EUROPEAN COMMISSION

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PUBLIC VERSION

PROFARM ANONYMI
ETAIREIA
PHARMAKAPOTHIKI,
EMPORIA – DIANOMI
PHARMAKON KALLYNTIKON
KAI PARAPHARMAKEUTIKON
EIDON
51 Agamemnonos Str
17675 Kallithea
Attica
GREECE

Subject: **Case AT.40185 – Amgen refusal to supply wholesalers**
Commission Decision rejecting your complaint pursuant to Article 13 of Council Regulation (EC) No 1/2003 and Article 9 of Commission Regulation (EC) No 773/2004, and pursuant to Art. 7(2) of Commission Regulation (EC) No 773/2004
(Please quote this reference in all correspondence)

Dear Sir or Madam,

(1) I am writing to inform you that the European Commission (the 'Commission') has decided to reject your complaint of 31 July 2013 against Amgen Hellas Pharmaceutical LLC, Amgen Worldwide Holdings B.V. and Amgen (Europe) GmbH (hereinafter referred to as 'Amgen'), pursuant to Article 13(2) of Council Regulation (EC) No 1/2003 ([1]) and Article 9 of Commission Regulation (EC) No 773/2004 ([2]), and pursuant to Article 7(2) of Commission Regulation (EC) No 773/2004.

([1]) Council Regulation (EC) No 1/2003 on the implementation of the rules on competition laid down in Articles 81 and 82 of the Treaty (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 (the "TFEU"). The two sets of provisions are, in substance, identical. Pursuant to Article 5(3) of the Treaty of Lisbon, references in legal acts to Articles 81 and 82 of the EC Treaty are to be understood as references to Articles 101 and 102 TFEU when appropriate.

([2]) Commission Regulation (EC) No 773/2004 relating to the conduct of proceedings by the Commission pursuant to Articles 81 and 82 of the EC Treaty (OJ L 123, 27.4.2004, p. 18).

1. THE COMPLAINT

(2) By letter dated 31 July 2013, you requested the Commission to launch an investigation into alleged anti-competitive conduct by Amgen. In your complaint and subsequent submissions to the Commission, you alleged that Amgen infringes Union competition law by refusing since 1 January 2013 to supply your pharmaceutical wholesaler company (Profarm Anonymi Etaireia Pharmakapothiki, Emporia – Dianomi Pharmakon Kallyntikon kai Parapharmakeutikon Eidon – hereinafter referred to as 'Profarm' or 'complainant') and other pharmaceutical wholesalers in Greece with Neulasta (pegfilgrastim) and Aranesp (darbepoetin alfa) (hereinafter also referred to as 'the Pharmaceutical Preparations'), and that Amgen also refused to supply with the said preparations wholesalers established on the markets in several "low-price" Member States other than Greece. You alleged that this refusal constitutes an abuse of a dominant position contrary to Article 102 TFEU.

(3) According to your complaint in relation to Amgen`s alleged conduct in Greece, Profarm was supplied with the Pharmaceutical Preparations from 2007 until the end of 2012 by [...]* (hereinafter referred to as [...]). [...] is an independent company but, under a commercial contract with Amgen, it was responsible for distributing the Pharmaceutical Preparations (and some other Amgen products) in Greece through local wholesalers. The commercial relationship between Amgen and [...] ended in December 2012. According to your complaint, Amgen then informed the wholesalers, including Profarm, that future orders had to be submitted directly to Amgen Hellas Pharmaceutical LLC (Amgen). Profarm submitted its orders for the Pharmaceutical Preparations in early 2013, but Amgen did not fulfil any of these orders. Profarm subsequently addressed a non-judicial notice to Amgen in order to, firstly, complain about an allegedly unjustified refusal to sell the Pharmaceutical Preparations and, secondly, to submit a new order. Amgen replied to this non-judicial notice, justifying its refusal to supply wholesalers by stating that, under Greek law, the Pharmaceutical Preparations could, according to Amgen, be supplied only to public hospital pharmacies and pharmacies of EOPYY (National Health System) and not to private pharmacies.

Follow-up exchanges in relation to the complaint

(4) You provided further clarifications at a meeting with the Commission services in Brussels on 7 February 2014. At this meeting, you handed over a copy of a letter (addressed to Profarm and dated 9 July 2013) from the Hellenic Medicine Agency stating that in certain cases the product Aranesp may also be made available outside a hospital.

(5) By letter of 4 March 2014, you submitted additional information to the Commission. By email of 18 March 2014, you confirmed that the complaint and its annexes were entirely non-confidential.

(6) On 16 September 2014, and with your consent, the Commission sent a copy of the complaint, its annexes and the abovementioned letter of the Hellenic Medicine Agency to Amgen, together with a request for information under Article 18(2) of Regulation (EC) No 1/2003, to which Amgen responded in writing on 7 and 10 November 2014.

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* Parts of this text have been edited to ensure that confidential information is not disclosed. Those parts are replaced by a non-confidential summary in square brackets or are shown as [...].

(7) By email of 17 February 2015, the Commission sent further questions to Amgen, to which Amgen replied on 4 March 2015.

(8) At a meeting with the Commission services in Brussels on 26 February 2015, you announced the submission of further information regarding the regulatory framework of sales and pricing of medicines in Greece, which you submitted on 27 April 2015. By email of 2 July 2015, the Commission services sent a list of questions to you, to which you replied on 24 July 2015. You also submitted additional information on 16 October 2015 and 29 December 2015.

(9) On 13 October 2015, the Commission issued a request for information under Article 18(2) of Regulation (EC) No 1/2003 to [...], to which [...] replied on 3 November 2015.

(10) The requests for information to Amgen and [...] and their respective replies focused on the allegation of refusal to supply in Greece.

(11) In an email of 15 February 2016, the Commission services addressed several questions to you. You replied on 11 and 24 March 2016. On 11 March 2016, you also completed, upon the Commission's request, your initial complaint by submitting annex 22, i.e. a copy of your earlier complaint of 27 June 2013 to the Hellenic Competition Commission (hereinafter referred to as 'HCC').

(12) At a meeting on 21 November 2016 with the Commission services, you were informed of the envisaged rejection of your complaint, subject to the analysis of additional information you submitted at that meeting and additional information to be submitted in the following days.

(13) You submitted additional written information to the Commission on 21 and 22 November 2016.

(14) Moreover, there have been email exchanges on various dates between you and the Commission services on the status of the complaint. ([3])

Rejection letters and reaction from the complainant

(15) By letter C(2017)268 final of 13 January 2017, the Commission informed you that, pursuant to Article 7(1) of Regulation (EC) No 773/2004, there are insufficient grounds for acting on your allegation that Amgen's conduct in "low-price" Member States other than Greece infringes EU competition law. The Commission also informed you that, on the basis of the information you have provided, it was not convinced you had a legitimate interest regarding the alleged infringement in "low-price" Member States other than Greece, as required by Article 7(2) of Regulation (EC) No 1/2003. You were given the possibility to submit written observations on this provisional assessment.

(16) By letter D(2017)003716 of 16 January 2017, the Commission services informed you that the practice described in your complaint that Amgen's conduct in Greece infringes Union competition law, was being dealt with by the HCC. In the same letter you were informed that the Commission may reject this part of your complaint, pursuant to Article 13(1) of Regulation (EC) No 1/2003, and you were given the possibility to submit written observations on this provisional assessment.

([3]) The complainant asked about the status of the complaint on 20 May 2014, 29 July 2014, 8 September 2015, 20 May 2016 and 6 February 2018. The Commission services replied on 21 May 2014, 1 August 2014, 8 September 2015, 24 May 2016, 15 September 2016, 15 September 2016, and 7 February 2018, respectively.

(17) By letters of 25 January and 7 February 2017, you asked to be granted access to the documents on which the Commission based its provisional assessment, and you also asked for a suspension of the deadline to submit written observations to the Commission regarding its intention to reject your complaint. By letter of 17 March 2017, the Commission services replied to your request, clarifying your rights for access to the documents in the present case, and granted an additional deadline of four weeks to submit written observations.

(18) By letter of 25 March 2017, you asked the Commission services to re-confirm their clarification about your rights for access to documents, and to extend the deadline for the submission of written observations until 2 May 2017. By letter of 29 March 2017, the Commission services re-confirmed their explanations regarding your rights for access to the documents in the present case, and agreed to your request to extend the deadline for the submission of written observations until 2 May 2017. You submitted written observations within this new deadline, namely by letter of 28 April 2017.

(19) You made additional written observations by email of 21 November 2017, two emails of 6 December 2017 and an email of 3 January 2018, for which the Commission acknowledged receipt by emails of 24 November 2017, 20 December 2017, and 10 January 2018 respectively. At this occasion, the Commission also recalled that it was not obliged to take into account written submissions received after the expiry of the deadline set to submit such observations (Article 7(1) of Regulation (EC) No 1/2003 and Regulation (EC) No 773/2004). With your email of 6 December 2017, you submitted also a copy of decision No 11/2017 of the HCC of 13 October 2017 (regarding your complaint to the HCC of 27 June 2013, which was filed with HCC reference 5214/28.6.2013).

(20) In a phone call with the Commission services on 19 January 2018, you discussed procedural issues regarding the present case, and the Commission services informed you that, since the HCC had recently "dealt with" the case (adopting a rejection decision on your complaint in Greece with the same subject matter), the Commission services envisaged to send you a new letter pursuant to Article 13(2) of Regulation (EC) No 1/2003.

(21) By letter of 28 March 2018, the HCC confirmed to the Commission that on 13 October 2017 it had adopted decision No 11/2017 in the case with the national number 5214/28.06.2013, which concerns the alleged refusal by Amgen to supply the Pharmaceutical Preparations to Profarm (and other wholesalers), as from 1 January 2013 (and on-going). The HCC thus confirmed that it had dealt with this case. It also informed the Commission that it had examined the case jointly in light of Article 2 of Greek Law 3959/2011 and Article 102 TFEU (which have in fact identical wording), and had concluded that the evidence and the claims brought to the attention of the HCC did not indicate an infringement of the above-mentioned provisions.

(22) Consequently, by letter D(2018)039910 of 25 April 2018, the Commission services informed you that the practice described in your allegation that Amgen's conduct in Greece infringes Union competition law, had been dealt with by the HCC. In the same letter you were informed that the Commission may reject your complaint, pursuant to Article 13(2) of Regulation (EC) No 1/2003 and you were given the possibility to submit written observations on the Commission's provisional assessment of your complaint.

(23) On 23 May 2018, you submitted written observations to the Commission, urging the Commission to not reject your complaint and to further investigate the matter. In essence, you stated that by dividing the complaint into Amgen's conduct in Greece on the one hand and into Amgen's conduct in Member States other than Greece on the other hand, the Commission was distorting the content of the complaint and the relevant factual background.

(24) On the rejection of the complaint pursuant to Article 13 of Regulation (EC) No 1/2003, you stated in your submission that the practice examined by the Commission is not the same as the practice that was subject of Profarm's complaint before the HCC. You argued that the subject matter of the complaint before the Commission is the entire practice of Amgen in numerous Member States, commencing in Member States applying a "low-price" regime on the Pharmaceutical Preparations and extending to Member States with a "high-price" regime, while the subject matter of the complaint before the HCC is Amgen's practice solely in Greece. You claimed that therefore the geographical market and the corresponding anti-competitive effects are not the same in the two complaints, and you added that the HCC has no competence to assess the practice in Member States other than Greece. You also stated that Article 13 of Regulation (EC) No 1/2003 does not impose on the Commission the obligation to reject the complaint but that the Commission has the discretion to examine a complaint even if a national competition authority is dealing or has dealt with a similar practice.

(25) By e-mail of 2 July 2018, you requested a meeting with the Commission services, in view of clarifying the documents you submitted on 23 May 2018. The meeting took place at the Commission's premises on 28 September 2018.

(26) By e-mail of 2 November 2018, you announced the submission of further evidence that should prove that the sole and only goal of Amgen's practice, which gave rise to Profarm's complaint, is to stop the parallel exports of the Pharmaceutical Preparations to Member States where the prices of these preparations are significantly higher than in the exporting Member States. You submitted the announced information by e-mail of 29 November 2018, asking once again for the Commission to not reject the complaint.

(27) By e-mail of 8 May 2019, you informed the Commission that the Athens Administrative Court of Appeal had annulled the HCC decision No 11/2017, by its judgment No 1727 of 22 April 2019.

(28) By e-mail of 21 May 2019, you asked the Commission to hold its assessment of the case pending until submission of a copy of the abovementioned judgment of the Athens Administrative Court of Appeal. You submitted a copy of that judgment by e-mail of 24 June 2019.

(29) By email of 22 December 2020, the HCC informed the Commission that Amgen as well as the HCC had appealed the decision of the Athens Administrative Court of Appeal.

(30) By email of 8 January 2021, you updated the Commission on national procedures (rejection of Profarm's action for damages in Greece, and Profarm appealing that decision, Amgen and the HCC appealing judgment No 1727 of the Athens Administrative Court of Appeal before the Council of State) and you asked the Commission to suspend its assessment until the judgment of the Council of State.

(31) In a call and a follow-up email of 10 June 2024, the Commission services asked you for an update on the national procedures. By email of 12 June 2024, you

informed the Commission that the judgment of the Council of State was still pending.

(32) By email of 18 November 2024, the Commission services again asked you for an update on the national procedures. You replied by email of 19 November 2024 that you had been notified on 4 November 2024 of the issuance of Council of State Decision No 1657/2024 referring the case back to the Administrative Court of Appeal of Athens. By email of 28 November 2024, the Commission services asked you to submit a copy of the Council of State Decision as soon as it was available. You sent a copy of the Council of State Decision to the Commission by email of 21 May 2025.

(33) By email of 25 February 2025, the Commission services asked the HCC to clarify the status of the initial HCC decision No 11/2017 of 13 October 2017 after the Council of State Decision referring the case back to the Administrative Court of Appeal of Athens. By email of 6 March 2025, the HCC replied that the Council of State, by virtue of Decision No 1657/2024, had held that the Administrative Court of Appeal erred in its Decision No 1727/2019 and thus the Council of State had granted the appeals, annulled the Court Decision No 1727/2019 and referred the case back to the Administrative Court of Appeal to be judged again. The HCC clarified that consequently the initial HCC decision No 11/2017 of 13 October 2017 had been reinstalled and was standing (and subject to a new legal judgment by the Administrative Court of Appeal of Athens).

2. ASSESSMENT

(34) Your complaint relates to alleged refusal by Amgen to supply the Pharmaceutical Preparations (i) in Greece and (ii) in other "low-price" Member States. You allege that the objective of the alleged conduct is to prevent parallel trade (by refusing the supply of the Pharmaceutical Preparations in "low-price" Member States and thereby preventing their resale to "high-price" Member States). The Commission has assessed your allegations related to the alleged conduct in Greece on the basis of Article 13 of Regulation (EC) No 1/2003 (see point 2.1 below) and has assessed your allegations related to the alleged conduct in "low-price" Member States other than Greece on the basis of Article 7(2) of Regulation (EC) No 773/2004 (see point 2.2 below).

2.1. Assessment based on Article 13 of Regulation (EC) No 1/2003

2.1.1. Principles

(35) Pursuant to Article 13 of Regulation (EC) No 1/2003, the Commission may reject a complaint on the ground that a competition authority of a Member State is dealing with, or has dealt with, the same agreement, decision of an association or practice ([4]).

(36) This means that the case that is being dealt with, or has been dealt with, by the competition authority of a Member State, is based on the same set of facts as those set out in the complaint brought before the Commission ([5]). However, the Commission is not bound by the subject-matter or the cause of action identified

([4]) See also Judgment of 17 December 2014, *Si.mobil v Commission*, T-201/11, EU:T:2014:1096, paragraphs 31 to 34.

([5]) See, to that effect, Judgment of 17 December 2014, *Si.mobil v Commission*, T-201/11, EU:T:2014:1096, paragraph 75.

by the complainant or by the manner in which the complainant characterises the matters ([6]).

(37) In order to reject a complaint pursuant to Article 13 of Regulation (EC) No 1/2003, the Commission may, therefore, rely on the fact that a competition authority of a Member State has previously dealt with the same agreement, decision of an association or practice ([7]). This is irrespective of whether the competition authority of the Member State concerned has dealt with the same agreement, decision of an association or practice by way of a decision within the meaning of Article 5 of Regulation (EC) No 1/2003 or by way of an administrative letter ([8]).

2.1.2. Assessment

(38) By letter dated 27 June 2013, registered by the HCC under reference 5214/28.6.2013, you requested the HCC to launch an investigation into the practice in Greece as described in paragraphs 2 and 3 above. The HCC informed the Commission on 24 June 2016 that it had started investigating the same practice in Greece, namely the refusal by Amgen to supply the Pharmaceutical Preparations to Profarm, within the same timeframe, namely as of January 2013. The HCC has examined the case both in light of Article 2 of Greek Law 3959/2011 and Article 102 TFEU (which have identical wording). On 13 October 2017, the HCC adopted a decision concluding that the evidence and the claims brought to the attention of the HCC do not constitute indication of an infringement of these Articles. ([9]) Consequently, the HCC terminated and archived the complaint.

(39) As explained above, you appealed that decision before the Athens Administrative Court of Appeal, which annulled the HCC decision by its judgment No 1727 of 22 April 2019. Both Amgen and the HCC appealed, and by judgment of 4 November 2024 the Council of State issued its Decision No 1657/2024, annulling the said judgment No 1727 and referring the case back to the Administrative Court of Appeal of Athens for a new judgment. By email of 6 March 2025, the HCC clarified to the Commission that consequently the initial HCC decision had been reinstated. It follows that the HCC has dealt with the complaint within the meaning of Article 13(2) of Regulation (EC) No 1/2003.

Your argument that the Commission's investigation was insufficient

(40) In your letter of 28 April 2017 (paragraph 6), you maintain that the investigation undertaken by the Commission was not sufficient, in so far as it was restrained to the sole consideration of documents provided by the complainant, without further investigation of the case.

(41) In this respect, the Commission considered the fact that the HCC has investigated the case insofar as it concerns the alleged conduct in Greece. For the rejection of a complaint under Article 13(2) of Regulation (EC) No 1/2003, the Commission is only bound to verify that another competition authority has dealt with the same practice.

([6]) Judgment of 17 December 2014, *Si.mobil v Commission*, T-201/11, EU:T:2014:1096, paragraph 76; Judgment of 12 March 2020, *LL-Carpenter v Commission*, T-531/18, EU:T:2020:91, paragraph 52.
([7]) Judgment of 17 December 2014, *Si.mobil v Commission*, T-201/11, EU:T:2014:1096, paragraph 50.
([8]) Judgment of 21 January 2015, easyJet Airline v Commission, T-355/13, EU:T:2015:36, paragraph 40.
([9]) Decision No 11/2017 of 13 October 2017 of the Hellenic Commission of Competition.

Your argument that the Commission is not obliged to reject the complaint

(42) In your letter of 23 May 2018 (paragraphs 13 to 14), you claim that, where both the Commission and a national competition authority are dealing with the 'same practice', Article 13 of Regulation (EC) No 1/2003 does not impose on the Commission the obligation to reject the complaint.

(43) In this respect, the Commission indeed has the discretion to examine a complaint, irrespective of the fact that a national competition authority is dealing or has dealt with the same complaint. However, the Commission notes that the purpose of Article 13 of Regulation (EC) No 1/2003 is to avoid the duplication of work among the European Competition Network and save administrative resources, which can be employed in other cases for the benefit of European citizens. Article 13 of Regulation (EC) No 1/2003 thus enables the Commission to decide, in its discretion, that a particular case "*which has already been dealt with by another competition authority*" does not warrant further investigation from its side. Such is the case in the situation at hand.

(44) It should also be noted that, according to settled case law, neither Regulation (EC) No 1/2003 nor the Commission Notice on cooperation within the Network of Competition Authorities ([10]) creates rights or expectations for an undertaking to have its case dealt with by a specific competition authority ([11]). The complainant has no right to have its case dealt with by the Commission, even assuming that the Commission was particularly well placed to deal with the case. ([12])

Your argument that the HCC cannot assess your complaint filed with the Commission because it does not relate to "the same practice"

(45) It appears that the practice in respect of which you have complained to the Commission is the same as the one that has already been dealt with by the HCC. In both complaints, you requested the respective competition authority to launch an investigation into Amgen's alleged abuse of a dominant position through its refusal – as of 1 January 2013 - to supply Profarm with the Pharmaceutical Preparations in Greece.

(46) You, however, argued in your letter of 28 April 2017 (paragraph 8) and in your letter of 23 May 2018 (paragraph 8) that the subject matter of your complaint before the Commission is the whole practice of Amgen, as exercised in numerous Member States, while the subject matter of your complaint before the HCC is the *application* of the pan-European practice of Amgen strictly and solely in Greece. You added in your letter of 23 May 2018 (paragraph 9) that the geographical market of your complaint before the Commission (with the corresponding anti-competitive effects) is therefore completely different from the geographical market of your complaint before the HCC. You stated in your letter of 23 May 2018 (paragraph 12) that consequently, this is not the *'same practice'* in the sense of Article 13 of Regulation (EC) No 1/2003.

(47) In your letter of 28 April 2017 (paragraphs 2 to 4) and in your letter of 23 May 2018 (paragraphs 2 to 5), you took note of the fact that the Commission assessed your complaint on the basis of two regulations, namely Article 13 of Regulation (EC) No 1/2003 for the above described alleged behaviour of Amgen in Greece,

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([10]) Commission Notice on the cooperation within the Network of Competition Authorities (OJ C 374, 13.10.2016, p. 10, hereinafter "the Cooperation Notice").

([11]) Case T-201/11 *Si.mobil* v *Commission*, EU:T :2014:1096, paragraph 39.

([12]) Case T-431/16, VIMC v Commission, EU:T:2017 :755, paragraph 34.

on the one hand, and, on the other hand, Article 7(1) of Regulation (EC) No 773/2004 for the above described alleged behaviour of Amgen in "low-price" Member States other than Greece. You claimed that such 'fragmentation' of your complaint is erroneous, because the subject matter of the complaint does not comprise two distinguishable practices but is a 'single and indivisible' practice applied by Amgen in almost all Union Member States and should thus be examined in its entirety. You stated that this practice commences in "low-price" Member States (such as Greece) and is completed in Member States where the Pharmaceutical Preparations are sold at a higher price (hereby excluding the parallel trade of Amgen's Pharmaceutical Preparations, with a view to increase Amgen's profits in those "high-price" Member States).

(48) You added in your letter of 28 April 2017 (paragraph 9) that the practice of the companies giving rise to the complaint has effects on competition in more than three Member States of the Union, which would require the involvement of the competition authorities of various Member States and action from the part of the Commission (pursuant to Article 14 of the Cooperation Notice).

(49) You concluded in your letter of 28 April 2017 (paragraph 10) that the HCC is unable to assess the practice of Amgen's companies in other Member States, and that therefore the HCC is not able to investigate your complaint submitted before the Commission. You reiterated this conclusion in your letter of 23 May 2018 (paragraph 11).

(50) For the following reasons, the Commission considers your argument that the HCC's investigation does not relate to the same practice not to be valid:

(51) First, your submissions do not dispute that the relevant markets are national in scope. In the first place, you confirmed as much - at the meeting with the Commission services on 28 September 2018, you agreed that the distribution of medicines constitutes a national geographic market in each Member State. In the second place, this is in line with the established decisional practice and case law, which took into account the specific regulatory framework in each Member State, i.e. the different pricing and reimbursement schemes, different brand and packaging strategies, different distribution systems. ([13])

(52) Second, a refusal to supply the Pharmaceutical Preparations in Greece – if established to be a breach of Article 102 TFEU – would constitute an infringement of the competition rules on the Greek national market, and would need to be assessed specifically with respect to this market, whereas similar alleged infringements (i.e. refusals to supply) in other Member States would need to be assessed separately for each respective national market concerned.

(53) Thus, it is exactly on the basis of the required separate assessment of the alleged behaviour on different relevant geographic (national) markets that the Commission has carried out its provisional assessment of your complaint applying both legal bases: (i) the alleged infringement in Greece, which has been dealt with by the HCC in the sense of Article 13 of Regulation (EC) No 1/2003, and (ii) the alleged behaviour in other Member States, which has not been dealt with by the HCC nor by any other national competition authority and to which Article 13 of Regulation (EC) No 1/2003 does not apply, and which therefore has

([13]) Commission Decision 2006/857/EC in Case COMP/A 37.507/F3 – *AstraZeneca* (OJ L 332, 30.11.2006, p. 24-25, paragraph 503).Case M. 7494- Brocacef/Medic Netherlands, M.7721- Celesio/Sainsbury's UK pharmacy business, T-168/01 - GlaxoSmithKline Services v Commission, ECLI:EU:T:2006:265, paragraph 150.

to be assessed under Article 7 of Regulation (EC) No 773/2004 (see below, section 2.2).

(54) With regard to your observation that Amgen's practice has effects on competition in more than three Member States of the Union, which cannot be investigated only by the HCC, the Commission notes that the simple fact that an alleged infringement on the national market of one Member State may also have effects on other markets than the one immediately concerned does not mean the competition authority of the first Member State could or should not investigate the conduct. The relevance of the national market as appropriate primary framework for assessing a possible infringement in that market, as well as the competence of the national competition authority responsible for enforcing the competition rules in that market, are not affected by possible consequential effects of such infringement in other geographic markets.

(55) The relevant case law points to strong connections between the alleged conduct and the national (export) market. Specifically, the Judgment of the European Court of Justice of 16 September 2008 ([14]) (the *Lelos* judgment – to which your complaint also refers) concerns a similar issue as addressed in your complaint, namely the refusal to meet orders (of certain pharmaceutical products) from wholesalers active in Greece on account of the fact that those wholesalers are involved in parallel exports of those products to other Member States. The *Lelos* judgment states that when an undertaking occupying a dominant position refuses to deliver its products in one Member State to wholesalers which export those products to other Member States, such behaviour may restrict competition not only in the first Member State, but also in other Member States (paragraph 35).

(56) In line with the *Lelos* judgment, the HCC is well placed to comprehensively assess the alleged conduct occurring on the Greek market. In such assessment, the HCC may need to take external factors into account and may investigate specific effects that may occur outside the Greek territory or facts relevant for assessing the likelihood of alleged anti-competitive effects). The HCC has the tools to do this and can also call on the assistance of other competition authorities.

(57) The case the HCC dealt with by its decision No 11/2017 of 13 October 2017 relates to the same set of facts as that set out in the complaint. ([15]) Indeed, the procedure of the HCC concerns the same alleged infringement as the one falling under the Commission's assessment focusing on Amgen's alleged practice in Greece, namely the same facts, refusal to supply the Pharmaceutical Preparations, by the same undertaking (Amgen), on the same market (same products on the same geographic market, i.e. the Greek national market), within the same timeframe (as from 1 January 2013 and on-going).

(58) With regard to your observation that the geographical market of your complaint before the Commission is completely different from the geographical market of your complaint before the HCC (see paragraphs 23 and 24 above), the Commission notes that the fact that similar practices are alleged in other Member States does not mean that together with the behaviour on the Greek market these practices would constitute a single and indivisible infringement (see also paragraphs (52) to 53 above).

([14]) Joined Cases C-468/06 to C-478/06, ECLI:EU:C:2008:504.
([15]) Case T-201/11 *Si.mobil v Commission*, EU:T:2014:1096, paragraph 75.

(59) It follows that the HCC has previously dealt with the same practice in Greece within the meaning of Article 13(2) of Regulation (EC) No 1/2003.

2.1.3. Conclusion based on Article 13 of Regulation (EC) No 1/2003

(60) For the above reasons, the Commission rejects your complaint pursuant to Article 13(2) of Regulation (EC) No 1/2003, insofar as it concerns Amgen's alleged practice in Greece. Pursuant to Article 9 of Regulation (EC) No 773/2004, the Commission informs you that the HCC has dealt with the case insofar as it concerns the alleged conduct in Greece.

2.2. Assessment based on Article 7(2) of Regulation (EC) No 773/2004

2.2.1. Legitimate interest

(61) According to Article 7(2) of Regulation (EC) No 773/2004, natural and legal persons shall show a legitimate interest in order to be entitled to lodge a complaint. According to the Commission Notice on the handling of complaints ([16]), undertakings can claim a legitimate interest where the conduct complained of is liable to directly and adversely affect their interest.

(62) In the present case, the Commission reaches the conclusion that Profarm lacks legitimate interest in so far as its complaint relates to an alleged refusal to supply the Pharmaceutical Preparations to wholesalers other than Profarm in "low-price" Member States other than Greece, for the following reasons.

(63) First, as explained in paragraphs 13 and 14 of its letter C(2017)268 final of 13 January 2017, based on the information you made available to the Commission, it does not appear that Profarm has any commercial activity in such "low-price" Member States.

(64) Second, you expressly confirmed this at the meeting with the Commission services that took place on 28 September 2018 in Brussels: Profarm operates from Greece and engages in parallel exports – through the brokerage company [...] – to "high-price" EU Member States.

(65) Third, your argument that Profarm is selling to other Member States does not change this assessment, as you would need to demonstrate legitimate interest for the Member States where the alleged conduct is taking place, i.e. the refusal to supply in "low-price" Member States other than Greece – where Profarm is not active as a buyer of the Pharmaceutical Preparations for export to "high-price" Member States.

(66) In your letter of 28 April 2017, you stated that even though Profarm has no relevant establishment in a Member State other than Greece, its action is not limited solely to Greece. You added that Profarm is active in parallel exports to other Union Member States (e.g. Germany, the Netherlands, the United Kingdom, Sweden) and that a considerable part of its turnover concerns such parallel exports, specifically, as regards the Pharmaceutical Preparations, 86.54% for Aranesp and 99.63% for Neulasta (2012 figures). You did not submit, however, that your company runs commercial activities in other "low-price" Member States than Greece.

([16]) Commission Notice on the handling of complaints by the Commission under Articles 81 and 82 of the EC Treaty (OJ C 101, 27.04.2004, p. 65).

(67) Moreover, since Profarm is not a parallel exporter from "low-price" Member States other than Greece, and may thus not be harmed by the alleged behaviour of Amgen in these Member States, the Commission takes the view that Profarm does not appear to be directly and adversely affected by Amgen's alleged supply restriction/refusal to wholesalers in "low-price" Member States other than Greece.

(68) In addition, the Commission understands that Profarm is not active as a buyer of the Pharmaceutical Preparations in any "high price" Member State. It would thus not suffer from the alleged anticompetitive effects that the alleged refusal to supply by Amgen would have on the markets in these Member States.

(69) Therefore, from the information submitted by you, it follows that you had no legitimate interest to launch a complaint in the meaning of Article 7 of Council Regulation (EC) No 1/2003 for those Member States.

2.2.2. The need for the Commission to set priorities

(70) Complaints facilitate the detection of infringements of the Union competition rules. They bring to the Commission's attention matters of fact and of law which the Commission examines ([17]).

(71) It is inherent to the complaints procedure that the obligation to substantiate the allegations lies with the complainant ([18]), while the Commission is responsible for defining and implementing the orientation of the Union's competition policy. In order to perform that task effectively, it is entitled to give differing degrees of priority to the complaints brought before it ([19]).

(72) The Commission has limited resources and is unable to pursue every alleged infringement of the Union competition rules which is brought to its attention. Therefore, the Commission must set priorities, in accordance with the principles set out notably at points 41 to 45 of the Notice on the handling of complaints ([20]), and reject a complaint when it considers that the case does not display a sufficient Union interest to justify a further investigation.

(73) When deciding which cases to pursue, the Commission takes various factors into account. There is no fixed set of criteria for the assessment ([21]).

(74) The Commission may take into consideration whether, on the basis of the information available, it seems unlikely that further investigation will ultimately result in the finding of an infringement.

(75) In addition, the Commission may consider the scope of the investigation required. If it emerges that an in-depth investigation would be a complex and time-consuming matter and the likelihood of establishing an infringement appears limited, this will weigh against further action by the Commission.

([17]) Judgment of 19 September 2013, *EFIM* v *Commission*, C-56/12 P, EU:C:2013:575, paragraph 71.

([18]) See, to that effect, judgment of 19 September 2013, *EFIM* v *Commission*, C-56/12 P, EU:C:2013:575, paragraph 72.

([19]) Judgment of 4 March 1999, *Ufex e.a.* v *Commission*, C-119/97 P, EU:C:1999:116, paragraph 88; judgment of 19 September 2013, *EFIM* v *Commission*, C-56/12 P, EU:C:2013:575, paragraph 72.

([20]) Commission Notice on the handling of complaints by the Commission under Articles 81 and 82 of the EC Treaty (OJ C 101, 27.4.2004, p. 65).

([21]) Judgment of 4 March 1999, *Ufex e.a.* v *Commission*, C-119/97 P, EU:C:1999:116, paragraphs 79 and 80; judgment of 19 September 2013, *EFIM* v *Commission*, C-56/12 P, EU:C:2013:575, paragraph 85; judgment of 20 September 2018, *Agria Polska e.a.* v *Commission*, C-373/17 P, EU:C:2018:756, paragraph 61.

(76) The fact that the Commission has already dedicated some time and resources to an investigation does not preclude a rejection of the complaint on grounds related to priority setting. Moreover, the Commission may take a decision to reject a complaint even at an advanced stage in the investigation ([22]).

(77) The Commission is also not obliged to make a final finding as to the existence or non-existence of the alleged infringement ([23]).

(78) Pursuant to Article 7(2) of Regulation (EC) No 773/2004, the Commission is entitled to reject your complaint by decision if the written submissions made in response to the Article 7(1) letter do not lead to a different assessment of the complaint.

2.2.3. Assessment

(79) In the light of the above principles and after a careful assessment of your complaint, the Commission has decided not to conduct a further investigation into your claims for the reasons set out below.

2.2.3.1. Limited likelihood of establishing the existence of an infringement

(80) In addition to the lack of legitimate interest, the likelihood of establishing the existence of an infringement of Article 102 TFEU in Member States other than Greece appears limited. Your complaint that Amgen abused its dominant position by refusing or restricting the supply of the Pharmaceutical Preparations to wholesalers in "low-price" Member States other than Greece is vague and – as demonstrated below – contains no specific evidence pointing to the existence of an infringement in other Member States than Greece.

(81) First, your complaint of 31 July 2013 only briefly mentioned (in paragraphs 109-110, 118-119, and 122) - without identifying any particular "low-price" Member State - that the abovementioned practice of refusing to sell to wholesalers who are engaged in parallel exports to "high-price" Member States consists a "*general policy of Amgen*", which "u*ndertakes, via its subsidiaries, the same practices*" in "low-price" Member States other than Greece.

(82) Later, in your submission of 4 March 2014 (paragraph 28), you called on the Commission to examine the "*practice of the Amgen Group*" in Member States other than Greece, specifically in Romania, Poland, and France. You further submitted, on 24 March 2016, a sworn affidavit by Mr [...] (main shareholder and manager of [...], the brokerage company which engages in parallel exports on behalf of Greek wholesalers, like Profarm), stating – without underlying documents – that "*on the basis of information supplied by* [his] *clients – purchasers in E.U. countries*", he wanted to point out that "*Amgen adopted a restrictive practice and "closed" or at least drastically restricted the markets of low-price Member States other than Greece (e.g. Portugal, Poland, Romania, etc.)*" ([24]).

(83) On 21 and 22 November 2016, you submitted information you obtained from parallel traders alleging sourcing problems for Aranesp and/or Neulasta (based on

([22]) Judgment of 17 May 2001, *IECC* v *Commission*, T-110/95, EU:T:1998:214, paragraphs 48 and 49.

([23]) Judgment of 4 March 1999*, Ufex e.a.* v *Commission*, C-119/97 P, EU:C:1999:116, paragraph 87; judgment of 19 September 2013, *EFIM* v *Commission*, C-56/12 P, EU:C:2013:575, paragraph 57; judgment of 20 September 2018, *Agria Polska e.a.* v *Commission*, C-373/17 P, EU:C:2018:756, paragraph 97.

([24]) Translated from Greek.

a request to members of the European Association of Euro-Pharmaceutical Companies - the professional and representative voice of pharmaceutical parallel distribution in Europe - at its general assembly of 11 November 2016, to supply you with evidence of Amgen's policy to restrict the supply of the Pharmaceutical Preparations). As explained below, this information either did not relate to other Member States than Greece, or did not clearly specify a sourcing country, or did not seem to constitute conclusive evidence of an abuse by Amgen of a (potential) dominant position:

– The letter from the [...] parallel importer [...], dated 18 November 2016, states a decrease of imports of Neulasta from Greece (minus 100% after 1 January 2013) and from Romania ([25]) (minus 67% after 1 January 2013 and minus 100% after 1 June 2013). [...] expresses the view that the decreases are the "result of a lack of supply in the Greek and Romanian markets" and that this is "to the exclusive benefit of Amgen's market shares". The annexes to the letter contain Neulasta sales data of Amgen and parallel importers in Germany, Sweden and Finland (and Aranesp in Germany) in 2012 to 2013. The data show a decrease for parallel import and an increase for Amgen after 2012, but contain no information on the source country of the parallel importers.

– The reply from the [...] company [...], dated 22 November 2016, does not allow to draw a clear conclusion on an alleged "general policy" by Amgen to refuse/restrict supply in "low-price" Member States other than Greece as from 2013, as the information is vague or not straightforward: it contains a table with figures on number of packs of Neulasta and syringes of Aranesp "*received from manufacturer or wholesalers*" from 2011 to 2015, without specifying the source country; for Neulasta, it shows a decrease as from 2011, and for Aranesp, it shows 30 items in 2011, 4081 in 2012, 232 in 2013, and below 100 after 2013.

– An email of 16 November 2016 from the [...] company [...], states that sourcing Aranesp "*from various European suppliers became almost impossible, as supply dropped dramatically from 2011 to 2015*". The attached table, containing data for different Aranesp products, indeed shows an overall decrease but for some items also an increase from 2012 to 2013, and the sourcing country is not specified.

– A letter of 16 November 2016 from [...], a Romanian parallel exporter, mentions that Amgen Romania has reduced its supplies of Neulasta to [...] by 70% in 2015 compared to what was supplied in the year 2013-2014. The data provided in the annexed table however seem to refer to sales (not to supplies), without specifying in which country these sales took place.

– The letter of 18 November 2016 from [...], a [...] pharmaceutical wholesaler, relates to Amgen's alleged reduction/refusal of supply of Neulasta in Greece (and thus falls under the assessment in point 2.1 above.

(84) On 29 November 2018, more than one year after the expiration of the deadline to submit written observations, set by the letter of 17 March 2017 D(2017)019659, and after the Commission services had informed you during the meeting of 28 September 2018 that the Commission is not obliged to take into account in its

([25]) Total supply of Neulasta to [...] in the last six months of 2012 amounts to 1012 items, while it is 338 in the first six months of 2013. The figures show big differences from one month to the other, e.g. lowest 25 (July 2012) and highest 360 (October 2012).

assessment any further submission, you submitted IQVIA ([26]) data regarding the sales of the Pharmaceutical Preparations in Germany's and the Netherlands' retail market both by parallel importers (PI) and by non-parallel importers (non-PI). The figures indicate a decrease of the PI sales and an increase of the non-PI sales. You stated - without providing evidence - that all the non-PI sales realised in the above-mentioned retail markets were realised by Amgen itself. You added that for Aranesp this was due to parallel importers being unable to import Aranesp from Member States such as Greece (which falls under the assessment in point 2.1 above). For Neulasta, you stated that this was due to parallel importers being unable to import Neulasta "*from other Member States and, especially, first from Greece (since 2013) and, followingly, from Romania (since 2016)*", without providing more details.

(85) The Commission has carefully assessed the above information and has concluded that it does not constitute sufficient evidence pointing to the existence of an abusive restriction or refusal to supply by Amgen of the Pharmaceutical Preparations to wholesalers in "low-price" Member States other than Greece. The above analysis indeed shows that: (i) you did not provide any concrete evidence of a restriction or refusal to supply as far as the pharmaceutical product Aranesp is concerned, (ii) all your relevant submissions referring to the pharmaceutical product Neulasta constitute general statements, which lack probative value, also because they sometimes contradict each other (for example, [...] supports that Neulasta imports from Romania ceased completely as of June 2013, whereas the Romanian exporter [...] reports a decrease in the supplies of Neulasta by Amgen only in 2015, therefore, for the years 2013 and 2014 it seems that [...] faced no difficulties in the supply of Neulasta).

(86) Moreover, an in-depth investigation into this allegation would require considerable resources and would probably be disproportionate in view of the limited likelihood of establishing the existence of an infringement. In order to find an infringement of Article 102 TFEU, the Commission would need to define a relevant market and analyse whether Amgen would be dominant in this relevant market. This is a very complex legal and economic assessment that would, among other things, require the Commission to analyse the market situation with regard to the Pharmaceutical Preparations in "low-price" Member States other than Greece. This would require an in-depth analysis of the regulatory framework of each of these Member States as well as a large-scale market investigation by sending a significant amount of information requests to the stakeholders involved in the relevant Member States. Considerable resources would be needed to analyse this market information.

2.2.3.2. Your argument that the Commission's investigation was insufficient

(87) In your letter of 28 April 2017 (paragraph 6), you maintain that the investigation undertaken by the Commission was not sufficient, in so far as it was restrained to the sole consideration of documents provided by Profarm, without further investigation of the case.

(88) In this respect, the Commission would like to observe that Article 7 of Regulation (EC) No 773/2004 does not give the complainant the right to insist that the Commission take a final decision as to the existence or non-existence of an

([26]) IQVIA is a Contract Research Organization providing clinical research, data analytics, and technology solutions to life sciences companies.

alleged infringement and does not oblige the Commission to continue the proceedings, whatever the circumstances, right up to the stage of a final decision ([27]). The case-law has accordingly recognised that if the Commission is under no obligation to decide on the existence or non-existence of an infringement, then it is allowed to reject complaints without taking any investigative measure, because the only purpose of such an investigation would be to seek evidence of the existence or non-existence of an infringement, which it is not required to establish. The Commission's only obligation is to examine the factual and legal elements brought to its notice by the complainant and it is not incumbent on the Commission to prove that it has adopted measures of investigation.([28])

2.2.4. Conclusion based on Article 7(2) of Regulation (EC) No 773/2004

(89) For the reasons set out above, and after carefully reviewing your observations made in response to the Article 7(1) letter, the Commission concludes that (i) you have no legitimate interest to launch a complaint in the meaning of Article 7 of Regulation (EC) No 773/2004 insofar your complaint concerns the alleged conduct in "low-price" Member States other than Greece, and that (ii) at any rate, there are insufficient grounds for conducting a further investigation due to the limited likelihood of finding an infringement. Your complaint concerning the alleged conduct in "low-price" Member States other than Greece is consequently rejected pursuant to Article 7(2) of Regulation (EC) No 773/2004.

3. CONCLUSION

(90) For the reasons set out above, the Commission rejects your complaint pursuant to Article 13(2) of Regulation (EC) No 1/2003 and to Article 7(2) of Regulation (EC) No 773/2004.

4. NEXT PROCEDURAL STEPS

4.1. Right to bring an action

(91) An action for annulment may be brought against this Decision before the General Court of the European Union, in accordance with Article 263 TFEU.

4.2. Confidential information

(92) The Commission may send a copy of this Decision to Amgen. Moreover, the Commission may decide to make this Decision, or a summary thereof, public on its website ([29]).

(93) If you consider that certain parts of this Decision contain confidential information, you are requested to inform [...] (e-mail: [...]) within two weeks from the date of receipt of this Decision, identifying clearly the information that you consider confidential. Also, you are requested to indicate why you consider that certain information should be treated as confidential.

([27]) T-574/14 *EAEPC* v *Commission*, ECLI:EU:T:2018:605, paragraph 71.

([28]) Case C-367/10 *EMC Development AB v Commission*, EU: C:2011:203, paragraph 77, and Case T-204/03 *Haladjian Frères v Commission*, EU:T:2006:273, paragraph 28.

([29]) See paragraph 150 of the Commission notice on best practices for the conduct of proceedings concerning Articles 101 and 102 TFEU (OJ C 308, 20.10.2011, p. 6).

(94) If you do not respond within that time-limit, the Commission may assume that you do not consider that this Decision contains confidential information and that it can be published on the Commission's website or sent to Amgen.

(95) The published version of this Decision may conceal your identity upon your request if this is necessary for the protection of your legitimate interests.

For the Commission

Signed

Teresa Ribera
Executive Vice-President