

***Case No COMP/M.4314 -
JOHNSON & JOHNSON
/ PFIZER CONSUMER
HEALTHCARE***

Only the English text is available and authentic.

**REGULATION (EC) No 139/2004
MERGER PROCEDURE**

Article 6(2) NON-OPPOSITION
Date: 11/12/2006

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COMMISSION OF THE EUROPEAN COMMUNITIES

Brussels, 11-12-2006

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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 Where possible the information omitted has been replaced by ranges of figures or a general description.

PUBLIC VERSION

MERGER PROCEDURE
ARTICLE 6(2) DECISION

To the notifying party

Dear Sir/Madam,

**Subject: Case No COMP/M.4314 - Johnson & Johnson / Pfizer Consumer Healthcare
Notification of 19/10/2006 pursuant to Article 4 of Council Regulation No 139/2004**

1. On 19 October 2006, the Commission received notification of a proposed concentration pursuant to Article 4 of Council Regulation (EC) No 139/2004¹ by which the undertaking Johnson & Johnson (“J&J”, United States) acquires within the meaning of Article 3(1)(b) of the Council Regulation control of Pfizer Inc.'s (“Pfizer”, United States) entire Consumer Healthcare division (“PCH”) by way of a purchase of shares and assets.
2. After examination of the notification, the Commission has concluded that the notified operation falls within the scope of the Merger Regulation. Following submission by the parties of undertakings designed to eliminate competition concerns identified by the Commission, in accordance with Article 6 (2) of the Merger Regulation, the Commission has concluded that the notified operation does not raise serious doubts as to its compatibility with the common market and with the functioning of the EEA Agreement.

¹ OJ L 24, 29.01.2004, p.1

I. THE PARTIES

3. J&J is a group active worldwide in three business segments: (i) consumer products; (ii) pharmaceuticals; and (iii) medical devices and diagnostics.
4. PCH is Pfizer's worldwide business division active in personal care products and over-the-counter pharmaceutical products ("OTC products"). OTC products represent 70% to 80% of PCH's revenues.

II. THE CONCENTRATION

5. On 25 June 2006, J&J entered into a Stock and Asset Purchase Agreement with Pfizer whereby J&J intends to acquire sole control of PCH. The notified operation will confer to J&J sole control over PCH. It therefore constitutes a concentration within the meaning of Article 3(1)(b) of the Merger Regulation.

III. COMMUNITY DIMENSION

6. The undertakings concerned have a combined aggregate world-wide turnover of more than EUR 5,000 million (J&J EUR 40,603 million, PCH EUR 3,117 million)². Each of them have a Community-wide turnover in excess of EUR 250 million (J&J EUR [...] million; PCH EUR [...] million), but they do not achieve more than two-thirds of their aggregate Community-wide turnover within one and the same Member State. The notified operation therefore has a Community dimension.

IV. THE RELEVANT MARKETS

7. The transaction gives rise to horizontal overlaps between the activities of J&J and PCH in the fields of OTC drugs and personal care products and to a vertical relationship in the field of nicotine replacement therapy ("NRT"). The definition of the relevant product markets for OTC drugs, personal care products and NRT products is discussed below.

² Turnover calculated in accordance with Article 5(1) of the Merger Regulation and the Commission Notice on the calculation of turnover (OJ C66, 2.3.1998, p25). To the extent that figures include turnover for the period before 1.1.1999, they are calculated on the basis of average ECU exchange rates and translated into EUR on a one-for-one basis.

A. OTC products

1. Introduction

ATC-3 level

8. In previous decisions dealing with pharmaceutical products³, the Commission has used the Anatomical Classification Guidelines (or “ATC” classification) devised by the European Pharmaceutical Marketing Research Association (“EphMRA”) as a reference for the definition of the relevant product markets. The ATC classification is hierarchical, and it includes 16 categories with each up to four levels.
9. The Commission has relied in previous decisions on the third level of the ATC classification (ATC3) which allows medicines to be grouped in terms of their therapeutic indications, i.e. their intended use, as a starting point for inquiring about product market definition in competition cases. However, in certain cases, it may be necessary to analyse pharmaceutical products at a higher or lower levels than ATC 3 or to combine ATC 3 classes on the basis of demand-related criteria. In the present case, the parties have accepted this view, subject to appropriate modifications on the basis of demand-related criteria.

Prescribed/non-prescribed (OTC)

10. The Commission has in the past⁴ defined separate product markets for OTC (non prescription-bound) pharmaceuticals and prescription-bound pharmaceuticals because medical indications (as well as side effects), legal framework, marketing and distributing tend to differ between these categories. The parties have followed this subdivision between OTC and prescribed medicines. The present transaction only concerns OTC drugs, as PCH, the Pfizer division purchased by J&J, is only active in OTC drugs and personal care products.

Geographic scope of OTC markets

11. In previous decisions the Commission held that the relevant geographic markets for pharmaceutical products including OTC products were national in scope. The parties share this view and assessed the relevant OTC product markets on the basis of national markets. The market investigation has confirmed the national dimension of OTC product markets notably due to differences in the market structure, in the products marketed in the different Member States, in consumer

³ See Case COMP/M.3544 – Bayer Healthcare/Roche (OTC Business), paragraphs 12 *et seq.*; Case COMP/M.3354 – Sanofi-Synthelabo/Aventis, paragraphs 14 *et seq.*; COMP/M.2922 – Pfizer/Pharmacia, paragraphs 15 *et seq.*

⁴ See, e.g., Case COMP/M.3544 – Bayer Healthcare/Roche (OTC business), and Case COMP/M.3394 – Johnson & Johnson/Johnson & Johnson MSD Europe, at paragraphs 14-15.

preferences and in national health and drug reimbursement systems⁵. For the purposes of the present decision, all OTC product markets will thus be considered as national in scope.

Relevant markets

12. For the purposes of determining horizontal overlaps, the parties have verified, on a national basis and for each product that PCH sells, whether J&J has on the market a prescription and non prescription-bound drug within the same ATC 3 class (or where appropriate ATC 4 class or a combination of ATC 3 classes). On this basis, the concentration gives rise to overlaps between the activities of the parties in seven OTC product areas. The definition of the relevant product markets for each of these segments is discussed below.

2. Relevant product markets

a) Topical dermatological antifungals

13. Antifungals are pharmaceuticals used to treat infections caused by a fungus or yeast. Fungus can grow anywhere on the body (for example, on the skin or nails) or inside the body (organs, mouth or throat). At level 3 of the ATC classification ("ATC3"), antifungals can fall into three different classes: A1B (mouth antifungals), D1A (antifungals, dermatological) and G1B (gynaecological antifungals).
14. The parties' products overlap exclusively for D1A. Within this class, three subclasses at the fourth level ("ATC4") can be distinguished: (i) D1A1: topical dermatological antifungals, which include topical forms of preparations for fungal infections of the skin, (ii) D1A2: systemic dermatological antifungals (taken orally), and (iii) D1A3: topical scalp antifungals. At the ATC4 level, the parties' activities only overlap in topical dermatological antifungals (D1A1).
15. In the case COMP/M.3544 – Bayer Healthcare/Roche (OTC business), the Commission considered topical antifungals (D1A1) as a relevant product market, although it excluded some of the products included in such category since, according to the results of the investigation, they were shampoos or other scalp treatments.
16. In this case, the parties consider that ATC4 is the appropriate level to define the relevant product market and the market investigation has confirmed this view. In any case, for the purposes of this decision, the final question of whether the whole D1A1 group constitutes the relevant product market or whether some shampoos or other scalp treatments included in this group should be excluded from it can be left open as the final competitive assessment does not change under both alternatives.

5 This factor is particularly relevant for those products which are not OTC in all the Member States (but are still prescription-bound in some Member States) and for semi-ethical products (i.e., products which are OTC but reimbursed when prescribed).

b) Cold and flu treatments

17. The products classified in R5A (cold and flu treatments) treat the symptoms of common cold and flu. Because of the multiple symptoms associated with cold and flu, cold and flu medications are often combination products. They can combine an analgesic/antipyretic (relieving pain and fever), an antihistamine (reducing the histamine production), a cough reliever (anti-tussives or expectorants, suppressing or facilitating the cough), and/or a decongestant (clearing the respiratory tract and facilitating breathing).
18. The Commission has previously⁶ considered the R5A classification as appropriate to define the relevant product markets. However, the Commission has also recently⁷ considered the possibility of a broader market definition, adding to R5A the following classes: R4A (chest rubs and other inhalants), R1B (systemic nasal preparations), R1A7 and R1A9 (nasal decongestants without anti-infective and anti-allergic compounds), although ultimately the market definition was left open. The Parties did not take a view as to whether the relevant product market should be the broad (R5A, R4A, R1B, R1A7 and R1A9) or the narrow (R5A) product market definition.
19. The majority of the responses to the Commission's market investigation have confirmed a broader market definition. The responses were, however, diverging as regards the precise scope of such a wider market. Whereas some respondents proposed to include the same products as mentioned above (see recital 18), others have proposed a market that would include all nasal remedies (R5A, R1B, R1A7 and R1A9) and a separate market for throat/chest remedies (R5A and R4A). Other market players suggested to include, in addition to the above-mentioned ATC 3 categories, also cough relief products (anti-tussives, R5D, and expectorants, R5C); or to consider only cold and flu remedies (R5A) and systemic nasal preparations (R1B) as part of the same product market. It is, therefore, at this stage not clear what the scope of a broader market for cold and flu remedies would be⁸.
20. In any event, the exact definition of the market can be left open, as the notified transaction would not raise serious competition concerns on any possible market.

c) Topical anti-haemorrhoidals

21. Haemorrhoids are like varicose veins, but in the canal of the anus. The parties only overlap as regards ATC classification C5A (topical anti-haemorrhoidals, which relieve the symptoms of haemorrhoids, but do not treat the cause), and not

⁶ Case M.3354 – Sanofi-Synthelabo/Aventis, paragraph 23.

⁷ Case M.4007 – Reckitt Benckiser/Boots Healthcare International, paragraph 27 *et seq.*

⁸ See also Case COMP/M.1878 – Pfizer/Warner Lambert, paragraphs 35 to 41 for doubts as regards the substitutability of products in the various ATC 3 classes that contain indications for the treatment of general cold and flu symptoms.

for C5C (Varicose Therapy, Systemic, which includes systemic anti-haemorrhoidals). The market investigation has confirmed that C5A and C5C pharmaceuticals are complementary and belong to separate relevant product markets.

22. The parties take the view that the topical anti-haemorrhoidal market should be defined based on the whole ATC C5A category, including both prescription-bound and non prescription-bound products. According to the parties, there is a clear competitive interaction between prescription-bound and non prescription-bound products in France, given that around 78% of all sales of the products in C5A are prescribed and that J&J's products (with one recent exception) are semi-ethical (i.e., available without prescription but reimbursed if prescribed), while PCH's product is not reimbursed even if prescribed. The market investigation has confirmed that prescription-bound products exert a strong competitive constraint on non prescription-bound products for topical anti-haemorrhoidals in France. In any event, the question of whether prescription-bound topical anti-haemorrhoidals and non prescription-bound topical anti-haemorrhoidals belong to the same relevant product market can however be left open for the purpose of the present decision since it does not modify the competitive assessment.

d) Analgesics and antipyretics

23. General purpose non-narcotic analgesics are classified under ATC 3 class N2B (analgesics and anti-pyretics). This class includes systemic products for the relief of non-specific pain, and excludes narcotic analgesics (e.g. morphine) (N2A), anti-migraine drugs (N2C), analgesics used in cold and flu remedies in combination with other active ingredients such as antihistamines or decongestants (R5A), and topical analgesic products (e.g. creams) (M2A). The Commission has considered in previous decisions⁹ that the market for medicines to treat mild to moderate pain relief (non-narcotic analgesics) should be defined at the ATC 3 level of N2B.
24. The parties have also taken the view that this is the relevant product market definition. Whereas they admitted that the OTC-IMS classification makes a distinction between pain relief products for adults (O1A1) and for paediatric use (O2A2), they explained that the distinction between adult and paediatric pain relief depends merely on the dosage (lower for children and infants). The parties submit that the boundaries between paediatric and adult use are blurred and that substitution is possible as adult pain relief is used adapting dosage for children (many adult SKUs have dosage instructions for children, for example breaking tablets in half for intake by children).
25. The market investigation has only partly confirmed the parties' view that non-narcotic analgesics for adults and paediatric use belong to the same product market. Several respondents have explained that the adjustment of the dosage is

⁹ Case COMP/M.3354 – Sanofi-Synthelabo/Aventis, paragraph 98, 99; Case COMP/M.3544 – Bayer Healthcare/Roche (OTC Business), paragraph 21 *et seq.*

only a theoretical option in many cases. Gel capsules and tablets, for example, cannot be broken in order to adjust the dosage for children. This possibility only exists for powders and certain types of tablets. Moreover, there are specific products that are used for children (i.e. syrups and suppositories), whereas adults generally use different means of administering these products (i.e. tablets). The fact that the active ingredient is identical may therefore not be sufficient to classify all non-narcotic analgesic products as belonging to the same product market.

26. The product market definition can, however, be left open, as the proposed transaction does not lead to serious doubts on any possible market.

e) Laxatives and heartburn relief

27. J&J and PCH sell a range of non prescription-bound gastro-intestinal remedies for the treatment of minor gastro-intestinal ailments such as heartburn, acid stomachs, constipation, bloating, flatulence and diarrhoea. The parties' activities overlap only with respect to laxatives and heartburn/indigestion products.
28. The Commission has previously concluded¹⁰ that laxatives (used for the treatment of constipation) fall under the A6A class and constitute a separate relevant product market. The parties agree with this market definition. Laxatives will thus be considered as a separate relevant product markets for the purposes of the present decision.
29. Heartburn drugs can be segmented into two categories: antacids which neutralise excess acids (A2A1) and H2 blockers (or H2 antagonists) which act upon the stomach's acid production (A2B1). Although they treat similar symptoms, they are not part of the same ATC3 class, and previous Commission decisions left open whether these products should be considered as a single relevant product market¹¹. The Commission has also analysed¹² whether anti-flatulents (A2A2 and A2A7 classes) belong to the same relevant product market as antacids and H2 blockers, but the market definition was left open. The same approach can be taken for the purposes of the present decision, since the final assessment does not change if anti-flatulents are included in the relevant product market.
30. For the purposes of the present decision, it can be left open whether the A2A1 (antacids), A2B1 (H2 antagonists), A2A2 and A2A7 (anti-flatulents) ATC4 categories belong to the same relevant product market, , as the proposed transaction does not raise competition concerns on any possible market.

¹⁰ Cases M.3853 – Solvay/Fournier and M.4007 – Reckitt Benckiser/Boots Healthcare International.

¹¹ Case M.3544 – Bayer Healthcare/Roche (OTC business) and Case M.3751 – Novartis/Hexal.

¹² Case M.3544 – Bayer Healthcare/Roche (OTC business).

f) Cough relievers

31. The parties submit that there are three types of cough (i) a dry (non-productive) cough, (ii) a productive cough, which is accompanied with the secretion of mucus and relieves the respiratory tract, and (iii) an allergic cough, and that each of them is treated differently. Allergic cough is treated with anti-allergics (a different type of drugs); productive cough is treated with expectorants (R5C), and dry cough is treated with anti-tussives (R5D).
32. In line with previous Commission's decisions¹³, the parties therefore submit that the ATC classification at level 3 is appropriate in order to define the relevant product markets regarding cough preparations. Whether cough relievers (R5D) and expectorants (R5C) belong to the same or two separate markets can be left open for the purposes of this decision, as the proposed transaction does not raise competition concerns on any possible market.

g) Ocular decongestants

33. Level 3 of ATC classification (S1G) groups together ocular decongestants and ocular anti-allergics. The parties however submit that eye decongestants and eye anti-allergics differ in indication and in mode of action (they are classified in two different groups at ATC 4 level) and therefore do not belong to the same relevant product market.
34. Ocular decongestants (such as PCH's *Visine*) are vascular constrictors that narrow the blood vessels of the eye reducing occasional redness, irritation and dryness of the eyes caused by wind, sun and other minor irritants such as smoke, artificial light and dust. So, while *Visine* treats some of the symptoms which may be caused by an allergic reaction (or another cause), it does not treat the cause of the irritation by blocking the action of the histamine in the body. In contrast, ocular anti-allergics (such as J&J's *Livocab*) actually prevent or stop the allergic reaction by blocking the body's histamine receptor/mast cell. The parties submit that the Commission has already made a similar distinction¹⁴ regarding the segmentation of topical nasal preparations into (i) topical nasal decongestants and (ii) topical nasal anti-allergics.
35. In any event, the relevant product market definition can be left open for the purposes of the present decision, since the transaction is not likely to create competition problems either at level 3 (ocular decongestants and ocular anti-allergics constituting a single relevant product market) or at level 4 (ocular decongestants and ocular anti-allergics constituting two separate relevant product markets).

¹³ Case M.3354 – Synthelabo/Aventis.

¹⁴ Case M.1846 – Glaxo Wellcome/SmithKline Beecham.

B. Personal care markets

36. PCH sells a number of personal care products, in particular oral care, hair care and skin care products. The parties' sales only overlap as regards mouthwash, toothpaste and shampoos.

1. Daily-use mouthwash

a) Relevant product markets

37. Mouthwashes are liquids to be rinsed or gargled around the mouth, usually after brushing teeth. Relying on a past Commission decision, the parties distinguish between (i) daily-use (cosmetic) mouthwashes which are mainly used to freshen the breath or protect the teeth or mouth against plaque development or tooth decay, and (ii) mouth infection treatments used to treat specific medical problems such as mouth ulcers, gingivitis and throat infections, only for a short period¹⁵.
38. The market investigation has confirmed that daily-use mouthwash and mouth infection treatments belong to two separate product markets, in particular, because of the different duration of their respective uses (daily v. short-term use), the different sales channels (grocery/retail v. pharmacies), their different indications (cosmetic v. infection treatment) and price differences.
39. It has also been largely confirmed that within daily-use mouthwash no distinction can be made to further separate the market. For the purposes of the present decision, the relevant product market is thus the market for daily-use mouthwash.

b) Relevant geographic markets

40. The parties submit that the relevant geographic markets for daily-use mouthwash are national markets. The large majority of respondents to the market investigation has confirmed this approach.
41. One respondent however pointed out that several factors indicate that the market is increasingly European in scope, i.e. the presence of all major players in most EU Member States; the small presence of purely national players; minimal variation in market shares of main players across different Member States; the fact that brand names are used EU-wide; the lack of importance of different oral care habits per Member State; the similarity of trade prices (as opposed to retail prices); the consolidation of customers (for example, Carrefour, Tesco, Ahold, Metro, Aldi); and the absence of national regulation.
42. Notwithstanding these indications there are a number of factors that contradict the notion of an EEA-wide market. Firstly, the retail prices differ significantly in each Member State by 15% to 20%. Respondents to the market investigation explained that such price differences result inter alia from the differences local

¹⁵ Case COMP/M.2192 – SmithKline Beecham/Block Drug, paragraphs 15 *et seq.*

competitive environments and the different costs for business activities (taxation, administration, transport costs). Secondly, the label and marketing is national, given that these have to be prepared in each language separately. Thirdly, the distribution channels remain national and sometimes local in scope. Fourthly, customer preferences vary significantly by country.

43. The Commission therefore concludes that, for the purpose of the present decision, the market for daily-use mouthwash is national in scope.

2. *Toothpaste*

a) Relevant product markets

44. The Commission has previously¹⁶ considered toothpaste as a relevant product market, leaving open whether a sub-segmentation according to the different variants (such as regular/family toothpaste, children's toothpaste, whitening or sensitive toothpaste) is needed. The parties claim that also in this case the product market definition can be left open since the final assessment does not change under any alternative.

b) Relevant geographic markets

45. As regards the geographic market definition, the Commission has previously¹⁷ assessed the toothpaste market both at national and at EEA-level, leaving open the final geographic market definition. Also in this case the definition can be left open since the final assessment does not change under both alternatives.

3. *Shampoos*

a) Relevant product markets

46. J&J sells baby shampoos, anti-dandruff shampoos and regular shampoos, while PCH sales "*Pregaine*", a volumising shampoo designed for those with thinning hair. The Commission has previously dealt with hair care products and considered that shampoos constitute a separate relevant product market¹⁸. The parties agree with this market definition.
47. The question whether shampoos constitutes the relevant product market or whether it can be further segmented by their intended use can in any event be left open since the transaction does not give rise to competition concerns under any alternative.

¹⁶ Case COMP/M.3732 – Procter & Gamble/Gillette, 15 July 2005.

¹⁷ Case COMP/M.3732 – Procter & Gamble/Gillette, 15 July 2005.

¹⁸ Case No COMP/M.4193 - L'Oréal / The Body Shop, 31 May 2006.

b) Relevant geographic markets

48. The Commission has previously left open the question of the geographic market definition for shampoos, leaving open the question of whether it is national or EEA-wide. Also in this case the definition can be left open given that, on the basis of any of the alternative geographic market definitions, the concentration does not give rise to competition concerns.

C. Nicotine Replacement Therapy ("NRT") products

1. Relevant product markets

a) Introduction

49. Smoking cessation products are aimed at reducing and ultimately eliminating the nicotine addiction that comes with smoking. There exist several pharmacological treatments for smoking cessation to deal with the physical withdrawal symptoms, such as cravings, irritability, inability to concentrate, and anxiety.
50. Over time, inhalation of nicotine through smoking increases the number of nicotine receptors in the brain; as a result, a smoker's brain requires a regular supply of nicotine to function normally. The vast majority of smoking cessation products are nicotine replacement therapy ("NRT") products, which provide smokers with a slow release of nicotine in gradually smaller doses, thereby reducing slowly smokers' dependence on nicotine. There are, however, other types of smoking cessation products, such as substances that acts as an inhibitor or antagonist of the nicotine neural receptor, thereby blocking the reward experience provided by nicotine.
51. The three main types of NRT products are (i) nicotine patches, (ii) nicotine gums and (iii) nicotine lozenges. Other formats include nicotine inhalators, nicotine nasal sprays and nicotine sublingual tablets, but these products account for less than 8% of NRT products sales in the EU. Transdermal patches were developed to deliver precise quantities of a drug through the skin for a prolonged period of time. Compared to traditional oral administration, transdermal delivery can increase the therapeutic effect of a drug and reduce side effects for example on the gastrointestinal tract. The patches can be applied to any hairless part of the upper body or the outside of the arm and allow the drug to permeate through the skin at a controlled rate over a period of time. A nicotine patch incorporates a series of thin, flexible films: a backing layer, a rate-controlling film and an adhesive and is designed to release nicotine. Nicotine patches either have a drug reservoir to store the nicotine or incorporate the nicotine into the adhesive.

b) The parties' activities

52. J&J's subsidiary ALZA¹⁹ develops and manufactures drug delivery mechanisms,

¹⁹ J&J acquired ALZA in 2001.

including transdermal drug delivery patches (based on ALZA's D-Trans technology platform) which are applied to the skin and serve as a mechanism for controlled release of a drug (such as pain relievers, hormones or nicotine) for a prolonged period of time. ALZA supplies nicotine patches to several third parties, under exclusive long-term supply contracts. ALZA supplies nicotine patches to Sanofi-Aventis (for sale in the U.S. and South Korea), to PCH (for sale in Canada), and to GlaxoSmithKline ("GSK") for sale everywhere in the world, except in the U.S., Canada and South Korea²⁰. GSK markets nicotine patches under its *NiQuitin* brand in Europe, pursuant to an exclusive [...] agreement from 1997. J&J does not however market nicotine replacement products anywhere in the world.

53. PCH manufactures and markets under the *Nicorette* brand a range of NRT products, including patches, gums, microtabs, nasal sprays and inhalators. It also supplies NRT products to the UK retailer Boots which Boots sells under its private label *NicAssist* brand in the UK.
54. The parties distinguish an upstream market for the manufacturing and direct sale of nicotine patches to pharmaceutical firms or retailers (private labels), and a downstream market for the supply of nicotine replacement therapy ("NRT") products which are classified as N7B in the ATC system. The parties take the view that it can be left open whether nicotine patches and other NRT products such as gums or lozenges are substitutable from the customers' point of view and constitute distinct product markets, as the case does not give rise to any horizontal overlap in the sale of NRT products.

c) Upstream market for the manufacturing and direct sale of nicotine patches

55. The market investigation has confirmed that the existence of a product market for the manufacturing and direct sale of nicotine patches, which is distinct from the manufacturing of other transdermal patches.
56. From the demand-side, nicotine patches and other transdermal patches are clearly not substitutable.
57. From the supply-side, the market investigation has confirmed the parties' view that manufacturers of (non-nicotine) transdermal patches could not develop, and

²⁰ In the mid-1980s, when ALZA first developed its nicotine patch product, it was a small, independent, research-based company and did not have the marketing or distribution capability to bring the product to market in the U.S., let alone worldwide. In 1989, ALZA thus granted the worldwide rights to its nicotine patch to Marion Merrel Dow ("MMD"). Over the years, MMD returned part of these rights to ALZA [...]. Eventually, all rights were returned except those for the U.S., Canada and South Korea. Through a subsequent merger and an assignment, the rights retained by MMD ended up with Sanofi-Aventis (in respect of the U.S. and South Korea), and with Pfizer Canada (in respect of Canada) respectively. In 1997, ALZA entered into an agreement with SmithKline Beecham p.l.c. granting SmithKline the marketing rights for the product in several countries, and by a series of amendments, the SmithKline territory eventually included the rest of the world. Via SmithKline's merger with Glaxo Welcome, these rights ended up with GSK.

start producing and marketing nicotine patches "in the short term without incurring significant additional costs or risks". Some respondents point out that some aspects of nicotine patches are protected by patents and other intellectual property rights, and that it may be an infringement to shift manufacturing from non-nicotine to nicotine. One respondent estimates that product development, testing, approval, and manufacturing would cost somewhere in the range of 15-26 million euros. Respondents generally estimate that it would take a minimum of four to five years for a patch manufacturer to supply a nicotine patch based on an existing non-nicotine patch. The time required for product testing and regulatory approvals alone is estimated at 2 years, and the time to construct a nicotine patch manufacturing site and have a nicotine patch line certified is estimated to be between 2 to 4 years.

d) Downstream market for the supply of NRT product/nicotine patches

58. Most NRT products are sold as OTC in pharmacies or, in the UK, as general items in other retail outlets such as grocery stores. In Luxembourg and Sweden, certain NRT products are only available on prescription, generally due to the fact that the product has only recently been launched on the market in question, but these products are likely to move to OTC status in the future. In some countries, such as the UK and France, NRT products are semi-ethical, i.e. reimbursed if prescribed (but also available without prescription and without reimbursement).
59. In their notification, the parties considered the NRT products only available on prescription as belonging to a prescription-bound market for N7B anti-smoking products, including *Zyban* (active substance bupropion, which acts as an inhibitor or antagonist of the nicotine neural receptor, thereby blocking the reward experience provided by nicotine) and prescription-bound NRT products.
60. The market investigation has clearly confirmed that other (non-NRT) smoking cessation products are not substitutable to NRT products. All respondents except two take the view that *Zyban* (with the active substance bupropion) is not substitutable as it is only available on prescription, and it relies on another mechanism of action to protect against physical cravings. Products based on clonidine (an anti-hypertension compound) and on nortriptyline (an antidepressant) are not registered for smoking cessation in Europe and are generally considered as "second line" therapies that should be given under close medical supervision.
61. Within the NRT products segment, the parties recognize that from a demand-side perspective, there are certain differences between different types of NRT products linked to customer preferences and possible side effects. PCH internal research indicates that patch users tend to be more serious about their quit attempt and more likely to have tried quitting before (with or without NRT), and tend to be more dependent on nicotine. They prefer the patch as it provides a steady dose of nicotine throughout the day. By contrast, gum users tend to be less serious about their attempt to quit and like the fact that gum keeps them from smoking and/or eating while trying to quit.

62. Most respondents in the market investigation take the view that there is some demand-side substitutability between nicotine patches and the other NRT products (nicotine chewing gums, nicotine lozenges, nicotine sublingual tablets, nicotine nasal sprays and nicotine inhalators²¹) on the grounds that they all rely on the same mechanism of action (slow delivery of nicotine into the patient's bloodstream) and do not need to be prescribed. However, some of the reasons provided for the reply point on the contrary to different product markets. In particular, respondents also stress that user preference for different NRT formats is very important as customers choose to use the form that it most suitable for them depending on side effects (for example, patches may cause skin irritation or a feeling of overdose at night while oral form allows a better control) or administration mode (patch being the easiest).
63. However, four respondents take the view that nicotine patches form a distinct product market from other NRT products on the ground that (i) patches are used differently from other products, as they are applied to the skin only once daily and constitute a passive and 'more medicinal' treatment (different administration mode); and (ii) consumer loyalty is high and consumers tend not to change between different NRT formats (user preference); patch users tend to purchase patches almost exclusively and gum users tend to purchase gum almost exclusively.
64. Given that the transaction raises problems on a separate market for OTC nicotine patches or a broader OTC market including other NRT products such as gums, lozenges, sublingual tablets and inhalators, the exact product market definition can be left open for the purpose of the present decision.

2. Relevant geographic markets

65. The parties take the view that the market for the manufacturing and direct sale of nicotine patches is worldwide, and the market for the supply of nicotine patches/NRT products is national.
66. The market investigation has entirely confirmed the parties' view that market for the manufacturing of nicotine patches is at least EEA-wide, and for most respondents, worldwide, and that the market for the supply of nicotine patches/NRT products is national for the same reasons as other OTC pharmaceuticals.

V. COMPETITIVE ASSESSMENT

67. Based on its market investigation, the Commission has identified serious competition concerns in three product areas: (i) topical dermatological antifungals in Italy; (ii) mouthwash in Greece; and (iii) nicotine patches and NRT

²¹ One respondent considers that nicotine nasal sprays are not substitutable; another respondent takes the view that nicotine nasal sprays and nicotine inhalators are not substitutable; one respondent takes the view that only nicotine gums is substitutable to nicotine patches.

products in general in the EEA markets.

A. OTC pharmaceuticals and personal care products

1. OTC products

a) Topical dermatological antifungals in Italy

68. In the field of antifungals, the only market affected by the proposed transaction is the market for topical dermatological antifungals in Italy, where the parties' combined market share in 2005 would be [60-70]% (J&J, [40-50]% and PCH, [10-20]%).
69. J&J is present in Italy with its brands *Daktarin*, *Pevaril* and *Nizoral*. These products are based on the following active ingredients: miconazole (*Daktarin*), econazole nitrate (*Pevaryl*) and ketoconazole (*Nizoral*). *Nizoral* is sold exclusively in cream, *Daktarin* is sold in emulsion and tincture, and both *Daktarin* and *Pevaryl* are sold in cream/spray, powder and sachets²².
70. PCH is active in Italy with its brand *Trosyd*, whose active ingredient is tioconazole and it is sold in the same forms and for the same applications as J&J's products (except for the treatment of fungal infections of the nails, for which *Trosyd* is in the form of ungueal solution instead of tincture).
71. The market investigation has confirmed that J&J's and PCH's products are close substitutes, and in particular that J&J's products constitute most of the times either the best or one of the best alternatives to PCH's products.
72. The most important competitor of J&J and PCH is Bayer with a market share of [20-30]% and other competitors are very fragmented with market shares around or below [0-5] %: Menarini ([0-5]%), Recordati ([0-5]%), Italfarmaco ([0-5]%) and others ([0-5] %).
73. Therefore, the transaction consists of the acquisition by the main player of the third largest player in the market, resulting in a combined market share of over [50-60]% and increasing the HHI²³ from 2,904 to 4,482, with a delta of 1,578.
74. Although the investigation has not revealed concerns from the competitors' point of view, it has confirmed that antifungals are not among the priority business of the smaller competitors who are more focused on other product areas. Therefore, it is highly unlikely that the remaining competitors (except Bayer) can constitute

²² Cream is used for the general treatment of skin mycosis due to certain fungi; Emulsion is indicated for the treatment of mycosis in hairy parts of the body; Powder is used to treat fungus on parts of the body where maceration/perspiration is especially significant (i.e. infection between toes); Sachets are detergents used instead of normal soap by people having mycosis infections; Tincture is used for fungal infections of the nails.

²³ Herfindahl-Hirschman Index (HHI).

a credible competitive constraint to the merged entity given the small size of their activities in topical dermatological antifungals and the different focus of their current pharmaceutical activities.

75. Concerns were raised by certain wholesalers as regards the possible negative effects that the transaction may have on them due to the increased concentration of the market. These negative effects could be in particular related to supply restrictions that can be imposed by pharmaceutical producers²⁴ and deterioration of business terms.
76. Given the high market share that J&J will acquire in the market post-transaction and the fact that only one strong competitor will remain in the marketplace with no other credible alternatives, the Commission considers that the transaction is likely to create competition problems in this market. In particular, the elimination of one of the two significant competition constraints to J&J and the fact that J&J will have an appreciably larger market share than its immediate competitor (Bayer) may give rise to non-coordinated effects resulting in price increases for the final consumers that Bayer may find profitable to follow. Therefore, the proposed transaction raises serious doubts as to its compatibility with the common market and the EEA agreement.

b) Cold and flu treatments in France

77. The parties are both active in France with products classified in R5A. PCH sells one of the leading cold and flu medications in France, *Actifed Rhume* and *Actifed Jour et Nuit*. J&J's product in France is *Rhinofebral (Rhinofebral Vit C and Rhinofebral Vervaine, Miel and Citron)*.
78. On the basis of a market comprising only products classified under ATC R5A, the parties would have a combined market share of [20-30]% in France (J&J [0-5]%, PCH [20-30]%). On the basis of a larger product market definition as discussed above (see recital 19), the parties would have a combined market share of [10-20]% in France (J&J [0-5]%, PCH [5-10]%).
79. After the proposed transaction the parties will continue to face competition from the leading cold and flu medication in France, *Oscillococcinum* (sold by Laboratoires Boiron, with a [20-30]% market share) and a number of other strong brands of other competitors (e.g., Bristol Myers Squibb with *Fervex*, [10-20]%, Urgo with *Humex Rhume*, [5-10]% and Sanofi-Aventis with *Doli Rhume*, [5-10]%). *Oscillococcinum* is a homeopathic product used by consumers as a cold and flu medication. It does therefore exercise competitive pressure on the parties' products.
80. Further competing products with lower market shares (under [0-5]%) are *Rhinureflex* and *Nurofen Rhume* (Reckitt Benckiser) and *L 52 Antigrippe*

²⁴ It has been claimed that these supply restrictions are normally aimed at preventing parallel traders from engaging in cross-border shipments of pharmaceutical products.

(Lehning). All of these products are classified in R5A and have a market share that is similar to *Rhinofebral's* share.

81. The Commission, therefore, concludes the proposed transaction does not raise serious doubts even on the basis of the narrowest possible product market definition (R5A).

c) Cold and flu treatments in Belgium and Luxembourg

82. On the basis of a market comprising only R5A, the parties' combined market share in Belgium would be [60-70]% (J&J [10-20]% and PCH [40-50]%) and in Luxembourg [60-70]% (J&J [30-40]% and PCH [20-30]%)²⁵.
83. PCH's product in R5A is *Sinutab*, which is indicated for nasal and sinus congestion accompanied with a headache. J&J sells *Rhinofebryl*, which is positioned as a cold and flu remedy. *Rhinofebryl* is exclusively distributed in Belgium and Luxembourg by Melisana, which holds the marketing authorisation for this product.
84. The parties consider that, although included in the same R5A class, J&J's and PCH's products are not close substitutes. *Sinutab* combines an analgesic (paracetamol) and a decongestion ingredient (pseudoephedrine), while J&J's *Rhinofebryl*²⁶ combines an analgesic (paracetamol) and an antihistamine (chlorpheniramine). The parties state that these products have different therapeutic indications, are positioned differently and are prescribed and used for different purposes (if prescribed, both are available OTC).
85. In fact, under the OTC-IMS classification, *Sinutab* is classified under 01B2 (nasal decongestants) and *Rhinofebryl* is classified under 01B1 (cold remedies). Under the OTC-IMS classification, the combined market shares would thus be much lower (in Belgium the combined market share would be [20-30]%).
86. The market investigation has not confirmed the parties view. Most respondents to the market investigation explained that the parties' products are substitutable and that the fact that they are marketed and/or positioned differently by the parties has only a very limited effect on the actual use of the products as competing products.
87. Nevertheless the market investigation has largely confirmed the parties' view that the transaction does not cause and concerns on the markets for cold and flu treatments in Belgium and Luxembourg. It has been pointed out by most respondents that there is a large number of competing products that will continue to exercise competitive pressure on the parties' products. Products that respondents considered to be direct competitors are in particular *Niocitran*

²⁵ On a wider market, comprising products classified in R5A, RB1, R4A, R1A7 and R1A9, the parties combined market share in Belgium would be only [10-20]% (J&J [0-5]% and PCH [5-10]%) and in Luxembourg [10-20]% (J&J [5-10]% and PCH [5-10]%).

²⁶ J&J owns *Rhinofebryl* but had given it in distribution to Melisana in Belgium and Luxembourg. [...].

(Novartis, ATC R5A), *Oscillococcinum* (Boiron, R5A); *Ratiogrippal* (Ratiopharm, R5A); *Lemsip* (Reckitt-Benckiser); *Afebryl* (SMB); *Cirrus* (UCB, ATC R1B) and *Rhinatiol* (Sanofi-Aventis, ATC R1B)²⁷. The market share of *Oscillococcinum* is significant with [20-30]%. Only a few respondents raised some moderate concerns about the effects of the transaction on the markets for cold and flu treatments in Belgium and Luxembourg due to the increase in competitive strength of the merged entity. These concerns have, however, not been substantiated.

88. It should finally be noted that no concerns would arise if the market were defined as being wider than R5A, which is supported by most market players (see recital 19).
89. For these reasons it can be concluded that the transaction does not give rise to competition concerns on the markets for cold and flu treatments in Belgium and Luxembourg (even if defined narrowly as R5A).
90. [...].

d) Topical anti-haemorrhoidals in France

91. J&J's *Titanoreïne* is the leading topical anti-haemorrhoidal product in France (non prescription-bound), the second largest product being Pfizer's *Proctolog* (prescription-bound). If a product market for all topical anti-haemorrhoidals is considered, J&J would have a market share of [30-40]% (*Titanoreïne* [30-40]% and *Anoreïne* [0-5]%), Pfizer [30-40]% (*Proctolog*), the other main competitors being Cooper ([5-10]%, *Sedorrhöide*), Wyeth ([5-10]%, *Préparation H*) and Pierre Fabre ([5-10]%, *Cirkan*). PCH would have a market share of [0-5]% with *Anusol*. If a product market only for non prescription-bound topical anti-haemorrhoidals is considered, J&J would have a market share of [60-70]% (*Titanoreïne* [60-70]%, *Anoreïne* [0-5]%), Cooper [10-20]% (*Sedorrhöide*), Wyeth [5-10]% (*Préparation H*) and Merck [5-10]% (*Phlebocreme* and *Phlebosup*). It should be noted that *Proctolog* is not acquired by J&J in the context of the present transaction since it is not part of PCH.
92. The market investigation has shown that *Titanoreïne*'s most significant competitor is *Proctolog* and that *Anusol* does not exercise any meaningful competitive pressure on *Titanoreïne*. Market players confirm that the vast majority (around 80%) of anti-haemorrhoidals are prescribed and that *Titanoreïne* and *Proctolog* are viewed by physicians as the two main alternatives. The two products are also reimbursed at the same rate (35%) if they are prescribed. According to the parties, *Titanoreïne* is prescribed in 75% of cases.
93. Most of the respondents consider *Anusol* as a marginal brand in France,

²⁷ When considering the OTC-IMS classification, further competitors are *Soria Natural* (by Soria), *Buccaline* (by Berna), *Nisyleen Forte*, *Grippikind*, and *Eupatorium* (by VSM Belgium), *Biolys* (by Tilman), *Vanocomplex*, *Allium cepa* and *Griptab* (by Dolisos) and *Viburcol*, *Gripp Heel* and *Aconitum* (by Heel).

confirming the parties' statements that the *Anusol* was a declining brand, not actively marketed and advertised by PCH. Certain respondents also pointed out that *Anusol* has an old formulation and that the brand name has a poor notoriety.

94. Thus, even if a narrow market definition is considered (only non prescription-bound anti-haemorrhoidals), the transaction does not give rise to any competitive concerns since PCH *Anusol* brand is marginal and J&J will remain mainly constrained by Pfizer's *Proctolog* and by other prescription-bound and non prescription-bound products.

e) Analgesics and antipyretics in Belgium and Luxembourg

95. On the Belgian and Luxembourg markets for analgesics and antipyretics, J&J sells *Perdolan* and *Perviam*, which are paracetamol-based. *Perdolan* is available in various formulations for adults and for children and infants. PCH sells *Curpol*, a paracetamol-based drug which is only available in formulations for infants and children.
96. The pain relief markets in Belgium and Luxembourg would only be affected markets if a distinction were made between pain relief for adults and pain relief for paediatric use. The parties' combined market shares on the market for analgesics for paediatric use would be [40-50]% in Belgium (J&J, [30-40]% and PCH, [0-5]%) and presumably similar in Luxembourg, for which such detailed data is not available²⁸. The parties' activities would not overlap on a separate market for analgesics for adults, as *Curpol* is only for paediatric use.
97. On a wider market comprising analgesics for adult and for paediatric use the parties' combined market share would be [10-20]% in Belgium (J&J, [10-20]% and PCH [0-5]%) and [5-10]% in Luxembourg (J&J, [5-10]% and PCH, [0-5]%).
98. Even considering at a separate market for systemic analgesics for paediatric use, the overlap between the parties is limited with only a small increment from PCH's product, *Curpol* of [0-5]%. Furthermore, there remain strong competitors: Reckitt Benckiser sells the leading product *Junifen* ([50-60]%, which is based on ibuprofen), Bristol Myers sells *Dafalgan* ([0-5]%, which is based on paracetamol), both of which have been growing over the years in the paediatric segment. Other products that compete with *Curpol* and *Perdolan* for paediatric use are *Panadol* (by GSK) and *Algotase* (by SMB), which are both based on paracetamol. Most respondents to the market investigation have confirmed that there is strong competition with a variety of different products to choose from. Moreover, market participants expect continuing competition from producers of generics. Accordingly, no serious concerns have been raised by any of the market participants.

²⁸ On the general market for systemic pain relief (both adult and paediatric), the parties' combined market share in 2005 is only [10-20]% in Belgium (J&J, [10-20]%; PCH: [0-5]%), and [10-20]% in Luxembourg (J&J: [10-20]%; PCH: [0-5]%).

99. For these reasons the Commission concludes that the proposed transaction does not raise any competition concerns under even the narrowest possible market definition.

f) Laxatives and heartburn relief in Germany

100. The parties' activities only overlap in Germany, both for laxatives and antacids/H2 blockers²⁹. If a market for antacids/H2 blockers and anti-flatulents (A2A and A2B1) is considered, it would not be affected (J&J, [5-10]% and PCH, [5-10]%). If a market for the combined antacids/H2 blockers (excluding anti-flatulents) (A2A1 and A2B1) is considered, it would be affected with a combined market share of the parties of [10-20]% (J&J, [5-10]% and PCH, [5-10]%). If antacids and H2 blockers are considered as separate markets, there would be no overlap, as PCH markets antacids and J&J markets H2 blockers. Even if a market for the combined antacids/H2 blockers (excluding anti-flatulents) is considered, the presence of a number of credible competitors with strong and well-know brands such as Bayer ([30-40]%), Klosterfrau ([10-20]%) or Altana ([10-20]%), and the fact that products are not close competitors as they belong to different ATC4 levels, lead to the conclusion the transaction does not give rise to any competition concerns as regards heartburn relief products in Germany.

g) Cough relievers in Spain

101. The parties overlap in cough relievers and/or expectorants in various Member States, but the transaction would give rise to an affected market only for cough relievers in Spain.

102. In Spain, PCH sells certain products that are indicated as cough suppressant: *Iniston Antitussivo*, *Iniston Antitussivo y Decongestivo*, *Inistolin Pediatrico Antitussivo*, and *Benylin Decongestivo Infantil*. These products are classified under R5D. J&J sells a plain cough suppressant classified in R5D, *Frenatus*. The parties combined market share on a market defined as R5D would be [20-30]% (PCH, [20-30]% and J&J, [0-5]%).

103. The combined entity will be faced with strong competition from other products. The market leader is Boehringer Ingelheim with *Bisolvon* ([30-40]%). Other strong competitors are Bayer with *Romilar* ([10-20]%) and *Pastillas Dr Andre* ([5-10]%), Ferrer with *Pilka* ([5-10]%) and Cinfa with *Cinfatos* ([5-10]%).

104. Given the strong competition that the combined entity will face post-transaction and the fact that the overlap is minimal, the Commission concludes that the transaction does not raise serious doubts on the market for cough relievers in Spain.

h) Ocular decongestants and ocular anti-allergics in Belgium,

²⁹ The parties' products do not overlap in anti-flatulents any more since PCH has discontinued the sale of Kompensam Dimeticon in Germany.

Czech Republic, Germany and Spain

105. If ocular decongestants and ocular anti-allergics are considered as a single product market, there would be affected markets in Belgium (J&J [20-30]% and PCH [0-5]%), the Czech Republic (J&J [0-5]% and PCH [20-30]%), Germany (J&J [10-20]% and PCH [10-20]%) and Spain (J&J [0-5]% and PCH [40-50]%). However, given the moderate levels of combined market shares post transaction (Belgium, Czech Republic and Germany) and/or the minimal accretion of market shares (Belgium and Spain), the transaction does not give rise to any competition problems.
106. If ocular decongestants and ocular anti-allergics are considered as two separate product markets, then the only overlap would occur in Spain, which would be an affected market for ocular decongestants with a combined market share of [60-70]% (J&J, [0-5]% and PCH, [50-60]%). Given the minor accretion of market share, the transaction does not change significantly the Spanish competitive market structure and therefore the transaction does not give rise to any competition problems either.

2. *Personal care markets*

a) Daily-use mouthwash

107. J&J sells daily-use mouthwash under the *ACT* or *REACH* brands only in the United Kingdom (*REACH*), Ireland (*REACH*), the Benelux (*ACT*), Greece (*ACT*) and Portugal (*REACH*)³⁰. PCH sells a daily-use mouthwash, *Listerine*, in all these countries, except Hungary. *Listerine* is a best selling mouthwash in many countries. PCH also sells a range of medicated mouthwashes containing hexitidine as their active ingredient (*Hextril*), an antiseptic used to treat mouth infections. J&J does not sell such mouth infection treatments. Accordingly, the parties' activities only overlap in daily-use mouthwash products.

30 Based on all J&J's sales of daily-use mouthwash in the Member States concerned, J&J's sales of *ACT* are [...].

108. The markets of daily-use mouthwash in Belgium/Luxembourg³¹, Greece, Ireland, the Netherlands and the United Kingdom are affected.

	PCH (<i>Listerine</i>)	J&J (<i>ACT</i> or <i>REACH</i>)
Belgium/Luxembourg	[20-30]%	[0-5]%
Greece	[70-80]%	[5-10]%
Ireland	[70-80]%	[0-5]%
Netherlands	[30-40]%	[0-5]%
United Kingdom	[40-50]%	[0-5]%

109. The Commission's market investigation focused on the markets in Greece and The Netherlands, as these are the only countries where the overlap was noticeable (above [0-5]%). It has found out that the transaction raises serious doubts as regards the effect of the transaction on competition only on the Greek market for daily-use mouthwash. The vast majority of respondents to the market investigation raised concerns about the strength of the parties in the Greek market with a combined market share of at least [80-90]%.³²

110. As regards the Dutch, Irish, Belgian, Luxembourg and UK markets, no competition concerns were identified due to the small overlap between the parties and the existing strong competition. The only other market with a noticeable overlap, The Netherlands, is characterised by strong competitors and strong private label products. Accordingly, no concerns were raised by the respondents to the market investigation.

111. In Greece, the parties' argument that J&J's brand *ACT* is [...] brand, into which no investment is made and that is losing market share has been accepted, in principle, by many respondents. However, *ACT* alone has a market share in Greece that equals the market share of the numbers 3 and 4 players combined.³² The decline of *ACT* – mostly due to a lack of advertising and promotion by J&J in recent years³³ – has, therefore, not been perceived as endangering its position as number 2 player in the Greek market. The market investigation has also shown that private labels are not yet very strong in Greece with an overall market share of below [0-5]%. Private labels would, therefore, not be able to exercise significant competitive pressure on the combined entity. There have been no indications that this would change in the near future, given the relatively strong brand recognition of the established brands.

³¹ According to the parties, it is difficult to have information specific to Luxembourg ; the parties believe that market shares for Belgium are very similar and representative of those in Luxembourg.

³² According to competitors, *ACT*'s market share even equals the market shares of the number 2, 3 and 4 combined.

³³ Respondents to the market investigation confirmed that brand recognition and reputation are particularly important for the competitiveness of daily-use mouthwash products.

112. A majority of respondents has raised concerns as regards the increased ability of the combined entity to compete for shelf space, advertising and promotional activities at retailers, which could lead to a marginalisation of competitors in Greece. The parties would, therefore, be able to dominate in store marketing opportunities and could leverage their position to negotiate favourable shelf space and promotional opportunities with retailers. These are important aspects for the effectiveness of daily-use mouthwash competitors in Greece, as the main barrier to entry is to achieve listings with retailers and obtain attractive shelf space. This is confirmed by the fact that in the past shelf space that was liberated by de-listed competitors has been occupied by the leading player rather than by smaller competitors or new entrants. Moreover, new entrants, such as GSK with *Sensodyne*, have not managed to gain significant market shares after their entry (*Sensodyne* had a market share of approximately [0-5]% in 2005 and entered in late 2003).
113. Accordingly, there are serious concerns that the proposed transaction would significantly strengthen the parties' market power on the Greek market for daily-use mouthwash, leading to a significant lessening of efficient competition.

b) Toothpaste

114. The transaction does not give rise to affected markets as regards toothpaste. On the basis of an overall market for toothpaste, the parties' combined market share at any national level would be well below [0-5]%. The same stands at the EEA level, with a combined market share of around [0-5]%. If narrower product markets are considered, there would be no overlap since J&J sells only whitening toothpaste under the *Rembrandt* brand while PCH does not sell whitening toothpaste.
115. The transaction therefore does not give rise to competition concerns as regards toothpaste.

c) Shampoos

116. PCH sells a specialised volume-enhancing shampoo under the *Pregaine* brand, designed to care for thinning hair, in several Member States. J&J sells shampoos in most countries in Europe with the brands *Neutrogena* (regular and therapeutic anti-dandruff shampoos), *Johnson's* (baby shampoos), *Nizoral* (anti-dandruff/antifungal shampoo) and *Aveeno* (regular shampoo).
117. There are no affected markets either at national or at EEA level if an overall shampoo market is considered (J&J's market share is below [0-5]% and PCH's market share below is [0-5]%), the clear market leaders being Procter & Gamble (with the brands *Pantene* and *Head & Shoulders*, with a market share of around [20-30]%), L'Oreal (e.g., *Elsève* and *Fructis*, with a market share of [10-20]%), and Unilever (e.g., *Dove*, with a market share of [5-10]%). If a narrower product market definition according to the intended use of the shampoo is retained, the transaction does not lead to any horizontal overlap.

118. The transaction therefore does not give rise to competition concerns as regards shampoos.

B. NRT products

1. Introduction

119. The three main players active in national markets for NRT products, including nicotine patches, in the EEA are PCH, GSK, and Novartis. In addition, Pierre Fabre is active in France, and since earlier this year, Ireland and Portugal. Riemser is active in Germany. There are also suppliers of homeopathic OTC anti-smoking products in Germany, Latvia, Lithuania and Poland. GSK is generally the leading market player as regards nicotine patches (in particular due to the *NiQuitin* clear patch), and PCH is the leading market player as regards gums (due to its extensive range of flavour offerings).

Table – 2005 market shares for NRT products in EU Member States (by volume)³⁴

	Company	All NRT	Patches	Gums	Lozenges	Other
Austria	<i>PCH</i>	[80-90]	[30-40]	[90-100]		[90-100]
	<i>Novartis</i>	[10-20]	[60-70]	[5-10]	[90-100]	
Belgium	<i>GSK</i>	[30-40]	[60-70]		[90-100]	
	<i>PCH</i>	[50-60]	[5-10]	[80-90]		[90-100]
	<i>Novartis</i>	[10-20]	[30-40]	[10-20]		
Cyprus	<i>N/A</i>	-	-	-	-	-
Czech Republic	<i>GSK</i>	[30-40]	[70-80]			
	<i>PCH</i>	[50-60]	[20-30]	[80-90]		[90-100]
	<i>Novartis</i>	[0-5]		[10-20]		
Denmark	<i>PCH</i>	[50-60]	[50-60]	[40-50]		[90-100]
	<i>Novartis</i>	[40-50]	[40-50]	[50-60]	[90-100]	
Estonia	<i>PCH</i>	[90-100]	[90-100]			[90-100]
	<i>Novartis</i>	[0-5]		[90-100]		
Finland	<i>PCH</i>	[50-60]	[40-50]	[50-60]		[90-100]
	<i>Novartis</i>	[40-50]	[50-60]	[40-50]	[90-100]	
France	<i>GSK</i>	[10-20]	[30-40]	[0-5]	[30-40]	
	<i>PCH</i>	[40-50]	[10-20]	[70-80]		[90-100]
	<i>Novartis</i>	[10-20]	[10-20]	[10-20]	[0-5]	
	<i>Pierre Fabre</i>	[20-30]	[40-50]	0	[50-60]	
Germany	<i>GSK</i>	[0-5]	[0-5]		[20-30]	
	<i>PCH</i>	[50-60]	[30-40]	[70-80]		[80-90]
	<i>Novartis</i>	[30-40]	[60-70]	[20-30]	[70-80]	
	<i>Riemser</i>	0	[0-5]			
	<i>Inter-Breviph</i>	0				[10-20]
	<i>Pharmakon</i>	0				[0-5]
Greece	<i>PCH</i>	[90-100]	[90-100]	[90-100]		
Hungary	<i>GSK</i>	[40-50]	[60-70]		[70-80]	
	<i>PCH</i>	[10-20]	[10-20]	[20-30]		
	<i>Novartis</i>	[30-40]	[10-20]	[70-80]	[20-30]	
Ireland	<i>GSK</i>	[10-20]	[40-50]		[70-80]	
	<i>PCH</i>	[70-80]	[40-50]	[80-90]		[90-100]
	<i>Novartis</i>	[5-10]	[5-10]	[10-20]	[20-30]	
Italy	<i>GSK</i>	[40-50]	[70-80]		[60-70]	
	<i>PCH</i>	[50-60]	[20-30]	[90-100]		[90-100]
	<i>Novartis</i>	[5-10]	[0-5]		[30-40]	
Latvia	<i>PCH</i>	[80-90]	[90-100]	[90-100]		
	<i>Novartis</i>	[0-5]	[0-5]			
	<i>Sopharma</i>	[10-20]				[90-100]
Lithuania	<i>PCH</i>	[80-90]	[90-100]	[90-100]		
	<i>Aconitum</i>	[10-20]				[90-100]
Luxembourg	<i>GSK</i>	[10-20]	[80-90]			
	<i>PCH</i>	[70-80]	[5-10]	[90-100]		[90-100]
	<i>Novartis</i>	[0-5]	[0-5]	[5-10]		
Malta	<i>N/A</i>	-	-	-	-	-
Netherlands	<i>GSK</i>	[30-40]	[30-40]		[40-50]	

³⁴ Market share data provided by the parties in the Form CO, which is based on IMS-MIDAS and OTC-IMS, which is consistent with market share data provided by third parties (with the exception of market shares for Luxembourg, Netherlands, Portugal and Spain).

	Company	All NRT	Patches	Gums	Lozenges	Other
	<i>PCH</i>	[30-40]	[5-10]	[70-80]		[90-100]
	<i>Novartis</i>	[50-60]	[60-70]	[20-30]	[50-60]	
Poland	<i>GSK</i>	[40-50]	[60-70]	[5-10]	[90-100]	
	<i>PCH</i>	[50-60]	[30-40]	[90-100]		[40-50]
	<i>P.Z. Cormay</i>	[0-5]				[40-50]
Portugal	<i>GSK</i>	[10-20]	[30-40]			
	<i>PCH</i>	[50-60]	[20-30]	[70-80]		
	<i>Novartis</i>	[30-40]	[30-40]	[20-30]	[90-100]	
Slovakia	<i>GSK</i>	[10-20]	[30-40]			
	<i>PCH</i>	[80-90]	[60-70]			
Slovenia	<i>PCH</i>	[90-100]				[90-100]
Spain	<i>GSK</i>	[0-5]	[10-20]			
	<i>PCH</i>	[50-60]	[20-30]	[60-70]		
	<i>Novartis</i>	[40-50]	[60-70]	[30-40]	[90-100]	
Sweden	<i>GSK</i>	[0-5]	[40-50]		[5-10]	
	<i>PCH</i>	[40-50]	[20-30]	[50-60]		[90-100]
	<i>Novartis</i>	[40-50]	[30-40]	[40-50]	[90-100]	
UK	<i>GSK</i>	[30-40]	[40-50]	[5-10]	[80-90]	
	<i>PCH</i>	[40-50]	[30-40]	[60-70]		[80-90]
	<i>Novartis</i>	[10-20]	[10-20]	[10-20]	[10-20]	
	<i>Boots</i>	[0-5]	[0-5]	[5-10]	[0-5]	[5-10]

120. Focusing on nicotine patches, this table shows that today PCH and GSK compete in the supply of nicotine patches in 15 out of 25 Member States. In most Member States where they are both active, GSK's *NiQuitin* has by far the highest market share (about [60-70]% in Belgium, Czech Republic, Hungary, Italy, and Poland; about [40-50]% in Ireland and the UK). In particular, GSK markets the only transparent patches on the market (although it still markets some pink/skin-colour patches under the *NiQuitin* brand). In seven Member States, *NiQuitin* and *Nicorette* account for over [70-80]% of the sales of nicotine patches, with each product accounting for over [10-20]% of the market.

2. Horizontal overlaps

121. There is a limited horizontal overlap between the parties in the upstream market for the manufacturing and supply to third parties of nicotine patches since PCH supplies nicotine patches to Boots. The other company active in this market is Lohmann Therapy Systems ("LTS").

122. ALZA's estimated share in the manufacturing of all nicotine patches sold worldwide is 45-50% according to the parties. In 2005, ALZA sold [...] million nicotine patches ([...] million to GSK). PCH produced and sold [...] million nicotine patches. The market investigation confirmed the parties' market share estimates.

123. The proposed transaction does not lead to any change on this upstream market as ALZA only supplies three companies under exclusive long-term agreements (Sanofi-Aventis for the U.S. and South Korea, Pfizer for Canada, and GSK for the rest of the world except the U.S., South Korea, and Canada). ALZA is therefore currently contractually prohibited from supplying other third parties with nicotine patches and was not competing with Pfizer for the supply of

nicotine patches to private label suppliers such as Boots or to other OTC suppliers such as Pierre Fabre. PCH sales of nicotine patches to Boots are in any event minimal.

124. On the downstream markets for NRT products, there is no horizontal overlap between the parties since J&J is not active in this segment.

3. Vertical relationship

125. However, the merger raises a vertical issue: as a result of the transaction, J&J will own a leading NRT patch brand (PCH's *Nicorette*) and it will be the sole supplier of nicotine patches to its principal downstream competitor, GSK.
126. The market investigation has confirmed that the vertical relationship created by the merger raises competition concerns at several levels. In particular, there is a risk that post-merger the merged entity will have the ability and incentive to foreclose its rival GSK from the market for nicotine patches/NRT products in the EEA by making it harder for it to obtain supplies of the *NiQuitin* patches under similar prices and conditions as absent the merger, to the advantage of the merged entity's *Nicorette* business, leading to harm to consumers (risk of input foreclosure). In addition, there is a risk that, through ALZA, J&J has access to confidential and sensitive information from a competition point of view relating to GSK's *NiQuitin* business which it could post-merger use to the benefit of the acquired PCH's *Nicorette* business.

a) Input foreclosure

127. J&J/ALZA would have the ability to reduce the competitiveness of *NiQuitin* through various means, such as limiting or reducing supply, degrading quality, increasing costs of goods, or disrupting R&D.
128. The market investigation has shown the importance of timely supply as the supply of nicotine patches can be characterised by seasonal peaks or other peaks following the introduction of a smoking ban in a country. GSK is also dependent on J&J's willingness to increase the volumes supplied in case of launch into a new country.
129. Any reduction in patch quality would also damage GSK's *NiQuitin* business. Although GSK has a contractual right to reject sub-standard patches, it would be inefficient for GSK to have to re-check the quality of the patches before delivery to the trade. GSK only rejects patches after retailers and consumers have identified a problem. J&J could also increase the price it charges for the nicotine patches supplied to GSK.
130. There are no alternative suppliers from which GSK can source its *NiQuitin* patches, as the contract is exclusive. The only other manufacturer of nicotine patches, LTS, has already structural links with Novartis. In addition, only J&J manufactures transparent nicotine patches and it has patent protection for this patch. Switching to only pink patches would severely damage the *NiQuitin* brand.

131. J&J/ALZA would also have the incentive to engage into input foreclosure. The market investigation has confirmed that PCH's *Nicorette* and GSK's *NiQuitin* are the two main nicotine patches marketed in the EEA, and that most consumers if they no longer had access to the *NiQuitin* patch would switch to *Nicorette*. J&J's input foreclosure strategy would therefore directly benefit its new *Nicorette* business, by increasing sales of *Nicorette* patches. Alternatively, by increasing its rival's costs, J&J could force GSK to either increase the prices it charges its customers or reduce its marketing and advertising expenses, thereby generally reducing the competitive constraints *NiQuitin* exerts on *Nicorette*. Respondents to the Commission's market investigation questioned the incentive for J&J to have two brands competing against each other.

132. Such input foreclosure strategy would have a direct impact on competition on the downstream markets for NRT products or nicotine patches, by reducing the competitive constraints *NiQuitin* exerts on *Nicorette*, leading to reduced choice and increase prices for consumers across the board.

b) Access to and use of confidential information

133. J&J will have access to commercially strategic information (e.g., costs, forecast volumes, sales data, marketing and sales strategy) relating to *NiQuitin*, which would allow it to adjust the pricing and marketing of its *Nicorette* products. As manufacturing costs represent a substantial share of the cost of the total cost of *NiQuitin* patch, information on the production costs of *NiQuitin* nicotine patches would provide a significant competitive advantage to J&J.

134. Under its agreement with ALZA, GSK has to disclose significant forecast information in relation to volumes per country, sales data and its marketing and sales strategy for the *NiQuitin* patches, up to [...] in advance. GSK would need to disclose impending launches to J&J, with sufficient notice to allow packaging preparations and stock-building.

135. For these reasons, the proposed concentration notified raises serious doubts as to its compatibility with the common market as regards the markets for the supply of nicotine patches, and NRT products in general, in the EEA.

VI. REMEDIES

A. Procedure

136. As explained in the Commission notice on remedies³⁵, where a concentration raises serious doubts about its compatibility with the common market, the parties may seek to modify the concentration in order to resolve the competition concerns identified by the Commission. In assessing whether or not the remedy

³⁵ Commission Notice on remedies acceptable under Council Regulation (EEC^o No 4064/89 and under Commission Regulation (EC) No 447/98.

will restore effective competition, the Commission considers the type, scale and scope of the remedies by reference to the structure of and particular characteristics of the markets in which competition concerns arise. In so doing, the Commission has to assess both, (i) the independence, the viability and the competitiveness of the divested business on the long term and (ii) the effectiveness of the proposed remedy in removing the competition concerns. In order to carry out this assessment, the Commission may seek the views of competitors and customers on the relevant markets.

137. The parties submitted remedies on 20 November 2006 and a revised version on 6 December 2006, taking into account of concerns that the Commission raised as a result of the market test of the first set of remedies.

B. Description of the remedies

1. Topical dermatological antifungals in Italy

138. With the objective of resolving the serious doubts identified by the Commission in the market for the supply of topical antifungals in Italy, J&J proposed the commitments summarised below:

- J&J commits to divest the OTC topical dermatological antifungal formulations currently supplied by PCH in Italy under the trademark “*Trosyd*”. These formulations include: *Trosyd* Ungeal Solution, *Trosyd* Cream, *Trosyd* Emulsion, *Trosyd* Powder and *Trosyd* Sachets.
- The divestiture will consist of the sale or assignment of the relevant assets, such as goods and inventory, marketing authorisations, clinical data and studies, exclusive right to use the *Trosyd* and *Trosid* trademarks in Italy and intellectual property rights and know-how for the manufacture and sale of the *Trosyd* Formulations.
- J&J and Pfizer also commit to enter, at the option of the Purchaser, into supply or toll-manufacturing agreements for a given period of time for the supply or toll-manufacturing of the *Trosyd* formulations, and the partial assignment of the current Pfizer’s contract with a third party for the production of one of the *Trosyd* formulations.

139. J&J and Pfizer also commit, at the option of the Purchaser, to provide reasonable technical assistance to the Purchaser to take over the production, sale and marketing of the *Trosyd* formulations for a period of time and at a cost plus basis to be agreed with the Purchaser.

2. Daily-use mouthwash in Greece

140. With the objective of resolving the serious doubts identified by the Commission in the market for the supply of mouthwash products in Greece, J&J proposed the commitments summarised below:

- J&J commits to divest its *ACT* daily-use mouthwash business in Europe

(including the EEA and Switzerland).

- The divestiture will consist of the sale of the assets associated with the *ACT* mouthwash business, such as goods and inventory, marketing authorisations, assignment of the *ACT* trademark in the EEA and Switzerland, intellectual property rights and know-how for the manufacture and sale of the product, bottle moulds (at the option of the Purchaser), batch control documents, domain name www.actfluoride.eu and other data, books and records.
- J&J also commits to:
 - enter, at the option of the Purchaser, into supply or toll-manufacturing agreements for a given period of time for the supply or toll-manufacturing of the *ACT* mouthwash products,
 - at the option of the Purchaser, to provide reasonable technical assistance to the Purchaser to take over the production, sale and marketing of the *ACT* mouthwash for a period of time and at a cost plus basis to be agreed with the Purchaser,
 - at the option of the Purchaser, transfer the agitator and filling line currently used for the production of the *ACT* mouthwash, and
 - at the option of the Purchaser, provide the necessary training for the production of the *ACT* mouthwash.

3. *Nicotine patches*

141. With the objective of resolving the serious doubts identified by the Commission in the market for the supply of nicotine patches in the EEA, J&J proposed the commitments summarised below:

Divestiture of ALZA's international nicotine patch manufacturing business ("International Nicotine Patch Business") (Paragraph 5 of J&J's Commitments)

- The Parties have offered to divest the International Nicotine Patch Business of ALZA, i.e. ALZA's supply business of transdermal nicotine patches outside the U.S., Canada and South Korea. This business consists in the manufacture of nicotine patches for exclusive supply to GlaxoSmithKline ("GSK").

Divestiture of ALZA's global nicotine patch manufacturing business ("Global Nicotine Patch Business")

- If within a first divestiture period, the parties do not conclude a final binding agreement for the sale of the International Nicotine Patch Business with a suitable Purchaser, the Global Nicotine Patch Business, i.e. including the U.S., Canada and South Korea, will be divested by the parties. The Global Nicotine Patch Business consists in the manufacture of

nicotine patches for supply to GSK as well as to other companies active in the U.S. and South Korea (Sanofi-Aventis), and Canada (Pfizer).

142. J&J has offered to transfer the entire International or Global Nicotine Patch Business including all tangible and intangible assets and personnel to a suitable purchaser. The following main assets would be transferred:

- upon the request of the Purchaser, all production equipment necessary for the manufacture of nicotine patch products for the requirements of the International/Global Nicotine Patch Business;
- ALZA’s transdermal patch production facility at Cashel by way of lease (or at the option of the Purchaser of a temporary sale) for a period of (at least) 3 years; the duration of the temporary transfer shall be at least until such time as the Purchaser has established the International/Global Nicotine Patch Business as a viable and independent business at its own premises as certified by the Monitoring Trustee;
- all relevant trademarks relating to the International/Global Nicotine Patch Business;
- an exclusive perpetual and irrevocable licence to use any of ALZA’s intellectual property rights in relation to nicotine patches (using nicotine or nicotine in combination with another compound) in the relevant territory (i.e., worldwide except U.S., Canada and South Korea in the case of the International Nicotine Patch Business and worldwide in the case of the Global Nicotine Patch Business), subject to pre-existing third party rights;
- a non-exclusive, perpetual and irrevocable licence to use any of ALZA’s intellectual property rights in relation to transdermal patches for other purposes than nicotine replacement therapy products, subject to any pre-existing third party rights and use for products that ALZA has already commercialised itself or that it is actively developing; and
- the perpetual, irrevocable and non-exclusive right to use any improvements to the underlying D-Trans technology, which arise up until the time of Closing (subject to pre-existing third party rights).
- Moreover, the parties commit to ensuring that the supply to ALZA’s current customers (GSK, Sanofi-Aventis and Pfizer) will be maintained during a transitional period of [...] (“Transitional Period”), which can be extended with the mutual consent of the parties and of the Monitoring Trustee (see section 4 of the International/Global Patch Business Schedules). The transitional supply will be ensured by way of ALZA providing contract manufacturing services for the Purchaser’s requirements of nicotine patches (for onward supply to the customers of the Global/International Nicotine Patch Business). ALZA will also provide technical assistance to the Purchaser during the Transitional Period.
- Firewalls are proposed to prevent that any confidential information is

exchanged between J&J/ALZA and PCH's *Nicorette* business.

- Last, the Parties propose to keep in place the hold-separate obligations ensuring that the International/Global Nicotine Patch Business is kept separate from the new entity until the end of the Transitional Period.

C. Assessment of the remedies

1. Topical dermatological antifungals in Italy

143. The Commission market tested the proposed remedies in the field of topical dermatological antifungals in Italy. The vast majority of respondents to the market test considered that the proposed remedies solve the competition concerns identified by the Commission. The proposed remedies would indeed entirely remove the overlap between the parties' activities.
144. As regards the transfer of the divested business, most respondents took the view that the transfer of J&J *Trosyd* business is not likely to raise particular difficulties. In particular, all respondents to the markets considered the duration of the supply or toll-manufacturing agreements for the supply of *Trosyd* formulations ([...]) was appropriate. Respondents have also considered that the provisions regarding technical assistance during the transition period as well as the supply of tioconazole for the production of *Trosyd* formulations (maximum [...]) are sufficient and adequate to guarantee a smooth and efficient transfer of the divested business.
145. The divested business is also considered as a viable business by the majority of respondents and it is expected that the purchaser of the divested business will become an independent competitive force on the market after the end of the transitional period.
146. On the basis of the foregoing, the Commission has concluded that the proposed remedies are sufficient to remove the competition concerns identified as regards topical dermatological antifungals in Italy.

2. Daily-use mouthwash in Greece

147. The Commission is of the view that the proposed remedy removes the competition concerns and restores effective competition, as it removes the entire overlap in Greece and even beyond. In particular, the divested business will have a sufficient size to constitute a viable competitor for daily-use mouthwash. The fact that the divestment concerns the European-wide business, rather than being limited to Greece, ensures that the purchaser will acquire a sizeable business with a well-known brand and a complete portfolio of product formulations that it can expand throughout Europe. The *ACT* brand is a recognised brand that can easily be promoted by additional advertising and marketing efforts.
148. As confirmed by the market test, the divested business contains all tangible and intangible assets that the purchaser will need to conduct the business as a viable and independent business, i.e. the relevant trademarks, product formulations,

know-how and customer details.

149. The activities relating to the manufacture and distribution of *ACT* mouthwash do not require specialised knowledge and could easily be outsourced to third parties. Should the purchaser, however, wish to take over the entire work-stream, the proposed remedy will provide for this as well. First, J&J offers to divest the two main pieces of equipment that are used for manufacturing *ACT* daily-use mouthwash, i.e. an agitator and a filling-line, if the purchaser so requests. Secondly, the additional commitments concerning technical assistance and the training of personnel will help to ensure that the purchaser will have the necessary expertise and abilities to establish the business as a viable and independent competitor as a going concern. The manufacture of daily-use mouthwash does not require any specialised personnel, as the process is standardised and can be performed by any appropriately trained personnel of a cosmetic's producer. The Commission is, therefore, satisfied that the training of the purchaser's personnel will be sufficient to ensure that the divested business can operate efficiently. The same is true for the distribution of *ACT* mouthwash, which can be done by any company with the relevant experience in the cosmetics retail sector.
150. The market test has also confirmed that the proposed remedy will remove the competition concerns. The Commission, therefore, concludes that the divestiture of the European-wide *ACT* business will restore effective competition and that the proposed transaction does not raise competition concerns on condition of the implementation of this remedy.

3. *Nicotine patches*

151. The Commission takes the view that the remedies proposed by the parties solve the competition concerns brought about by the vertical relationship between J&J's activities in the supply of nicotine patches, through its subsidiary ALZA, and GSK *NiQuitin* NRT business. The proposed remedies will structurally eliminate this vertical relationship as J&J will divest part or all of ALZA's nicotine patch manufacturing business and will not supply any more GSK in the EEA.
152. The market test of the remedies has confirmed that the divested business is attractive and viable and that the commitments will enable the Purchaser to set up its own nicotine patch business. The commitments also foresee specific measures to prevent any competition problem during a transitional period (e.g. Hold Separate manager, lease of Cashel plant, firewalls) and to support the establishment of the Purchaser's nicotine patch manufacturing business (e.g. technical assistance, transfer of certain raw material supply contracts).
153. The divested business covers a broad range of material and immaterial assets to be transferred to the Purchaser. As regards manufacturing facilities, the Purchaser will have the option to purchase two out of three (International business) or all (Global business) of ALZA's nicotine patch production lines and related equipment. Combined with J&J's technical assistance and the optional transfer of key production personnel, this will allow the Purchaser to take over ALZA's

position and manufacture nicotine patches independently.

154. As regards immaterial assets, ALZA's supply contract with GSK will be assigned to the Purchaser (subject to GSK's consent for the International business) which will supply GSK in the EEA, as of the closing of ALZA's nicotine patch business divestiture. On the raw material side, the relevant existing supply contracts of ALZA that can be assigned will be transferred to the Purchaser and J&J commits to assist the Purchaser in sourcing the other raw materials required for the production of nicotine patches. If the Purchaser is not able to source such raw materials, J&J commits to enter into back-to-back supply agreements with certain raw material suppliers and the Purchaser to make such raw materials available to the Purchaser.
155. The Purchaser will also acquire the entire ALZA nicotine patch technology (existing and on-going developments) and will have the exclusive right to further develop such technology for nicotine patches in the relevant territory. In addition, the Purchaser will be granted a non-exclusive right to further develop such technology for other end applications. The Purchaser will also be granted the option to hire part of ALZA's research and development personnel to set up its own capabilities in this domain. The ability to receive the licensed technology and to further develop, or have developed, such technology is also part of the criteria set out in the Commitments for the suitability of the Purchaser.
156. These provisions ensure that the Purchaser will not only have the capability to manufacture nicotine patches but also to continue to improve such products and bring innovations on the market. In particular, the Commission considers that Purchaser's right to develop the transferred technology in other fields of use increases the attractiveness of the divested business and may significantly increase the Purchaser's incentives to invest in research and development on transdermal patches.
157. The market investigation has clearly confirmed that both the International and the Global business are sizeable and viable businesses. In terms of size, it should be recalled that ALZA's nicotine patch production accounts for roughly half of the global production and that the capacity of [...] production lines of ALZA (International business) is sufficient to meet GSK's global nicotine patch need.
158. Moreover, the commitments provide sufficient guarantees for the period before the closing of the divestiture and the transitional period (during which the Purchaser will transfer, install and validate the production lines).
159. As regards the period before the closing of the divestiture, J&J will voluntarily renounce to certain of its right under the GSK supply agreement, in particular the right to increase prices retroactively and certain information right concerning GSK's downstream marketing and sales.
160. As regards the transitional period, first, the Purchaser will lease or acquire the Cashel plant immediately after the divestiture of ALZA's nicotine patch business and will thus immediately be able to supply GSK with nicotine patches in the EEA, independently from GSK. The Purchaser will lease or own the Cashel plant

as long as it has not become fully operational, as verified by a Monitoring Trustee.

161. Secondly, J&J commits to provide technical assistance during the transitional period to facilitate the transfer and the validation of the production lines. In addition, the commitments foresee that J&J is to provide such technical assistance in accordance with good industry practice and expeditiously.
162. Thirdly, during this transitional period, the risks of input foreclosure and access to confidential information will be eliminated by various measures. ALZA's nicotine patch business will be operated by a Hold Separate Manager, which will enforce strict firewalls and separating measures between this business and PCH's *Nicorette* business under the supervision of the Monitoring Trustee.
163. The vast majority of respondents to the market considered that the lease of the Cashel plant during the transitional period (or its temporary purchase) is necessary to fully remove competition concerns over this period and would facilitate the start-up of the Purchaser's nicotine patch business. Most of the respondents considered that the temporary transfer of the plant was operable and was not expected to raise insurmountable industrial issues.
164. One respondent, however, expressed concerns as regards the security of supply during the transfer of ALZA's production lines to the Purchaser, in particular in case of disruption of the production in the Cashel plant. This respondent submitted that the temporary transfer of the Cashel plant could raise serious operational issues depending on the identity of the Purchaser and that it was essential that the personnel running the production facility would remain in place during the transitional period.
165. Although these issues have not been raised by other market respondents, the parties have included additional safeguards in the final version of the commitments to address these concerns. First, the commitments foresee very strict criteria for the suitability of the Purchaser to ensure it is able to run such production facility. Secondly, the commitments state that J&J will incentivise the Key Personnel at Cashel to continue employment with the Purchaser and include a non-solicitation clause for the personnel of Cashel during the transition period. Finally, J&J commits to keep an adequate safety stock of products during the duration of the transitional supply agreement and the Monitoring Trustee may recommend additional supply-related measures to ensure availability of the product.
166. In view of the above, the Commission, therefore, concludes that the divestiture of ALZA International or Global nicotine patch business will restore effective competition and that the proposed transaction does not raise competition concerns on condition of the implementation of this remedy.

D. Conditions and obligations

167. The commitments under Section B, points 1 to 3 of the Commitments attached herewith constitute conditions of this decision, as the structural change on the

relevant markets can only be achieved through full compliance therewith.

168. The remaining commitments constitute obligations, as they concern the implementing steps, which are necessary to achieve the sought structural change.

VII. CONCLUSION

169. In view of the above, the Commission has decided not to oppose the notified operation and to declare it compatible with the common market and with the EEA Agreement. This decision is adopted in application of Article 6(2) of Council Regulation (EC) No 139/2004.

For the Commission
signed
Benita FERRERO-EALDNER
Member of the Commission

**Johnson & Johnson/Pfizer Consumer Healthcare
Case No. COMP/M.4314**

**Commitments to the European Commission
(J&J Commitments)**

Pursuant to Article 6(2) of Council Regulation (EC) No. 139/2004 (the “**Merger Regulation**”), Johnson & Johnson (“**J&J**”) hereby provides the following commitments (the “**Commitments**”) in order to enable the European Commission (the “**Commission**”) to declare the acquisition of Pfizer Consumer Healthcare (“**PCH**”) by J&J compatible with the Common Market and the EEA Agreement.

Pfizer will provide separate commitments limited to specific obligations pertaining to the Trosyd divestiture and the preservation of the viability, marketability and competitiveness of the Divestiture Businesses held by Pfizer prior to the closing of the J&J/PCH transaction. Pfizer will sign a separate undertaking to this effect. All other Commitments are given by J&J.

The Commitments shall take effect upon the date of adoption of the Commission Decision pursuant to Article 6(1)(b) of the Merger Regulation in this case (the “**Decision**”) but the divestiture commitments in Section B shall be subject to the closing of J&J’s acquisition of PCH.

This text shall be interpreted in the light of the Decision to the extent that the Commitments are attached as conditions and obligations, within the general framework of Community law, in particular the Merger Regulation and by reference to the Commission Notice on remedies acceptable under the Merger Regulation.

Section A. Definitions

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

Affiliated Undertakings: undertakings controlled by J&J, whereby the notion of control shall be interpreted pursuant to Article 3 of the Merger Regulation and in the light of the Commission Notice on the concept of concentration under the Merger Regulation.

ALZA: ALZA Corporation, an Affiliated Undertaking of J&J, incorporated under the laws of Delaware, with its registered office at 1900 Charleston Road, Mountain View,

California 94943, U.S.A.

Closing: the transfer of the legal title of each Divestiture Business to the Purchaser.

Divestiture Businesses: the assets comprising the businesses that J&J commits to divest, as further defined in Section B and the attached Schedules (each respective business defined in the Schedules herein referred to as a “**Divestiture Business**”).

Divestiture Trustee: one or more natural or legal person(s), independent from J&J or Pfizer, who is approved by the Commission and appointed by J&J and who has received from J&J the exclusive mandate to sell one or more of the Divestiture Businesses to a Purchaser at no minimum price.

Effective Date: the date of the Decision.

Extended Divestiture Period: the period of [...] from the date of expiry of the First Divestiture Period within which the Divestiture Trustee shall have the irrevocable and exclusive mandate from J&J to sell those Divestiture Businesses for which a binding agreement is not yet concluded at the end of the First Divestiture Period.

First Divestiture Period: the period of [...] from the Effective Date within which J&J may conclude one or more binding agreements to sell the Divestiture Businesses before providing a mandate to the Divestiture Trustee.

Hold Separate Manager: the person appointed by J&J to manage the day-to-day business of a Divestiture Business that is held separate pursuant to paragraph 10, under the supervision of the Monitoring Trustee.

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, U.S.A.

Key Personnel: all personnel necessary to maintain the viability and competitiveness of a Divestiture Business, as listed in the applicable Schedule.

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

PCH: Pfizer Consumer Healthcare, a division of Pfizer Inc., with its registered office at 201 Tabor Road, Morris Plains, New Jersey, NJ 07950, U.S.A.

Personnel: the personnel currently employed by the Divestiture Business, if applicable, as

listed in the applicable Schedule.

Pfizer: Pfizer Inc., incorporated under the laws of Delaware, with its registered office at 235 East 42nd Street, New York, NY 10017, U.S.A.

Purchaser: with regard to each Divestiture Business, the undertaking approved by the Commission as acquirer of the Divestiture Business in accordance with the criteria set out in Section D.

Transitional Period: The transitional period defined in Section 4 of the Global Nicotine Patch Business Schedule and Section 4 of the International Nicotine Patch Business Schedule.

Trustee(s): the Monitoring Trustee and/or the Divestiture Trustee.

Section B. The divestiture commitment

Commitment to divest

1. In order to maintain or restore effective competition, J&J commits to divest, or procure the divestiture of, the Divestiture Businesses as going concerns to one or more Purchasers on terms of sale approved by the Commission in accordance with the procedure described in paragraph 19 (the “**Divestiture Commitment**”). J&J commits to do so by the end of the Extended Divestiture Period. To carry out each divestiture, J&J shall seek to find, for each Divestiture Business, a Purchaser and to enter into a final binding agreement for the sale of such Divestiture Business within the First Divestiture Period. If J&J has not entered into such an agreement at the end of the First Divestiture Period, J&J shall grant the Divestiture Trustee an exclusive mandate to sell the Divestiture Business within the Extended Divestiture Period in accordance with the procedure described in paragraph 29.
2. J&J shall be deemed to have complied with the Divestiture Commitment if, (i) by the end of the Extended Divestiture Period, J&J or an Affiliated Undertaking has entered into a final binding sale and purchase agreement for each of the Divestiture Businesses; (ii) the Commission approves the Purchasers and the terms in accordance with the procedure described in paragraphs 18 and 19; and (iii) Closings take place in each case within a period not exceeding [...] after the approval of the respective Purchaser and the terms of sale by the Commission.
3. In order to maintain the structural effect of the Divestiture Commitment, J&J shall, for a period of ten (10) years after the Effective Date, not acquire direct or indirect influence over the whole or part of any of the Divestiture Businesses, unless the Commission has previously found that the market structure has changed to such an extent that the absence of influence over the Divestiture Business in question is no longer necessary to render the proposed concentration compatible with the Merger Regulation.
4. In any event, the sale of any Divestiture Business must only occur if the J&J acquisition of PCH has closed.

The Divestiture Businesses

5. The Divestiture Businesses consist of the following:
- (i) the Trosyd business in Italy (the "**Trosyd Divestiture**");
 - (ii) the ACT business in the EEA and Switzerland (the "**ACT Divestiture**");
 - (iii) either of two alternatives for the ALZA supply business of transdermal nicotine patches: J&J has the option to seek the Divestiture of ALZA's supply business of transdermal nicotine patches outside the U.S.A. Canada and Korea (the "**International Nicotine Patch Business Divestiture Alternative**") but commits that if a final binding agreement for the sale of this business is not concluded, in accordance with paragraph 1, by the end of the [...], it shall pursue the Divestiture of ALZA's worldwide nicotine patch supply business (the "**Global Nicotine Patch Business Divestiture Alternative**") within [...];
- each time as further defined in the relevant Schedule.
- These businesses will be divested to one or more Purchaser(s).
6. The divestiture of the Divestiture Businesses will proceed by way of asset transactions (including transfer, sale, assignment, license, as the case may be and insofar as legally permissible). As a general rule, each divestiture transaction shall include the following elements, as more specifically defined in the relevant Schedule:
- (i) all tangible and intangible assets (including the relevant intellectual property rights), by way of transfer, sale, assignment or license, which are necessary to ensure the viability and competitiveness of the Divestiture Business;
 - (ii) all licences, permits and authorisations issued by any governmental organisation for the benefit of the Divestiture Business;
 - (iii) all contracts, leases, commitments and customer orders of the Divestiture Business;
 - (iv) all customer, credit and other records of the Divestiture Business;
- hereinafter collectively referred to as "**Assets**")
- (v) the Personnel, as further specified in the applicable Schedule;
 - (vi) at the option of the Purchaser, transitional agreements with J&J or Affiliated Undertakings for the supply of products and/or technical assistance, as specified in the applicable Schedule.
7. For the avoidance of doubt, the Divestiture Businesses shall not include:
- (i) intellectual property rights which do not contribute to the current operation of the Divestiture Business;
 - (ii) the Johnson & Johnson, Pfizer, ALZA, McNeil names and logos in any form;
 - (iii) books and records required to be retained pursuant to any statute, rule, regulation or ordinance, provided that copies of such documents necessary for the Divestiture Business shall be provided to the Purchaser, upon request; and

- (iv) general books of account and books of original entry that comprise J&J's or PCH's or an Affiliated Undertaking's permanent accounting or tax records provided that copies of such documents necessary for the Divestiture Business shall be provided to the Purchaser, upon request.

Section C. Related commitments

Preservation of viability, marketability and competitiveness

- 8. From the Effective Date (and if the Divestiture Business is a former PCH business from the date of closing of the J&J/PCH transaction) until Closing, J&J shall preserve the economic viability, marketability and competitiveness of each Divestiture Business, in accordance with good business practice, and shall minimise as far as possible any risk of loss of competitive potential. In particular J&J commits:
 - (i) not to carry out any act upon its own authority that might have a significant adverse impact on the value, management or competitiveness of the Divestiture Business or that might alter the nature and scope of activity, or the industrial or commercial strategy or the investment policy of the Divestiture Business;
 - (ii) to make available sufficient resources for the development of the Divestiture Business, on the basis and continuation of the existing business plans;
 - (iii) to take all reasonable steps, including appropriate incentive schemes (based on industry practice), to encourage Key Personnel to remain with the Divestiture Business, if applicable.

Hold separate obligations

- 9. J&J commits, from the Effective Date (and if the Divestiture Business is a former PCH business from the date of closing of the J&J/PCH transaction) until Closing and subject to paragraph 8, to (i) keep the Divestiture Business separate from the businesses it is retaining; (ii) ensure that Key Personnel (if applicable) of the Divestiture Business - including the Hold Separate Manager - have no involvement in any retained business and vice versa; and (iii) ensure that the Personnel do not report to any individual outside the Divestiture Business (if applicable).
- 10. Prior to Closing, J&J shall assist the Monitoring Trustee in ensuring that the Divestiture Business is managed as a distinct and saleable entity or group of assets separate from the businesses it is retaining. J&J shall also appoint (a) Hold Separate Manager(s) who shall be responsible for the management of the Divestiture Businesses, under the supervision of the Monitoring Trustee. The Hold Separate Manager shall manage the Divestiture Business in the best interest of the business with a view to ensuring its continued economic viability, marketability and competitiveness and its independence from the businesses retained by J&J.
- 11. With regard to the Global or International Nicotine Patch Business Divestiture Alternatives only, the hold separate obligations referred to in paragraphs 9 and 10 shall continue until the end of the Transitional Period.

Ring-fencing

12. J&J shall implement all necessary measures to ensure that it does not after the Effective Date obtain any business secrets, know-how, commercial information, or any other information of a confidential or proprietary nature relating to the Divestiture Businesses. However, J&J may obtain information relating to such Divestiture Business which is reasonably necessary for the divestiture of the Divestiture Business or whose disclosure to J&J is required by law.
13. The participation of the ALZA Nicotine Patch Business in a central information technology network shall be severed to the extent possible, without compromising the viability of the Nicotine Patch Business.

Non-solicitation clause

14. J&J undertakes, subject to customary limitations, not to solicit, and to procure that Affiliated Undertakings do not solicit, the Key Personnel transferred with any Divestiture Business for a period of [...] after Closing.

Due diligence

15. In order to enable potential purchasers to carry out a reasonable due diligence of the Divestiture Businesses, J&J shall, subject to customary confidentiality assurances and dependent on the stage of the divestiture process, (i) provide to potential purchasers sufficient information as regards the relevant Divestiture Business; and (ii) provide to potential purchasers sufficient information relating to the Personnel and allow them reasonable access to the Personnel, if applicable.

Reporting

16. J&J shall submit written reports in English to the Commission and the Monitoring Trustee on potential purchasers of the Divestiture Businesses and developments in the negotiations with such potential purchasers. It shall do so no later than ten (10) days after the end of every month following the Effective Date (or otherwise at the Commission's request).
17. J&J shall inform the Commission and the Monitoring Trustee on the preparation of data room documentation and the due diligence procedure and shall submit a copy of any information memorandum to the Commission and the Monitoring Trustee before sending the memorandum out to potential purchasers.

Section D. The Purchaser

18. In order to ensure the maintenance or immediate restoration of effective competition, the Purchaser, in order to be approved by the Commission, must:
 - (i) be independent of and unconnected to J&J ;
 - (ii) have the financial resources, proven expertise and incentive to maintain and develop the Divestiture Business as a viable and active competitive force in competition with J&J and other competitors;

- (iii) neither be likely to create, in the light of the information available to the Commission, *prima facie* competition concerns nor give rise to a risk that the implementation of the Divestiture Commitment will be delayed, and must, in particular, reasonably be expected to obtain all necessary approvals from the relevant regulatory authorities for the acquisition of the Divestiture Business

(the before-mentioned criteria for the purchaser are hereafter referred to as the “**Purchaser Requirements**”).

With regard to the Trosyd Divestiture and the Nicotine Patch Business Divestiture Alternatives, further specifications to the Purchaser Requirements mentioned under (ii) above are provided in the respective Schedules.

- 19. The final binding sale and purchase agreement shall be conditional on the Commission’s approval. When J&J has reached an agreement with a Purchaser, it shall submit a fully documented and reasoned proposal, including a copy of the final agreement(s), to the Commission and the Monitoring Trustee. J&J must be able to demonstrate to the Commission that the Purchaser meets the Purchaser Requirements and that the Divestiture Business is being sold in a manner consistent with the Divestiture Commitment. For the approval, the Commission shall verify that the Purchaser fulfils the Purchaser Requirements and that the Divestiture Business is being sold in a manner consistent with the Divestiture Commitment. In the event that J&J receives offers from more than one potential purchaser which, upon verification by the Commission, fulfil the Purchaser Requirements, J&J shall be free to take whichever offer that J&J deems the most appropriate to its interests. The Commission may approve the sale of the Divestiture Business without one or more assets or members of the Personnel, if this does not affect the viability and competitiveness of the Divestiture Business after the sale, taking account of the proposed Purchaser.

Section E. Trustee

I. Appointment procedure

- 20. J&J shall appoint a Monitoring Trustee to carry out the functions specified below with regard to the Monitoring Trustee.
- 21. If J&J has not entered into a binding sale and purchase agreement one (1) month before the end of the First Divestiture Period or if the Commission has rejected a Purchaser proposed by J&J at that time or thereafter, J&J shall appoint a Divestiture Trustee to carry out the functions specified below with regard to the Divestiture Trustee. The appointment of the Divestiture Trustee shall take effect upon the commencement of the Extended Divestiture Period.
- 22. The Trustee(s) shall be independent of J&J or Pfizer, possess the necessary qualifications to carry out its mandate, for example as an investment bank or consultant or auditor, and shall neither have nor become exposed to a conflict of interest. The Trustee(s) 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 Divestiture Business, the fee shall also be linked to a divestiture within the Extended Divestiture Period.

Proposal by J&J

23. No later than one (1) week after the Effective Date, J&J shall submit to the Commission for approval a list of one or more persons whom J&J proposes to appoint as the Monitoring Trustee. No later than one (1) month before the end of the First Divestiture Period, J&J shall submit to the Commission for approval a list of one or more persons whom J&J proposes to appoint as Divestiture Trustee. The proposal shall contain sufficient information for the Commission to verify that the proposed entities fulfil the requirements set out in paragraph 22 and shall include:
- (i) the full terms of the proposed mandate, which shall include all provisions necessary to enable the Trustee to fulfil its duties under these Commitments;
 - (ii) the outline of a work plan which describes how the Trustee intends to carry out its assigned tasks;
 - (iii) 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

24. 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 individual or institution 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 J&J

25. If all the proposed Trustees are rejected, J&J shall submit the names of at least two (2) more individuals or institutions within one (1) week of being informed of the rejection, in accordance with the requirements and the procedure set out in paragraph 23.

Trustee nominated by the Commission

26. 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.

II. Functions of the Trustee

27. The Trustee shall assume its specified duties in order to ensure compliance with the 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

28. The Monitoring Trustee shall:
- (a) 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.
 - (b) oversee the ongoing management of each Divestiture Business with a view to ensuring its continued economic viability, marketability and competitiveness and monitor compliance with the conditions and obligations attached to the Decision, and in particular shall:
 - (i) monitor the preservation of the economic viability, marketability and competitiveness of the Divestiture Businesses in accordance with paragraph 8;
 - (ii) ensure that the Divestiture Business is kept separate from the businesses retained by J&J, in accordance with paragraph 9;
 - (iii) supervise the management of the Divestiture Business as a distinct and saleable entity, in accordance with paragraph 10;
 - (iv) supervise the implementation of the transitional supply and technical assistance arrangements with regard to the Nicotine Patch Business divestiture as well as the implementation of compliance with the firewall arrangements with regard to that divestiture;
 - (v) in consultation with J&J, determine all necessary measures to ensure that the competitive businesses retained by J&J does not after the Effective Date obtain any business secrets, know-how, commercial information, or any other information of a confidential or proprietary nature relating to that Divestiture Business, in particular strive for the severing of the Divestiture Business' participation in a central information technology network to the extent possible, without comprising the viability of the Divestiture Business, and decide whether such information may be disclosed to J&J as its disclosure is reasonably necessary to allow J&J to carry out the divestiture or as the disclosure is required by law;
 - (vi) monitor the splitting of assets and the allocation of Personnel (if applicable) between the Divestiture Business and J&J or Affiliated Undertakings.
 - (c) assume the other functions assigned to the Monitoring Trustee under the conditions and obligations attached to the Decision, including the monitoring of the implementation of the technical assistance agreement and the supply agreement referred to in the Schedules with regard to the ALZA Nicotine Patch Business.
 - (d) 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, in particular the maintenance of the full economic viability, marketability or competitiveness of the Divestiture Businesses, the holding separate of Divestiture Businesses and the non-disclosure of competitively sensitive information.

- (e) review and assess potential purchasers as well as the progress of the divestiture process and verify that, dependent on the stage of the divestiture process, (i) potential purchasers receive sufficient information relating to the Divestiture Business and the Personnel, in particular by reviewing, if available, the data room documentation, the information memorandum and the due diligence process, and (ii) potential purchasers are granted reasonable access to the Personnel.
- (f) provide to the Commission a written report within fifteen (15) days after the end of every month, and send J&J a non-confidential copy at the same time. The report shall cover the operation and management of the Divestiture Business so that the Commission can assess whether the business is held in a manner consistent with the Commitments and the progress of the divestiture process as well as potential purchasers. In addition to these reports, the Monitoring Trustee shall 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.
- (g) within one week after receipt of the documented proposal referred to in paragraph 19, submit to the Commission a reasoned opinion as to the suitability and independence of the proposed purchaser and the viability of the Divestiture Business after the sale and as to whether the Divestiture Business is sold in a manner consistent with the conditions and obligations attached to the Decision, in particular, if relevant, whether the sale of the Divestiture Business without one or more assets or not all of the Personnel affects the viability of the Divestiture Business after the sale, taking account of the proposed purchaser.

Duties and obligations of the Divestiture Trustee

- 29. Within the Extended Divestiture Period, the Divestiture Trustee shall sell at no minimum price any Divestiture Business that remains unsold to a Purchaser, provided that the Commission has approved both the Purchaser and the final binding sale and purchase agreement in accordance with the procedure laid down in paragraph 19. The Divestiture Trustee shall include in the sale and purchase agreement such terms and conditions as it considers appropriate for an expedient sale in the Extended Divestiture Period. In particular, the Divestiture Trustee may include in the sale and purchase agreement such customary representations and warranties and indemnities as are reasonably required to effect the sale. 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 Extended Divestiture Period.
- 30. In the Extended 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 fifteen (15) days after the end of every month with a simultaneous copy to the Monitoring Trustee and a non-confidential copy to J&J.

III. Duties and obligations of J&J

- 31. 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, its Affiliated

Undertakings', or the Divestiture Business' books, records, documents, management or other personnel, facilities, sites and technical information necessary for fulfilling its duties under the Commitments and J&J and the Divestiture Business shall provide the Trustee upon request with copies of any document. The Trustee shall agree in writing to keep any confidential information and business secrets disclosed to it in confidence, except to the extent necessary to perform its duties hereunder. J&J, its Affiliated Undertakings, or the Divestiture Business shall make available to the Trustee one or more offices on its premises and shall be available for meetings in order to provide the Trustee with all information necessary for the performance of its tasks.

32. J&J shall provide the Monitoring Trustee with all managerial and administrative support that it may reasonably request on behalf of the management of the Divestiture Business. This shall include all administrative support functions relating to the Divestiture Business which are currently carried out at headquarters level. J&J shall provide and shall cause its advisors to provide the Monitoring Trustee, on request, with the information submitted to potential purchasers, in particular give the Monitoring Trustee access to the data room documentation and all other information granted to potential purchasers in the due diligence procedure. J&J shall inform the Monitoring Trustee on possible purchasers, submit a list of potential purchasers, and keep the Monitoring Trustee informed of all developments in the divestiture process.
33. J&J shall grant or procure Affiliated Undertakings to grant comprehensive powers of attorney, duly executed, to the Divestiture Trustee to effect the sale during the Extended Divestiture Period, the Closing and all actions and declarations which the Divestiture Trustee considers necessary or appropriate to achieve the sale and the Closing, including the appointment of advisors to assist with the sale process. Upon request of the Divestiture Trustee, J&J shall cause the documents required for effecting the sale and the Closing to be duly executed.
34. 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.
35. 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 trustee 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 34 shall apply *mutatis mutandis*. In the Extended 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.

IV. 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:
- (i) The Commission may, after hearing the Trustee, require J&J to replace the Trustee; or
 - (ii) J&J, with the prior approval of the Commission, may replace the Trustee.
37. If the Trustee is removed according to paragraph 36, 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 handover of all relevant information. The new Trustee shall be appointed in accordance with the procedure referred to in paragraphs 20 through 26.
38. Beside the removal according to paragraph 36, 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. Dispute resolution

39. Should a dispute arise between J&J and the Purchaser regarding the implementation of any term of the technical assistance agreement or the supply arrangement referred to in ALZA Nicotine Patch Business Schedule, such dispute shall be submitted to a fast track resolution procedure (the **"Fast Track Resolution Procedure"**).
40. The Fast Track Resolution Procedure will operate as follows:
- (i) The party who seeks to initiate the Procedure (the **"Initiating Party"**) shall notify the other party (the **"Other Party"**) of its request and specify the reasons why it believes that a failure by the Other Party to meet such request would be inconsistent with these Commitments.
 - (ii) The Purchaser and J&J (including the relevant Affiliated Undertaking) shall use their best efforts to resolve all differences of opinion and to settle all disputes that may arise through co-operation and consultation within a reasonable period of time not to exceed fifteen (15) calendar days.
 - (iii) Should the Purchaser and J&J fail to resolve their differences of opinion through co-operation and consultation, the Initiating Party shall within seven (7) days initiate an arbitration process.
 - (iv) To initiate the arbitration process, the Initiating Party shall give written notice to the Other Party nominating an arbitrator and stating the specific nature of the claim, the factual basis of its position and the relief requested. In such case, the Other Party shall appoint another arbitrator within fourteen (14) calendar days after receipt of the written notice. The arbitrators so appointed shall appoint a third arbitrator to be president of the arbitration tribunal within seven (7) calendar days after both arbitrators have been nominated. If the arbitrators nominated by the Purchaser and J&J cannot agree on the nomination of a third arbitrator, they shall request that the London Court of International Arbitration appoint the third arbitrator.

- (v) Any of the arbitrators will be entitled to request any relevant information from the Purchaser, J&J or the relevant Affiliated Undertaking. The arbitrators shall agree in writing to keep any confidential information and business secrets disclosed to them in confidence. Throughout these Commitments the standards attributed to confidential information and business secrets are those as set out in accordance with European Community law.
 - (vi) The burden of proof in any dispute governed by this Section shall be as follows: (i) the Initiating Party must produce evidence of a prima facie case, and (ii) if the Initiating Party produces evidence of a prima facie case, the arbitrators must find in favour of the Initiating Party unless the Other Party can produce evidence to the contrary.
 - (vii) The arbitration procedure shall follow the Rules of the London Court of International Arbitration. The arbitration shall be conducted in London. The language of the arbitration shall be English. In the event of disagreement between the parties to the arbitration regarding the interpretation of the Commitments, the arbitrators shall inform the Commission and may seek the Commission's interpretation of the Commitments before finding in favour of any party to the arbitration. The Commission may, at any time, issue a submission during the arbitration procedure
 - (viii) The arbitration award shall, in addition to dealing with the merits of the claim, impose the fees and costs of the prevailing party upon the party that is unsuccessful.
 - (ix) Decisions of the arbitrators shall be final and binding on all persons submitting to arbitration.
 - (x) Nothing in the above-described arbitration procedure shall affect the powers of the Commission to take decisions in relation to the Commitments in accordance with its powers under the Merger Regulation and the EC Treaty.
41. The parties shall report to the Commission any matters which the Commission reasonably requests in order to determine whether the parties have complied with the present commitments with regard to dispute resolution. Any such report shall be sent to the Commission within fifteen (15) working days from the date the Commission makes a request.

Section G. The review clause

42. The Commission may, where appropriate, in response to a request from J&J showing good cause and accompanied by a report from the Monitoring Trustee:
- (i) grant an extension of the time periods foreseen in the Commitments; or
 - (ii) waive, modify or substitute, in exceptional circumstances, one or more of the conditions or obligations in these Commitments.
43. Where J&J seeks an extension of a time period, it shall submit a request to the Commission no later than one (1) month before the expiry of that period, showing good cause. Only in exceptional circumstances shall J&J be entitled to request an extension within the last month of any period.

44. If the approval of the J&J/PCH merger by another antitrust authority is made subject to requirements that (i) are potentially inconsistent with these Commitments or (ii) would, when combined with the obligations in these Commitments, result in the divestiture of assets or businesses beyond that which is necessary to maintain or restore effective competition in the EEA, J&J may request a review and adjustment of these Commitments in order to avoid such inconsistencies or obligations beyond those necessary to restore effective competition.

Name: [...]

Title: [...]

for and on behalf of Johnson & Johnson

Date: 6 December 2006

}

**Johnson & Johnson/Pfizer Consumer Healthcare
Case No. COMP/M.4314**

**Commitments to the European Commission
(Pfizer Commitments)**

Pursuant to Article 6(2) of Council Regulation (EC) No. 139/2004 (the “**Merger Regulation**”), Pfizer Inc. (“**Pfizer**”) hereby provides the following commitments in order to enable the European Commission (the “**Commission**”) to declare the acquisition of Pfizer Consumer Healthcare (“**PCH**”) by J&J compatible with the Common Market and the EEA Agreement.

These commitments shall take effect upon the date of adoption of the Commission Decision pursuant to Article 6(1)(b) of the Merger Regulation in this case (the “**Decision**”).

This text shall be interpreted in the light of the Decision to the extent that the Commitments are attached as conditions and obligations, within the general framework of Community law, in particular the Merger Regulation and by reference to the Commission Notice on remedies acceptable under the Merger Regulation.

1. From the date of the Decision until closing of the J&J/PCH transaction, Pfizer shall preserve the economic viability, marketability and competitiveness of the Divestiture Businesses (as defined in J&J’s commitments of this date) held by Pfizer prior to the closing of the J&J/PCH transaction. In particular, Pfizer commits:
 - (iii) not to carry out any act upon its own authority that might have a significant adverse impact on the value, management or competitiveness of the Divestiture Business or that might alter the nature and scope of activity, or the industrial or commercial strategy or the investment policy of the Divestiture Business;
 - (iv) to make available sufficient resources for the development of the Divestiture Business, on the basis and continuation of the existing business plans.

2. In relation to the Trosyd Divestiture, Pfizer commits, at the option of the Purchaser, to:
 - (i) enter into a supply or toll-manufacturing agreement with the Purchaser for the non-exclusive supply or toll manufacturing of the Trosyd Formulations still manufactured by Pfizer at the date of Closing at its plant in Latina, Italy (and for so long as such manufacture is not transferred to a third party contract manufacturer or to the PCH plant at Orléans which is transferred to J&J as a result of the

J&J/PCH transaction) for an appropriate period of time, not to exceed [...], and on a reasonable cost plus basis to be agreed with the Purchaser;

(ii) enter into a supply agreement with the Purchaser for the non-exclusive supply of the active ingredient tioconazole for the Trosyd Formulations, for an appropriate period of time, not to exceed [...], at commercial arms' length terms to be agreed with the Purchaser;

(iii) provide reasonable technical assistance to the Purchaser to assume responsibility for the manufacture, sale and marketing of the Trosyd Formulations in Italy for such period as is required by the Purchaser to establish the Divestiture Business as a viable and independent business, as certified by the Monitoring Trustee, and on a reasonable cost plus basis to be agreed with the Purchaser.

(h)

Name: [...]

Title: [...]

for and on behalf of Pfizer Inc.

Date: 6 December 2006

}

Johnson & Johnson/Pfizer Consumer Healthcare
Case No. COMP/M.4314

Trosyd Divestiture Schedule

45. This Divestiture Business consists of rights, title and interest in the tioconazole based formulations (ungueal solution, cream, emulsion, powder, sachets) currently marketed under the trademark Trosyd, which have already been marketed in Italy prior to the Effective Date (“Trosyd Formulations”).
46. The Trosyd Divestiture includes the sale or assignment (or licence if indicated) of:
- (v) finished goods inventory, sales and promotional material relating to the Trosyd Formulations for sale in Italy held at the date of Closing;
 - (vi) the marketing authorisation for the Trosyd Formulations in Italy, including all relevant dossiers relating to the marketing authorisation;
 - (vii) all clinical data and studies relating to the Trosyd Formulations (copies if these data pertain also to other countries than Italy);
 - (viii) the exclusive right to use the Trosyd and Trosid trademarks in Italy for the Trosyd Formulations by way of an exclusive, perpetual, irrevocable licence;
 - (ix) the partial assignment of the contract that Pfizer currently has with [...] for the manufacture of one of the Trosyd Formulations, if requested by the Purchaser;
 - (x) the intellectual property rights necessary for the manufacture and sale of the Trosyd Formulations in Italy by way of assignment or exclusive, perpetual irrevocable licence (if assignment is not possible); these intellectual property rights include product formulations, manufacturing know-how and other know-how, packaging specifications, rights to the trade dress and copyright; and
 - (xi) all relevant data, books and records relating to the Trosyd Formulations and existing customers of the Trosyd Formulations in Italy.
47. At the option of the Purchaser, J&J shall enter into a supply or toll-manufacturing agreement with the Purchaser for the non-exclusive supply or toll-manufacturing of the Trosyd Formulations (except for the Trosyd Formulations manufactured by Pfizer at its plant in Latina), for an appropriate period of time, not to exceed [...] from the date of Closing, and on a reasonable cost plus basis to be agreed with the Purchaser.
48. At the option of the Purchaser, J&J shall provide reasonable technical assistance to the Purchaser to assume responsibility for the manufacture, sale and marketing of the Trosyd Formulations in Italy for such period as is required by the Purchaser to establish the Divestiture Business as a viable and independent business, as certified by the Monitoring Trustee, and on a reasonable cost plus basis to be agreed with the Purchaser.
49. At the option of the Purchaser, J&J shall provide reasonable assistance to the Purchaser to facilitate the procurement of raw materials necessary for the manufacture of the Trosyd

Formulations (without prejudice to the specific provision regarding the supply of tioconazole).

Pfizer shall enter in commitments corresponding to those in paragraphs 3 and 4 for the Trosyd Formulations supplied by Pfizer (and whose production or supply is not transferred to J&J as a result of the J&J/PCH transaction). In addition, at the option of the Purchaser, Pfizer shall enter into a supply agreement with the Purchaser for the non-exclusive supply of the active ingredient tioconazole for the Trosyd Formulations, for an appropriate period of time, not to exceed [...], at commercial arms' length terms to be agreed with the Purchaser.

With regard to the Purchaser Requirements referred to in paragraph 18 of the J&J Commitments, it is further specified that the Purchaser must have knowledge of the Italian OTC market or plans to enter that market.

Johnson & Johnson/Pfizer Consumer Healthcare
Case No. COMP/M.4314

ACT Divestiture Schedule

1. This Divestiture Business consists of J&J's rights, title and interest in the daily mouthwash formulations currently marketed under the trademark ACT which have already been marketed in the EEA and Switzerland prior to the Effective Date.
2. This Divestiture Business includes:
 - (xii) finished goods inventory, sales and promotional material relating to ACT in the EEA and Switzerland held at the date of Closing;
 - (xiii) any relevant registrations held by J&J for the sales and marketing of ACT mouthwash (to the extent they can be transferred);
 - (xiv) assignment of the ACT trademark in the EEA and Switzerland subject to a licence back to J&J in Switzerland for a period not exceeding [...] during which J&J will re-brand those of its non-mouthwash products currently sold under the ACT trademark in Switzerland;
 - (xv) the intellectual property rights necessary for the manufacture and sale of ACT mouthwash (including product formulations, manufacturing know how and other know how, artwork, rights to trade dress and copyright);
 - (xvi) at the option of the Purchaser, the bottle moulds currently used for the manufacture of the bottles for ACT mouthwash in the EEA and Switzerland;
 - (xvii) batch control documents (or copies thereof in so far as they relate to ACT);
 - (xviii) the domain name www.actflouride.eu;
 - (xix) all relevant data, books and records relating to existing customers and suppliers of ACT mouthwash in the EEA and Switzerland; and
 - (xx) all other records maintained by J&J with respect to ACT mouthwash in the EEA and Switzerland (or copies thereof).
3. At the option of the Purchaser, J&J will enter into a supply or toll-manufacturing agreement with the Purchaser for the non-exclusive supply or toll manufacturing of ACT mouthwash in the EEA and Switzerland, for an appropriate period of time, not to exceed [...] from the date of Closing, and on a reasonable cost plus basis to be agreed with the Purchaser.
4. At the option of the Purchaser, J&J will provide reasonable technical assistance to the Purchaser to assume responsibility for the manufacture, sale and marketing of ACT mouthwash in the EEA and Switzerland for such period as is required by the Purchaser to establish the Divestiture Business as a viable and independent business, as certified by the Monitoring Trustee, and on a reasonable cost plus basis to be agreed with the Purchaser.

5. At the option of the Purchaser, J&J shall provide reasonable assistance to the Purchaser to facilitate the procurement of raw materials necessary for the manufacture of ACT.
6. At the option of the Purchaser, J&J will transfer to the Purchaser the agitator and filling line currently used for the production of ACT mouthwash for the EEA and Switzerland.
7. At the option of the Purchaser, if the Purchaser intends to manufacture ACT mouthwash itself, J&J will either:
 - (xxi) make available for interview by the Purchaser one of its Mandra-based mixing vessel operators and one of its Mandra-based filling line operators, both of whom would be familiar with the production process for ACT mouthwash; or
 - (xxii) provide reasonable training for up to 4 operators employed by the Purchaser in the manufacture and production processes for ACT mouthwash.

Case No COMP/M.4314 - J&J/Pfizer Consumer Healthcare

Nicotine Patch Commitment International Nicotine Patch Business Schedule

1. This Divestment Business consists of the assets and personnel directly and predominantly associated with the manufacture and supply of ALZA's transdermal nicotine patch for sale to the whole world with the exception of the U.S., Canada and Korea (the "International Territory"). Those products will be referred to hereafter as the "Nicotine Patch Products".
2. Following paragraph 6 of the Commitments, the International Nicotine Patch Business includes but is not limited to:
 - (a) the following main tangible assets:
 - (iii) ALZA's inventory of finished Nicotine Patch Products attributable to the International Nicotine Patch Business.
 - (iv) ALZA's transdermal patch production facility at Cashel, Ireland, by way of lease to the Purchaser for a period of three (3) years, or another duration agreed with the Purchaser. The duration of the lease shall be at least until such time as the Purchaser has established the International Nicotine Patch Business as a viable and independent business at premises independent from J&J/ALZA, as certified by the Monitoring Trustee. If the Purchaser so elects, J&J shall make the ALZA transdermal patch production facility at Cashel available for purchase (subject to the right for J&J at its option to repurchase the facility for the same consideration once the International Nicotine Patch Business is established as a viable and independent business at premises independent from J&J/ALZA, as certified by the Monitoring Trustee). Annex 1 describes ALZA's transdermal patch production facility at Cashel.
 - (v) At the option of the Purchaser, all production equipment necessary for the manufacture of Nicotine Patch Products ("Major Equipment") attributable to the International Nicotine Patch Business, as listed in the attached Annex 2.
 - (vi) At the option of the Purchaser, all other equipment, ancillary to the Major Equipment, used in the manufacture of the Nicotine Patch Products attributable to the International Nicotine Patch Business.
 - (vii) Copies of all technical files and drawings, product and production specifications, manufacturing process descriptions, packaging specifications, quality control documents, stability reports, validation documentation and other regulatory records, relating to the International Nicotine Patch Business. These technical files are listed at Annex 3.
 - (viii) Copies of all data results and records of clinical trials relevant to the Nicotine Patch Products attributable to the International Nicotine Patch Business.
 - (ix) Copies of all books, ledgers and other business records related to the International Nicotine Patch Business.

- (x) Copies of any and all other materials that are specific to the Nicotine Patch Products attributable to the International Nicotine Patch Business.
- (b) the following main intangible assets, to the extent they are owned or licensed by ALZA:
 - (xi) The assignment of all relevant trademarks owned by ALZA attributable to the International Nicotine Patch Business. These are listed in Annex 4.
 - (xii) The grant of a perpetual and irrevocable licence to use in the International Territory, any intellectual property rights (including patents, patent applications, technology, trade secrets, inventions and know-how) which ALZA currently holds and uses in connection with the Nicotine Patch Products, as listed in Annex 5 (the "Licensed Technology"). This licence shall be exclusive with respect to transdermal patch formulations of nicotine or nicotine in combination with other compounds and non-exclusive with respect to transdermal patch formulations of any other compound. This licence shall include the right to sublicense. Both the exclusive and non-exclusive licences are subject to any pre-existing third party rights (e.g., as a result of patent settlements, or licenses to other parties) at the Effective Date and the non-exclusive licence excludes use for products that ALZA, or an affiliated undertaking, has commercialised, itself or through a commercial partner, or has in active development at the Effective Date. For the avoidance of doubt, J&J shall continue to have the right to exploit the Licensed Technology outside of the International Territory and for any purposes other than the development, manufacture and supply of transdermal nicotine patches (including the right to grant licences for any fields of use other than transdermal nicotine patches).
 - (xiii) The grant of a perpetual, irrevocable and non-exclusive right to use in the International Territory, any improvements (including patents and know-how) relating to the Licensed Technology which arise up to the date of Closing. Such rights are subject to pre-existing third party rights and the same exclusions as under (ii). For the avoidance of doubt, J&J shall continue to have the right to exploit the Licensed Technology and improvements thereto outside of the International Territory and for any purposes other than the development, manufacture and supply of transdermal nicotine patches (including the right to grant licences for any fields of use other than transdermal nicotine patches).
- (c) To the extent legally transferable (by way of assignment or licence), all licences, permits and other governmental authorisations and registrations relating to the ALZA Cashel plant and others relating predominantly to the International Nicotine Patch Business. If such licences, permits, authorisations or registrations are not legally transferable or do not predominantly relate to the Nicotine Patch Products, J&J (or an Affiliated Undertaking) shall reasonably assist the Purchaser in obtaining the necessary licences, permits, authorisations or registrations or other approvals in connection with the Purchaser operating the Cashel ALZA transdermal patch production facility. The licences which ALZA currently holds are listed in Annex 6.
- (d) At the option of the Purchaser, the assignment of ALZA's contracts (or portions thereof) with suppliers of raw materials for the manufacture of the Nicotine Patch Products sold in the International Territory, to the extent they are assignable. If such contracts are not assignable, in whole or in part, ALZA shall use reasonable efforts to obtain consent to assign or shall introduce the Purchaser to the relevant supplier in order that a new supply

agreement may be entered into. If ALZA is unable to obtain consent to assign an agreement and the Purchaser is unable to enter into a new agreement, ALZA shall enter into a back-to-back arrangement, under the existing supply agreement, with the Purchaser in order to enable the Purchaser to procure the relevant raw material. These supply contracts are listed in Annex 7.

- (e) Assignment of the Transdermal Nicotine Product Distribution Agreement, dated [...] 1997, with GlaxoSmithKline (“GSK”) (the “GSK Distribution Agreement”), as described in Annex 8. [...] the Agreement will only be assigned either to GSK itself, or to a [...] approved third party Purchaser. J&J shall cause ALZA to renounce certain of its rights under the GSK Distribution Agreement (but not the rights of any of its assignees) and enter into additional obligations, for as long as ALZA remains a party to that agreement (that is until Closing). These supplemental waivers and obligations are set out in Annex 12. For the avoidance of doubt, Annex 12 shall only apply to ALZA and does not apply to the assignee of the GSK Distribution Agreement.
- (f) The Personnel listed in Annex 9. J&J shall not solicit the Personnel during the Transitional Period.
- (g) J&J shall cause ALZA to incentivise (in accordance with normal business practices) the Key Personnel at Cashel, as listed in Annex 10A, to continue employment with the Purchaser. At the option of the Purchaser, J&J shall cause ALZA to incentivise (in accordance with normal business practices) the other Personnel, as listed in Annex 10B, to take up employment with the Purchaser.
- (h) Any R&D assets (excluding intellectual property: this is dealt with in Section 2(b)(ii) and (iii) above) predominantly associated with the International Nicotine Patch Business (under the form of a non-exclusive licence if those assets pertain also to other ALZA products), in particular, to the extent legally transferable, any rights to development projects with regard to the Nicotine Patch Products, whether they are finished or still ongoing up to the date of full transfer of the manufacturing.
- (i) At the request of the Purchaser, J&J shall cause ALZA to make available several of the ALZA employees and former employees who are, or were, primarily dedicated to research and development as regards ALZA’s D-TRANS transdermal patch technology platform to take up employment with the Purchaser. The titles of those R&D employees are listed at Annex 11.
- (j) For the avoidance of doubt, the International Nicotine Patch Business shall not include:
 - (xiv) Ancillary manufacturing equipment that is customised for the particular configuration of, and “built-in” to either the Vacaville or Cashel manufacturing facility (but at Cashel this equipment is available for the period that the Purchaser occupies the ALZA transdermal patch production facility at Cashel referred to in 2(a)(ii)). As regards such equipment J&J shall cause ALZA to use reasonable efforts to assist the Purchaser to purchase any new equipment required.
 - (xv) Ancillary manufacturing equipment that is shared with other manufacturing lines in ALZA’s Vacaville or Cashel manufacturing facilities and cannot be transferred, including laboratory, warehouse, facilities, calibration and information management equipment (but at Cashel this equipment is available for the period that the Purchaser occupies the ALZA transdermal patch production facility at Cashel

referred to in 2(a)(ii)). Such equipment is commonly found and used in most existing pharmaceutical manufacturing enterprises, or would be built into any new facility. As regards such equipment, J&J will cause ALZA to use reasonable efforts to assist the Purchaser to purchase any new equipment required.

- (xvi) The right to use the ALZA or J&J name and logos of any affiliate in the Johnson & Johnson Family of Companies.
- (k) In the event that materials to be transferred contain information that is confidential to J&J's retained businesses, these shall be redacted as appropriate.
- 3. J&J commits that the assets to be transferred are sufficient for the Purchaser to operate the divested business as a viable and independent business.
- 4. J&J shall cause ALZA to provide the following transitional supply and technical assistance services during a period of [...] from Closing. This period can be extended by the Monitoring Trustee until such time that the Purchaser has established the International Nicotine Patch Business as a viable and independent business at premises independent from J&J/ALZA, as certified by the Monitoring Trustee (the "Transitional Period").
 - (xvii) J&J shall cause ALZA to provide technical assistance (including appropriate training of the Purchaser's employees) required by the Purchaser regarding the construction, installation, qualification and validation of suitable manufacturing equipment and facilities, on a reasonable cost plus basis to be agreed with the Purchaser.
 - (xviii) J&J shall cause ALZA to provide back up supply as requested by the Purchaser, if need be, and for quantities agreed between the parties on terms consistent with the principles set out in Annex 13.
- 5. J&J shall comply with the Firewall Principles in Annex 14 for the duration of the Transitional Period referred to above.
- 6. The transitional technical assistance agreement referred to above shall include appropriate provisions designed to incentivise ALZA to provide technical assistance to the Purchaser expeditiously. These provisions may include terms whereby the price payable by the Purchaser for technical assistance is reduced over time. J&J shall cause ALZA to carry out the technical assistance for the technology transfer in accordance with good industry practice including as regards the timing and responsiveness with which this assistance is provided through the different stages of the transfer.
- 7. The transitional technical assistance agreement and the transitional supply arrangements, referred to above shall include the Fast Track Resolution Procedure provisions set out in the J&J Commitments and will be subject to the supervision of the Monitoring Trustee for as long as these agreements remain in place.

8. At the option of the Purchaser, J&J shall cause ALZA to conduct R&D for the Purchaser in order to develop improvements to the Nicotine Patch Products, on a reasonable cost plus basis to be agreed with the Purchaser, following Closing for a period of [...].
9. If GSK is the Purchaser of the International Nicotine Patch Business, J&J shall cause ALZA to renounce certain of its rights under the GSK Distribution Agreement and enter into additional obligations, until the end of the Transitional Period set out above in paragraph 3. These supplemental waivers and obligations are set out in Annex 12. For the avoidance of doubt, Annex 12 shall only apply to ALZA and shall not apply to the assignee of the GSK Distribution Agreement if ALZA sells the business to an entity other than GSK.
10. With regard to the Purchaser Requirements referred to in paragraph 18 of the J&J Commitments, it is further specified that the Purchaser must have:
 - (xix) sufficient capability to supply products that are marketed as branded products in the pharmaceutical sector; and
 - (xx) sufficient capability to receive the Licensed Technology and, having regard to the resources transferred pursuant to these Commitments, to further develop or have developed, such Technology.

Case No COMP/M.4314 - J&J/Pfizer Consumer Healthcare

Annex 1 to the International Nicotine Patch Business Commitment ALZA Transdermal Patch Production Facility

The Cashel Plant, which is currently owned by ALZA Ireland Limited, is located at IDA Industrial Park, Cahir Road, Cashel, Co. Tipperary, Ireland and currently occupies a surface area of approximately 60,000 square feet and is on 22 acres of land.

The ALZA Cashel Plant currently comprises Durogesic® manufacturing and Nicotine Patch manufacturing, Ionsys Testing and Release Laboratory, the Cordis Stent Development Laboratory and Shared Service Space (administrative, security and maintenance, warehouse, utilities and laboratory and analytical services).

The Transdermal Patch Production Facility and Shared Service Space would be leased to the Purchaser as part of the divestiture. ALZA Ireland Limited would retain the area occupied by the Cordis Stent Development Laboratory and the Ionsys Testing and Release Laboratory. If the Transdermal Patch Production Facility is sold, the Cordis Stent Development Laboratory and the Ionsys Testing and Release Laboratory would not be included (or would benefit from a rent free lease). ALZA would contract with the Purchaser for any Shared Services that it needs.

J&J shall retain the right to build other, separate facilities not related to transdermal patches on the site and would have the right to share utilities, maintenance, security and other support services with the Purchaser.

Since ALZA currently produces both the Nicotine Patch Products and Durogesic (fentanyl) patches at the Transdermal Patch Production Facility, the Purchaser shall carry out the Durogesic manufacturing activities as part of the lease, which shall be conditional upon the Purchaser manufacturing Durogesic as a contract manufacturer for J&J, on standard industry terms.

Case No COMP/M.4314 - J&J/Pfizer Consumer Healthcare

Annex 2 to the International Nicotine Patch Business Commitment Major Equipment

Overview of the manufacturing process

The ALZA nicotine patch manufacturing process consists of three main processes: extrusion, converting and pouching. Through the extrusion process, nicotine and polymer are mixed in an inert, temperature controlled environment and extruded and calendered between plastic films. The resulting laminate is then wound onto rolls. The converting line laminates the adhesive onto rollstock, slits and laminates the liner, treats and prints the patches, die-cuts the patches into the final size and rewinds the patches onto spools. Finally, the pouching line feeds the patches from the spools, cuts the liner to separate the individual patches, prints the lot and expiration date on the pouch stock, seals the systems in the pouch stock and cuts the pouches to their final size. The nicotine patches are supplied as pouch stock to the customer.

ALZA manufactures the Nicotine Patch Products at two sites: Vacaville, California, U.S.A. (which has two dedicated production lines) and Cashel, Ireland (which has one dedicated production line). Neither plant is dedicated to the manufacture of nicotine patches.

Major Equipment

The Major Equipment comprises two equipment lines for the manufacture of the Nicotine Patch Products; one at Cashel and one at Vacaville. In total, this will comprise two extruders, one convertor and two pouchers. If required under the regulations governing the Purchaser's manufacturing facility, an isolator will also be included in the transfer.

- Each extruder has the capacity to manufacture [...] million patches per year.
- The convertor has the capacity to process [...] million patches per year.
- The Cashel poucher has the capacity to process [...] million patches per year and the Vacaville poucher has the capacity to process [...] million patches per year.
- An isolator is currently used at the Cashel plant, in accordance with applicable regulatory requirements, to protect operators sampling nicotine from chemical hazard. There is no such requirement at Vacaville, where operators handling nicotine wear special protective suits for the same purpose.

Case No COMP/M.4314 - J&J/Pfizer Consumer Healthcare

Annex 3 to the International Nicotine Patch Business Commitment Technical Files

Manufacturing Facility

Proprietary information regarding specialised facility configurations, to the extent relating to the International Nicotine Patch Business, as required by the Purchaser.

Active Pharmaceutical Ingredients & Critical / Novel Excipients

Information regarding the raw materials used to manufacture the Nicotine Patch Products, including:

- Manufacturing Sites
- List of Components and Quality/Grades
- Vendor Specifications and Quality Requirements
- Analytical Test Methods & Test Method Validation
- Certificates of Analysis
- Reference Standards
- Stability and Expiration Dating Information (if applicable)
- Compendial, Regulatory, and Internal Specifications
- Analytical and Microbiological Summary Report with Historical Data
- Component Supplier/Site Qualification (if applicable)
- Component Storage and Handling

Drug Product & Manufacturing

Information regarding the finished Nicotine Patch Product and its manufacture, including:

- Quantitative Composition / Formulation of Drug Product
- Description of Production and Packaging Processes / Equipment Train
- Process Flow Diagrams
- Description of Software driven Controls
- Batch Records (Master Formulas and Associated Forms)
- In Process Controls, Test Methods, and Limits
- Standard Operating Procedures (SOP) for Manufacturing

- Critical Parameters and Historical Capabilities
- Maximum Allowable Hold Times
- Equipment Description
- Intermediate Storage Conditions
- Bulk Storage and Handling Conditions
- Cleaning Procedures, Test Methods, and Validations
- Microbial Cleaning Assessment
- Process Validations
- Bio – Batch Data
- Drug Product Specifications
- Analytical and Microbiological Test Methods and Validations
- Historical Test Results Summary
- Certificates of Analyses

Information regarding the packaging used for the Nicotine Patch Products, including:

- Schematics
- Rationale for packaging
- Materials of Construction
- Specifications and Test Methods
- Compatibility and Stability Reports

Drug Product Stability

- The following stability studies and reports:
- Shipping Studies
- Historical and Current Stability Reports
- Degradation Pathways
- Stability Specifications
- Stability Test Methods and Validation

Case No COMP/M.4314 - J&J/Pfizer Consumer Healthcare

Annex 4 to the International Nicotine Patch Business Commitment Trademarks

ALZA does not own, or have any rights or licence to the Nicoderm or NiQuitin trademarks anywhere in the International Territory. These trademarks are owned by the downstream marketing partner for the territory, GSK, or by third parties. Similarly, GSK owns the Nicabate trademark in Australia and New Zealand. ALZA owns, and commits to transfer, the Nicabate trademark, as registered in the following countries:

- China, Peoples Republic (PRC)
- European Union
- Iceland
- India
- Japan
- Norway
- Romania
- Russian Federation (formerly USSR)
- Serbia/Montenegro
- Switzerland

Case No COMP/M.4314 - J&J/Pfizer Consumer Healthcare

Annex 5 to the International Nicotine Patch Business Commitment Intellectual Property

ALZA Patents

The patents listed below are the main patents owned by ALZA, issued or pending, for each patent family relating to the Nicotine Patch Products. Paragraph (b)(ii) of the Schedule shall apply with respect to these patent families to the extent they relate to the International Territory. Therefore, equivalent patents in other jurisdictions within the International Territory will also be licensed in order to give the Purchaser full rights in the International Territory for nicotine patches.

Patent family number	Status	Expiry date	Owner	Title and Field
EP1140039A 1	Pending ³⁶	13/12/19	ALZA	<u>Transparent transdermal nicotine delivery devices.</u> A transparent transdermal delivery device for delivering nicotine which has an Opacity Index of less than 48.6%.
EP0525105B1	Granted	11/02/11	ALZA	<u>Polyisobutylene adhesives for transdermal devices.</u> Invention pertains to polyisobutylene (PIB) adhesives useful in transdermal drug delivery systems.
EP0506860B1	Granted	16/12/10	ALZA	<u>Nicotine packaging materials.</u> Invention pertains to materials and methods for the manufacture of nicotine storage pouches.

³⁶ Patents within this family have been granted outside of the EU.

Patent family number	Status	Expiry date	Owner	Title and Field
EP0427741B1	Granted	12/06/09	ALZA	<p><u>Subsaturated transdermal delivery device.</u></p> <p>Invention relates to transdermal delivery devices intended to deliver biologically active agents through skin at substantially constant rates for extended periods of time and more particularly to such devices in which the active agent to be delivered is present in the device at a concentration below saturation.</p>

Patent family number	Status	Expiry date	Owner	Title and Field
US5342623	Granted	02/04/08	ALZA	<p><u>Subsaturated transdermal therapeutic system having improved release characteristics</u></p> <p>Invention relates to medical devices in the form of transdermal delivery devices intended to deliver biologically active agents through skin at substantially constant rates for extended periods of time and more particularly to such systems which utilize rate controlling membranes and in-line adhesives.</p>

Third Party Patents

In addition, ALZA benefits from certain covenants on the part of third parties not to sue in connection with certain patents. Where such protection does not automatically extend to

ALZA's licensees, J&J shall use reasonable efforts to ensure that the Purchaser is afforded equivalent protection in this regard in respect of the International Territory. Where such covenants are mutual, this may involve a commitment on the part of the Purchaser not to sue the relevant third party with regard to certain of the ALZA patents.

Details of the relevant third parties and patent numbers are as follows:

[...].

Other intellectual property rights

ALZA will transfer all proprietary information necessary to manufacture Nicotine Patch Products, including all relevant content from the ALZA Master Index, which contains details of the methods, formulae, instructions, advisories and analytical tools relating to ALZA's products together with all those materials listed in Annex 3. J&J will use reasonable efforts to ensure that the Purchaser is afforded equivalent protection in this regard.

J&J represents and warrants that the intellectual property, as defined in the Schedule and further specified in this Annex, is sufficient to run the divested business as a viable and independent business.

Case No COMP/M.4314 - J&J/Pfizer Consumer Healthcare

Annex 6 to the International Nicotine Patch Business Commitment Licences and permits

The licences and permits required by the Purchaser in order to manufacture the Nicotine Patch Products are the same as those generally required to manufacture any other pharmaceutical product, and will vary according to the location of the Purchaser's manufacturing plant.

By way of indication of the type of authorisation that is generally required, Vacaville is licensed under a Drug Manufacturing License, issued by the State of California, Department of Health Services, Food and Drug Branch and is also registered as Drug Establishment by the Food and Drug Administration, Department of Health and Human Services. Cashel operates under a Manufacturer's Licence and a Certificate of Good Manufacturing Practice Compliance of a Manufacturer, both issued by the Irish Medicines Board. ALZA is also licensed at Cashel to hold an inventory of a controlled substance and to manufacture using a controlled substance. In addition, it holds an integrated pollution control license, issued by the Environmental Protection Agency. [...], which carries out chemical and microbiological analysis of starting materials, raw materials, finished products and water on behalf of ALZA is authorised under an Quality Control Laboratory Approval, also issued by the Irish Medicines Board.

The above licences and permits are not legally transferable. Therefore, J&J shall cause ALZA to use reasonable efforts to assist the Purchaser to obtain the necessary licences and permits, which may be required.

Case No COMP/M.4314 - J&J/Pfizer Consumer Healthcare

**Annex 7 to the International Nicotine Patch Business Commitment
Supplier Contracts**

There are [...] contracts. ALZA shall employ reasonable efforts to ensure that the Purchaser is able to source the relevant products from these suppliers.

Contract	Summary
[...]	[...]

Case No COMP/M.4314 - J&J/Pfizer Consumer Healthcare

**Annex 8 to the International Nicotine Patch Business Commitment
Customer Contracts**

Contract	Summary
[...]	[...]

Case No COMP/M.4314 - J&J/Pfizer Consumer Healthcare

**Annex 9 to the International Nicotine Patch Business Commitment
Personnel**

Cashel Personnel

Name	Function
[...]	[...]

Case No COMP/M.4314 - J&J/Pfizer Consumer Healthcare

**Annex 10 to the International Nicotine Patch Business Commitment
Key Personnel**

A. Cashel Key Personnel

[...]

B. Other Personnel to be incentivised

For the avoidance of doubt the Personnel below are not required for the viability of the International Nicotine Patch Business. However, J&J shall, at the option of the Purchaser, cause ALZA to undertake the incentive efforts set out in the Schedule with respect to Key Personnel.

[...]

Case No COMP/M.4314 - J&J/Pfizer Consumer Healthcare

Annex 11 to the International Nicotine Patch Business Commitment R&D

[...]

Case No COMP/M.4314 - J&J/Pfizer Consumer Healthcare

Annex 12 to the International Nicotine Patch Business Commitment Supplemental provisions to GSK Distribution Agreement

J&J shall cause ALZA to comply with the following provisions for as long as ALZA remains party to the GSK Distribution Agreement (which is until Closing). In the event of conflict between the terms of the agreement and the provisions below, the latter shall prevail:

- (i) ALZA shall renounce its rights to any retroactive price increases. [...]
- (ii) [...].
- (iii) J&J shall cause ALZA to waive information rights regarding GSK's downstream marketing and sales. [...]
- (iv) J&J shall cause ALZA to not prevent GSK from using trademarks owned by GSK following termination of the agreement in relation to the Nicotine Patch Products in the International Territory.
- (v) [...].
- (vi) Any dispute concerning the GSK Distribution Agreement shall be governed by the Fast Track Resolution Procedure provisions set out in the J&J Commitments, if GSK so elects.
- (vii) The compliance with these principles, as well as with the terms of the GSK Distribution Agreement, for as long as it remains in place, shall be subject to the supervision of the Monitoring Trustee.

Case No COMP/M.4314 - J&J/Pfizer Consumer Healthcare

Annex 13 to the International Nicotine Patch Commitment Supply Agreement Principles

- The supply agreement will cover the Nicotine Patch Products. The agreement will include appropriate provisions allowing the Purchaser to withdraw specific Nicotine Patch Products from the scope of the agreement.
- ALZA will sell Nicotine Patch Products to the Purchaser on a reasonable cost-plus margin basis. Cost shall be defined in accordance with Generally Acceptable Accounting Principles and negotiated by J&J or ALZA and the Purchaser at a level consistent with standard industry practice; the margin shall be set at a discount to standard industry practice.
- ALZA shall be required to provide support to the Purchaser on a reasonable cost plus basis in its application for product approval from the competent regulatory bodies, and in particular shall provide to the Purchaser or the regulatory body such information as is requested by that body.
- The supply agreement shall include appropriate provisions with regard to regulatory compliance.
- The Purchaser shall be required to send ALZA non-binding twelve (12) month rolling monthly forecasts of its reasonably expected requirements of Nicotine Patch Products (firm and binding as to the next two months). If, for any reason (e.g. production shortages or events akin to force majeure), ALZA is unable to meet the Purchaser's requirements of Nicotine Patch Products, J&J shall allocate deliveries of that product to the Purchaser in the proportion that represents [...] of the proportion that prevailed between ALZA and the Purchaser on average during the [...] preceding completed quarters.
- The supply agreement shall include appropriate provisions with regard to ALZA building and keeping an adequate safety stock of products at all times during the duration of the transitional supply agreement. The Monitoring Trustee may recommend appropriate safety stock levels to ensure security of supply, or if necessary, such additional supply-related measures as may be reasonably needed to ensure that product is available to the Purchaser.
- The Purchaser may terminate the supply agreement at its discretion on [...] notice.
- Delivery of the Nicotine Patch Products will be made in a timely manner and according to a pre-defined schedule, in line with standard industry practice.

Case No COMP/M.4314 - J&J/Pfizer Consumer Healthcare

Annex 14 to the International Nicotine Patch Commitment Firewall Principles

- J&J shall implement firewalls which will prevent, during the “Transitional Period”, any exchange, communication or flow of Confidential Information, as defined below, between ALZA and the Consumer Division of J&J (where the Pfizer Consumer Healthcare nicotine patch business shall be held).
- Confidential Information means all information that is not in the public domain relating to the research, technology, development, manufacture, marketing, commercialisation, distribution, cost, pricing, supply, sales, or use of nicotine patch products or other nicotine replacement products manufactured, sold or in development. ALZA Confidential Information means all Confidential Information pertaining to the ALZA Nicotine Patch Business subject to this remedy. PCH Confidential Information means all Confidential Information pertaining to the Pfizer Consumer Healthcare nicotine replacement products acquired by J&J.
- J&J will submit to the Monitoring Trustee within two weeks of the appointment of the latter, suitable proposals for firewalls between ALZA and the Consumer Division. These proposals will include confidentiality agreements (the terms of which shall be subject to the approval of the Monitoring Trustee, IT arrangements regarding access and storage of information, monitoring mechanisms, procedures for release, change of positions, reporting lines, etc.

Case No COMP/M.4314 - J&J/Pfizer Consumer Healthcare

Nicotine Patch Commitment Global Nicotine Patch Business Schedule

1. This Divestment Business consists of the worldwide assets and personnel directly and predominantly associated with the manufacture and supply of ALZA's transdermal nicotine patch (the "Global Nicotine Patch Business"). The ALZA transdermal nicotine patch products will be referred to hereafter as the "Nicotine Patch Products".
2. Following paragraph 6 of the J&J Commitments, the Global Nicotine Patch Business includes but is not limited to:
 - (a) the following main tangible assets:
 - (xxi) ALZA's inventory of finished Nicotine Patch Products.
 - (xxii) ALZA's transdermal patch production facility at Cashel, Ireland, by way of lease to the Purchaser for a period of three (3) years or another duration agreed with the Purchaser. The duration of the lease shall be at least until such time that the Purchaser has established the Global Nicotine Patch Business as a viable and independent business at premises independent from J&J/ALZA, as certified by the Monitoring Trustee. If the Purchaser so elects, J&J shall make the ALZA transdermal patch production facility at Cashel available for purchase (subject to the right for J&J at its option to repurchase the facility for the same consideration once the Global Nicotine Patch Business is established as a viable and independent business at premises independent from J&J/ALZA, as certified by the Monitoring Trustee). Annex 1 describes ALZA's transdermal patch production facility at Cashel.
 - (xxiii) At the option of the Purchaser, all production equipment necessary for the manufacture of Nicotine Patch Products ("Major Equipment"), as listed in the attached Annex 2.
 - (xxiv) At the option of the Purchaser, all other equipment, ancillary to the Major Equipment, used in the manufacture of the Nicotine Patch Products.
 - (xxv) Copies of all technical files and drawings, product and production specifications, manufacturing process descriptions, packaging specifications, quality control documents, stability reports, validation documents and other regulatory records. These technical files are listed at Annex 3.
 - (xxvi) Copies of all data results and records of clinical trials relevant to the Nicotine Patch Products.
 - (xxvii) Copies of all books, ledgers and other business records related to the Global Nicotine Patch Business.
 - (xxviii) Copies of any and all other materials that are specific to the Nicotine Patch Products.
 - (b) the following main intangible assets, to the extent they are owned or licensed by ALZA:
 - (xxix) The assignment of all relevant trademarks insofar as owned by ALZA. These are listed in Annex 4.

- (xxx) The grant of a perpetual and irrevocable licence to use any intellectual property rights (including patents, patent applications, technology, trade secrets, inventions and know-how) which ALZA currently holds and uses in connection with the Nicotine Patch Products, as listed in Annex 5 (the "Licensed Technology"). This licence shall be exclusive with respect to transdermal patch formulations of nicotine or nicotine in combination with other compounds and non-exclusive with respect to transdermal patch formulations of any other compound. This licence shall include the right to sublicense. Both the exclusive and non-exclusive licences are subject to any pre-existing third party rights (e.g., as a result of patent settlements, or licences to other parties) at the Effective Date and the non-exclusive licence excludes use for products that ALZA, or an affiliated undertaking, has commercialised, itself or through a commercial partner, or has in active development at the Effective Date. For the avoidance of doubt, J&J shall continue to have the right to exploit the Licensed Technology for any purposes other than the development, manufacture and supply of transdermal nicotine patches (including the right to grant licences for any fields of use other than transdermal nicotine patches).
- (xxxi) The grant of a perpetual, irrevocable and non-exclusive right to use any improvements (including under patents and know-how) relating to the Licensed Technology which arise up to the date of Closing. Such rights are subject to pre-existing third party rights and the same exclusions apply as under (ii). For the avoidance of doubt, J&J shall continue to have the right to exploit the Licensed Technology for any purposes other than the development, manufacture and supply of transdermal nicotine patches (including the right to grant licences for any fields of use other than transdermal nicotine patches).
- (c) To the extent legally transferable (by way of assignment or licence), all licences, permits and other governmental authorisations and registrations relating to the ALZA Cashel plant and others relating predominantly to the Global Nicotine Patch Business. If such licences, permits, authorisations or registrations are not legally transferable or do not predominantly relate to the Nicotine Patch Products, J&J (or an Affiliated Undertaking) shall reasonably assist the Purchaser in obtaining the necessary licences, permits, authorisations or registrations or other approvals in connection with the Purchaser operating the Cashel ALZA transdermal patch production facility. The licences which ALZA currently holds are listed in Annex 6.
- (d) At the option of the Purchaser, the assignment of ALZA's contracts (or portions thereof) with suppliers of raw materials for the manufacture of the Nicotine Patch Products, to the extent they are assignable. If such contracts are not automatically assignable, in whole or in part, ALZA shall use reasonable efforts to obtain consent to assign or shall introduce the Purchaser to the relevant supplier in order that a new supply agreement may be entered into. If ALZA is unable to obtain consent to assign an agreement and the Purchaser is unable to enter into a new agreement, ALZA shall enter into a back-to-back arrangement, under the existing supply agreement, with the Purchaser in order to enable the Purchaser to procure the relevant raw material. These supply contracts are listed in Annex 7.
- (e) To the extent legally assignable, assignment of the relevant agreements with downstream customers (GSK, Sanofi-Aventis, PCH), as listed in Annex 8. If such contracts are not assignable without consent of the other party, ALZA shall make reasonable efforts to obtain such consent. Absent such consent, J&J shall cause ALZA to enter into a supply arrangement with the Purchaser whereby ALZA shall source the Nicotine Patch Products from the Purchaser on a reasonable cost plus basis to be agreed with the Purchaser and

shall continue to supply such products to the relevant customer. J&J shall cause ALZA to renounce certain of its rights under the GSK Distribution Agreement (but not the rights of any of its assignees) and enter into additional obligations, for as long as ALZA remains a party to that agreement (that is until Closing). These supplemental waivers and obligations are set out in Annex 12. For the avoidance of doubt, Annex 12 shall only apply to ALZA and does not apply to the assignee of the GSK Distribution Agreement.

- (f) The Personnel, which are located at Cashel, as further specified in Annex 9. J&J shall not solicit those Personnel located at Cashel during the Transitional Period. Those Personnel listed in Annex 9, which are located at Vacaville shall be made available for transfer. This means that J&J shall cause ALZA to provide the Purchaser with the opportunity to enter into employment contracts with such staff, (b) not interfere with the Purchaser's hiring, employing, or contracting of such staff, (c) remove any impediments within the control of ALZA that may deter such staff from accepting an employment relationship with the Purchaser, and (d) eliminate any provisions of any relevant employment contracts with ALZA that have the potential to interfere with such employees' ability to perform work related to the Nicotine Patch Products.³⁷
- (g) J&J shall cause ALZA to incentivise (in accordance with normal business practices) the Key Personnel at Cashel, as listed in Annex 10A, to continue employment with the Purchaser. At the option of the Purchaser, J&J shall cause ALZA to incentivise (in accordance with normal business practices) the other Personnel, as listed in Annex 10B, to take up employment with the Purchaser.
- (h) Any R&D assets (excluding intellectual property: this is dealt with in Section 2(b)(ii) and (iii) above) predominantly associated with the Global Nicotine Patch Business (under the form of a non-exclusive licence if those assets pertain also to other ALZA products), in particular, to the extent legally transferable, any rights to development projects with regard to the Nicotine Patch Products, whether they are finished or still ongoing up to the date of full transfer of the worldwide manufacturing.
- (i) At the request of the Purchaser, J&J shall cause ALZA to make available several of the ALZA employees and former employees who are, or were, primarily dedicated to research and development as regards ALZA's D-TRANS transdermal patch technology platform to take up employment with the Purchaser. The titles of those R&D employees are listed at Annex 11.
- (j) For the avoidance of doubt, the Global Nicotine Patch Business shall not include:
 - (xxxii) Ancillary manufacturing equipment that is customised for the particular configuration of, and "built-in" to either the Vacaville or Cashel manufacturing facility (but at Cashel this equipment is available for the period that the Purchaser occupies the ALZA transdermal patch production facility at Cashel referred to in 2(a)(ii)). As regards such equipment, J&J shall cause ALZA to use reasonable efforts to assist the Purchaser to purchase any new equipment required.

³⁷ For the avoidance of doubt, this does not include the waiver of confidentiality provisions set out in the employment contracts to the extent that those relate to other confidential J&J information.

- (xxxiii) Ancillary manufacturing equipment that is shared with other manufacturing lines in ALZA's Vacaville or Cashel manufacturing facilities and cannot be transferred, including laboratory, warehouse, facilities, calibration and information management equipment (but at Cashel this equipment is available for the period that the Purchaser occupies the ALZA transdermal patch production facility at Cashel referred to in 2(a)(ii)). Such equipment is commonly found and used in most existing pharmaceutical manufacturing enterprises, or would be built into any new facility. J&J shall cause ALZA to use reasonable efforts to assist the Purchaser to purchase any new equipment required.
- (xxxiv) The right to use the ALZA or J&J names and logos of any affiliate in the Johnson & Johnson Family of Companies.
- (k) In the event that materials to be transferred contain information that is confidential to J&J's retained businesses, these shall be redacted as appropriate.
3. J&J commits that the assets to be transferred are sufficient for the Purchaser to operate the divested business as a viable and independent business.
4. J&J shall cause ALZA to provide the following transitional supply and technical assistance services during a period [...] from Closing. This period can be extended by the Monitoring Trustee until such time that the Purchaser has established the Global Nicotine Patch Business as a viable and independent business at premises independent from J&J/ALZA, as certified by the Monitoring Trustee (the "Transitional Period").
- (xxxv) J&J shall cause ALZA to provide technical assistance (including appropriate training of the Purchaser's employees) required by the Purchaser regarding the construction, installation, qualification and validation of suitable manufacturing equipment and facilities, on a reasonable cost plus basis to be agreed with the Purchaser.
- (xxxvi) J&J shall cause ALZA to provide the Purchaser with contract manufacturing services for the Purchaser's requirements of the Nicotine Patch Products on terms consistent with the principles set out in Annex 13 for the Transitional Period.
5. J&J shall comply with the Firewall Principles in Annex 14 for the duration of the Transitional Period.
6. The transitional technical assistance agreement referred to above shall include appropriate provisions designed to incentivise J&J to provide technical assistance to the Purchaser expeditiously. These provisions may include terms whereby the price payable by the Purchaser for technical assistance is reduced over time. J&J shall cause ALZA to carry out the technical assistance for the technology transfer in accordance with good industry practice including as regards the timing and responsiveness with which this assistance is provided throughout the different stages of the transfer.
7. The transitional technical assistance agreement and the transitional supply arrangements referred to above shall include the Fast Track Resolution Procedure provisions set out in the J&J Commitments and will be subject to the supervision of the Monitoring Trustee for as long as these agreements remain in place.

8. At the option of the Purchaser, J&J shall cause ALZA to conduct R&D for the Purchaser in order to develop improvements to the Nicotine Patch Products on a reasonable cost plus basis to be agreed with the Purchaser following Closing for a period of [...].
9. With regard to the Purchaser Requirements referred to in paragraph 18 of the J&J Commitments, it is further specified that the Purchaser must have:
 - (xxxvii) sufficient capability to supply products that are marketed as branded products in the pharmaceutical sector; and
 - (xxxviii) sufficient capability to receive the Licensed Technology and, having regard to the resources transferred pursuant to these Commitments, to further develop or have developed, such Technology.

Case No COMP/M.4314 - J&J/Pfizer Consumer Healthcare

Annex 1 to the Global Nicotine Patch Business Commitment ALZA Transdermal Patch Production Facility

The Cashel Plant, which is currently owned by ALZA Ireland Limited, is located at IDA Industrial Park, Cahir Road, Cashel, Co. Tipperary, Ireland and currently occupies a surface area of approximately 60,000 square feet and is on 22 acres of land.

The ALZA Cashel Plant currently comprises Durogesic® manufacturing and Nicotine Patch manufacturing, Ionsys Testing and Release Laboratory, the Cordis Stent Development Laboratory and Shared Service Space (administrative, security and maintenance, warehouse, utilities and laboratory and analytical services).

The Transdermal Patch Production Facility and Shared Service Space would be leased to the Purchaser as part of the divestiture. ALZA Ireland Limited would retain the area occupied by the Cordis Stent Development Laboratory and the Ionsys Testing and Release Laboratory. If the Transdermal Patch Production Facility is sold, the Cordis Stent Development Laboratory and the Ionsys Testing and Release Laboratory would not be included (or would benefit from a rent free lease). ALZA would contract with the Purchaser for any Shared Services that it needs.

J&J shall retain the right to build other, separate facilities not related to transdermal patches on the site and would have the right to share utilities, maintenance, security and other support services with the Purchaser.

Since ALZA currently produces both the Nicotine Patch Products and Durogesic (fentanyl) patches at the Transdermal Patch Production Facility, the Purchaser shall carry out the Durogesic manufacturing activities as part of the lease, which shall be conditional upon the Purchaser manufacturing Durogesic as a contract manufacturer for J&J, on standard industry terms.

Case No COMP/M.4314 - J&J/Pfizer Consumer Healthcare

Annex 2 to the Global Nicotine Patch Business Commitment Major Equipment

Overview of the manufacturing process

The ALZA nicotine patch manufacturing process consists of three main processes: extrusion, converting and pouching. Through the extrusion process, nicotine and polymer are mixed in an inert, temperature controlled environment and extruded and calendered between plastic films. The resulting laminate is then wound onto rolls. The converting line laminates the adhesive onto rollstock, slits and laminates the liner, treats and prints the patches, die-cuts the patches into the final size and rewinds the patches onto spools. Finally, the pouching line feeds the patches from the spools, cuts the liner to separate the individual patches, prints the lot and expiration date on the pouch stock, seals the systems in the pouch stock and cuts the pouches to their final size. The nicotine patches are supplied as pouch stock to the customer.

Major Equipment

The Major Equipment comprises three equipment lines in total for the manufacture of nicotine patches. The three equipment lines are made up of three extruders, two convertors, four pouchers and an isolator. Further details are provided below. Currently, two equipment lines suffice in order to cover the worldwide supply of ALZA nicotine patches.

ALZA manufactures the Nicotine Patch Products at two sites: Vacaville, California, U.S.A. and Cashel, Ireland. Neither of these plants are dedicated to the manufacture of nicotine patches.

Cashel

At Cashel, there is one equipment line, which consists of:

One extruder, which has the capacity to [...] million patches per year.

One convertor,³⁸ which has a capacity of [...] million patches per year.

38 [...].

One poucher, with the capacity to process [...] million patches per year.

An isolator, which is used, in accordance with applicable regulatory requirements, to protect operators sampling nicotine from chemical hazard.

Vacaville

At Vacaville, there are two equipment lines. These comprise:

Two extruders, each with the capacity to manufacture [...] million patches per year.

One convertor,³⁹ which currently has a capacity of [...] million patches per year and processes the output of both Vacaville extruders.⁴⁰

Three pouching lines, each of which has the capacity to manufacture [...] million patches per year. (While only two pouching lines are required to meet current worldwide volumes, ALZA also commits to transfer an additional pouching line, if the Purchaser so requests.)

There are no regulatory requirements for an isolator to be used at Vacaville. Instead, operators handling nicotine wear special protective suits to protect them from chemical hazard.

39 [...].

40 [...].

Case No COMP/M.4314 - J&J/Pfizer Consumer Healthcare
Annex 3 to the Global Nicotine Patch Business Commitment
Technical Files

Manufacturing Facility

Proprietary information regarding specialised facility configurations, as required by the Purchaser.

Active Pharmaceutical Ingredients & Critical / Novel Excipients

Information regarding the raw materials used to manufacture the Nicotine Patch Products, including:

Manufacturing Sites

List of Components and Quality/Grades

Vendor Specifications and Quality Requirements

Analytical Test Methods & Test Method Validation

Certificates of Analysis

Reference Standards

Stability and Expiration Dating Information (if applicable)

Compendial, Regulatory, and Internal Specifications

Analytical and Microbiological Summary Report with Historical Data

Component Supplier/Site Qualification (if applicable)

Component Storage and Handling

Drug Product & Manufacturing

Information regarding the finished Nicotine Patch Product and its manufacture, including:

Quantitative Composition / Formulation of Drug Product

Description of Production and Packaging Processes / Equipment Train

Process Flow Diagrams

Description of Software driven Controls

Batch Records (Master Formulas and Associated Forms)

In Process Controls, Test Methods, and Limits

Standard Operating Procedures (SOP) for Manufacturing

Critical Parameters and Historical Capabilities

Maximum Allowable Hold Times

Equipment Description

Intermediate Storage Conditions

Bulk Storage and Handling Conditions

Cleaning Procedures, Test Methods, and Validations

Microbial Cleaning Assessment

Process Validations

Bio – Batch Data

Drug Product Specifications

Analytical and Microbiological Test Methods and Validations

Historical Test Results Summary

Certificates of Analyses

Information regarding the packaging used for the Nicotine Patch Product, including:

Schematics

Rationale for packaging

Materials of Construction

Specifications and Test Methods

Compatibility and Stability Reports

Drug Product Stability

The following stability studies and reports:

Shipping Studies

Historical and Current Stability Reports

Degradation Pathways

Stability Specifications

Stability Test Methods and Validation

Case No COMP/M.4314 - J&J/Pfizer Consumer Healthcare

Annex 4 to the Global Nicotine Patch Business Commitment Trademarks

ALZA does not own, or have any rights or licence to the Nicoderm or NiQuitin trademarks anywhere in the world. These trademarks are owned by the downstream marketing partners Sanofi-Aventis, GSK and PCH, or by third parties. ALZA owns, and commits to transfer, the Nicabate trademark, as registered in the following countries:

China, Peoples Republic (PRC)

European Union

Iceland

India

Japan

Norway

Romania

Russian Federation (formerly USSR)

Serbia/Montenegro

Switzerland

Case No COMP/M.4314 - J&J/Pfizer Consumer Healthcare

**Annex 5 to the Global Nicotine Patch Business Commitment
Intellectual Property**

ALZA Patents

The patents listed below are the main patents owned by ALZA, issued or pending for each patent family relating to the Nicotine Patch Products. Equivalent patents in other jurisdictions will also be licensed in order to give the Purchaser the full worldwide rights for nicotine patches.

Patent family number	Status	Expiry date	Owner	Title and Field
EP1140039A 1	Pending ⁴¹	13/12/19	ALZA	<u>Transparent transdermal nicotine delivery devices.</u> A transparent transdermal delivery device for delivering nicotine which has an Opacity Index of less than 48.6%.
EP0525105B1	Granted	11/02/11	ALZA	<u>Polyisobutylene adhesives for transdermal devices.</u> Invention pertains to polyisobutylene (PIB) adhesives useful in transdermal drug delivery systems.
EP0506860B1	Granted	16/12/10	ALZA	<u>Nicotine packaging materials.</u> Invention pertains to materials and methods for the manufacture of nicotine storage pouches.
EP0427741B1	Granted	12/06/09	ALZA	<u>Subsaturated transdermal delivery device.</u>

⁴¹ Patents within this family have been granted outside of the EU.

Patent family number	Status	Expiry date	Owner	Title and Field
				Invention relates to transdermal delivery devices intended to deliver biologically active agents through skin at substantially constant rates for extended periods of time and more particularly to such devices in which the active agent to be delivered is present in the device at a concentration below saturation.

Patent family number	Status	Expiry date	Owner	Title and Field
US5342623	Granted	02/04/08	ALZA	<p><u>Subsaturated transdermal therapeutic system having improved release characteristics</u></p> <p>Invention relates to medical devices in the form of transdermal delivery devices intended to deliver biologically active agents through skin at substantially constant rates for extended periods of time and more particularly to such systems which utilize rate controlling membranes and in-line adhesives.</p>

Third Party Patents

In addition, ALZA benefits from certain covenants on the part of third parties not to sue in connection with certain patents. Where such protection does not automatically extend to ALZA's licensees, J&J shall use reasonable efforts to ensure that the Purchaser is afforded equivalent protection in this regard. Where such covenants are mutual, this may involve a commitment on the part of the Purchaser not to sue the relevant third party of certain of the ALZA patents.

Details of the relevant third parties and patent numbers are as follows:

[...]

Other intellectual property rights

ALZA will transfer all proprietary information necessary to manufacture the Nicotine Patch Products, including all relevant content from the ALZA Master Index, which contains details of the methods, formulae, instructions, advisories and analytical tools relating to ALZA's products together with all those materials listed in Annex 3.

J&J represents and warrants that the intellectual property, as defined in the Schedule and further specified in this Annex, is sufficient to run the divested business as a viable and independent business.

Case No COMP/M.4314 - J&J/Pfizer Consumer Healthcare

Annex 6 to the Global Nicotine Patch Business Commitment Licences and permits

The licences and permits required by the Purchaser in order to manufacture the Nicotine Patch Products are the same as those generally required to manufacture any other pharmaceutical product, and will vary according to the location of the Purchaser's manufacturing plant.

By way of indication of the type of authorisation that is generally required, Vacaville is licensed under a Drug Manufacturing License, issued by the State of California, Department of Health Services, Food and Drug Branch and is also registered as Drug Establishment by the Food and Drug Administration, Department of Health and Human Services. Cashel operates under a Manufacturer's Licence and a Certificate of Good Manufacturing Practice Compliance of a Manufacturer, both issued by the Irish Medicines Board. ALZA is also licensed at Cashel to hold an inventory of a controlled substance and to manufacture using a controlled substance. In addition, it holds an integrated pollution control license, issued by the Environmental Protection Agency. [...], which carries out chemical and microbiological analysis of starting materials, raw materials, finished products and water on behalf of ALZA is authorised under an Quality Control Laboratory Approval, also issued by the Irish Medicines Board.

The above licences and permits are not legally transferable. Therefore, J&J shall cause ALZA to use reasonable efforts to assist the Purchaser to obtain necessary licences and permits, which may be required.

Case No COMP/M.4314 - J&J/Pfizer Consumer Healthcare

**Annex 7 to the Global Nicotine Patch Business Commitment
Supplier Contracts**

There are [...] supply contracts. ALZA shall employ reasonable efforts to ensure that the Purchaser is able to source the relevant products from these suppliers.

Contract	Summary
[...]	[...]

Case No COMP/M.4314 - J&J/Pfizer Consumer Healthcare

**Annex 8 to the Global Nicotine Patch Business Commitment
Customer Contracts**

Contract	Summary
[...]	[...]

Case No COMP/M.4314 - J&J/Pfizer Consumer Healthcare

**Annex 9 to the Global Nicotine Patch Business Commitment
Personnel List**

Cashel Personnel

Name	Function
[...]	[...]

Vacaville Personnel

Name	Function
[...]	[...]

Case No COMP/M.4314 - J&J/Pfizer Consumer Healthcare

**Annex 10 to the Global Nicotine Patch Business Commitment
Key Personnel**

A. Cashel Key Personnel

[...]

B. Other Personnel to be incentivised

For the avoidance of doubt, the Personnel below are not required for the viability of the Global Nicotine Patch Business. However, J&J shall, at the option of the Purchaser, cause ALZA to undertake the incentive efforts set out in the Schedule with respect to Key Personnel.

[...]

Case No COMP/M.4314 - J&J/Pfizer Consumer Healthcare
Annex 11 to the Global Nicotine Patch Business Commitment
R&D Personnel

[...]

Case No COMP/M.4314 - J&J/Pfizer Consumer Healthcare

Annex 12 to the Global Nicotine Patch Business Commitment Supplemental provisions to GSK Distribution Agreement

J&J shall cause ALZA to comply with the following provisions for as long as ALZA remains party to the GSK Distribution Agreement (which is until Closing). In the event of conflict between the terms of the agreement and the provisions below, the latter shall prevail:

- (viii) ALZA shall renounce its rights to any retroactive price increases. [...]
- (ix) [...]
- (x) J&J shall cause ALZA to waive information rights regarding GSK's downstream marketing and sales. [...]
- (xi) J&J shall cause ALZA to not prevent GSK from using trademarks owned by GSK following termination of the agreement in relation to the Nicotine Patch Products in the International Territory.
- (xii) [...].
- (xiii) Any dispute concerning the GSK Distribution Agreement shall be governed by the Fast Track Resolution Procedure provisions set out in the J&J Commitments, if GSK so elects.

The compliance with these principles, as well as with the terms of the GSK Distribution Agreement, for as long as it remains in place, shall be subject to the supervision of the Monitoring Trustee.

Case No COMP/M.4314 - J&J/Pfizer Consumer Healthcare

Annex 13 to the Global Nicotine Patch Business Commitment Supply Agreement Principles

The supply agreement will cover the Nicotine Patches. The agreement will include appropriate provisions allowing the Purchaser to withdraw specific Nicotine Patch Products from the scope of the agreement, thus allowing it to self-manufacture once it is in a position to do so.

During the Transitional Period, ALZA will sell Nicotine Patches to the Purchaser on a reasonable cost-plus margin basis. Cost shall be defined in accordance with Generally Acceptable Accounting Principles and negotiated by J&J or ALZA and the Purchaser at a level consistent with standard industry practice; the margin shall be set at a discount to standard industry practice.

ALZA shall be required to provide support to the Purchaser on a reasonable cost plus basis in its application for product approval from the competent regulatory bodies, and in particular shall provide to the Purchaser or the regulatory body such information as is requested by that body.

The supply agreement shall include appropriate provisions with regard to regulatory compliance.

The Purchaser shall be required to send ALZA non-binding twelve (12) month rolling monthly forecasts of its reasonably expected requirements for Nicotine Patch Products (firm and binding as to the next two months). If, for any reason (e.g. production shortages or events akin to force majeure), ALZA is unable to meet the Purchaser's requirements of Nicotine Patch Products, J&J shall allocate deliveries of that product to the Purchaser in the proportion that represents [...] % of the proportion that prevailed between ALZA and the Purchaser on average during the [...] preceding completed quarters.

The supply agreement shall include appropriate provisions with regard to ALZA building and keeping an adequate safety stock of products at all times during the duration of the transitional supply agreement. The Monitoring Trustee may recommend appropriate safety stock levels to ensure security of supply, or if necessary, such additional supply-related measures as may be reasonably needed to ensure that product is available to the Purchaser.

The Purchaser may terminate the supply agreement at its discretion on [...] notice.

Delivery of the Nicotine Patches will be made in a timely manner and according to a pre-defined schedule, in line with standard industry practice.

Case No COMP/M.4314 - J&J/Pfizer Consumer Healthcare

Annex 14 to the International Nicotine Patch Commitment Firewall Principles

J&J shall implement firewalls which will prevent, during the Transitional Period, any exchange, communication or flow of Confidential Information, as defined below, between ALZA and the Consumer Division of J&J (where the Pfizer Consumer Healthcare nicotine patch business shall be held).

Confidential Information means all information that is not in the public domain relating to the research, technology, development, manufacture, marketing, commercialisation, distribution, cost, pricing, supply, sales, or use of nicotine patch products or other nicotine replacement products manufactured, sold or in development. ALZA Confidential Information means all Confidential Information pertaining to the ALZA Nicotine Patch Business subject to this remedy. PCH Confidential Information means all Confidential Information pertaining to the Pfizer Consumer Healthcare nicotine replacement products acquired by J&J.

J&J will submit to the Monitoring Trustee within two weeks of the appointment of the latter, suitable proposals for firewalls between ALZA and the Consumer Division. These proposals will include confidentiality agreements (the terms of which shall be subject to the approval of the Monitoring Trustee), IT arrangements regarding access and storage of information, monitoring mechanisms, procedures for release, change of positions, reporting lines etc.
