EUROPEAN COMMISSION
DG Competition

Case M.8401 - J&J / ACTELION

Only the English text is available and authentic.

REGULATION (EC) No 139/2004
MERGER PROCEDURE

Article 6(1)(b) in conjunction with Art 6(2)
Date: 09/06/2017

In electronic form on the EUR-Lex website under document number 32017M8401

EUROPEAN COMMISSION

In the published version of this decision, some information has been omitted pursuant to Article 17(2) of Council Regulation (EC) No 139/2004 concerning non-disclosure of business secrets and other confidential information. The omissions are shown thus […]. Where possible the information omitted has been replaced by ranges of figures or a general description.

Brussels, 9.6.2017
C(2017) 4099 final

PUBLIC VERSION

To the notifying party:

Subject: **Case M.8401 – JOHNSON & JOHNSON /ACTELION Commission decision pursuant to Article 6(1)(b) in conjunction with Article 6(2) of Council Regulation No 139/2004[1] and Article 57 of the Agreement on the European Economic Area[2]**

Dear Sir or Madam,

(1) On 12 April 2017, the European Commission (the "Commission") received notification of a proposed concentration pursuant to Article 4 of the Merger Regulation by which Johnson & Johnson ("J&J", USA), through Janssen Holding GmbH ("Janssen", Switzerland), acquires within the meaning of Article 3(1)(b) of the Merger Regulation control of the whole of Actelion Pharmaceuticals Ltd ("Actelion", Switzerland) by way of purchase of shares (the "Transaction").

(2) J&J is hereinafter referred to as the "Notifying Party". J&J and Actelion are designated hereinafter as the "Parties".

1. THE PARTIES

(3) **J&J** is a publicly traded company headquartered in New Jersey (USA), active in three major business sectors: (i) consumer; (ii) pharmaceuticals; and (iii) medical devices. The pharmaceuticals sector, which is the Janssen business,

1 OJ L 24, 29.1.2004, p. 1 (the 'Merger Regulation'). With effect from 1 December 2009, the Treaty on the Functioning of the European Union ('TFEU') has introduced certain changes, such as the replacement of 'Community' by 'Union' and 'common market' by 'internal market'. The terminology of the TFEU will be used throughout this decision.

2 OJ L 1, 3.1.1994, p. 3 (the 'EEA Agreement').

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includes treatments in five therapeutic areas: (i) cardiovascular and metabolic diseases; (ii) immunology; (iii) infectious diseases and vaccines; (iv) neuroscience; and (v) oncology.

(4) **Actelion** is a publicly traded company headquartered in Allschwil (Switzerland), active in the research, development and commercialisation of prescription medicinal products in a number of therapeutic areas, including most notably, pulmonary arterial hypertension (cardiovascular area).

2. THE OPERATION

(5) Pursuant to a public tender offer, J&J will acquire, through Janssen, a subsidiary of Cilag Holding AG, up to 100% and at least 67% of the share capital of Actelion.

(6) Prior to the shares acquisition, Actelion will demerge the majority of its medicinal product discovery operations and early-stage clinical development assets into a newly company, Idorsia Ltd ("Idorsia") in which J&J intends to acquire a minority interest, 16% immediately after closing of the tender with an additional 16% convertible at J&J's option.[3]

(7) The Transaction gives rise to a concentration within the meaning of Article 3(1)(b) of the Merger Regulation.

3. UNION DIMENSION

(8) The undertakings concerned have a combined aggregate world-wide turnover of more than EUR 5 000 million[4] (EUR 67 155 million). Each of them has an EU-wide turnover in excess of EUR 250 million (J&J: EUR […] ; Actelion: EUR […]), but they do not achieve more than two-thirds of their aggregate EU-wide turnover within one and the same Member State.

(9) The notified operation therefore has a Union dimension pursuant to Article 1(2) of the Merger Regulation.

4. COMPETITIVE ASSESSMENT

(10) The Transaction gives rise to a limited number of overlaps and no vertical relations. Actelion's marketed products in the European Economic Area (EEA) primarily relate to the treatments of pulmonary arterial hypertension, where J&J is not active.

(11) The main overlap is between the Parties' research and development activities in the treatments for insomnia (see Section 4.1). The Transaction also leads to an overlap between marketed products of Biogen, Inc. ("Biogen", USA) distributed

3 Actelion's existing shareholder base will be diluted *pro rata*, proportionally to their current stakes.

4 Turnover calculated in accordance with Article 5 of the Merger Regulation and the Commission Consolidated Jurisdictional Notice (OJ C 95, 16.4.2008, p. 1).

by J&J in a number of Central and Eastern European countries and one pipeline product of Actelion for the treatments for multiple sclerosis (see Section 4.2).[5]

4.1. Insomnia

4.1.1. Introduction

(12) The Parties' activities overlap in the development of new medicines for insomnia.

(13) J&J is developing a selective orexin-2 antagonist compound (called JNJ-7922) for the treatment of primary insomnia and depression. The compound is currently in Phase II[6] and is being co-developed with Minerva Neurosciences, Inc. ("Minerva").

(14) Pursuant to the co-development agreement dated 13 February 2014 (the "Co-Development Agreement"), the product will be commercialised by Minerva in the EEA.

(15) Actelion is developing a dual orexin receptor antagonist (DORA) for primary and secondary insomnia (compound name ACT-541468, currently in Phase II). This pipeline will be transferred to the newly created company Idorsia.

(16) The Parties' pipeline products are both expected to be launched in the EEA around […].

4.1.2. Market definition

4.1.2.1. Product market

(17) Insomnia is characterized by acute or chronic sleep disturbance, which creates daytime fatigue, hyperarousal, impaired social or occupational functioning, and

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[5] Another area there the Parties have research programs targeting the same illness is the treatment of Systemic Lupus Erythematotus (SLE), where J&J has several pipeline products (in pre-clinical, Phase I and Phase II stages) and Actelion one pipeline product (in Phase II[…]). However, the parties compounds and research programs are very differentiated: the two compounds in Phase II have different mechanisms of action (J&J's pipeline, Stelara – *ustekinumab*- is a biologic drug that targets the interleukin-12/23 pathways, while Actelion's pipeline, *cenerimod* is a small molecule, S1P1 immunomodulator); different routes of administration (intravenous injectable vs. oral tablets); and are likely to be used at different stages of the treatment. Additionally, there are many competitors developing pipeline drugs for SLE. For this reason, no concerns could be identified and it can be concluded that the Transaction does not raise serious doubts as to its compatibility with the internal market for SLE.

[6] The Phases of Clinical Development can be described as follow: Phase I starts with the initial administration of a new drug into humans generally on healthy volunteers. It typically involves one or a combination of the following aspects: estimation of initial safety and tolerability, characterisation of a drug's absorption, distribution, metabolism, and excretion, and early measurement of drug activity. Phase II usually starts with the initiation of studies to explore therapeutic efficacy in patients. Studies in Phase II are typically conducted on a small group of patients that are closely monitored. An important goal for this phase is to determine the dose(s) and regimen for Phase III trials. Phase III usually starts with the initiation of studies to demonstrate, or confirm therapeutic benefit. Studies in Phase III are designed to confirm the preliminary evidence accumulated in Phase II that a drug is safe and effective for use in the intended indication and recipient population. These studies are intended to provide an adequate basis for marketing approval. Phase IV begins after drug approval.

reduced quality of life. Originally, insomnia was regarded as a symptom, not an illness in itself. This was based on the fact that insomnia is not present in isolation in the vast majority of patients. However, in some patients no underlying cause can be identified, which is called primary insomnia.[7] Secondary or co-morbid insomnia is characterized by a coexistence of insomnia with psychiatric, medical, other sleep or substance use disorders.

(18) In the Anatomical Therapeutic Classification (ATC),[8] drugs against insomnia are classified under the ATC3 level N5B containing hypnotics/sedatives. In previous decisions,[9] the Commission left open whether this class should be further subdivided into (i) barbiturates and non-barbiturates and (ii) within non-barbiturates, between modern hypnotics that have light addictive effect and no residue in the morning (non-benzodiazepines), and older hypnotics which have strong potential for causing addiction and have prolonged effects (benzodiazepines).

(19) The Parties' pipeline products for insomnia fall within the class of non-barbiturates non-benzodiazepines modern hypnotics.

(20) The Commission also considered, but ultimately left open, the possibility of further segmentations of the N5B class (i) according to the different effect of the molecules (inducing vs maintaining sleep medicines) and (ii) between prescription and non-prescription medicines.[10]

Notifying Party's view

(21) In the present case, the Notifying Party acknowledges the precedent segmentations identified by the Commission without giving further indications regarding the relevant market definition.

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7 Based on the Diagnostic and Statistical Manual of Mental Disorders (DSMIV-TR) of the American Psychiatric Association, primary insomnia is characterised by one or more of the following main criteria that last for at least one month: (i) difficulties in initiating sleep; (ii) disorders of maintaining sleep (frequent or long awakening); (iii) premature awakening; and (iv) feeling of non-restorative sleep; all with subsequent impaired daytime functioning, and not associated with an underlying condition such as depression, Alzheimer's Disease, etc.

8 The ATC is devised by the European Pharmaceutical Marketing Research Association (EphMRA) and maintained by EphMRA and Intercontinental Medical Statistics (IMS). 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, 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 or any other subdivision of the group. Finally, the level of the chemical substance is the so-called molecule level.

9 See e.g. M.7975- *Mylan/Meda*, para. 515-519; M.5253 - *Sanofi-Aventis/Zentiva*, para.159-165; M.3751 - *Novartis/Hexal*.

10 See e.g. M.5253 - *Sanofi-Aventis/Zentiva*, para.159-165; M.3751 – *Novartis/Hexal*.

Commission's assessment

(22) The market investigation confirmed the segmentation identified in precedent cases, based on different mechanisms of action for the treatment of insomnia, as well as possible other segmentations based on the time of onset (rapid/slow), whether the drugs treat sleep onset or sleep maintenance, the subtype of insomnia, the adverse effects profiles and ability for long term use of the insomnia drugs.[11]

(23) As to the mechanisms of action, the market investigation confirmed the distinction between barbiturates and benzodiazepines on the one hand (which would have higher risk of abuse, tolerance and undesirable side-effects), and non-benzodiazepines on the other hand. The market investigation also revealed a possible sub-segmentation of non-benzodiazepines between non non-benzodiazepines but acting via the GABAergic pathways (*GABAergic molecules*, which are acting hypnotics such as *zolpidem* and represent the current standard treatment in the EEA), antihistamines[12] and melatonin (which would be less efficacious treatments), and orexin-antagonists (which are currently under development, with no marketed products in the EEA yet).[13]

(24) Orexins are small proteins that work as neurotransmitters, i.e. to transmit signals between neurons in the brain. Orexins impact arousal and sleep: a loss of the orexin-producing neurons causes sleepiness. The market investigation has indicated that the discovery of this effect has fuelled a strong interest in developing orexin-antagonists (drugs that inhibits the effects of orexins) as a novel approach for promoting sleep and treating insomnia.

(25) Competitors and doctors indicated that the orexin-antagonists pipeline products are promising for the treatment of insomnia and have the potential to be used for the treatment of long term insomnia, currently a largely unmet need.[14]

(26) The responses received in the market investigation indicated that orexin-antagonists, if successfully brought to market, could constitute a significant improvement over the existing standards of care, causing less dependency, minimal risk of abuse and fewer central nervous system side-effects (such as drowsiness or residual effects on the next day). For example, one doctor stated that orexin-antagonists were "*likely to cause a paradigm shift in the sense that the dependency potential is low*".[15] A competitor further explained that "*Because the GABAergic molecules considered, as the current standard of care, have a lot of huge and debilitating side effects, and as soon as a better option is available,*

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11 Replies to questions 17 and 18 of Questionnaire *Q1 – Competitors* and replies to questions 3 and 4 of Questionnaire *Q3 – Doctors Insomnia*.

12 These are usually over-the-counter (OTC) hypnotics. In addition, also low efficacy exist herbal hypnotics.

13 Replies to question 17 of Questionnaire *Q1 – Competitors* and to question 3 of Questionnaire *Q3 – Doctors Insomnia*.

14 Replies to questions 20 and 21 of Questionnaire *Q1 – Competitors* and to question 7 of Questionnaire *Q3 – Doctors Insomnia*.

15 Reply of a doctor to question 7 of Questionnaire *Q3 – Doctors Insomnia*.

prescribers and, more importantly, patients, would like to move to the newer, more promising drugs".[16]

(27) This is also confirmed by the Parties' internal documents. In an internal document, Actelion mentions that its orexin-antagonists pipeline "[a quote from a confidential Actelion internal document]".[17] This is also observed by Minerva in a press release: *"The compound JNJ-7922 is quickly absorbed to facilitate rapid sleep onset and has an appropriately short half-life, which may avoid daytime sedation"*.[18]

(28) Moreover, as regards efficacy, the market investigation indicated the expectations that the relevant pipeline products, due to their specific mechanism of action, will act more naturally interfering with insomnia to induce sleep and will potentially preserve sleep architecture (good effects on sleep maintenance).[19] Minerva specified that: "*the specificity of the pharmacological target makes the approach unique and may have a meaningful effect on primary insomnia and insomnia related to an underlying disorder by preserving/restoring physiological sleep and by promoting "restorative sleep" (allowing unimpaired function during the day)*".[20] In view of this new efficacy/safety profile, old treatments are likely not to be considered by doctors and patients as being substitutable to these new treatments.

(29) The market investigation further indicated that orexin-antagonist drugs will probably be priced higher than their competitors, as most of the marketed treatments are genericised or non-prescription products. A doctor explained that currently, insomnia treatments are a "*low-price market"* while the "*novel drugs"*, namely orexin-antagonists, will be in "*another pricing segment*".[21]

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16 Reply of a competitor to question 20 of Questionnaire *Q1 – Competitors*. For example: Zolpidem may cause drowsiness and slower reactions the day after medication administration, which could cause impaired driving ability and increase the risk of road accidents.

17 Actelion internal document titled […], dated February 2017 (page 22).

18 See http://ir.minervaneurosciences.com/releasedetail.cfm?releaseid=892355.

19 Replies to question 17 of Questionnaire *Q1 – Competitors* and to questions 3, 4 and 7 of Questionnaire *Q3 – Doctors Insomnia.*

20 Reply of Minerva to question 17 of Questionnaire *Q1 – Competitors.*

21 Reply of a doctor to question 7 of Questionnaire *Q3 – Doctors Insomnia*.

Conclusion

(30) In view of the above, for the purpose of assessing the present case, the Commission concludes that within non-benzodiazepine drugs, orexin-antagonists would be a distinct product market.

4.1.2.2. Geographic market

(31) The Commission has previously defined the geographic markets for innovative pharmaceutical pipeline products to be global or at least EEA-wide.[22]

(32) In this case, both Parties' orexin-antagonist pipelines are developed at global level.

(33) In view of the above, for the purpose of assessing the present case, the Commission concludes the geographic market for the development of orexin-antagonist products for insomnia treatments is global or at least EEA-wide.

4.1.3. Competitive assessment

4.1.3.1. The Notifying Party's view

(34) The Notifying Party submits that the combination of the two orexin-antagonists pipelines would not have a significant impact on competition since:

i. the two pipelines have different mechanisms of action (JNJ-7922 targets only the orexin-2 receptor while ACT-541468 belongs to the DORA class and targets both the orexin-1 and orexin-2 receptors);

ii. the two pipelines are at an early stage of development and still many years away from launch. There are other DORA products that are at later stages of development than ACT-541468 (i.e. Eisai/Purdue Pharma's *lemborexant* in phase III);

iii. ACT-541468, if it is approved for insomnia, will compete with a number of other existing drugs that are already indicated for insomnia and a highly competitive pipeline.

(35) The Notifying Party submits that in any event the combination of the two compounds will have no impact in the EEA since JNJ-7922 is out-licensed to Minerva for commercialisation in the EEA. Finally, J&J considers that it will have no ability post-Transaction to delay, discontinue or reorient ACT-541468, since it will be transferred to Idorsia over which J&J will not exercise control.

[22] See M.7275– *Novartis/GlaxoSmithKline oncology business*, para. 33 and 72; see also M.7872 – *Novartis / GlaxoSmithKline (ofatumumab autoimmune indications)*, para. 29 and M.7559 – *Pfizer / Hospira*, para. 30.

4.1.3.2. Commission's assessment

4.1.3.2.1. Competitive landscape

(36) The market investigation revealed that there is a very limited number of orexin-antagonists products for insomnia currently under development. More specifically, only three pipelines are in Phase II or Phase III of development with an intended launch in the EEA, namely ACT-541468, JNJ-7922 and Eisai/Purdue *lemborexant*.[23] By way of example, one market participant stated that "*there are a few pipelines competitors but they are either in preclinical or early stage clinical development*".[24] The only orexin-antagonist to have reached the market so far, Merck's[25] *suvorexant*, is currently marketed in the United States but not in the EEA, where Phase III comparative studies have not been conducted and there is no indication that Merck will do so.[26] The limited number of pipelines is also confirmed in Actelion's internal documents, one of which states that [a quote from a confidential Actelion internal document].[27] Given the lengthy time required for the development of new medicinal products, which need to go through Phase I, II and III clinical trials as explained in footnote 6, it is highly unlikely that other competitors' orexin-antagonists will appear on the market before the Parties' expected launch date.

(37) While ACT-541468 and JNJ-7922 have a slightly different mechanism of action, one being a DORA product and the other one a selective orexin-2 product, the market investigation showed that both products would likely be close in their efficacy/safety profile and are among the most promising treatments for insomnia.[28] Even compared to Eisai's Phase III product, one competitor indicated that the "*shorter half-life with novel J&J or Actelion drug candidates would offer advantage over suvorexant and potentially to Eisai compound in Phase III*".[29]

4.1.3.2.2. Impact of the Transaction

(38) In view of the above and in particular the limited competition in the global development of orexin-antagonists drugs for insomnia and the closeness of innovation competition between the Parties on insomnia, the combination of ACT-541468 and JNJ-7922 brings a risk for innovation competition, stemming from a possible discontinuation, delay or reorientation (e.g. targeting specific therapeutic indication(s) or patients' group(s) within insomnia in order not to make the two pipelines directly compete with each other) of one of the two

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23 See replies to questions 1, 16, 17 and 20 of Questionnaire *Q1 – Competitors* and to questions 3–6 of Questionnaire *Q3 – Doctors Insomnia*.

24 See replies to question 20 of Questionnaire *Q1 – Competitors*.

25 In the EEA is known as Merck Sharp & Dohme, MSD.

26 See replies to questions 19 and 21 of Questionnaire *Q1 – Competitors* and to questions 3 and 4 of Questionnaire *Q3 – Doctors Insomnia*.

27 Actelion internal document titled […], dated May 2016, (page 14).

28 Replies to questions 20 and 21 of Questionnaire *Q1 – Competitors* and to questions 7 and 8 of Questionnaire *Q3 – Doctors Insomnia*.

29 See reply to question 18 of Questionnaire *Q1 – Competitors*.

pipelines.[30] Consumers would be harmed in this case by both the loss of product variety, and the reduced intensity of future product market competition in the markets where the discontinued/deferred/redirected pipeline product would have been introduced but for the merger.

(39) The Commission assesses below whether J&J will have the ability and incentives to discontinue, delay or reorient the development of one of the two pipelines and ultimately its launch and commercialisation in the EEA.

4.1.3.2.2.1. J&J's ability to discontinue, delay or re-orient JNJ-7922 and/or ACT-541468

JNJ-7922

(40) As described above, JNJ-7922 is co-developed by J&J and Minerva at global level under the Co-Development Agreement. Pursuant to this agreement, Minerva will commercialise the product in the EEA.

(41) J&J holds JNJ-7922's patent rights and know-how, and has granted Minerva an exclusive license to sell products containing JNJ-7922 in the EEA. As to the development, Minerva owns a co-exclusive license to use and develop JNJ-7922 in the EEA, and will contribute to 40% of the development costs. Pursuant to the Co-Development Agreement, J&J and Minerva are co-developing JNJ-7922 in accordance with a joint development plan and under the supervision of a joint steering committee. The agreement provides that, if J&J and Minerva fail to reach an agreement on […], J&J has the final decision making authority with respect to issues related to the development or manufacturing of the compound, […]. Moreover, J&J's has a minority shareholding of 11% in Minerva.

(42) In view of the above and in particular J&J's participation to the global co-development of JNJ-7922 and its […], post-Transaction, J&J will have the ability to discontinue, delay or reorient the global development of JNJ-7922 and ultimately impact its launch and commercialisation in the EEA.

ACT-541468

(43) Before the acquisition by J&J of 100% of Actelion's shares, part of Actelion's research and development activities, including the development of ACT-541468, will be de-merged into the newly created company Idorsia.

(44) Pursuant to the agreements entered into in the context of the Transaction:[31]

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[30] According to paragraph 38 of the Guidelines on the assessment of horizontal mergers under the Council Regulation on the control of concentrations between undertakings (Official Journal C 31 of 05.02.2004) (Horizontal Merger Guidelines), "*effective competition may be significantly impeded by a merger between two important innovators, for instance between two companies with 'pipeline' products related to a specific product market*". See in particular replies to question 8 of Questionnaire *Q3 – Doctors Insomnia*.

[31] Transaction Agreement dated 26 January 2017 (Transaction Agreement), Demerger Agreement in relation to certain pipeline and discovery business (Demerger Agreement) dated 26 January 2017 (Demerger Agreement), Shareholders Agreement dated 26 January 2017 (Shareholders Agreement), Convertible Loan Agreement dated 15 February 2017 (Convertible Loan Agreement), IP Licence

i. J&J will provide to Idorsia a ten year loan worth an aggregate principal amount of CHF 580 million (approx. EUR 542 million)[32] with no interest, convertible into shares. By conversion of this loan, J&J will acquire a minority interest in Idorsia, initially 16% with an additional 16% at J&J's option;[33]

ii. If J&J's shareholding exceeds 20%, J&J will have the right to nominate one board member (out of […] to 6) or two board members (out of 7 to […]);[34]

iii. J&J offers a credit facility of an amount of the equivalent in CHF 250 million (approx. EUR 234 million)[35] for a period of 15 years at an interest rate based on the LIBO rate;[36]

iv. J&J will pay milestone payments and/or royalties in relation to the sale of the compounds *ponesimod* and *cadazolid*;[37]

v. J&J will acquire from Idorsia an exclusive licence to the compound ACT-132577 for the treatment of pulmonary hypertension indications,[38] whose R&D activities will be transferred to Idorsia, and an option to co-develop and commercialize this compound for resistant hypertension management.[39]

vi. J&J will provide […] licenses on IP rights for Idorsia to operate its R&D business.[40]

(45) In line with Article 3 of the Merger Regulation, decisive influence on strategic decisions can be acquired through rights, contracts or any other means, having regard to the considerations of fact or law involved. Pursuant to paragraph 20 of the Commission Jurisdictional Notice ("CJN"),[41] in exceptional circumstances, decisive influence can be acquired on a *de facto* basis in situation of economic dependency, through economic and other links between the two undertakings. More specifically, paragraph 20 of CJN specifies that "*for example, very*

Agreement dated 26 January 2017 (IP License Agreement), Royalty Rights Agreement dated 26 January 2017 (Royalty Rights Agreement) and Collaboration Agreement dated 26 January 2017 (Collaboration Agreement).

32 Using European Central Bank exchange rate at 26 January 2017 (CHF 1= EUR 0.9352).

33 See e.g. Sections 4.1 and 4.2 of the Convertible Loan Agreement.

34 See section 4.2 of the Shareholders Agreement.

35 Using European Central Bank exchange rate at 26 January 2017 (CHF 1= EUR 0.9352).

36 Sections 1.01, 2.05 and 2.08 of the Credit Facility Agreement.

37 Section 2.5 of the Royalty Rights Agreement.

38 Article II of the Collaboration Agreement.

39 Article III of the Collaboration Agreement.

40 See Sections 10.15 – 10.18 and Schedule 10.15 of the Demerger Agreement; section 2.3 of the IP Licence Agreement

41 Commission Consolidated Jurisdictional Notice under Council Regulation on the control of concentrations between undertakings, OJ C 95, 16 April 2008.

important long-term supply agreements or credits provided by suppliers or customers, coupled with structural links" may confer decisive influence and that "*the Commission will carefully analyse whether such economic links, combined with other links, are sufficient to lead to a change of control on a lasting basis*".

(46) In this case, there will be strong economic links between J&J and Idorsia on a long-term basis. As an R&D company, Idorsia's activities strongly depend on financing and IP rights. In that respect, J&J will provide to Idorsia a 10-year loan of approximately EUR 542 million, as well as a 15-year credit facility of approximately EUR 234 million. J&J will also provide Idorsia access to IP rights […] through the cross licensing arrangement. These economic links will be coupled with a structural link, with J&J acquiring between 16% and 32% of Idorsia's share capital while all the other shareholders will each hold less than 5% of the shares. J&J will also appoint one or two board member(s) if it decides to convert its loan to hold more than 20% shares. Therefore, there will be strong economic and structural links between J&J and Idorsia on a lasting basis in the sense of paragraph 20 of the CJN.

(47) In that respect, one company stressed during the Commission's investigation that "*it is likely through: i) the credit facility, ii) any J&J representative appointed to the board of directors of Idorsia under the terms of the Shareholders Agreement (referred to in Article 3.3 of the report); and iii) the terms of the IP Cross-Licence Agreement that J&J will retain significant influence on Idorsia as a result of Idorsia's financial reliance upon J&J and its affiliates' funding, and the potential flow up to J&J and its affiliates of development IP under the IP Cross-Licence Agreement.*".[42]

(48) In view of the above, J&J is likely to have the ability to *de facto* influence strategic decisions on the development of Actelion's pipeline ACT-541468, which represents one among the 11 pipeline programs in Idorsia's portfolio.

(49) In any event, J&J's ability to nominate one or two board member(s) if it exercises its option to convert part of its loan up to more than 20% will give J&J access to sensitive information on Idorsia's commercial strategy, including on the development of ACT-541468. With J&J having access to such information, innovation competition between the two pipeline products may be distorted. For example, J&J could re-orient its JNJ-7922 pipeline product (e.g. targeting specific therapeutic indications or patients' group within insomnia) not to directly compete with ACT-541468. In this case ultimately, price competition between the two products would be weakened in the EEA.

4.1.3.2.2.2. J&J's incentives to discontinue, delay or re-orient JNJ-7922 or ACT-541468

(50) If the pipeline product of one of the Parties is likely to capture significant revenues from the competing product of the other Party, the merged entity will likely have the incentives to discontinue, delay or re-orient one of the two pipelines. Indeed, from the perspective of each innovator, the expected loss of profits on the products of the other party (i.e. because of sales cannibalisation)

42 See reply of a competitor to question 4 of Questionnaire *R1 – Market test of the Commitments.*

adds to the opportunity cost of innovating, making it more likely that an early pipeline product is suppressed, deferred or re-directed (particularly in the presence of significant development and commercialisation costs).

(51) In this case, as explained above, JNJ-7922 and ACT-541468, if successfully developed, will compete closely and will not face sufficient competitive constraints from other products. It could therefore be economically viable for J&J, for example, to influence Idorsia to discontinue, delay or re-orient the development of ACT-541468 given that the sales of that product are likely to cannibalise the sales of J&J's JNJ-7922. Conversely, J&J could also discontinue, delay or re-orient the development of JNJ-7922 since its sales would risk cannibalising the sales of ACT-541468, provided that the expected revenues obtained by J&J from ACT-541468 (through its minority shareholding interest or a global commercialisation agreement[43]) are higher than J&J's revenues from JNJ-7922. Under both scenarios, J&J would take into consideration the savings in R&D costs resulting from the discontinuation, delay or re-orientation of the respective pipeline product.

(52) In view of the above, the Commission considers that J&J is likely to have the incentives already at the stage of development to discontinue, delay or re-orient one of the two pipelines so as to limit future competition between these two products, reduce the overall costs of their development (in particular Phase III clinical trials) and extract higher revenues.

4.1.3.2.2.3.Likely effects on competition

(53) In view of the competitive situation described above, a discontinuation, delay or reorientation of one of the two pipelines will weaken competition between orexin-antagonist products for insomnia. Consumers, in particular doctors and patients, would suffer from the loss of product variety and reduced intensity of future product market competition, with the likely resultant price increases, in the market where the discontinued, delayed or re-oriented product would have been introduced but for the Transaction.

Conclusion

(54) In view of the above, the Commission concludes that serious doubts as to the compatibility of the Transaction with the internal market arise with respect to the market for orexin-antagonists developed for the treatment of insomnia and the likely discontinuation, delay or reorientation of one of the two pipeline products, ACT-541468 and JNJ-7922, post-Transaction.

4.2. Multiple sclerosis

4.2.1. Introduction

(55) The Parties' activities overlap in the treatments for multiple sclerosis ("MS").

[43] Currently, there is no agreement on which company will commercialise ACT-541468. However, J&J already has a commercialisation agreement with Idorsia for another compound (ACT-132577) and in view of the *de facto* decisive influence described above, J&J is likely to have the ability to conclude a similar arrangement with Idorsia for ACT-541468.

(56) J&J acts as local distributor and local representative for the Biogen's multiple sclerosis medicinal products in the Baltics (Estonia, Latvia and Lithuania, since October 2014 and in Romania, since December 2016). J&J also acts as a contract manufacturer for Biogen for certain of these products.[44]

(57) Actelion is developing (in Phase III clinical trial) a product, *ponesimod*, for the treatment of MS, with expected market launch in the EEA in […].

4.2.2. Market definition

4.2.2.1. Product market

(58) MS is an autoimmune disease in which the body immune system attacks the nerve fibres in the central nervous system – degenerating the myelin coating that insulates the nerves and helps the transmission of nerve impulses between the brain and other parts of the body. MS affects about 2.5 million people worldwide and is the most common cause of progressive neurological disability in young adults. As to the treatment architecture, there is no curative therapy for MS but only long term disease modifying therapies (DMT) aimed at reducing the disease activity, or symptomatic treatments.

(59) In previous decisions,[45] the Commission considered that DMT 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 markets. The market for DMT had also been further subdivided according to (i) the mechanism of action of the respective medicinal products (immunosuppressants, immunostimulants and other symptomatic treatments), (ii) the type of MS (Relapsing Remitting (RR), Secondary Progressive (SP), Primary Progressive (PP) and Progressing Relapsing (PR)) or (iii) according to different attributes of disease-modifying MS medicinal products (efficacy, side effects, route and frequency of administration) or lines of treatments,[46] but the Commission left open the three subdivisions.

(60) In the most recent decision, the Commission examined the market of RRMS[47] medicinal products as a separate market and also examined a possible segmentation according to the route of administration of the product (oral,

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44 Biogen is the Marketing Authorisation Holder of Avonex, Plegridy, Tysabri, Tecfidera and Zinbryta.

45 See M.7872 – *Novartis/ GlaxoSmithKline (ofatumumab autoimmune indications*); M.5999 – *Sanofi Aventis/Genzyme*, para.25-31; M.4049 –*Novartis/Chiron*, para.17.

46 There are broadly three types of DMTs reflecting similar efficacy/safety profiles with different routes of administration:

i. Interferon-based injectable therapies, which provide for moderate efficacy and have a good long-term safety profile with mild side effects (first line treatments, treatment naive patients, young family planning patients);

ii. Oral therapies, which offer improved efficacy (moderate to high efficacy), convenient route of administration, but also lead to increased serious side effects (first or second line treatments);

iii. Monoclonal antibodies, which deliver further improved efficacy but have significant increased risks of side effects (second or third line treatments).

47 'Relapsing-remitting' means that the patient has flare-ups of symptoms (relapses) followed by periods of recovery (remissions).

injectable, intramuscular and subcutaneous) but the exact definition of the product market was left open.[48]

The Notifying Party's view

(61) The Notifying Party acknowledges the possible segmentation as considered in past decisional practise, and submits in particular that there are three different types of RRMS medicinal products: injectable therapies, oral therapies and monoclonal antibodies.

(62) However, the Notifying Party considers that there is no need to conclude on the exact product market definition in this case.

Commission's assessment

(63) The market investigation confirmed that RRMS medicinal products can be classified according to their mechanism of action and efficacy/safety profiles. Interferon-based drugs, which are mostly injectables, are generally considered as less efficient but safer than oral therapies and monoclonal antibodies. Interferon-based drugs are generally used as first line of treatments. Monoclonal antibodies would be more efficacious but would cause more undesirable side effects than other products, and are generally prescribed as second or third line of treatment.[49]

(64) The market investigation also corroborated a distinction according to the attributes of the MS medicinal products. Indeed, oral and interferon-based injectable therapies would be used for first line of treatment, while monoclonal antibodies would be rather used for second and third line of treatment.[50]

Conclusion

(65) For the purpose of assessing the present case, the relevant product market covers DMTs for MS, to the exclusion of symptomatic treatments, with possible sub-segmentations among the lines explained above. The exact product market definition for DMTs for MS can be left open, since, irrespective of whether the market is segmented by mechanism of action, type of disease, routes of administration or efficacy/safety attributes, the Transaction does not raise serious doubts as to its compatibility with the internal market.

4.2.2.2. Geographic market

(66) In line with the findings of the Commission in past decisions regarding MS finished dose pharmaceuticals,[51] the Notifying Party submits that the market for

48 See M.7872 – *Novartis/ GlaxoSmithKline (ofatumumab autoimmune indications*), para.20-28.

49 See replies to questions 6 and 7 of questionnaire *Q1 – Competitors* and to questions 3 and 4 of questionnaire *Q2 – Doctors Multiple Sclerosis*, and minutes of conference call with [competitor] on 6 April 2017.

50 See replies to questions 6 and 7 of questionnaire *Q1 – Competitors* and to questions 3 and 4 of questionnaire *Q2 – Doctors Multiple Sclerosis.*

51 See M.7872 – *Novartis / GlaxoSmithKline (ofatumumab autoimmune indications),* M.5999 – *Sanofi Aventis/Genzyme*, para.25-31; M.4049 –*Novartis/Chiron*, para.17.

MS treatment is national in scope for MS marketed products and at least EEA-wide in scope for pipeline products.

(67) The Commission has consistently considered that the markets for finished dose pharmaceutical products are national in scope, in particular in view of the national regulatory and reimbursement schemes and the fact that competition between pharmaceutical firms still predominantly takes place at a national level.[52] For innovative pipeline products, as described above for insomnia pipelines, the Commission has previously considered the market at global or at least EEA level.[53]

(68) For the purpose of assessing this case, the geographic market for MS marketed products should be defined at national level. However, it is not necessary to conclude on the exact geographic market definition for MS pipelines, since, irrespective of whether the market for pipeline medicinal products is defined at global or EEA level, the Transaction does not raise serious doubts as to its compatibility with the internal market.

4.2.3. Competitive assessment

Presentation of the overlapping products

(69) J&J distributes several MS products of Biogen in Estonia, Latvia, Lithuania and Romania, namely Avonex, Plegridy, Tysabri, Tecfidera and Zinbryta.[54] Actelion has a Phase III pipeline product, *ponesimod*, expected to be launched in the EEA in […]. Biogen's products and Actelion's pipeline are for the treatment of RRMS.

52 See M.7559 – *Pfizer / Hospira* and M.5253 – *Sanofi-Aventis / Zentiva.*

53 See M.7275– *Novartis/GlaxoSmithKline oncology business*, para. 33 and 72.

54 Biogen's MS product Fampyra, also distributed by J&J, is not a disease modifying treatment (DMT) but rather a symptomatic treatment (improves walking disability). Therefore Fampyra is not in the same market as Biogen's other MS medicinal products.

Table 1 – Characteristics of Biogen and Actelion's products for RRMS

Product (company)	Status	Line of treatment	Market segment	Route of administration[55]	EEA presence
ACT-128800 *ponesimod* (Actelion)	pipeline	1st or 2nd line	oral treatment	Oral, tablets	EEA […]
Avonex *interferon* (Biogen)	marketed	1st line	interferon	Injectable (IM)	ROM, LT, LV
Plegridy *peginterferon* (Biogen)	marketed	1st line	interferon	Injectable (SC)	LT, LV, ES
Tysabri *natalizumab* (Biogen)	marketed	2nd or 3rd line	monoclonal antibody	Injectable (IV)	ROM, LT, LV, ES
Tecfidera *dimethyl fumarate* (Biogen)	marketed	2nd or 3rd line	oral treatment	Oral	LT

Competitive landscape

(70) In the market for RRMS, J&J's market share, through the distribution of Biogen's products, was above 35% in Romania (up to [35-40]% in value in 2016) and slightly below 20% in Estonia, Latvia and Lithuania. J&J's main competitors in these countries are for first line of RRMS treatment, Merck KGaA (Rebif, *interferon*, injectable), Bayer (Betaferon, *interferon*, injectable), Novartis (Extavia, *interferon*, injectable), Teva (Copaxone, *glatiramer acetate*, injectable) and Sanofi (Aubagio, *teriflunomide*, oral) and for 2nd/3rd lines of treatment, Novartis (Gilenya, *fingolimod,* oral) and Sanofi (Lemtrada, *alemtuzumab*, monoclonal antibody, intravenous infusion).

(71) The table below presents the market shares of J&J (with the sale of Biogen's products) and its main competitors in Romania, Lithuania, Latvia and Estonia for RRMS treatments in the last three years.

55 Method of administration: IV – intravenous, IM - intramuscular and SC - subcutaneous use. For example Plegridy is to be injected subcutaneously (SC) every 2 weeks by patients self-administering using the pre-filled syringe. On the contrary, monoclonal antibodies, such as Tysabri, are administered by intravenous infusion every four weeks to patients at the hospital.

Table 2 – Market shares of Biogen (distributed by J&J) and its main competitors for RRMS products in Romania, Lithuania, Latvia and Estonia

Product (company) / Year		Romania		Lithuania		Latvia		Estonia	
		Val	Vol	Val	Vol	Val	Vol	Val	Vol
Avonex	*2016*	[20-30] %	[20-30] %	[10-20] %	[10-20] %	[10-20] %	[10-20] %	[5-10] %	[10-20] %
	2015	[20-30]%	[20-30]%	[10-20]%	[10-20]%	[10-20]%	[10-20]%	[5-10]%	[10-20]%
	2014	[20-30]%	[20-30]%	[10-20]%	[10-20]%	[10-20]%	[10-20]%	[10-20]%	[10-20]%
Tysabri	*2016*	[10-20] %	[5-10] %	[0-5]%	[0-5]%	<[0-5]%	<[0-5]%	[5-10] %	[0-5]%
	2015	[10-20]%	[5-10]%	[0-5]%	[0-5]%	-	-	[5-10]%	[0-5]%
	2014	[10-20]%	[5-10]%	-	-	-	-	[5-10]%	[0-5]%
Plegridy	*2016*	-	-	<[0-5]%	<[0-5]%	[0-5]%	[0-5]%	[0-5]%	[0-5]%
	2015	-	-	<[0-5]%	<[0-5]%	-	-	-	-
	2014	-	-	-	-	-	-	-	-
Tecfidera	*2016*	-	-	<[0-5]%	<[0-5]%	-	-	-	-
	2015	-	-	-	-	-	-	-	-
	2014	-	-	-	-	-	-	-	-
TOTAL BIOGEN	*2016*	[30-40] %	[30-40] %	[10-20] %	[10-20] %	[10-20] %	[10-20] %	[10-20] %	[10-20] %
	2015	[30-40] %	[20-30] %	[10-20] %	[10-20] %	[10-20] %	[10-20] %	[10-20] %	[10-20] %
	2014	[30-40] %	[30-40] %	[10-20] %	[10-20] %	[10-20] %	[10-20] %	[10-20] %	[10-20] %
Rebif (Merck KGaA)	*2016*	[30-40] %	[30-40] %	[20-30] %	[20-30] %	[20-30] %	[20-30] %	[10-20] %	[10-20] %
	2015	[20-30]%	[20-30]%	[30-40]%	[20-30]%	[20-30]%	[20-30]%	[10-20]%	[20-30]%
	2014	[20-30]%	[20-30]%	[30-40]%	[30-40]%	[30-40]%	[20-30]%	[10-20]%	[20-30]%
Betaferon (Bayer)	*2016*	[10-20] %	[20-30] %	[10-20] %	[10-20] %	[5-10] %	[5-10] %	[10-20] %	[10-20] %
	2015	[10-20]%	[20-30]%	[10-20]%	[10-20]%	[5-10]% %	[10-20]%	[10-20]%	[10-20]%
	2014	[10-20]%	[10-20]%	[10-20]%	[10-20]%	[10-20]%	[10-20]%	[10-20]%	[20-30]%

Product (company) / Year		Romania		Lithuania		Latvia		Estonia	
		Val	Vol	Val	Vol	Val	Vol	Val	Vol
Copaxone (Teva)	*2016*	**[10-20] %**	**[10-20] %**	**[20-30] %**	**[20-30] %**	**[20-30] %**	**[20-30] %**	**[30-40]% %**	**[30-40] %**
	2015	**[10-20]%**	**[10-20]%**	**[20-30]%**	**[20-30]%**	**[20-30]%**	**[20-30]%**	**[30-40]%**	**[30-40]%**
	2014	**[10-20]%**	**[10-20]**	**[20-30]%**	**[20-30]%**	**[10-20]%**	**[20-30]%**	**[40-50]% %**	**[30-40]%**
Extavia (Novartis)	*2016*	**<[0-5]%**	**<[0-5]%**	**[0-5]%**	**[0-5]%**	**[10-20] %**	**[10-20] %**	**<[0-5]%**	**[0-5]%**
	2015	**[0-5]%**	**[0-5]%**	**[0-5]%**	**[0-5]%**	**[10-20]%**	**[10-20]%**	**[0-5]%**	**[0-5]%**
	2014	**[10-20]%**	**[10-20]%**	**[0-5]%**	**[5-10]%**	**[10-20]%**	**[10-20]%**	**[0-5]%**	**[0-5]%**
Gilenya (Novartis)	*2016*	**<[0-5]%**	**<[0-5]%**	**[20-30] %**	**[10-20] %**	**[5-10] %**	**[5-10] %**	**[5-10] %**	**[0-5]%**
	2015	**<[0-5]%**	**<[0-5]%**	[10-20]%	**[5-10]%**	**[5-10]%**	**[0-5]%**	**[5-10]%**	**[0-5]%**
	2014	**<[0-5]%**	**<[0-5]%**	**[0-5]%**	**[0-5]%**	**[0-5]%**	**<[0-5]%**	**[0-5]%**	**[0-5]%**
Aubagio (Sanofi)	*2016*	-	-	**[0-5]%**	**[0-5]%**	-	-	**[10-20] %**	**[10-20] %**
	2015	-	-	-	-	-	-	**[5-10]% %**	**[5-10]% %**
	2014	-	-	-	-	-	-	**-**	**-**

(72) The market investigation indicated that post-Transaction many strong competitors for RRMS treatments, including in the market segments addressed by *ponesimod*, namely for 1st and for 2nd/3rd line of treatments, as well as for oral treatments, will remain in the four Eastern European countries.[56] In particular, the following competitors can be mentioned:

i. Merck KGaA (Rebif), Teva (Copaxone) and Bayer (Betaferon) for 1st line of RRMS treatments;

ii. Novartis (Gilenya, *fingolimod,* oral) and Sanofi (Lemtrada, *alemtuzumab*, monoclonal antibody, intravenous infusion) as well as other pipeline products, such as Roche (Ocrevus, *ocrelizumab*, monoclonal antibodies), Merck KGaA (Movectro, *cladribine*, oral), Teva (Laquinimod, oral) and Novartis (*ofatumumab*, monoclonal antibodies) for 2nd/3rd line of RRMS treatments;

[56] See replies to questions 6 and 7 of questionnaire *Q1 – Competitors* and to questions 3 and 4 of questionnaire *Q2 – Doctors Multiple Sclerosis*.

iii. Novartis (Gilenya, *fingolimod*, oral) and Sanofi (Aubagio, *teriflunomide*, oral) for oral RRMS treatments and pipelines such as Teva (Laquinimod, oral) and Merck KGaA (Movectro, *cladribine*, oral).

(73) Biogen's products are not mentioned among the closest possible substitutes of *ponesimod*. Market respondents generally identified Novartis (Gilenya) as *ponesimod*'s closest competitor in these countries, since both products have the same mechanism of action, route of administration (oral) and would be intended for 1st or 2nd line of treatment.[57]

Impact of the Transaction

(74) In view of the competitive landscape, market participants did not identify any possible negative impact of the Transaction on competition for RRMS treatments in Romania, Lithuania, Latvia and Estonia.[58]

(75) Moreover, the market investigation indicated that Biogen, which is the marketing authorisation holder and controls the IP rights, final manufacturing and clinical development of the overlapping products, could find an alternative distributor of its products within an adequate period of time.[59] J&J only distributes Biogen products since 2014/2016.

Conclusion

(76) In view of the above, and in particular the competitive environment for DMTs for RRMS in Lithuania, Latvia, Estonia and Romania, the Transaction does not raise serious doubts as to its compatibility with the internal market. The same conclusion applies irrespective of the exact product market definition for DMTs for MS (larger market encompassing all DMTs for MS and market segment by mechanism of action, routes of administration or efficacy/safety attributes).

5. COMMITMENTS

(77) In order to ensure that effective competition will be maintained, the Parties submitted a set of commitments under Article 6(2) of the Merger Regulation on 16 May 2017 ("Initial Commitments").

(78) The Commission market tested the Initial Commitments in order to assess whether they are sufficient and suitable to remedy serious doubts identified in the global market for the development of orexin-antagonist treatments for insomnia. Following the feedback received during the market test, the Initial Commitments were refined and improved, and amended commitments were submitted on 1 June 2017 ("Final Commitments"). These Final Commitments are annexed to this Decision and form an integral part thereof.

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57 See replies to question 11 of questionnaire *Q1 – Competitors* and to question 7 of questionnaire *Q2 – Doctors Multiple Sclerosis.*

58 See replies to questions 8–11 of questionnaire *Q1 – Competitors* and to questions 5, 6 and 8 of questionnaire *Q2 – Doctors Multiple Sclerosis*, and minutes of conference call with [competitor] on 06 April 2017 and with [competitor] on 11 April 2017.

59 See replies to question 13 of questionnaire *Q1 – Competitors*.

5.1. Framework for the assessment of the Commitments

(79) Where a concentration raises serious doubts as regards its compatibility with the internal market, the Parties may undertake to modify the concentration so as to remove the grounds for the serious doubts identified by the Commission.

(80) As set out in the Commission's Remedies Notice,[60] the commitments have to eliminate the competition concerns entirely, and have to be comprehensive and effective from all points of view.[61] Furthermore, commitments must be capable of being implemented effectively within a short period of time.[62]

(81) Divestiture commitments are normally the best way to eliminate competition concerns resulting from horizontal overlaps, from the point of view of the Merger Regulation's objective, but the possibility cannot automatically be ruled out that other types of commitments may also be capable of preventing the significant impediment of effective competition.[63] Divestiture commitments may be a divestiture of a business to a suitable purchaser, but also a removal of links with competitors, such as minority shareholding or the specific rights linked to such shareholding such as representations on the board, veto rights and also information rights.[64] Other structural commitments may be suitable to resolve all types of concerns if those remedies are equivalent to divestitures in their effects. [65]

(82) In assessing whether commitments will maintain effective competition, the Commission stresses that this question has to be examined on a case-by-case basis.[66]

(83) It is against this background that the Commission analysed the proposed commitments in this case.

5.2 Initial Commitments

(84) The Initial Commitments consisted in:

i. ensuring that J&J cannot acquire influence over the global development of ACT-541468 by removing some links with Idorsia (the "Idorsia Commitments");

ii. granting Minerva control over the global development of JNJ-7922 for insomnia and not acquiring any influence over the commercialisation of JNJ-7922 in the EEA (the "Minerva Commitments").

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60 Commission Notice on remedies acceptable under Council Regulation (EC) No 139/2004 and under Commission Regulation (EC) No 802/2004 (OJ C 267, 22.10.2008, p. 1-27.

61 Remedies Notice, paragraphs 9 and 61.

62 Remedies Notice, paragraph 9.

63 Remedies Notice, paragraph 15.

64 Remedies Notice, paragraphs 58-59.

65 Remedies Notice, paragraph 17.

66 Remedies Notice, paragraph 16.

Idorsia Commitments

(85) Under the Idorsia Commitments, J&J committed for a period of […]:

a. Not to increase its minority shareholding in Idorsia beyond 16%;[67]

b. To waive any right to nominate any board representatives;[68]

c. Not to obtain information on Idorsia's activities regarding ACT-541468 for insomnia other than what is publicly available;

d. Not to […].

(86) The necessary amendments to the agreements entered into in the context of the Transaction will have to be implemented within a short period of time.

Minerva Commitments

(87) Under the Minerva Commitments, J&J committed as follows:

a. To divest its minority shareholding in Minerva;

b. To grant Minerva the final say on all decisions concerning the development of JNJ-7922 for the insomnia indication on a global basis;

c. To forgo its right to […]% royalties on Minerva future insomnia sales in the EEA;

d. To continue to fund […]% of total development costs of the insomnia pipeline, including in relation to Phase II[…] and Phase III, should Minerva conclude that the clinical trials show technical success and have a positive regulatory pathway;

e. [J&J's commitment to continue supporting Minerva in relation to JNJ-7922 compound]

(88) The necessary amendments to the Co-Development Agreement would have to be implemented within a short period of time.

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67 More specifically, J&J's shareholding shall not exceed 9.9% unless […] increases its share in Idorsia to at least 20%, and in that case J&J's shareholding can increase up to 16%.

68 J&J also committed that it shall not […].

5.3. Results of the market test

Idorsia Commitments

(89) Market respondents indicated that the Commitments shall ensure that J&J, as a minority shareholder, will not take part in any decision regarding the development strategy of ACT-541468 nor receive any confidential information.[69]

(90) Market respondents generally considered that the Commitments address the Commission's concerns and will allow Idorsia to continue the development of ACT-541468 for insomnia independently from J&J.[70]

(91) One respondent however added that the Commission should ensure that the remaining agreements between J&J and Idorsia on financing in particular do not concern ACT-541468.[71]

Minerva Commitments

(92) Very few comments were made on the content of the Minerva Commitments.[72] One market participant indicated that the nature and scope of the Commitments appear to address both the Actelion and the J&J's pipelines "*with the result that J&J would not appear to have the ability to influence the development of either pipeline asset*" and that therefore both Commitments together would not be necessary.[73]

(93) Minerva stressed that the divestiture of […].[74]

5.4. Final Commitments

(94) In light of the results of the market test, J&J submitted the Final Commitments on 1 June 2017, which are annexed to this decision and form an integral part thereof.

(95) The Idorsia Commitments remained unchanged. As to the Minerva Commitments, J&J committed in addition to the Initial Commitments, to cancel its minority shareholding within Minerva without consideration and to fund 100% of JNJ-7922 Phase II development costs. [J&J's commitment to continue supporting Minerva in relation to JNJ-7922 compound].

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69 Replies to question 1 of Questionnaire *R1 – Market test of the Commitments*.

70 Replies to questions 1 and 3 of Questionnaire *R1 – Market test of the Commitments*.

71 Reply of a company to question 4 of Questionnaire *R1 – Market test of the Commitments*.

72 Replies to question 3 of Questionnaire *R1 – Market test of the Commitments*.

73 Reply of a company to question 1 of Questionnaire *R1 – Market test of the Commitments*.

74 Minerva submission, 18 May 2017.

5.5. Assessment of the Final Commitments

(96) As described above, the Commission expressed serious doubts that, in view of the limited competition in the global development of orexin-antagonists drugs for insomnia for the EEA, J&J could have the ability and incentives to discontinue, delay or reorient either ACT-541468 or JNJ-7922, thereby significantly impede effective competition. In this case, instead of proposing to divest one of the two programs, J&J committed to take structural measures ensuring that it would not to have the ability to influence any of the two pipelines.

(97) The Commitments have been designed having regard to the special circumstances of the case, which are explained below.

(98) First, as detailed above, J&J would not acquire a majority of Idorsia's shares but only a minority shareholding (up to 32%), coupled with a number of rights. Through the Idorsia Commitments, J&J commits to ensure that it will have no influence over strategic decisions of Idorsia.

(99) More specifically, J&J commits that its shareholding will be below 10% or up to 16% but in the latter case only if […] has a larger share of at least 20% so that J&J will not be the largest shareholder. J&J also commits not to nominate any board member and not to access any confidential information in relation to ACT-541468.

(100) The Commission considers that these commitments are structural in nature (limitation of shares and rights) and capable of being monitored. These commitments will be in particular implemented in a short timeframe into agreements concluded between J&J and Idorsia, including the shareholders agreement.

(101) To address the comments of one market test respondent (see above, paragraph (91)), the remaining agreements between J&J and Idorsia do not concern specifically ACT-541468, including the financing of its development. […].

(102) As to the timeline of the Commitments, the Commission notes that their duration is […]. The Commission considers this time limit is appropriate to the concern identified in this specific case, since the development of ACT-541468 or JNJ-7922 is expected to be finalised within the next […]. At the stage of commercialisation, pursuant to the Co-Development Agreement, it will be Minerva and not J&J commercialising JNJ-7922 in the EEA.

(103) Second, as detailed above, J&J did not have full control over the global development of JNJ-7922 which is co-developed with Minerva. Through the Commitments, J&J is granting Minerva additional independence to further alleviate the Commission's concerns.

(104) More specifically, J&J will no longer have a final say on the decisions related to the development of JNJ-7922 for insomnia and commits to continue funding the program, while not receiving the royalties from Minerva.

(105) To address the comments of one market respondent (see above, paragraph (92)), the Commission notes that J&J offered the Minerva Commitments, in addition

to the Idorsia Commitments, so as to fully eliminate the Commission's concerns. The Commission also notes that, as such and on a stand-alone basis, the Minerva Commitments would be insufficient to solve the Commission's concerns in this case as J&J did not commit to divest the whole JNJ-7922 R&D program but remains co-contractor of and providing support to Minerva. These Commitments are acceptable on a long-term basis only as a complement to the Idorsia Commitments, to further limit J&J's incentives and ability to negatively influence the development of JNJ-7922 for insomnia.

(106) To address Minerva's concern […], J&J committed to cancel its shares in Minerva or transfer them back to Minerva without consideration.

(107) In view of the agreement reached between Minerva and J&J on 30 May 2017,[75] the Commission considers that J&J commitments will be implemented within a short timeframe, including through amendments to the Co-development Agreement where necessary.

(108) For the reasons outlined above, the commitments entered into by the Parties are sufficient to eliminate the serious doubts as to the compatibility of the Transaction with the internal market.

(109) The commitments in section B of the Annex constitute conditions attached to this decision, as only through full compliance therewith can the structural changes in the relevant markets be achieved. The other commitments set out in the Annex constitute obligations, as they concern the implementing steps which are necessary to achieve the modifications sought in a manner compatible with the internal market.

6. CONCLUSION

(110) For the above reasons, the Commission has decided not to oppose the notified operation as modified by the commitments and to declare it compatible with the internal market and with the functioning of the EEA Agreement, subject to full compliance with the conditions in section B of the commitments annexed to the present decision and with the obligations contained in the other sections of the said commitments. This decision is adopted in application of Article 6(1)(b) in conjunction with Article 6(2) of the Merger Regulation and Article 57 of the EEA Agreement.

For the Commission
(Signed)
Margrethe VESTAGER
Member of the Commission

[75] On 30 May 2017, Minerva and J&J signed a binding Term Sheet reflecting the main terms of the J&J Commitments.

Case M.8401 – Johnson & Johnson / Actelion

COMMITMENTS TO THE EUROPEAN COMMISSION

Pursuant to Article 6(2) of Council Regulation (EC) No 139/2004 (the ***Merger Regulation***), Johnson & Johnson (***J&J***) hereby enters into the following Commitments (the ***Commitments***) vis-à-vis the European Commission (the ***Commission***) with a view to rendering its proposed acquisition of Actelion (the ***Concentration***) compatible with the internal market and the functioning of the EEA Agreement.

This text shall be interpreted in light of the Commission's decision pursuant to Article 6(1)(b) of the Merger Regulation of the Merger Regulation to declare the Concentration compatible with the internal market and the functioning of the EEA Agreement (the ***Decision***), in the general framework of European Union law, in particular in light of the Merger Regulation, and by reference to the Commission Notice on remedies acceptable under Council Regulation (EC) No 139/2004 and under Commission Regulation (EC) No 802/2004 (the ***Remedies Notice***).

The Schedules form an integral part of these Commitments.

SECTION A. DEFINITIONS

1. For the purpose of the Commitments, the following terms shall have the following meaning:

   Affiliated Undertakings: undertakings controlled by the Parties and/or by the ultimate parents of the Parties, whereby the notion of control shall be interpreted pursuant to Article 3 of the Merger Regulation and in light of the Commission Consolidated Jurisdictional Notice under Council Regulation (EC) No 139/2004 on the control of concentrations between undertakings (the ***Consolidated Jurisdictional Notice***).

   Confidential Information: any business secrets, know-how, commercial information, or any other information of a proprietary nature that is not in the public domain.

   Conflict of Interest: any conflict of interest that impairs the Trustee's objectivity and independence in discharging its duties under the Commitments.

   Convertible Loan Agreement: […].

   Co-Development and License Agreement: the co-development and license agreement dated 13 February 2014 by and between Janssen Pharmaceutical. N.V. and Minerva Neurosciences Inc. (attached as **Annex 2**).

   Divestiture Trustee: one or more natural or legal person(s) who is/are approved by the Commission and appointed by J&J and who has/have received from J&J the exclusive Trustee Mandate to dispose of the Minerva Divestment Assets at no minimum price.

Effective Date: the date of adoption of the Decision.

J&J: Johnson & Johnson, incorporated under the laws of New Jersey, with its registered office at One Johnson & Johnson Plaza, New Brunswick, New Jersey 08933, United States.

Idorsia: Idorsia Ltd, incorporated under the laws of Switzerland with its registered office at Allschwil BL and registered with the Commercial Register of the Canton of Basel-Landschaft under company number CHE-340.129.854.

Idorsia Commitments: J&J commitment not to acquire any influence over the global development of the dual orexin compound (ACT-541468) for insomnia by Idorsia for a period of […] from the Effective Date, in the form of the commitments set out in Section B.

Minerva: Minerva Neurosciences Inc., incorporated under the laws of Delaware, with its registered office at 245 First Street, Cambridge, Massachusetts, whose shares are traded on the Nasdaq Global Market.

Minerva Commitments: J&J commitment to grant Minerva control over the global development of the orexin-2 compound (JNJ-7922) for insomnia and not to influence Minerva's commercialisation of the orexin-2 compound (JNJ-7922) for insomnia in the EEA, in the form of the commitments set out in Section B.

Minerva Divestment Assets: all shares that J&J holds in Minerva at the Effective Date. On the day of submitting these Commitments, J&J holds approximately 3,892,256 Minerva shares, amounting to approximately 11.0% of Minerva's outstanding share capital.

Minerva Divestment Assets Trustee Divestiture Period: the period of […] from the end of the Minerva Divestment Assets First Divestiture Period.

Minerva Divestment Assets First Divestiture Period: the period of […] from the Effective Date.

Monitoring Trustee: one or more natural or legal person(s) who is/are approved by the Commission and appointed by J&J, and who has/have the duty to monitor J&J's compliance with the conditions and obligations attached to the Decision.

Parties: J&J and Actelion.

Placing: […].

Trustee(s): the Monitoring Trustee and/or the Divestiture Trustee as the case may be.

SECTION B. GENERAL

Minerva Commitments

2. In order to maintain effective competition, as of the Effective Date and for a period of […], J&J commits to grant Minerva control over the global development of the orexin-2 compound (JNJ-7922) for insomnia and not to acquire any influence over the commercialisation of the orexin-2 compound (JNJ-7922) in the EEA, in the form of the following commitments […]:

a) J&J commits to agree to the cancellation of the Minerva Divestment Assets by Minerva (or the transfer back) by J&J of the Minerva Divestment Assets to Minerva without consideration to J&J (or at nominal value), to be implemented within […] from the Effective Date. […].

b) J&J commits not to […].

c) J&J commits to procure that each of the following commitments referred to in this paragraph are put into effect, […]:

i. J&J commits to grant Minerva the final say on all decisions related to the development of JNJ-7922 for the insomnia indication on a global basis. […].

ii. J&J commits to forgo its right to […] royalties on Minerva insomnia sales in Minerva territories, including the EEA.

iii. J&J commits to fund […] of Phase II insomnia development costs. In addition, J&J commits to contribute to Phase III insomnia development costs through an upfront cash payment of US$30 million to Minerva, a waiver of Minerva's additional financial contribution to the Phase II program (US$13 million), a cash payment of US$20 million at the start of a Phase III insomnia trial, and a cash payment of US$20 million when 50% of the patients are enrolled in a Phase III insomnia trial. Minerva will assume financial responsibility for all remaining Phase III insomnia development costs.

3. J&J commits that, for the purposes of fulfilling its obligations under these commitments, it will […].

4. Following the Effective Date, and until implementation of the commitments in accordance with paragraph 2(c) above, J&J commits to unilaterally implement the following […]:

a) J&J commits not to exercise its right under the […] to have final say on all decisions related to the development of JNJ-7922 for the insomnia indication on a global basis. […].

b) J&J commits to forgo its right to […] royalties on Minerva insomnia sales in Minerva territories, including the EEA.

c) J&J commits to fund […] of Phase II insomnia development costs.

d) J&J commits that, for the purposes of fulfilling its obligations under these commitments, it will at all time […].

5. J&J shall be deemed to have complied with the Minerva Commitments if:

a) by the end of the Minerva Divestment Assets Trustee Divestiture Period, the disposal of the Minerva Divestment Assets has been completed;

b) within a period of […] from the Effective Date, each of the commitments referred to in paragraph 2(c) have been put into effect, and the Commission has approved […] as being consistent with the Commitments in accordance with the procedure described in paragraph 14; and

c) J&J has complied with all the conditions and obligations set forth in paragraph 2 (and, until implementation of the commitments in accordance with paragraph 2(c) above, paragraph 4) for the duration of the Minerva Commitments.

6. In order to maintain the structural effect of the Commitments, J&J shall, for a period of […] after disposal of the Minerva Divestment Assets, not acquire, whether directly or indirectly, the

possibility of exercising influence (as defined in paragraph 43 of the Remedies Notice, footnote 3) over Minerva.

Idorsia Commitments

7. In order to maintain effective competition, as of the Effective Date and for a period of […], J&J commits not to acquire any influence over the global development by Idorsia of the dual orexin compound ACT-541468 for insomnia, in the form of the following commitments:

   a) J&J commits not to increase its equity interest in Idorsia above 9.9%, whether directly or indirectly, for a period of […] from Effective Date. In this regard,

      i. J&J […];

      ii. J&J […];

      iii. J&J […];

      iv. […];

      v. J&J waives any right to nominate any board representatives to the board of Idorsia for a period of […] after the Effective Date. […].

   b) J&J commits not to […]. As soon as […] equity interest in Idorsia […] reaches or exceeds 20%, J&J may increase its equity in Idorsia to a maximum of 16% and as a result, all references to "9.9%" in paragraph 7(a) above shall be read as "16%", […].

   c) for a period of at least […] from Effective Date, […].

   d) J&J commits not to obtain any commercially sensitive information from Idorsia that is not in the public domain relating to Idorsia's activities in orexin antagonist products.

8. J&J shall be deemed to have complied with the Idorsia Commitments if:

   a) within a period of […] from the Effective Date, each of the commitments referred to in paragraph 7(a)-(d) have been put into effect including by […], and the Commission has approved […] as being consistent with the Commitments in accordance with the procedure described in paragraph 14.

   b) J&J has complied with all the conditions and obligations set forth in paragraph 7 (a) to (d) for the duration of the Idorsia Commitments

9. Without prejudice to paragraph 7(a), in order to maintain the structural effect of the Commitments, J&J shall, for a period of […] after the Effective Date, not acquire, whether directly or indirectly, the possibility of exercising influence (as defined in paragraph 43 of the Remedies Notice, footnote 3) over the whole or part of Idorsia.

SECTION C. RELATED COMMITMENTS

Preservation of viability, marketability and competitiveness

10. From the Effective Date until J&J disposes of the Minerva Divestment Assets;, J&J shall preserve or procure the preservation of the economic viability and marketability of the Minerva Divestment Assets, in accordance with good business practice, and shall minimise as far as possible any risk of loss of competitive potential of the Minerva Divestment Assets. In particular, J&J undertakes

not to carry out any action that might have a significant adverse impact on the value and competitiveness of the Minerva Divestment Assets.

Hold-separate obligations

11. J&J commits, from the Effective Date until it disposes of the Minerva Divestment Assets, to keep the Minerva Divestment Assets separate from the business(es) it is retaining.

Due diligence

12. To the extent that due diligence is customary bearing in the mind the equity interest in Minerva being disposed of, J&J shall, subject to customary confidentiality assurances and dependent on the stage of the divestiture process, provide to any potential purchaser(s) sufficient information as regards the Minerva Divestment Assets.

SECTION D. PURCHASER

13. To the extent the Minerva Divestment Assets are disposed of to a single purchaser, and not cancelled or transferred back to Minerva, such purchaser shall be:

    a) independent of and unconnected to J&J and its Affiliated Undertakings […]; and

    b) the acquisition of the Minerva Divestment Assets by such a purchaser must neither be likely to create *prima facie* competition concerns nor give rise to a risk that the implementation of the Commitments will be delayed. In particular, any purchaser must reasonably be expected to obtain all necessary approvals from the relevant regulatory authorities for the acquisition of the Minerva Divestment Assets, if any.

14. The […] referred to in paragraphs 5(b) and 8(a) of these Commitments shall be conditional on the Commission's approval. When J&J has reached agreement on the […], it shall submit a fully documented and reasoned proposal, including a copy of the […] within one week to the Commission and the Monitoring Trustee. J&J must be able to demonstrate to the Commission that […] are consistent with the Commission's Decision and the Commitments. For the approval, the Commission shall verify that the […] are consistent with the Commission's Decision and the Commitments.

SECTION E. TRUSTEE

Appointment procedure

15. J&J shall appoint a Monitoring Trustee to carry out the functions specified in these Commitments for a Monitoring Trustee and monitor and ensure J&J's compliance with these Commitments.

16. If J&J has not transferred the Minerva Divestment Assets pursuant to paragraph 2(a), J&J shall appoint a Divestiture Trustee. The appointment of the Divestiture Trustee shall take effect upon the commencement of the Minerva Divestment Assets Trustee Divestiture Period.

17. The Trustee shall:

    (a) at the time of appointment, be independent of J&J and their respective Affiliated Undertakings;

    (b) possess the necessary qualifications to carry out its mandate, for example have sufficient relevant experience as an investment banker or consultant or auditor; and

    (c) neither have nor become exposed to a Conflict of Interest.

18. The Trustee shall be remunerated by J&J in a way that does not impede the independent and effective fulfilment of its mandate. In particular, where the remuneration package of a Divestiture Trustee includes a success premium linked to the final sale value of the Minerva Divestment Assets, such success premium may only be earned if the divestiture takes place within the Minerva Divestment Assets Trustee Divestiture Period.

Proposal by J&J

19. No later than two weeks after the Effective Date, J&J shall submit the name or names of one or more natural or legal persons whom J&J proposes to appoint as the Monitoring Trustee to the Commission for approval. No later than one month before the end of the Minerva Divestment Assets First Divestiture Period or on request by the Commission, J&J shall submit a list of one or more persons whom J&J proposes to appoint as Divestiture Trustee to the Commission for approval. The proposal shall contain sufficient information for the Commission to verify that the person or persons proposed as Trustee fulfil the requirements set out in paragraph 17 and shall include:

    (a) the full terms of the proposed mandate, which shall include all provisions necessary to enable the Trustee to fulfil its duties under these Commitments;

    (b) the outline of a work plan which describes how the Trustee intends to carry out its assigned tasks;

    (c) an indication whether the proposed Trustee is to act as both Monitoring Trustee and Divestiture Trustee or whether different trustees are proposed for the two functions.

Approval or rejection by the Commission

20. The Commission shall have the discretion to approve or reject the proposed Trustee(s) and to approve the proposed mandate subject to any modifications it deems necessary for the Trustee to fulfil its obligations. If only one name is approved, J&J shall appoint or cause to be appointed the person or persons concerned as Trustee, in accordance with the mandate approved by the Commission. If more than one name is approved, J&J shall be free to choose the Trustee to be appointed from among the names approved. The Trustee shall be appointed within one week of the Commission's approval, in accordance with the mandate approved by the Commission.

New proposal by the J&J

21. If all the proposed Trustees are rejected, J&J shall submit the names of at least two more natural or legal persons within one week of being informed of the rejection, in accordance with paragraphs 15 and 20 of these Commitments.

Trustee nominated by the Commission

22. If all further proposed Trustees are rejected by the Commission, the Commission shall nominate a Trustee, whom J&J shall appoint, or cause to be appointed, in accordance with a trustee mandate approved by the Commission.

Functions of the Trustee

23. The Trustee shall assume its specified duties and obligations in order to ensure compliance with the Commitments, including all aspects of the Minerva Commitments and the Idorsia Commitments. The Commission may, on its own initiative or at the request of the Trustee or J&J, give any orders or instructions to the Trustee in order to ensure compliance with the conditions and obligations attached to the Decision.

Duties and obligations of the Monitoring Trustee

24. The Monitoring Trustee shall:

(i) propose in its first report to the Commission a detailed work plan describing how it intends to monitor compliance with the obligations and conditions attached to the Decision.

(ii) monitor and ensure compliance with all the Commitments, and in particular the commitment to divest the Minerva Divestment Assets, as well as all steps necessary to give effect to such disposal, and the steps related to the Idorsia Commitments pursuant to paragraph 7. To that end the Monitoring Trustee shall monitor the preservation of the economic viability and marketability of the Minerva Divestment Assets and the keeping separate of the Minerva Divestment Assets from the business retained by J&J.

(iii) propose to J&J such measures as the Monitoring Trustee considers necessary to ensure J&J's compliance with the conditions and obligations attached to the Decision;

(iv) act as a contact point for any requests by third parties in relation to the Commitments;

(v) provide to the Commission, sending J&J a non-confidential copy at the same time, a written report within 15 days after the end of every month. The report shall cover the progress of the divestiture of the Minerva Divestment Assets as well as the steps related to the Minerva Commitments pursuant to paragraph 2 and the Idorsia Commitments pursuant to paragraph 7;

(vi) within one week after receipt of the documented proposal referred to in paragraph 14 of these Commitments, submit to the Commission, sending J&J a non-confidential copy at

the same time, a reasoned opinion as to whether […] referred to paragraphs 2(c) and 8(a) of these Commitments are consistent with the conditions and obligations attached to the Decision.

(vii) promptly report in writing to the Commission, sending J&J a non-confidential copy at the same time, if it concludes on reasonable grounds that J&J is failing to comply with these Commitments;

(viii) assume the other functions assigned to the Monitoring Trustee under the conditions and obligations attached to the Decision.

25. If the Monitoring and Divestiture Trustee are not the same legal or natural persons, the Monitoring Trustee and the Divestiture Trustee shall cooperate closely with each other during and for the purpose of the preparation of the Minerva Divestment Assets Trustee Divestiture Period in order to facilitate each other's tasks.

Duties and obligations of the Divestiture Trustee

26. Within the Minerva Divestment Assets Trustee Divestiture Period, the Divestiture Trustee shall dispose at no minimum price of the Minerva Divestment Assets. The Divestiture Trustee shall protect the legitimate financial interests of J&J, subject to J&J's unconditional obligation to divest at no minimum price in the Minerva Divestment Assets Trustee Divestiture Period.

27. In the Minerva Divestment Assets Trustee Divestiture Period or otherwise at the Commission's request), the Divestiture Trustee shall provide the Commission with a comprehensive monthly report written in English on the progress of the divestiture process. Such reports shall be submitted within 15 days after the end of every month with a simultaneous copy to the Monitoring Trustee and a non-confidential copy to J&J.

Duties and obligations of the Parties

28. J&J shall provide and shall cause its advisors to provide the Trustee with all such co-operation, assistance and information as the Trustee may reasonably require to perform its tasks. The Trustee shall have full and complete access to any of J&J's books, records, documents, management or other personnel, facilities, sites and technical information necessary for fulfilling its duties under the Commitments and J&J shall provide the Trustee upon request with copies of any document. J&J shall make available to the Trustee one or more offices on their premises and shall be available for meetings in order to provide the Trustee with all information necessary for the performance of its tasks.

29. J&J shall provide the Monitoring Trustee with all managerial and administrative support that it may reasonably request. This shall include all administrative support functions relating to the Idorsia Commitments and the divestment of the Minerva Divestment Assets which are currently carried out at headquarters level. J&J shall keep the Monitoring Trustee informed of all developments in the divestiture process.

30. J&J shall grant or procure Affiliated Undertakings to grant comprehensive powers of attorney, duly executed, to the Divestiture Trustee to effect the sale (including ancillary agreements) of the

Minerva Divestment Assets and all actions and declarations which the Divestiture Trustee considers necessary or appropriate to achieve the same, including the appointment of advisors to assist with the sale process. Upon request of the Divestiture Trustee, J&J shall cause any sale documents related to the above to be duly executed.

31. J&J shall indemnify the Trustee and its employees and agents (each an ***Indemnified Party***) and hold each Indemnified Party harmless against, and hereby agrees that an Indemnified Party shall have no liability to J&J for, any liabilities arising out of the performance of the Trustee's duties under the Commitments, except to the extent that such liabilities result from the wilful default, recklessness, gross negligence or bad faith of the Trustee, its employees, agents or advisors.

32. At the expense of J&J, the Trustee may appoint advisors (in particular for corporate finance or legal advice), subject to J&J's approval (this approval not to be unreasonably withheld or delayed) if the Trustee considers the appointment of such advisors necessary or appropriate for the performance of its duties and obligations under the Mandate, provided that any fees and other expenses incurred by the Trustee are reasonable. Should J&J refuse to approve the advisors proposed by the Trustee, the Commission may approve the appointment of such advisors instead, after having heard J&J. Only the Trustee shall be entitled to issue instructions to the advisors. Paragraph 31 of these Commitments shall apply *mutatis mutandis*. In the Minerva Divestment Assets Trustee Divestiture Period , the Divestiture Trustee may use advisors who served J&J during the Divestiture Period if the Divestiture Trustee considers this in the best interest of an expedient sale.

33. J&J agrees that the Commission may share Confidential Information proprietary to J&J with the Trustee. The Trustee shall not disclose such information and the principles contained in Article 17 (1) and (2) of the Merger Regulation apply *mutatis mutandis*.

34. J&J agrees that the contact details of the Monitoring Trustee are published on the website of the Commission's Directorate-General for Competition and they shall inform interested third parties of the identity and the tasks of the Monitoring Trustee.

35. For a period of […] from the Effective Date, the Commission may request all information from J&J that is reasonably necessary to monitor the effective implementation of these Commitments.

Replacement, discharge and reappointment of the Trustee

36. If the Trustee ceases to perform its functions under the Commitments or for any other good cause, including the exposure of the Trustee to a Conflict of Interest:

    (a) the Commission may, after hearing the Trustee and J&J, require J&J to replace the Trustee; or

    (b) J&J may, with the prior approval of the Commission, replace the Trustee.

37. If the Trustee is removed according to paragraph 36 of these Commitments, the Trustee may be required to continue in its function until a new Trustee is in place to whom the Trustee has effected a full hand over of all relevant information. The new Trustee shall be appointed in accordance with the procedure referred to in paragraphs 15-22 of these Commitments.

38. Unless removed according to paragraph 36 of these Commitments, the Trustee shall cease to act as Trustee only after the Commission has discharged it from its duties after all the Commitments with which the Trustee has been entrusted have been implemented. However, the Commission may at any time require the reappointment of the Monitoring Trustee if it subsequently appears that the relevant remedies might not have been fully and properly implemented.

SECTION F. THE REVIEW CLAUSE

39. The Commission may extend the time periods foreseen in the Commitments in response to a request from J&J or, in appropriate cases, on its own initiative. Where J&J requests an extension of a time period, it shall submit a reasoned request to the Commission no later than one month before the expiry of that period, showing good cause. This request shall be accompanied by a report from the Monitoring Trustee, who shall, at the same time send a non-confidential copy of the report to the Notifying Party. Only in exceptional circumstances shall J&J be entitled to request an extension within the last month of any period.

40. The Commission may further, in response to a reasoned request from J&J showing good cause waive, modify or substitute, in exceptional circumstances, one or more of the undertakings in these Commitments. This request shall be accompanied by a report from the Monitoring Trustee, who shall, at the same time send a non-confidential copy of the report to the Notifying Party. The request shall not have the effect of suspending the application of the undertaking and, in particular, of suspending the expiry of any time period in which the undertaking has to be complied with.

SECTION G. ENTRY INTO FORCE

41. The Commitments shall take effect upon the date of adoption of the Decision.

(Signed)

……
duly authorised for and on behalf of J&J

SCHEDULE 1

[…]

SCHEDULE 2

[…]