter in that respect. There is no legal obligation for the Commission to disclose provisional drafts of minutes of those contacts to Teva. Article 3(3) of Commission Regulation 773/2004, read in conjunction with Article 19(1) of Regulation 1/2003, stipulates that any recording must be made available to the person interviewed for approval. There is no obligation for the Commission to disclose provisional, unapproved minutes to the undertaking under investigation.

para 125 and footnote 76), but after the Commission noted that the call originally scheduled for 8 January 2020 was postponed and actually took place the following day, as confirmed in the related agreed minutes (see ID 5942, Letter to Teva on Access to File request, 5 July 2024, para. 32), Teva agreed with the Commission’s reconstruction (see ID 5940, Teva’s letter of 19 July 2024, para. 12).

³¹⁴⁵ Judgment of 9 March 2023, *Intermarché Casino Achats v Commission*, C-693/20 P, EU:C:2023:172, paragraph 106; judgment of 9 March 2023, *Les Mousquetaires and ITM Entreprises v Commission*, C-682/20 P, EU:C:2023:170, paragraph 90; judgment of 9 March 2023, *Casino, Guichard-Perrachon and Achats Merchandises Casino v Commission*, C-690/20 P, EU:C:2023:171, paragraph 86.

³¹⁴⁶ ID 5940, Teva’s letter of 19 July 2024, para. 16.

³¹⁴⁷ Judgment of 9 March 2023, *Intermarché Casino Achats v Commission*, C-693/20 P, EU:C:2023:172, paragraphs 106-107.

³¹⁴⁸ See, *inter alia*, judgment of 15 June 2022, *Qualcomm v Commission*, T-235/18, EU:T:2022:358, paragraph 189, 199; judgment of 9 March 2023, *Les Mousquetaires and ITM Entreprises v Commission*, C-682/20 P, EU:C:2023:170, paragraph 90; judgment of 9 March 2023, *Casino, Guichard-Perrachon and Achats Merchandises Casino v Commission*, C-690/20 P, EU:C:2023:171, paragraph 86.

14.1.2. *Teva's claim that the minutes agreed after the Oral Hearing cannot represent an accurate record of the related contacts*

- (2197) Teva claims that the minutes provided to it in the Supplemental Access to File were agreed up to six years after the related contacts took place, and thus cannot represent an accurate record of the information discussed.³¹⁴⁹ Teva also claims that the references in the agreed minutes to contemporaneous documents submitted by the complainants' external counsels do not remedy the Commission's alleged "failure" to provide full access to file at the time of the adoption of the Statement of Objections.³¹⁵⁰ These claims are unfounded.
- (2198) The Commission considers that, despite the lapse of time between the contacts in question and the complainants' approval of the related notes, the agreed minutes represent an accurate and reliable record of the relevant contacts for the following reasons.
- (2199) First, as explained to Teva in the letter of 5 July 2024, the minutes in question are the result of a comprehensive reconstruction exercise involving Commission contemporaneous internal records and the complainants' recollection of underlying meetings or calls. The accuracy of the minutes was confirmed by the complainants, who provided their comments and requested certain corrections prior to their finalisation. The fact that the draft minutes were finalised a considerable time after the contact occurred does not mean that they are inaccurate.
- (2200) Second, the minutes in question include numerous footnotes linking them with contemporaneous documents included in the Commission's case file and made available to Teva. These footnotes provide Teva with a clear indication as regards the nature of the information provided on those occasions or the topics discussed.

14.1.3. *Teva's claim that the agreed minutes are too vague to serve as complete records of the discussion*

- (2201) Teva claims that the minutes contain only high-level summaries of the subjects discussed during the contacts in question.³¹⁵¹ This claim is unfounded.
- (2202) The Commission notes that, first, the length and detail of the minutes depends on the nature and content of the contacts. Thus, the length and detail of the provided minutes vary significantly depending on the contact.
- (2203) Second, as explained in Recital (2187) above, some of the contacts in question were not interviews within the meaning of Article 19 of Regulation 1/2003. They rather served for the Commission to request information or clarifications to be provided in writing at a later date, and agreed minutes were provided to Teva in a spirit of transparency. Accordingly, the level of information provided by the complainants during these contacts (and reported in the related minutes) can be expected to be limited.

14.2. Teva's claim that the alleged violation of its rights of defence is irremediable

- (2204) In its written observations of 9 November 2023 concerning the Supplemental Access to File, Teva claims that the alleged breach of its rights of defence related to its access to minutes is "*irremediable*". Apart from the alleged incompleteness of access to file, Teva claims that it has not been able to rely on the documents in the

³¹⁴⁹ See, e.g., ID 5192, Teva's Observations on the Supplemental Access to File, para. 63.

³¹⁵⁰ See ID 5192, Teva's Observations on the Supplemental Access to File, Section 3.2.2(c).

³¹⁵¹ ID 5192, Teva's Observations on the Supplemental Access to File, Section 3.2.2(b)

Supplemental Access to File to prepare its Reply to the Statement of Objections and during the Oral Hearing held on 24 March 2023.³¹⁵² This claim is unfounded.

- (2205) First, since the Supplemental Access to File, Teva has been several times in a position to make its views on this matter known to the Commission prior to the adoption of this Decision, as Teva did make substantive submissions on 9 November 2023 (with its Observations on the Supplemental Access to File), 26 March 2024 (with its reply to the Letter of Facts I), 11 June 2024 (with its reply to the Letter of Facts II).³¹⁵³
- (2206) Teva does not clarify why the alleged procedural error (i.e. that Teva's views could not be heard orally or in writing by the Oral Hearing) could not be remedied by written submission in the course of the proceedings. While the right to be heard is a fundamental right in EU law, the opportunity to provide comments in writing allows the exercise of that right, and there is thus no general right to be heard orally.³¹⁵⁴
- (2207) Second, Teva does not demonstrate, as required by the case law of Union Courts³¹⁵⁵, that such a procedural error resulted in a breach of its rights of defence. Teva has not shown that it would have been better able to ensure its defence (including by presenting different arguments or exculpatory evidence based on information provided by the complainants) if it had received access to the minutes in question at the time of the Statement of Objections.
- (2208) Third, Teva's claims concerning minutes relate exclusively to contacts with the complainants. It is highly implausible that exculpatory evidence would have been submitted by complainants who have alleged that Teva's practices infringe Article 102 TFEU and who have documented these claims in numerous written submissions to the Commission, made available to Teva.

15. REMEDIES AND FINES

15.1. Article 7(1) of Regulation (EC) No 1/2003

- (2209) Where the Commission finds that there is an infringement of Article 102 of the TFEU, it may by decision require the undertaking concerned to bring such infringement to an end, in accordance with Article 7(1) of Regulation (EC) No 1/2003.
- (2210) The infringement found in this Decision has ceased.³¹⁵⁶ Therefore, there is no need to require Teva to bring the infringement to an end. However, as there is a real danger that Teva might commit similar practices as those considered in this Decision in the

³¹⁵² ID 5192, Teva's Observations on the Supplemental Access to File, Section 3.

³¹⁵³ For the consequences drawn from a similar situation, see judgment of 18 September 2024, *Qualcomm v Commission*, T-671/19, EU:T:2024:626, paragraphs 181-182.

³¹⁵⁴ See, for example, judgment in *HeidelbergCement and Schwenk Zement v Commission*, T-380/17, EU:T:2020:471, paragraph 634: "*The right to be heard does not mean that the person concerned must be given the opportunity to express his or her views orally. Thus, the exercise of the right to be heard does not necessarily require the person concerned to be given an oral hearing, since the opportunity to provide comments in writing also allows that right to be observed*".

³¹⁵⁵ Judgment of 15 June 2022, *Qualcomm v Commission*, T-235/18, EU:T:2022:358, paragraph 202, judgment of 14 September 2022, *Google and Alphabet v Commission (Google Android)*, T-604/18, EU:T:2022:541, paragraphs 913, 934, 937 and 938, and judgment of 6 September 2017, *Intel v Commission*, C-413/14 P, EU:C:2017:632, paragraphs 96 and 97.

³¹⁵⁶ See Chapter 12.

future,³¹⁵⁷ there is a need to expressly recall Teva's obligation to refrain from engaging again in such practices.³¹⁵⁸

- (2211) In particular, with respect to the infringement described in Chapter 9, Teva should refrain from disseminating misleading messages towards competing GAs. In particular, as regards Synthon GA, Teva should refrain from instilling doubts with Payers and HCPs concerning the safety and efficacy of Synthon GA, and its therapeutic equivalence with Copaxone as established by the competent authorities, whether in the context of communications concerning automatic substitution or otherwise, such as by disseminating the Misleading Complexity Message. For instance, Teva should refrain from claiming or implying before Payers and HCPs (i) that there are possible safety and efficacy issues related to Synthon GA, or that Synthon GA is not therapeutically equivalent to Copaxone, (ii) that risks observed with respect to any other glatiramer-related substances are equally applicable to Synthon GA or (iii) that the design and the results of the GATE study raise doubts concerning the validity of the study's conclusions, (iv) any other message relating to Synthon GA having the same or similar object or effect as the dissemination of messages (i) to (iii).

15.2. Article 23(2) of Regulation (EC) No 1/2003

- (2212) Under Article 23(2) of Regulation (EC) No 1/2003, the Commission may by decision impose fines upon undertakings where, either intentionally or negligently, they infringe Article 102 TFEU.
- (2213) In the present case, the Commission concludes that, by engaging in the practices described in Chapter 8 and Chapter 9, Teva intentionally or, at the very least, negligently infringed Article 102 TFEU since Teva knew or should have known that the conduct in question was anticompetitive.³¹⁵⁹ By this Decision, the Commission therefore imposes a fine on Teva.
- (2214) Pursuant to Article 23(3) of Regulation (EC) No 1/2003, in fixing the amount of the fine, the Commission must have regard both to the gravity and the duration of the infringement. In doing so, the Commission will set the fines at a level sufficient to ensure deterrence. In setting the fines to be imposed, the Commission will refer to the principles laid down in its Guidelines on the method of setting fines imposed

³¹⁵⁷ The Commission acknowledges that, at the time of this Decision, Teva's patents in the process and dosage patent families are no longer in force in the Relevant Member States (see Section 8.3.2.1).

³¹⁵⁸ See in this context, for instance, judgment of 2 March 1983, *GVL v Commission*, C-7/82, EU:C:1983:52, paragraph 27; judgment of 28 April 2010, *Gütermann and Zwicky v Commission*, T-456/05 and T-47/05, EU:T:2010:168, paragraphs 66-67; judgment of 18 June 2008, *Hoechst v Commission*, T-410/03, EU:T:2008:211, paragraphs 199-200. In addition, the Commission started to investigate Teva's conduct addressed in this Decision while it was still ongoing (see Section 3). Finally, Teva's conduct addressed in this Decision (both misuse of divisional patents and exclusionary disparagement) has been long recognized as potentially anticompetitive (see Pharmaceutical Sector Inquiry, Final Report, 8 July 2009, Sections C.2.1 and C.2.3 on patent filing strategies and oppositions and appeals and Section C.2.5. describing a number of other practices employed by the originator companies including interventions before pricing and reimbursement authorities and marketing and promotion strategies and contacts with doctors and pharmacists) and attracted attention from the national competition authorities (see for example, Decision no. 23194 of the Autorità Garante della Concorrenza e del Mercato of 11 January 2012, Ratiopharm/Pfizer for abuse of divisional patents; for exclusionary disparagement see Decision n°13-D-11 of 14 May 2013 of the Autorité de la Concurrence against Sanofi Aventis France; Decision n° 13-D-21 of 18 December 2013 of the Autorité de la Concurrence against Schering-Plough and others; and Decision n° 17-D-25 of 20 December 2017 of the Autorité de la Concurrence against Janssen-Cilag SAS).

³¹⁵⁹ For an assessment of Teva's intention or negligence see Section 15.2.2.1.

pursuant to Article 23(2)(a) of Regulation (EC) No 1/2003 (hereafter, “the Guidelines on Fines”).³¹⁶⁰

15.2.1. *General methodology of the Guidelines on Fines*

- (2215) Under the general methodology laid down in the Guidelines on Fines, the Commission sets the fine to be imposed in a given case as follows.
- (2216) First, the Commission determines the basic amount of the fine in view of the gravity and the duration of the infringement.³¹⁶¹ The basic amount is set by reference to the value of sales of goods or services to which the infringement directly or indirectly relates in the relevant geographic area within the EEA.³¹⁶² It consists of a proportion of the value of sales of up to 30 %, ³¹⁶³ depending on the degree of gravity of the infringement, multiplied by the number of years of the infringement.³¹⁶⁴ The Commission may also include in the basic amount an additional amount as a proportion of the value of sales³¹⁶⁵ to deter undertakings from infringing competition rules.
- (2217) The assessment of the gravity of the infringement is carried out on the basis of a number of factors, such as the nature of the infringement, the market shares of the undertaking concerned, the geographic scope of the infringement and whether or not the infringement has been implemented.³¹⁶⁶
- (2218) Second, where applicable, the Commission adjusts the basic amount upwards or downwards to take into account any aggravating and/or mitigating circumstances.³¹⁶⁷ It will do so on the basis of an overall assessment which takes account of all the relevant circumstances, some of which are listed non-exhaustively in points 28 and 29 of the Guidelines on Fines.
- (2219) When setting the fine, the Commission will pay particular attention to the need to ensure that fines have a sufficient deterrent effect and may therefore increase the fine under points 30 or 31 of the Guidelines on Fines.
- (2220) Finally, pursuant to Article 23(2) of Regulation (EC) No 1/2003, the fine for an infringement must not exceed 10 % of the undertaking’s total turnover in the preceding business year.³¹⁶⁸

15.2.2. *Imposition of a fine*

- (2221) In the course of the proceedings, Teva raised a number of general arguments as to why no fines or why only symbolic fines should be imposed in the present case. These arguments are not convincing for the reasons set out below.

15.2.2.1. Intention or negligence

- (2222) Teva argues that the documents to support Teva's awareness of the anticompetitive nature of the conducts at stake are “*very few*” and not convincing. Teva explains that

³¹⁶⁰ Guidelines on the method of setting fines imposed pursuant to Article 23(2)(a) of Regulation No 1/2003, OJ C 210, 1.9.2006, p. 2.

³¹⁶¹ Point 10 of the Guidelines on Fines.

³¹⁶² Point 13 of the Guidelines on Fines.

³¹⁶³ Point 21 of the Guidelines on Fines.

³¹⁶⁴ Point 19 of the Guidelines on Fines.

³¹⁶⁵ Point 25 of the Guidelines on Fines.

³¹⁶⁶ Point 22 of the Guidelines on Fines.

³¹⁶⁷ Point 27 of the Guidelines on Fines.

³¹⁶⁸ Council Regulation (EC) No 1/2003 of 16 December 2002 on the implementation of the rules on competition laid down in Articles 81 and 82 of the Treaty (Text with EEA relevance).

these documents³¹⁶⁹ are not convincing because they (i) refer to a potential infringement not of competition law but of other areas of law (specifically unfair competition and advertising and promotion) and because (ii) they originate from third party consultants or from Teva's medical director and therefore should not be mistaken for Teva's view on a legal matter.³¹⁷⁰ Teva also asserts that its previous submissions to the Commission during the pharmaceutical sector inquiry or as a complainant before the French competition authority are irrelevant since they were made in different context or related to completely different sets of facts.³¹⁷¹

- (2223) Teva's arguments are unfounded. According to well-established jurisprudence of the Union Courts, “[f]or an infringement of the competition rules to be regarded as having been committed intentionally, it is not necessary for an undertaking to have been aware that it was infringing those rules; it is sufficient that it could not have been unaware that its conduct was aimed at restricting competition”.³¹⁷² In reaching its conclusion that Teva committed the single and continuous infringement described in this Decision intentionally or at least negligently, the Commission relied on contemporaneous evidence showing that Teva knew or at least should have been aware that its misuse of divisional patents and its exclusionary disparagement not only did not represent competition on the merits but were clearly “aimed at restricting competition”.³¹⁷³
- (2224) Both abuses addressed in this decision, were integral part of Teva's CCP with the aim to restrict competition to Copaxone from the competing GAs (see Section 5.2). Moreover, Teva was aware that its conduct may raise issues from the competition law perspective. As to the misuse of divisional patents, it suffices to reiterate that a document outlining the divisionals game devised by Teva's {...} expressly refers to the need to check the conduct from the antitrust perspective.³¹⁷⁴ In addition, numerous other documents show that Teva was aware that CCP could raise concerns under EU competition law and that it put in place instructions keeping all mentions of Teva's actions targeting competing products out of the written communications.³¹⁷⁵ As to the exclusionary disparagement, the Commission reiterates that its analysis of each of the facets of Teva's Complexity Message reveals that Teva was aware of its misleading character. This analysis is based on a number of contemporaneous documents.³¹⁷⁶ Finally, Teva itself acknowledged its dominant

³¹⁶⁹ See the documents cited in footnote 3159 above.

³¹⁷⁰ ID 4032, Teva's Reply to the Statement of Objections, para. 1471.

³¹⁷¹ ID 4032, Teva's Reply to the Statement of Objections, para. 1472.

³¹⁷² Judgment of 5 October 2011, *Romana Tabacchi Srl v Commission*, T-11/06, EU:T:2011:560, paragraph 227; Judgment of 14 May 1998, *Enso Española v Commission*, T-348/94, EU:T:1998:102, paragraph 277; judgment of 13 July 2018, *Stührk Delicatessen Import GmbH & Co. KG v Commission*, T-58/14, EU:T:2018:474, paragraphs 226-227.

³¹⁷³ *Ibid.*

³¹⁷⁴ See Recital (1076).

³¹⁷⁵ See Section 5.2.4.2.

³¹⁷⁶ See Recitals (1574)-(1583), (1597)-(1601), (1623)-(1624). For example, in the internal email of 6 November 2015 Teva's {...} expressly warned that “{...}” (ID 455-3034. Teva internal email dated 6 November 2015 from {...} to {...} and others, p. 2). Similarly, in the draft PowerPoint presentation “*The Complexity of COPAXONE*” (September 2016), statements emphasising observed molecular differences and linking them with possible clinical effects were accompanied by internal comments by Teva's consultant “{...}” or “{...}” or even “{...}” (ID 404-848, *The Complexity of COPAXONE®* (glatiramer acetate), pp. 12, 15) Teva's {...} marked in 2017 that “{...}” (ID 455-383, Teva internal email dated 4 May 2017 from {...} to {...}, p. 1). These documents are given only as examples of internal documents evidencing widespread awareness that Teva's dissemination of misleading messages may indeed seriously harm Teva's competitor. The fact that these statements are made by a medical

position and was aware of the special responsibility of an undertaking in such a position.³¹⁷⁷

- (2225) These statements were made in the normal course of business in the specific context described in Chapters 8 and 9 and are directly related to the conduct at stake in the present case. In addition, they should be considered together with the fact that Teva's conduct consists in essentially the same or similar practices that it had previously described with regard to other pharmaceutical undertakings as anticompetitive either to the Commission³¹⁷⁸ or as a complainant in front of the French competition authority.³¹⁷⁹ It clearly follows that Teva, at the very least, should have been aware that it held a dominant position on the relevant market and that its misuse of divisional patents and its exclusionary disparagement campaign could potentially be anticompetitive.³¹⁸⁰

15.2.2.2. Novelty

- (2226) Teva argues that imposing fines would not be justified in light of the alleged novelty of the case. In Teva's view, "*Teva could not anticipate that the alleged practices targeted by the SO would be found to be in violation of Article 102 TFEU*".³¹⁸¹ According to Teva, "*the Commission should abstain from imposing a fine, or should apply only a symbolic fine, in accordance with the applicable guidance and the relevant decisional practice of the Commission and the case law of the General Court. At the very least, when calculating a hypothetical fine, the Commission should acknowledge that Teva could not anticipate the novel types of legal theory that the SO articulates*".³¹⁸² In support of its position, Teva refers to the alleged lack of

director or by the outside consultant (and not, as Teva asserts would be necessary, by Teva's legal team) or that they refer to violation of other areas of law is irrelevant for this conclusion. These documents, as well as other documents relied on by the Commission in this Decision show that Teva, at the very least, should have been aware that casting doubt on the safety and efficacy of Synthron GA, may indeed harm the chances of Teva's competitors to compete with Copaxone on the merits.

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See Section 7.2.4.

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ID 2442, Comments by Teva Pharmaceuticals Europe B.V. on the Pharmaceutical Sector Inquiry, Final Report, 8 July 2009, pp. 4-5, 7. For example, on pp. 4-5 of its submission, Teva agrees with the Commission's findings that "*innovator companies may file subsequent patents when the main patent is about to expire, that such filings can be used strategically to create further uncertainty and delays for generic entrants*," (while Teva did not refer to the divisional patents, the description corresponds to the general strategy of the infringement described in Chapter 8) or that "*interventions before regulatory bodies, while potentially addressing legitimate concerns, are also a 'standard tool in originator companies' tool-box' that can be 'used to delay or block the marketing authorisation or the pricing or reimbursement status of the generic product' or that 'the tool-box of originator companies includes other types of interventions, such as '[q]uestioning the reputation of generic competitors and their products'*".

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Decision n°13-D-11 of 14 May 2013 of the Autorité de la Concurrence against Sanofi Aventis France, which was upheld on appeal. The case originated from a complaint by Teva Santé. Decision n° 17-D-25 of 20 December 2017 of the Autorité de la Concurrence against Janssen-Cilag SAS. The case originated from a complaint by Ratiopharm (Teva Santé).

3180

Contrary to Teva's argument, the fact that Teva complained to the Commission about anticompetitive effects of patent practices within the pharmaceutical sector inquiry or about disparagement by an originator company to the French competition authority on two different occasions, supports the Commission's conclusion as to its awareness that such practices were anticompetitive. The fact that Teva formulated its concerns about practices essentially same as or similar to the practices described in this Decision in its formal submissions to third parties (i.e. not only in its internal documents) clearly shows that Teva cannot be surprised with the Commission's finding that the misuse of divisional patents and exclusionary disparagement represent infringements of Article 102 TFEU.

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ID 4032, Teva's Reply to the Statement of Objections, para. 1470.

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ID 4032, Teva's Reply to the Statement of Objections, para. 1466.

applicable precedents and the absence of predictability of infringement based on existing law.³¹⁸³

- (2227) In this context, it is important to recall that in *AstraZeneca*, the Court of Justice stated the following: “concerning the novelty of the two abuses of a dominant position, it must be stated that those abuses [...] had the deliberate aim of keeping competitors away from the market. It is therefore common ground that even though the Commission and the Courts of the European Union had not yet had the opportunity to rule specifically on conduct such as that which characterised those abuses, AZ was aware of the highly anticompetitive nature of its conduct and should have expected it to be incompatible with competition rules under European Union law”.³¹⁸⁴
- (2228) At the time when Teva implemented the practices described in Chapter 8 and Chapter 9, there may not have been any precedents established by the Commission or the Union Courts specifically in relation to misuse of divisional patents or exclusionary disparagement under Article 102 TFEU. However, the state of the law was clear: conduct consisting in a dominant company’s misuse of rules and procedures (be it regulatory or intellectual property related) and disseminating misleading information about its competitor with the aim of preventing and obstructing competition is not compatible with competition on the merits and is capable of producing exclusionary effects. Such practices were expressly condemned by the Commission and the Court in *AstraZeneca* and described in detail in the Commission Pharmaceutical Sector Inquiry.³¹⁸⁵ In addition, as noted above, the fact that its practices might be illegal and attract antitrust scrutiny was well known within Teva both with respect to the misuse of divisional patents and exclusionary disparagement. The practices at stake in the present case clearly fall within the prohibition of Article 102 TFEU and their characterisation as anticompetitive, based on the assessment of the specific facts and the economic and legal context of the present case, cannot be seen as novel.³¹⁸⁶
- (2229) Teva’s reference to certain past cases where the Commission refrained from imposing a fine due to novelty,³¹⁸⁷ is irrelevant. First, as already explained above, the fact that there may not have been any precedents established by the Commission or the Union Courts specifically in relation to misuse of divisional patents or

³¹⁸³ ID 4032, Teva’s Reply to the Statement of Objections, paras. 1467-1469.

³¹⁸⁴ Case C-457/10 P, *AstraZeneca v Commission*, paragraph 164.

³¹⁸⁵ Pharmaceutical Sector Inquiry, Final Report, 8 July 2009, Sections C.2.1 and C.2.3 on patent filing strategies and oppositions and appeals and Section C.2.5. describing a number of other practices employed by the originator companies including interventions before pricing and reimbursement authorities and marketing and promotion strategies and contacts with doctors and pharmacists. In addition, the Autorité de la Concurrence has pursued several cases where disparagement was found to constitute abusive conduct under Article 102 TFEU. These decisions were adopted before or during the period of infringement (see Section 12.2): Decision n°13-D-11 of 14 May 2013 of the Autorité de la Concurrence against Sanofi Aventis France, paragraph 346; Decision n° 13-D-21 of 18 December 2013 of the Autorité de la Concurrence against Schering-Plough and others; and Decision n° 17-D-25 of 20 December 2017 of the Autorité de la Concurrence against Janssen-Cilag SAS. Teva initiated two of these proceedings as a complainant: Decision n°13-D-11 of 14 May 2013 against Sanofi Aventis France and Decision n° 17-D-25 of 20 December 2017 of the Autorité de la Concurrence against Janssen-Cilag SAS.

³¹⁸⁶ General principle of special responsibility of dominant companies and of competition on the merits (or normal competition) is long confirmed in the jurisprudence of the Court of Justice of the European Union (see for example C-209/10, *Post Danmark*, EU:C:2012:172, paragraph 24 and the case-law cited therein and C-413/14 P, *Intel v Commission*, EU:C:2017:632, paragraphs 134-136.

³¹⁸⁷ ID 4032, Teva’s Reply to the Statement of Objections, paras. 1468-1469.

exclusionary disparagement under Article 102 TFEU does not imply that the state of the law was unclear. Moreover, even novelty (which, as shown above, does not occur in the present case) does not prevent the Commission from imposing a fine.³¹⁸⁸

(2230) Second, in any event, in the circumstances of this case the Commission considers it appropriate to impose fines having regard to the need for appropriate sanctioning and deterrence. The former is aimed at ensuring Teva does not profit from illegal practices. The latter has a dual objective, ensuring that both the addressee of this Decision specifically and other undertakings generally refrain from implementing such types of anticompetitive practices. The Commission's discretion in this case is not fettered by its approach in certain other cases. Whilst a consistent approach must be adopted by the Commission within the same case to ensure the respect of the principle of equal treatment, an undertaking cannot rely on the Commission's approach in other cases to escape sanctions,³¹⁸⁹ especially in a case, such as the present one, which involves exclusionary behaviour towards a competitor.

15.2.2.3. Legal certainty, legitimate expectations, *nullum crimen, nulla poena sine lege* and non-retroactivity

(2231) According to Teva, the closely-related principles of legal certainty, non-retroactivity, legitimate expectations, and *nullum crimen, nulla poena sine lege* require the Commission to refrain from imposing a fine where the undertakings could not reasonably foresee, at the time when the alleged offense was committed, that the conduct at issue infringed Union competition law, in particular, when the infringement was not predictable based on existing case law. Teva could (allegedly) not anticipate that its practices described in this Decision would be found to be violation of Article 102 TFEU.

(2232) This claim is unfounded for the reasons detailed below.

(2233) First, it is settled case-law that the principle of legal certainty requires that rules such as Article 102 TFEU enable those concerned to know precisely the extent of the obligations which are imposed on them and that these persons must be able to ascertain unequivocally what their rights and obligations are and take the appropriate steps accordingly.³¹⁹⁰ Teva could not ignore that its practices were injurious to the proper functioning of normal competition since they aimed at preventing and limiting entry and uptake of competing GAs to the detriment of Teva's competitors and ultimately customers. The notion that such practices when implemented by a company in a dominant position constitute an infringement of Article 102 TFEU is well established in the case law of the Union Courts.

(2234) Second, as to the principle of legitimate expectations, according to the case-law of the Union Courts, no one may plead infringement of that principle unless precise, unconditional and consistent assurances, from authorised, reliable sources, have been given to him by the authorities.³¹⁹¹ In this respect, the Commission did not at any point give assurances as to the compatibility with Union competition law of the

³¹⁸⁸ Case C-591/16 P, *Lundbeck*, paragraphs 156-157.

³¹⁸⁹ See judgment of 27 February 2014, *InnoLux v Commission*, T-91/11, EU:T:2014:92, paragraph 144, and the case-law cited therein.

³¹⁹⁰ See, for example, Judgment of 10 March 2009, *Gottfried Heinrich*, C-345/06, EU:C:2009:140, paragraph 44.

³¹⁹¹ Judgment of 20 May 2015, *Timab Industries and Cie financière et de participations Roullier (CFPR) v European Commission*, T-456/10, EU:T:2015:296, paragraph 123.

conduct undertaken by Teva.³¹⁹² To the contrary, the Commission Pharmaceutical Sector Inquiry raised concerns with respect to both patenting practices involving divisional patents and disparagement of competitors.³¹⁹³

- (2235) Third, it is settled case-law that the principle of *nullum crimen, nulla poena sine lege* precludes the retroactive application of a new interpretation of a rule establishing an offence where such an interpretation was not reasonably foreseeable at the time when the offence was committed.³¹⁹⁴ This is not the case here and Teva's claims with respect to non-retroactivity should be rejected. In the present case, the Commission simply applied Article 102 TFEU which covers any abuse of dominant position and, as shown above (see Section 15.2.2.1), Teva, at the very least, should have been aware of the anticompetitive nature of its conduct.³¹⁹⁵ The illegality of Teva's practices was therefore foreseeable for Teva.
- (2236) Fourth, for Teva's awareness of the anticompetitive nature of the conduct addressed in this Decision, see Section 15.2.2.1 above.

15.2.3. Amount of the fine to be imposed on Teva

- (2237) In the present case, the Commission imposes a fine on Teva for the single and continuous infringement of Article 102 TFEU covering the Relevant Member States and consisting of Teva's misuse of divisional patents (Chapter 8) and Teva's exclusionary disparagement (Chapter 9).
- (2238) Considering that the duration of the single and continuous infringement depends on the Relevant Member State under consideration, in the present case the Commission calculates the fine separately for each of the Relevant Member States.
- (2239) In line with the general methodology set out in the Guidelines on Fines, the Commission will first determine the basic amount of the fine (see Section 15.2.3.1 below). Since, in this case, no aggravating or mitigating circumstances apply, the Commission will not adjust the basic amount of the fine, and will only ensure that it does not exceed 10 % of the undertaking's total turnover in the preceding business year (see Section 15.2.3.2 below).

15.2.3.1. Determination of the basic amount of the fine

- (2240) The basic amount of the fine is to be determined on the basis of a proportion of the value of sales, depending on the degree of gravity of the infringement, multiplied by the number of years of the infringement.³¹⁹⁶

³¹⁹² “In accordance with settled case-law, that principle extends to any individual in a situation where the authorities have caused him to entertain legitimate expectations, it being understood that no one may plead infringement of that principle unless precise, unconditional and consistent assurances, from authorised, reliable sources, have been given to him by the authorities” (Judgment of the General Court of 14 April 2011, *Visa Europe and Visa International Service v Commission*, T-461/07, EU:T:2011:181, paragraph 38).

³¹⁹³ See Recital (2228).

³¹⁹⁴ Judgment of 5 September 2015, *Koninklijke Philips Electronics NV*, T-92/13, EU:T:2015:605, paragraph 136.

³¹⁹⁵ See also Case C-591/16 P, *Lundbeck*, paragraph 156: “a penalty may be imposed on an undertaking for conduct falling within the scope of Article 101(1) TFEU where that undertaking could not be unaware of the anticompetitive nature of its conduct, whether or not it is aware that it is infringing the competition rules of the Treaty”.

³¹⁹⁶ Point 19 of the Guidelines on Fines.

15.2.3.1.1. Value of sales

- (2241) For the calculation of the value of sales, the Commission normally takes into account the value of the undertaking's sales of goods or services to which the infringement directly or indirectly relates in the relevant geographic area within the EEA during the last full business year of the infringement.³¹⁹⁷
- (2242) However, if justified by the circumstances of a case, the Commission may consider taking into account the annual revenues for the entire period of the infringement and derive, for the purpose of calculating a fine, an annualised value of sales from the average over this period.
- (2243) In the present case, basing the fine calculation on an average annual value of sales calculated over the entire period rather than the value of sales during the last full business year of the infringement is more appropriate. This is because the revenues Teva derived from its anticompetitive conduct were significantly higher at the onset of the infringement and, in most of the Relevant Member States, gradually reduced over time as Teva, despite its ongoing conduct, did not succeed in eliminating all competition from Synthon GA. Therefore, relying on the revenue in the last full business year of the infringement would significantly understate the value of sales to which the infringement related and would not be representative of the economic importance of Teva's single and continuous infringement.
- (2244) Accordingly, the value of sales to be considered when setting the fine in the present case is the average value of annual sales of Copaxone that Teva reported during the whole duration of the single and continuous infringement in each Relevant Member State, as detailed below:³¹⁹⁸

Table 17: Value of sales

Relevant Member State	Annualised value of sales of Copaxone (EUR, average over infringement period)
Belgium	{...}
Czechia	{...}
Germany	{...}
Spain	{...}
Italy	{...}

³¹⁹⁷ Point 13 of the Guidelines on Fines.

³¹⁹⁸ See ID 5826, Copaxone's 2015-2024Q1 Consolidated sales of Copaxone (Excluding UK post-Brexit). When calculating the average annual sales of Copaxone in each Relevant Member State, the Commission first calculated the average daily sales for each year (by dividing the annual sales by the number of days of that year), then weighted such average daily sales by the number of days of each year during which the single and continuous infringement was ongoing; lastly, it multiplied such weighted average daily sales for 365 in order to obtain the average annual sales of Copaxone relevant for fines calculations. This ensures that, for example, for 2015 only the 332 days after 2 February are relevant for the calculation. By the same token, for Belgium, Czechia, Germany and Spain, only the 38 days of 2024 until 7 February (included) contribute to the calculation of the average annual sales of Copaxone.

The Netherlands	{...}
Poland	{...}

15.2.3.1.2. Gravity

- (2245) The basic amount of the fine is derived from a proportion of the (average) annual value of sales of up to 30 %, depending on the degree of gravity of the infringement, multiplied by the number of years of the infringement.
- (2246) In assessing the gravity of the infringement in this case, the Commission takes into account a number of factors (detailed below). Since these factors depend on the Relevant Member State being considered, this will result in different gravity coefficients being set, to fully take into account any different degrees of gravity of the single and continuous infringement in each Relevant Member State.
- (2247) First, as regards the nature of Teva’s infringement, the Commission finds that it is very serious because it was aimed at (and was capable of) excluding, hindering or delaying any and all competition to Teva in the GA markets in all Relevant Member States. Contrary to Teva’s contention³¹⁹⁹, this does not necessarily apply to “*any type of exclusionary conduct*”, since Teva’s conduct aimed in particular at (and was capable of) excluding from the market Copaxone’s most direct and immediate competitive constraint (Synthon GA).
- (2248) Second, the Commission’s case file includes evidence suggesting that Teva committed the infringement intentionally, or at least negligently (see Section 15.2.2.1 above).
- (2249) Third, both abusive practices have been implemented, as shown in Chapters 8 and 9.
- (2250) Fourth, Teva held high market shares in each Relevant Member State for the whole duration of the single and continuous infringement.
- (2251) Fifth, the Commission has established that Teva’s infringement affected seven Member States, covering approximately two thirds of Teva’s sales of GA in the EEA by value. For example, in 2015 (when Teva’s misuse of divisional patents and, consequently, Teva’s single and continuous infringement began) the infringement covered more than {...} % of its sales of Copaxone in the EEA by value.³²⁰⁰ Likewise, in 2017 (the first full business year when both Teva’s abuses were ongoing), the infringement covered more than {...} % of its sales of Copaxone in the EEA by value.³²⁰¹
- (2252) Sixth, while the parameters considered above (nature of the infringement, intention or negligence, actual implementation, high market shares and coverage of the single and continuous infringement) do not depend on the specific Relevant Member State being assessed, it is necessary to consider that the two abusive practices constituting the single and continuous infringement found in this Decision were highly complementary, and reinforced one another by largely overlapping in time.

³¹⁹⁹ ID 4032, Teva’s Reply to the Statement of Objections, para. 1483(a).

³²⁰⁰ Commission’s calculations based on ID 5826, Teva’s reply to Article 18(2) request of 15 February 2024, Copaxone’s 2015-2024Q1 Consolidated sales of Copaxone (Excluding UK post-Brexit).

³²⁰¹ Commission’s calculations based on ID 5826, Teva’s reply to Article 18(2) request of 15 February 2024, Copaxone’s 2015-2024Q1 Consolidated sales of Copaxone (Excluding UK post-Brexit).

Therefore, to take into account the different intensity of the infringement³²⁰² resulting from the overlap between the two abusive practices in each of the seven Relevant Member States, the Commission decides to set two different gravity coefficients. In particular, in light of the Commission’s conclusions on the duration of each of the two abusive practices set out in Chapter 12 above and of the discretion enjoyed by the Commission when setting the amount of fines for antitrust infringements, the Commission sets a gravity coefficient of {...} % for those Relevant Member States where the two practices were both ongoing at the same time for more than one third of the duration of the single and continuous infringement (i.e. Germany, Spain, and Italy).³²⁰³ Conversely, a {...} % gravity coefficient is set for those Relevant Member States where the two abuses overlapped for less than a third of the duration of the single and continuous infringement (i.e. Belgium, Czechia, the Netherlands and Poland).³²⁰⁴

- (2253) Seventh and lastly, the Commission notes that the fine may also reflect the impact of the conduct on the market concerned. The case law of the Union Courts has indeed confirmed that, although “*the Commission is not, as a general rule, obliged to take into consideration the actual impact of the infringement on the market when setting the proportion of the value of sales determined by reference to the gravity*”, the Guidelines on Fines do not prevent the Commission from considering the actual impact of an infringement on the market in order to increase the gravity coefficient if the Commission provides “*specific, credible and adequate evidence with which to assess what actual influence the infringement may have had on competition in that market*”.³²⁰⁵
- (2254) In that respect, the Commission notes that the impact of Teva’s single and continuous infringement was not just limited to preventing, restricting or distorting competition, or to hindering and/or delaying the actual market entry of Synthron GA as shown in Chapters 8 and 9 above. In some Member States, one aspect of the infringement’s impact is indirectly revealed by the protection of Teva’s revenues and profits for a prolonged period of time. Indeed, Copaxone was a global blockbuster, and, for Europe, Teva indicated internally that “{...}”.³²⁰⁶
- (2255) The Commission therefore considers that, when setting the gravity coefficient to be applied in the present case, it is necessary to take into account the amount of gains

³²⁰² See Judgment of the General Court of 14 September 2022, *Google and Alphabet v Commission (Google Android)*, T-604/18, EU:T:2022:541, paragraph 84.

³²⁰³ More precisely, as detailed in Chapter 12 above, in Germany the two abuses were both ongoing between 12 April 2016 and 24 March 2020 (i.e. 1443 days, or 44% of the duration of the single and continuous infringement in Germany). In Spain, the two abuses were both ongoing between 12 April 2016 and 20 September 2020 (i.e. 1623 days, or 49% of the duration of the single and continuous infringement in Spain). In Italy, the two abuses were both ongoing between 12 April 2016 and 20 October 2020 (i.e. 1653 days, or 65% of the duration of the single and continuous infringement in Italy).

³²⁰⁴ More precisely, as detailed in Chapter 12 above, in Belgium the two abuses were both ongoing between 12 April 2016 and 11 March 2019 (i.e. 1064 days, or 32% of the duration of the single and continuous infringement in Belgium). In Czechia, the two abuses were both ongoing between 12 April 2016 and 18 August 2017 (i.e. 494 days, or 15% of the duration of the single and continuous infringement in Czechia). In the Netherlands, the two abuses were both ongoing between 12 April 2016 and 4 April 2017 (i.e. 358 days, or 25% of the duration of the single and continuous infringement in the Netherlands). In Poland, the two abuses were both ongoing between 12 April 2016 and 8 August 2017 (i.e. 484 days, or 17% of the duration of the single and continuous infringement in Poland).

³²⁰⁵ Judgment of the General Court of 12 June 2014, *Intel*, T-286/09, EU:T:2014:547, paragraph 1625.

³²⁰⁶ See Recital (105) above.

improperly made by Teva as a result of such infringement.³²⁰⁷ According to the case law of the Union Courts, “*the gravity of the infringement must be assessed on an individual basis and that, in order to determine the amount of a fine, it is necessary to take account of the duration of the infringement and of all the factors capable of affecting the assessment of its gravity, such as, inter alia, the conduct of the undertaking concerned, its role in the establishment of the abusive practices, the profit which it was able to derive from those practices or the intensity of the incidents of anticompetitive conduct*” (emphasis added).³²⁰⁸

- (2256) In that regard, evidence on the Commission’s case file specifically shows that the infringement allowed Teva to maintain supra-competitive profits over a long period of time in Czechia and Germany. In these two Relevant Member States, Teva obtained preliminary injunctions based on the divisionals that Teva sought to protect with its abusive conduct, thereby preventing or significantly delaying the effective uptake of Synthon GA.³²⁰⁹ Some representative examples of the evidence in question are discussed in turn below.

³²⁰⁷ The possibility for the Commission to consider the amount of gains resulting from the infringement when setting the fines is also acknowledged by Point 31 of the Guidelines on Fines. In the present case, since the amount of gains resulting from the infringement is only considered by the Commission in relation to two Relevant Member States out of seven (as shown below), the Commission considers it more appropriate to take such gains into account when setting the gravity coefficient for these Relevant Member States, instead of increasing the overall fine by applying Point 31 of the Guidelines on Fines.

³²⁰⁸ Judgment of the General Court of 14 September 2022, *Google and Alphabet v Commission (Google Android)*, T 604/18, EU:T:2022:541, paragraph 84. See also the judgment of the General Court of 18 October 2023, *Clariant and Clariant International v Commission*, T 590/20, EU:T:2023:650, paragraph 145.

³²⁰⁹ Despite the fact that Teva obtained preliminary injunctions also in Belgium, Italy and Poland, the Commission is not able to demonstrate to the same degree that these preliminary injunctions resulted in higher profits. The Commission will therefore not increase the gravity factor for these three Relevant Member States. Teva argued during the proceedings that it is “implausible” that preliminary injunctions resulted in higher profits in certain jurisdictions (Germany and Czechia) and not in others (Belgium, Italy and Poland) and this would allegedly show that the high profits that Teva achieved in Germany and Czechia would be due to “*specific features of those markets*”, such as (i) the existence of single-dose injection pens for Copaxone 40 mg in Germany, not available for Synthon GA, (ii) the fact that health insurers in Germany primarily procure GA via open house tenders (for which competition allegedly is “less intense” than for exclusive tenders), and (iii) the fact that Synthon GA has not yet entered the Czech market, so it is allegedly not possible to determine whether the profits Teva has obtained in that jurisdiction are a result of the preliminary injunction (see ID 5909, Teva’s Reply to the Letter of Facts II of 17 May 2024, para. 223). However, the Commission notes that the present Decision does not conclude that the preliminary injunctions in Belgium, Italy and Poland did not generate any additional profits for Teva, but just notes that such profits (if any) may be more difficult to prove to the same degree as those in Czechia and Germany from the evidence on the Commission’s case file. In addition, if a preliminary injunction prevents (like in Czechia) the only competitor in the same relevant market from entering or (like in Germany) it causes the market exit of a competing product, then it must be concluded that lack of price competition from Copaxone’s most direct and immediate competitive constraint must have resulted in higher profits for Teva and that specific market features can only account for a portion of Teva’s profits or for their evolution after market entry. Conversely, specific features of the market and of the preliminary injunctions in question may explain the difference between the effects of the preliminary injunctions in Czechia/Germany and those in Belgium/Italy/Poland. For example, the preliminary injunction against Synthon GA in Italy was in place for just 3 months – not for more than one year (like in Germany) or several years (like in Czechia) – and was also issued before a MA was granted to Synthon GA 20 mg in Italy. In any event, the Commission notes that the preliminary injunction in Germany (i) allowed Teva to gain time to switch some patients under Copaxone 40 mg to the single-dose injection pens without being contested by the cheaper Synthon GA 40 mg pre-filled injections, which could not be marketed as a result of the injunction and (ii) dissuaded German insurers from awarding exclusive tenders to Synthon GA (as the health insurer

- (2257) First, one of Teva’s internal presentations dated November 2017 (i.e., when no preliminary injunctions against Synthron GA were in place in Germany and one had just been lifted in Czechia) shows that, {...}.³²¹⁰ {...} (see below). The same presentation also shows that Teva recorded in the EU “{...}”.³²¹¹
- (2258) Second, one of Teva’s internal presentations dated July 2020 (when preliminary injunctions were in place in both Germany and Czechia) shows that, in the second quarter of 2020, “{...}”, and that the {...}.³²¹² This is a {...}.³²¹³ For illustrative purposes only, this difference would mean that the {...}. This would in turn translate into {...}.³²¹⁴ The same presentation also shows that Teva estimated a {...}.³²¹⁵ A later presentation dated October 2020 shows that, already for {...}.³²¹⁶
- (2259) Third, Figure 49 below shows that, even when Teva waived the German preliminary injunction against Synthron GA 40 mg in September 2020 (following the EPO judgment on EP ‘335³²¹⁷), {...}. This suggests that the preliminary injunction had strong lingering effects further protecting Teva’s profits in Germany resulting from the alleged infringement.

{...} had just done in April 2019) or organising them altogether, thereby making Synthron GA’s entry or expansion in the German market more difficult (see, in this regard, Recitals (801) and ff., and Recital (901)).

³²¹⁰ ID 455-3114, Copaxone EU AOP2018, pp. 2--6.

³²¹¹ *Ibid.*

³²¹² ID 806-4, TPE Board Meeting Finance - Q2 2020, 9 July 2020, p. 10.

³²¹³ According to Teva, the fact that the statistics used in this presentation do not differentiate between the countries where a preliminary injunction was in place and those where Synthron GA was “*off market*” would likely “*significantly overstate*” the average selling price of Copaxone in the countries where a preliminary injunction was in place (see ID 5909, Teva’s Reply to the Letter of Facts II of 17 May 2024, para. 227(c)(i)). However, Teva does not substantiate such assertion with any detailed reason. Whether Synthron GA stayed out of a certain market because of a preliminary injunction or for other reasons, this still confirms a certain {...} % average price differential if compared to countries where Synthron GA had managed to enter and compete with Copaxone.

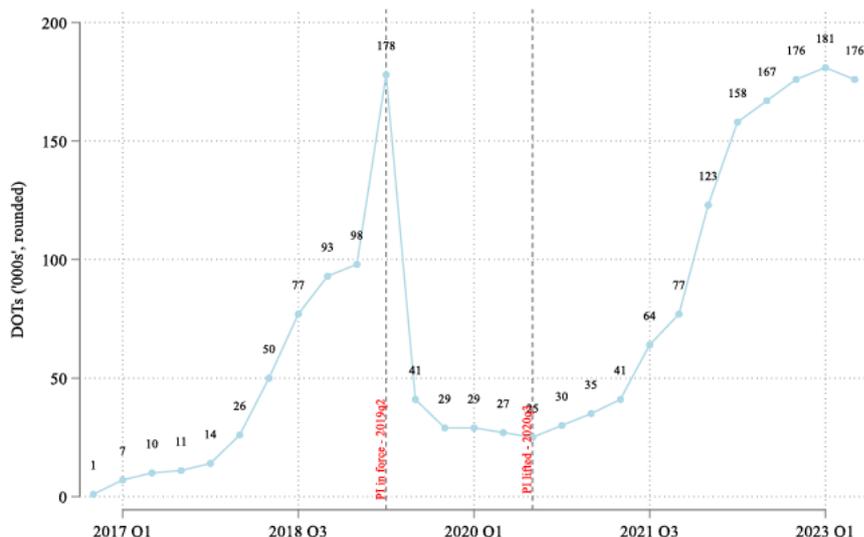
³²¹⁴ Commission estimates based on ID 5710, Teva’s Reply to the Letter of Facts I of 9 February 2024, data pack, file “Annex RFI9Q7 - RFI3Q2 follow-up.xlsx”.

³²¹⁵ ID 806-4, TPE Board Meeting Finance - Q2 2020, 9 July 2020, p. 20.

³²¹⁶ ID 806-36, TPE Board Meeting Finance - Q3 2020, 5 October 2020, p. 14.

³²¹⁷ See Recital (1399) above.

Figure 49: Synthron GA sales in Germany (k DOTs)



Source: Commission calculations based on IQVIA data³²¹⁸

(2260) Teva argued that Figure 49 above only shows that the preliminary injunction resulted in lower volumes for Synthron GA, and this does not prove that the preliminary injunction enabled Teva to make improper gains from sales of Copaxone.³²¹⁹ However, this argument is unfounded for two reasons. In the first place, Figure 25 above shows a strong (inverse) correlation between the volumes of Copaxone and of Synthron GA sold in Germany, so much so that the (limited) increase in sales of Synthron GA corresponds to practically a one-to-one decrease in volumes for Copaxone (see Recital (786) above). In the second place, as evidenced above, Synthron GA was the only product capable of effectively constraining Copaxone’s volumes, prices and profits (also in Germany, see Section 6.3.3.4.3.3.1 above). Accordingly, the Commission concludes that the decrease in Synthron GA volumes sold in Germany during and after the preliminary injunction resulted in higher volumes of Copaxone sold in Germany, hence in higher profits for Teva.

(2261) Fourth, Figure 50 below shows that Teva’s Copaxone profits in Czechia and Germany decreased on average much more slowly than in other Relevant Member States, where the single and continuous infringement was on-going, but where Teva had not obtained a preliminary injunction against Synthron GA.

Figure 50: Copaxone profits percentage change

{...}

Source: Commission calculations based on Teva’s Reply to the Letter of Facts I of 9 February 2024.³²²⁰

(2262) Teva argues (i) that its profits from sales of Copaxone decreased much quicker in Czechia while a preliminary injunction was also in place than in Spain, Poland, Italy and the Netherlands where there was no preliminary injunction, and (ii) that this

³²¹⁸ ID 5737, Teva’s Reply to the Letter of Facts I of 9 February 2024, data pack, data file “EU_MIDAS_quarterly_with_DOT_CLEAN - including 2022-Q22023.dta”. The Commission calculations include both dosages of Synthron GA (20 mg and 40 mg).

³²¹⁹ See ID 5909, Teva’s Reply to the Letter of Facts II of 17 May 2024, para. 227(d).

³²²⁰ ID 5710, Teva’s Reply to the Letter of Facts I of 9 February 2024, data pack, file “Annex RFI9Q7 - RFI3Q2 follow-up.xlsx”. The Commission calculations are based on Teva’s Copaxone net profits data, which the Commission understands to include both dosages (20 mg and 40 mg).

(allegedly) suggests that Teva's profits in Czechia and Germany were “*not strongly correlated*” with the preliminary injunctions.³²²¹

(2263) The Commission rejects this argument. In fact, the decrease in Copaxone's profits in Czechia after 2021 (i.e. while a preliminary injunction against Synthron GA was still in place) is attributable to the inclusion of Copaxone in the same reference group as interferons in Czechia discussed at Recital (761) above. As a result, contrary to Teva's view, the decrease in Teva's profits from Copaxone sales in Czechia after 2021 cannot put into question the conclusion that the preliminary injunctions in Czechia likely had an impact on Teva's profits such that, absent such injunctions, these would have decreased earlier and/or more significantly (similarly to other Relevant Member States, where interferons have not been classified as in Czechia). Teva's argument that its profits were “*not strongly correlated*” with the preliminary injunctions is all the more unfounded in Germany, where they were higher in 2019 (first year of the preliminary injunction) than in 2018. The evolution of such profits confirms the conclusion that the preliminary injunction in Germany likely had an impact on Teva's profits such that, absent such injunction, these would have decreased earlier and/or more significantly (similarly to other Relevant Member States).³²²²

(2264) For these reasons, the Commission decides to increase the gravity coefficient to be applied for Czechia and Germany by {...} points, so as to reflect the fact that, as a result of the infringement, Teva has likely maintained higher prices and obtained higher profits compared to other Relevant Member States (and, *a fortiori*, compared to a hypothetical scenario of undistorted competition in Czechia and Germany).

15.2.3.1.2.1. Teva's other claims in relation to the gravity coefficient and the Commission's assessment

(2265) During the proceedings, Teva raised a number of additional arguments in relation to the gravity coefficient. These arguments are unfounded for the reasons set out below.

(2266) First, Teva claims that it is not aware of any precedents in which the Commission used separate gravity coefficients to impose a fine on an undertaking found to have committed a single and continuous infringement of Article 102 TFEU.³²²³ Teva also argues that, in cases with similar fact patterns (i.e., multiple complementary abuses spanning multiple EU jurisdictions) the Commission used a single gravity coefficient in its fine calculation (citing the examples of *Prokent-Tomra*³²²⁴, *Intel*³²²⁵ and *Google Android*³²²⁶) and that the facts of this case “*may not justify a departure from the standard practice*”.³²²⁷

(2267) Teva's arguments do not convince. Indeed, Teva's argument (based on the General Court's judgment in *Intel*) that “*the Commission was not required to state specifically in the grounds of the contested decision how it took into account each of the components of the abuse for the purposes of setting the fine*”³²²⁸ does not

³²²¹ See ID 5909, Teva's Reply to the Letter of Facts II of 17 May 2024, para. 227(g).

³²²² The alleged “*specific features*” of the German and Czech markets mentioned by Teva are also not sufficient to influence the Commission's conclusion, for the reasons already specified in footnote 3209 above.

³²²³ ID 5909, Teva's Reply to the Letter of Facts II of 17 May 2024, para. 187.

³²²⁴ Commission Decision of 29 March 2006, *Prokent/Tomra*, Case COMP/E-1/38.113.

³²²⁵ Commission Decision of 13 May 2009, *Intel*, Case COMP/37.990.

³²²⁶ Commission Decision of 18 July 2018, *Google Android*, Case AT.40099.

³²²⁷ ID 5909, Teva's Reply to the Letter of Facts II of 17 May 2024, paras. 187-188.

³²²⁸ Judgment of the General Court of 12 June 2014, *Intel*, T-286/09, EU:T:2014:547, paragraph 1564.

preclude the Commission from specifying in the present Decision how it took into account the complementarity of the two abuses. On the contrary, setting for this case different gravity coefficients depending on the Relevant Member State being considered is appropriate to take into account the different intensity of the single and continuous infringement in the different Relevant Member States. Using a lower gravity coefficient for Relevant Member States where such intensity was lower is also in Teva's favour and ensures compliance with the principle of proportionality.

- (2268) It would be incorrect to assert that the lack of uniformity of a single and continuous infringements across jurisdictions or in time has never been considered relevant by the Union Courts. Indeed, in its *Google Android* judgment (i.e. precisely the most recent example mentioned by Teva), the General Court re-calculated the amount of the fine originally imposed by the Commission, exercising its unlimited jurisdiction with regards to fines for antitrust infringements. In so doing, the General Court took into account “*both the respective duration of the various aspects of the single and continuous infringement and [the] differences between the various periods [...] in order to assess the variable intensity of the effects of that infringement*”.³²²⁹ This was also done to better ensure, “*in accordance with the principle of proportionality and the principle that penalties should be specific to the offender and the offence, that the particularities of [each] case are duly taken into account, without thereby undermining the need to achieve a satisfactory level of deterrence*”.³²³⁰ In any event, Teva itself acknowledged during the proceedings that it “*would take no issue, generally, with an unprecedented approach that is reasoned, reasonable, and proportionate*”.³²³¹
- (2269) Second, Teva also argued that the threshold of one third of the overall duration of the single and continuous infringement as regards the overlap of the two abusive conducts in each Relevant Member State, and which the Commission uses to determine whether to apply a gravity coefficient of {...} % or {...} % is “*arbitrary*”.³²³²
- (2270) However, this argument should be rejected. As noted above (see Recital (2252)), the Commission may exercise its discretion when setting the fines for antitrust infringements, when determining that an overlap between the two infringements was significant (thus resulting in a higher gravity coefficient) where these individual infringements were both ongoing for more than a third of the overall duration of the single and continuous infringement. Since the two infringements found in this Decision were part of a single and continuous infringement, it is not necessary to identify two separate gravity coefficients. However, as the two abuses reinforced one another, the more they overlapped, the more their actual or potential impact on competition was significant. For this reason, the Commission considers it appropriate and proportionate in this case to increase the gravity coefficient by 3 percentage points (i.e. by a quarter of its original amount) when the two abuses were both ongoing in each Relevant Member State for more than a third of the duration of the single and continuous infringement.
- (2271) Third, Teva argued that the Commission cannot consider the improper gains resulting from the infringement when setting the gravity coefficient, as this is

³²²⁹ See Judgment of the General Court of 14 September 2022, *Google and Alphabet v Commission (Google Android)*, T-604/18, EU:T:2022:541, paragraph 1094.

³²³⁰ Ibid, paragraph 1086.

³²³¹ ID 5909, Teva's Reply to the Letter of Facts II of 17 May 2024, para. 183.

³²³² ID 5909, Teva's Reply to the Letter of Facts II of 17 May 2024, paras. 190-192.

allegedly not reflected in the Guidelines on Fines or in the recent Commission Decision on the *Apple App Store Practices (music streaming)* case and, in any event, the seriousness of an infringement and the profits that can result therefrom are (allegedly) two separate concepts.³²³³

- (2272) In view of, the case law of the Union Courts quoted in Recital (2253) above and for the additional reasons set out below, this claim must be rejected.
- (2273) In the first place, point 31 of the Guidelines on Fines indicates that the Commission will “*take into account the need to increase the fine in order to exceed the amount of gains improperly made as a result of the infringement where it is possible to estimate that amount*”. While point 31 does not concern directly the factors to be considered when setting the gravity coefficient, this does not mean that improper gains resulting from the infringement cannot be considered – as an alternative to applying point 31 – when setting the gravity coefficient.
- (2274) In any event, the Guidelines clearly indicate that “[t]he assessment of gravity will be made on a case-by-case basis for all types of infringement, taking account of all the relevant circumstances of the case”.³²³⁴ Thus, the Guidelines on Fines are not exhaustive when listing the factors to be considered when setting the gravity coefficient.³²³⁵ Moreover, as confirmed by the case law of Union Courts, “the Guidelines [do not] preclude consideration of the actual impact of the infringement on the market in order to increase” the gravity coefficient³²³⁶, and the Commission considers in this case that the improper gains resulting from Teva’s single and continuous infringement are one aspect of its impact on certain relevant markets.
- (2275) In the second place, Teva’s reference to the Commission Decision in the *Apple App Store Practices (music streaming)* case – as well as its claims based on the principles of good administration and equal treatment – are unfounded. In that instance, the Commission rejected Apple’s argument that its “*very little*” profits from music streaming subscriptions (i.e., if compared to Apple’s core business) should have made the Commission consider a lower gravity coefficient and concluded that, in that case, the gravity coefficient was to reflect “*the degree of gravity of the infringement and not the profits made by the undertaking infringing Article 102 of the Treaty*”.³²³⁷ This does not undermine the Commission’s ability to consider appropriate an increase in the gravity coefficient in a different case, when it can prove that an antitrust infringement actually resulted in additional gains, all the more so if this concerns the investigated undertaking’s most important, blockbuster product. In the case at hand, Teva itself acknowledged Copaxone as being “*hugely significant*” for the entire company.³²³⁸

³²³³ ID 5909, Teva’s Reply to the Letter of Facts II of 17 May 2024, paras. 199-205.

³²³⁴ Point 20 of the Guidelines on Fines. By the same token, point 22 of the same Guidelines on Fines indicates that “[i]n order to decide whether the proportion of the value of sales to be considered in a given case should be at the lower end or at the higher end of [the scale up to 30% of the value of sales], the Commission will have regard to a number of factors, such as the nature of the infringement, the combined market share of all the undertakings concerned, the geographic scope of the infringement and whether or not the infringement has been implemented” (emphasis added).

³²³⁵ See also the case law mentioned in Recital (2253) above.

³²³⁶ Judgment of the General Court of 12 June 2014, *Intel*, T-286/09, EU:T:2014:547, paragraph 1625.

³²³⁷ See Commission Decision of 4 March 2024, *Apple – App Store Practices (music streaming)*, Case AT.40437, Recitals 935-936.

³²³⁸ ID 4032, Teva’s Reply to the Statement of Objections, para. 110.

- (2276) In the third place, the claim that the seriousness of an infringement is a separate concept from the illegal gains an undertaking can receive therefrom is ineffective for the purposes of the present calculation. Indeed, it is within the Commission’s discretion when setting fines for antitrust infringements to consider that, in addition to the seriousness or type of the infringement, it also needed to take into account other factors, such as the illegal gains likely resulting therefrom as representing one aspect of the infringement’s impact in some of the Relevant Member States. As noted in Recital (2274) above, the Guidelines on Fines are not exhaustive when listing the factors to be considered when setting the gravity coefficient. In addition, Teva has acknowledged during the proceedings that an infringement “*less serious*” than a hardcore price fixing cartel “*(e.g., disparagement) could result in extraordinary profits in an industry with high-margin products*”³²³⁹ and this, in the Commission’s view, needs to be taken into account when setting the gravity coefficient to ensure deterrence, and in light of the fact that the difference in prices (and the corresponding significantly higher cost for health systems) may be possibly leading to misallocations of funding to the detriment of other market participants and patients and to the benefit of Teva’s profits.
- (2277) Fourth, Teva also argues that the Commission cannot increase the fine related to Czechia and Germany on the basis of events that occurred after the abuses ended.³²⁴⁰ However, this argument is misguided since, as concluded in Chapters 8 and 12, Teva’s misuse of divisional patents was still ongoing when preliminary injunctions based on such divisional patents were granted against Synthon GA as a consequence of Teva’s conduct in Czechia and Germany.
- (2278) Lastly, Teva argues that the gravity coefficient for Czechia and Germany could only be increased on the basis of a hypothetical counterfactual analysis in these two Relevant Member States and that, since the Commission has not performed this exercise, it cannot assert that Teva’s profits were higher than in a hypothetical scenario of undistorted competition.³²⁴¹ Teva’s argument is unfounded. The increase in the gravity coefficient for Czechia and Germany is based on the finding that the single and continuous infringement likely resulted in higher profits in those Relevant Member States (as even Teva itself estimated), chiefly due to the preliminary injunctions which almost eliminated all competition from Synthon GA for the periods in which they were in place and with lingering effects thereafter (see Recitals (2254)-(2263)). For that purpose, it is not necessary to reconstruct the exact magnitude of the profits specifically attributable to the infringement.

15.2.3.1.2.2. Conclusion on the gravity coefficient

- (2279) In light of the above, the gravity coefficients used when setting the fine to be imposed on Teva are the following: {...} % for Belgium, the Netherlands and Poland; {...} % for Italy and Spain; {...} % for Czechia; and {...} % for Germany.

15.2.3.1.3. Duration

- (2280) As set out in Chapter 12 above, the single and continuous infringement of Article 102 TFEU found in this Decision started on 3 February 2015.
- (2281) Chapter 12 above also indicates that the end date of the single and continuous infringement varies between Relevant Member States. More precisely, the single and

³²³⁹ ID 5909, Teva’s Reply to the Letter of Facts II of 17 May 2024, para. 205.

³²⁴⁰ See ID 5909, Teva’s Reply to the Letter of Facts II of 17 May 2024, paras. 207-215.

³²⁴¹ See ID 5909, Teva’s Reply to the Letter of Facts II of 17 May 2024, paras. 219(b) and 227(c)(iii).

continuous infringement ended on 7 February 2024 (i.e. when the TBA effectively revoked EP ‘962 and EP ‘172) in Belgium, Czechia, Germany and Spain, while it ended on 31 December 2018 in the Netherlands, on 31 December 2021 in Italy and on 31 December 2022 in Poland (i.e., the last day Teva has been found to hold a dominant position on the GA markets in the Netherlands, Italy and Poland respectively).

(2282) The Commission therefore concludes that the duration of the single and continuous infringement is 3292 days in Belgium, Czechia, Germany and Spain, 1428 days in the Netherlands, 2524 days in Italy and 2889 days in Poland.

15.2.3.1.4. Additional amount

(2283) The Commission concludes that an additional amount of the relevant values of sales must be applied to contribute to the deterrent effect that the fine should have on an undertaking of a size and with resources such as Teva.³²⁴² This is particularly the case because, as shown in Section 9.4.3 above, Teva enjoyed a special position in its communication with Payers and HCPs in the field of multiple sclerosis, while being at the same time the largest generic company in the world.

(2284) In light of the factors set out in Section 15.2.3.1.2 above (and, in particular, of the geographic scope and different intensity of the single and continuous infringement), the Commission applies an additional amount equal to the following proportion of the value of sales for each of the seven Relevant Member States: {...} % for Belgium, the Netherlands and Poland; {...} % for Italy and Spain; {...} % for Czechia; and {...} % for Germany.

15.2.3.1.5. Conclusion on the basic amount

(2285) The basic amount of the fine to be imposed on Teva for the single and continuous infringement of Article 102 TFEU found in this Decision amounts to EUR 462 578 000, i.e. to the sum of the following amounts for the Relevant Member States:

Table 18: Composition of the basic amount of the fine

Relevant Member State	Component of the basic amount of the fine (EUR)
Belgium	{...}
Czechia	{...}
Germany	{...}
Spain	{...}
Italy	{...}
The Netherlands	{...}
Poland	{...}

³²⁴² Point 25 of the Guidelines on Fines.

15.2.3.2. Application of Article 23(2) of Regulation (EC) No 1/2003

(2286) Pursuant to Article 23(2) of Regulation (EC) No 1/2003, the fine for an infringement must not exceed 10 % of the undertaking's total turnover in the preceding business year.

(2287) {...}.³²⁴³

(2288) As the basic amount of the fine set out above is below 10 % of that figure, no adaptation pursuant to Article 23(2) of Regulation (EC) No 1/2003 is necessary in this case.

15.2.3.3. Conclusion: final amount of the fine

(2289) The fine to be imposed on Teva pursuant to Article 23(2) of Regulation (EC) No 1/2003 and in light of the single and continuous infringement found in this Decision is therefore equal to EUR 462 578 000.

16. CONCLUSION

(2290) In light of the considerations set out in this Decision, the Commission:

- (a) finds that Teva committed an infringement of Article 102 TFEU in the Netherlands in the period from 3 February 2015 until 4 April 2017, in Italy in the period from 3 February 2015 until 31 December 2021, in Poland in the period from 3 February 2015 until 31 December 2022, and in Belgium, Czechia, Germany and Spain in the period from 3 February 2015 until 7 February 2024, by, without objective justification, creating multiple divisional patents with overlapping content, intentionally staggering their filings and repeatedly and strategically withdrawing them with the aim of prolonging legal uncertainty, and such conduct being capable of hindering and/or delaying market entry and uptake of competing GAs on the relevant national markets and, thereby, eliminating or delaying price competition;
- (b) finds that Teva committed an infringement of Article 102 TFEU in Poland in the period from 12 April 2016 until 8 August 2017, in Czechia in the period from 12 April 2016 until 18 August 2017, in the Netherlands in the period from 12 April 2016 until 31 December 2018, in Belgium in the period from 12 April 2016 until 11 March 2019, in Germany in the period from 12 April 2016 until 24 March 2020, in Spain in the period from 12 April 2016 until 20 September 2020, and in Italy in the period from 12 April 2016 until 20 October 2020, by, without objective justification, disseminating, to Payers and HCPs objectively misleading information capable of discrediting Synthon GA (the only GA product competing with Copaxone in the EU), such conduct being capable of producing exclusionary effects by hindering and/or delaying the market entry and uptake of Synthon GA;
- (c) finds that the two infringements defined under points (a) and (b) above constitute a single and continuous infringement of Article 102 TFEU, and Teva committed this single and continuous infringement of Article 102 TFEU in the Netherlands in the period from 3 February 2015 until 31 December 2018, in Italy in the period from 3 February 2015 until 31 December 2021, in Poland in the period from 3 February 2015 until 31 December 2022, and in Belgium,

³²⁴³ ID 5897, Certification of Teva's turnover data.

Czechia, Germany and Spain in the period from 3 February 2015 until 7 February 2024;

- (d) requires Teva to refrain from repeating the infringement and from any act or conduct having the same or similar object or effect as the conduct identified as abusive; and
- (e) imposes a fine on Teva Pharmaceutical Industries Ltd and Teva Pharmaceuticals Europe B.V..

HAS ADOPTED THIS DECISION:

Article 1

1. Teva Pharmaceutical Industries Ltd and Teva Pharmaceuticals Europe B.V. have infringed Article 102 of the Treaty by, without objective justification, creating multiple divisional patents with overlapping content, intentionally staggering their filings and repeatedly and strategically withdrawing them with the aim of prolonging legal uncertainty, such conduct being capable of hindering and/or delaying market entry and uptake of competing GAs on the relevant national markets and, thereby, eliminating or delaying price competition in the Netherlands in the period from 3 February 2015 until 4 April 2017, in Italy in the period from 3 February 2015 until 31 December 2021, in Poland in the period from 3 February 2015 until 31 December 2022, and in Belgium, Czechia, Germany and Spain in the period from 3 February 2015 until 7 February 2024.
2. Teva Pharmaceutical Industries Ltd and Teva Pharmaceuticals Europe B.V. have infringed Article 102 of the Treaty by, without objective justification, disseminating to Payers and HCPs objectively misleading information capable of discrediting Synthron GA (the only GA product competing with Copaxone in the EU), such conduct being capable of producing exclusionary effects by hindering and/or delaying the market entry and uptake of Synthron GA, in Poland in the period from 12 April 2016 until 8 August 2017, in Czechia in the period from 12 April 2016 until 18 August 2017, in the Netherlands in the period from 12 April 2016 until 31 December 2018, in Belgium in the period from 12 April 2016 until 11 March 2019, in Germany in the period from 12 April 2016 until 24 March 2020, in Spain in the period from 12 April 2016 until 20 September 2020, and in Italy in the period from 12 April 2016 until 20 October 2020.
3. The two infringements defined in the above two paragraphs constitute a single and continuous infringement of Article 102 of the Treaty, and Teva Pharmaceutical Industries Ltd and Teva Pharmaceuticals Europe B.V. have committed this single and continuous infringement of Article 102 of the Treaty in the Netherlands in the period from 3 February 2015 until 31 December 2018, in Italy in the period from 3 February 2015 until 31 December 2021, in Poland in the period from 3 February 2015 until 31 December 2022, and in Belgium, Czechia, Germany and Spain in the period from 3 February 2015 until 7 February 2024.

Article 2

For the infringements referred to in Article 1, a fine of EUR 462 578 000 is imposed on Teva Pharmaceutical Industries Ltd jointly and severally with Teva Pharmaceuticals Europe B.V.

The fine shall be credited, in euros, within three months of the date of notification of this Decision, to the following bank account held in the name of the European Commission:

BANQUE CENTRALE DU LUXEMBOURG
2, Boulevard Royal
L-2983 Luxembourg

IBAN: LU27 9990 0001 1400 100E
BIC: BCLXLULL
Ref.: EC/BUFI/AT.40588

After the expiry of that period, interest shall automatically be payable at the interest rate applied by the European Central Bank to its main refinancing operations on the first day of the month in which this Decision is adopted, plus 3.5 percentage points.

Where an action pursuant to Article 263 of the Treaty is brought before the Court of Justice of the European Union against this Decision, the fine shall be covered by its due date, either by providing an acceptable financial guarantee or by making a provisional payment of the fine in accordance with Article 108 of Regulation (EU, Euratom) 2024/2509 of the European Parliament and of the Council.³²⁴⁴

Article 3

Teva Pharmaceutical Industries Ltd and Teva Pharmaceuticals Europe B.V. shall refrain from repeating any act or conduct described in Article 1 and from any act or conduct having the same or equivalent object or effect.

³²⁴⁴ Regulation (EU, Euratom) 2024/2509 of the European Parliament and of the Council of 23 September 2024 on the financial rules applicable to the general budget of the Union (OJ L, 26.09.2024, p. 1)

Article 4

This Decision is addressed to

Teva Pharmaceutical Industries Ltd
located at 124 Devorah Hanevia,
Tel Aviv 6944020,
Israel,

and

Teva Pharmaceuticals Europe B.V.
located at Busweg 1,
2031 DA Haarlem,
the Netherlands.

This Decision shall be enforceable pursuant to Article 299 of the Treaty.

Done at Brussels, 31.10.2024

For the Commission

(signed)

Margrethe VESTAGER
Executive Vice-President