



EUROPEAN COMMISSION  
Competition DG

## ***CASE AT.39685 - Fentanyl***

(Only the English text is authentic)

### **ANTITRUST PROCEDURE**

### **Council Regulation (EC) 1/2003**

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Article 7 of Regulation (EC) 1/2003

Date: 10/12/2013

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**EUROPEAN COMMISSION**  
Competition DG

Strasbourg, 10.12.2013  
C(2013) 8870 final

**COMMISSION DECISION**

**of 10.12.2013**

**addressed to**

- Johnson & Johnson**
- Janssen-Cilag B.V.**
- Novartis AG**
- Sandoz B.V.**

**relating to a proceeding under Article 101 of the Treaty on the Functioning of the  
European Union**

**(AT.39685 - FENTANYL)**

(Only the ENGLISH text is authentic)

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# COMMISSION DECISION

of 10.12.2013

addressed to

- **Johnson & Johnson**

- **Janssen-Cilag B.V.**

- **Novartis AG**

- **Sandoz B.V.**

relating to a proceeding under Article 101 of the Treaty on the Functioning of the European Union

(AT.39685 - FENTANYL)

(Only the ENGLISH text is authentic)

THE EUROPEAN COMMISSION,

Having regard to the Treaty on the Functioning of the European Union<sup>1</sup>,

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

Having regard to the Commission decision of 18 October 2011 to initiate proceedings in this case,

Having given the undertakings concerned the opportunity to make known their views on the objections raised by the Commission pursuant to Article 27(1) of Regulation (EC) No 1/2003 and Article 12 of Commission Regulation (EC) No 773/2004 of 7 April 2004 relating to the conduct of proceedings by the Commission pursuant to Articles 81 and 82 of the Treaty<sup>3</sup>,

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

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

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<sup>1</sup> OJ C 115, 9.5.2008, p.47.

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

<sup>3</sup> OJ L 123, 27.4.2004, p. 18

Whereas:

## 1. INTRODUCTION

- (1) This Decision concerns a Co-promotion agreement<sup>4</sup> between the Dutch originator pharmaceutical company Janssen-Cilag B.V., a subsidiary of Johnson & Johnson<sup>5</sup> and the Dutch generic pharmaceutical companies Hexal B.V.<sup>6</sup> and Sandoz B.V.<sup>7</sup> Hexal B.V. and Sandoz B.V. were both, at the time of the alleged infringement, subsidiaries of Novartis AG.<sup>8</sup>
- (2) The Agreement in question concerns the Dutch market for the medicinal product fentanyl, a strong pain-killer, in the form of transdermal patches. Janssen-Cilag B.V. entered into the Co-promotion agreement with Hexal B.V./Sandoz B.V. which was amongst the most advanced generic competitors of J&J in the Netherlands on 11 July 2005. According to the terms of the Co-promotion agreement, Novartis/Sandoz agreed to jointly promote (but not sell) J&J's fentanyl matrix patches to pharmacists in the Netherlands. J&J agreed to make monthly payments to Novartis/Sandoz. The Agreement could be terminated immediately by J&J if Novartis/Sandoz launched its own generic transdermal fentanyl patch on the Dutch market.
- (3) The initial co-promotion agreement entered into force on 11 July 2005 and it was later extended by an addendum, which entered into force on 11 July 2006. The total period covered by the Agreement (including the addendum) was from 11 July 2005 to 15 December 2006 ("the period concerned").
- (4) The Agreement was characterised by the fact that it contained a considerable payment from the originator, J&J, to a close potential generic competitor, Novartis/Sandoz, for the duration of the Agreement, with the objective that the latter would not enter with generic fentanyl patches in the Netherlands.
- (5) This Decision examines the Agreement under the competition provisions of Article 101 of the Treaty. This Decision finds that the Agreement in question infringed Article 101 of the Treaty in that it had the object of restricting competition.

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<sup>4</sup> "Co-promotion agreement" or "Agreement" thereafter refers jointly to both, the initial co-promotion agreement between Janssen-Cilag B.V. and Hexal B.V. and Sandoz B.V. that entered into force on 11 July 2005 and the Addendum signed by Janssen-Cilag B.V. and Hexal Pharma B.V. and Sandoz B.V. that entered into force on 11 July 2006, unless indicated otherwise.

<sup>5</sup> Johnson & Johnson and all companies controlled by it, including Janssen-Cilag B.V., are hereafter jointly referred to as "J&J" unless reference is made to a specific company within the undertaking.

<sup>6</sup> Hexal B.V. was indirectly owned by Novartis as of 6 June 2005. On 12 September 2007, it was merged into Sandoz B.V. and no longer exists as a separate legal entity. See Recital (61) and ID0311, p. 5.

<sup>7</sup> For events that occurred after 6 June 2005 - the date of acquisition of Hexal B.V. by Novartis AG - Hexal B.V. and Sandoz B.V. are jointly referred to as "Hexal B.V./Sandoz B.V." unless reference is made only to one company of the two.

<sup>8</sup> Novartis AG and all companies controlled by it are hereafter referred to as "Novartis/Sandoz" unless reference is made to a specific company within the undertaking.



## 2. PROCEDURE

### 2.1. The Commission's investigation

- (6) In July 2010 the Commission carried out inspections pursuant to Article 20(4) of Regulation (EC) No 1/2003.
- (7) After the inspections, issues of claimed legal professional privilege were clarified and further investigation was conducted, including requests for information to parties and other market players pursuant to Article 18 of Regulation (EC) No 1/2003.
- (8) On 18 October 2011, the Commission opened formal proceedings against Johnson & Johnson, Janssen-Cilag B.V., Novartis AG and Sandoz B.V.
- (9) On 30 November 2011, a state of play meeting with Johnson & Johnson and Janssen-Cilag B.V. took place. On 13 March 2012, a state of play meeting was held with Novartis AG and Sandoz B.V.
- (10) On 12 and 14 December 2012, state of play meetings were held respectively with Novartis AG and Sandoz B.V., and Johnson & Johnson and Janssen-Cilag B.V.
- (11) On 30 January 2013 the Commission issued a Statement of Objections to Johnson & Johnson, Janssen-Cilag B.V., Novartis AG and Sandoz B.V.
- (12) On 22 April 2013, Novartis AG and Sandoz B.V. submitted their joint written reply to the Statement of Objections.<sup>9</sup> In that reply to the Statement of Objections, Sandoz B.V. requested "*to be given the opportunity to express its views orally at a hearing in accordance with Article 12 of Regulation No 773/2004 only to the extent that any other party would make such a request*".<sup>10</sup> Novartis AG did not request an oral hearing.
- (13) On 30 April 2013, Johnson & Johnson and Janssen-Cilag B.V. submitted their joint written reply to the Statement of Objections.<sup>11</sup> In that reply to the Statement of Objections, Johnson & Johnson and Janssen-Cilag B.V. "*waived their right to explain their views orally at an administrative hearing*".<sup>12</sup> Therefore no oral hearing took place.
- (14) On 17 October 2013, the Commission sent a Letter of Facts to all parties, which submitted comments.<sup>13</sup>
- (15) On 13 and 14 November 2013, state of play meetings were held respectively with Novartis AG and Sandoz B.V., and Johnson & Johnson and Janssen-Cilag B.V.
- (16) The hearing officer issued his final report on 6 December 2013.

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<sup>9</sup> ID1537.

<sup>10</sup> ID1537, p. 23.

<sup>11</sup> ID1541-1554.

<sup>12</sup> ID1542, p. 21.

<sup>13</sup> ID1702 and ID1709.

## **2.2. The main evidence relied on**

- (17) The main evidence relied on in this Decision includes the actual text of the Co-promotion agreement and its addendum, documents found during the inspections and the companies' replies to requests for information.

## **3. THE REGULATORY FRAMEWORK**

- (18) This section explains some of the key features of the Union and the Dutch regulatory framework in the period concerned, which are relevant for the case. Section 3.1 deals with patent protection, followed by section 3.2 on marketing authorisation, by section 3.3 on loss of exclusivity and generic entry, and by section 3.4 on pricing, reimbursement and substitution. In each section this is followed by a brief explanation on how the regulatory framework applied to fentanyl patches in the Netherlands in the period concerned and references are provided to the relevant sections of this Decision where those elements are described in more detail.

### **3.1. Patent Protection**

- (19) In the EEA, the market exclusivity of innovative medicinal products can be protected by patents for up to 20 years.<sup>14</sup>
- (20) Patents are territorial rights, in that they only apply in countries in which they have been granted. The term European patent is used to refer to patents granted by the European Patent Office (EPO) under the European Patent Convention (EPC). European patents, however, do not provide a single patent title, but provide its proprietor patent protection in as many of the 38 Contracting States to the EPC as desired by its proprietor.
- (21) In addition to patents, Council Regulation (EEC) No 1768/92<sup>15</sup> provided for a supplementary protection certificates (SPC) for medicinal products. The SPC amounts to an extension of the patent right for a maximum of five years. Regulation (EEC) No 1768/92 provided that holders of both a patent and an SPC for a medicinal product must be able to enjoy a maximum period of up to 15 years' effective protection in every Member State from the time the medicinal product in question first received marketing authorisation in the EEA.<sup>16</sup>
- (22) Concerning the patent protection of fentanyl transdermal patches, the fentanyl compound patent expired already in 1982 (see Recital (70)). The fentanyl depot patch<sup>17</sup> has never been protected by a valid patent in the Netherlands. A patent application for the depot patch in the Netherlands was filed in 1985, but, according to J&J, the application was abandoned in the course of 1993 (see Recital (82)).

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<sup>14</sup> See European Commission, DG Competition: Report on the pharmaceutical sector inquiry, 8 July 2009, p. 116. In accordance with Article 33 TRIPS, Article 63 of the European Patent Convention (EPC) provides that the term of a European patent is 20 years from the date of filing of the application.

<sup>15</sup> On 6 July 2009, Regulation (EEC) No 1768/92 was repealed by Regulation (EC) No 469/2009.

<sup>16</sup> See European Commission, DG Competition: Report on the pharmaceutical sector inquiry, 8 July 2009, p. 131.

<sup>17</sup> Defined at section 5.1.1.

- (23) On 15 March 2002, three patent applications were filed with the EPO for the ("second generation") fentanyl matrix patch by Alza Corporation, a company acquired by J&J in 2001.<sup>18 19</sup> Only one of the three patent applications was eventually granted on 13 June 2007, European patent EP1381352B1 covering a transdermal patch for administering fentanyl (hereafter also referred to as "Matrix Patch Patent").<sup>20</sup> The Matrix Patch Patent was supposed to expire on 15 March 2022, but it was revoked by the opposition division of EPO and, as pointed out by J&J in its reply to the Statement of Objections, the revocation of the patent "*took legal effect on 17 May 2011*".<sup>21</sup>
- (24) This means that for the period before and during the Co-promotion agreement in the Netherlands there was no granted patent protecting either the fentanyl depot patch or the matrix patch. There was a pending patent application for the matrix patch.<sup>22</sup>

## 3.2. Marketing authorisation

### 3.2.1. General requirements

- (25) With a view to safeguarding public health, no medicinal product for human use may be placed on a market in the EEA unless a marketing authorisation has been issued for it.<sup>23</sup>
- (26) For the Netherlands, marketing authorisations are issued by the Dutch Medicines Evaluation Board (College ter Beoordeling van Geneesmiddelen). The pharmaceutical company must apply for a marketing authorisation, providing data concerning the medicinal product, including its name, pharmaceutical form, indications, dosage and risk information as well as documenting the product's pharmaceutical quality, safety and efficacy. Obtaining a marketing authorisation involves therefore the availability of the results of a certain number of pre-clinical toxicological and pharmacological tests as well as clinical trials, which together permit an assessment of the safety and efficacy of the medicine.
- (27) In the pharmaceutical industry, companies active in research and development, manufacturing and marketing of innovative medicines, which are usually patented, are referred to as "originator companies". In this case, Janssen-Cilag B.V. is considered as an originator company. Once the medicinal product is no longer protected by patents (see section 3.1) and data exclusivity (see Recitals (30) and (31)), that medicinal product can in principle be produced and sold by third parties,

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<sup>18</sup> See Recital (82).

<sup>19</sup> ID1044, ID1043 and ID1042 (on EP1381352, EP1757280 and EP1875898). <https://register.epo.org/>. Also see ID0533, p. 1.

<sup>20</sup> The other two patent applications were never granted. They were deemed to be withdrawn in 2010 (EP1757280) and 2012 (EP1875898) respectively, due to failure to reply to the examining report. See ID1042 and ID1043.

<sup>21</sup> ID1542, p. 6 and ID1044, p. 4.

<sup>22</sup> Under the Dutch law, the patent holder would only have a right to fair compensation after the grant of the patent. This compensation is subject to limitations, in particular the requirement of having put the opposing party on notice, and only arises with the publication of the application.

<sup>23</sup> Recital 2 and Article 6 of Directive 2001/83/EC of the European Parliament and the Council of 6 November 2001 on the Community Code relating to medicinal products for human use (OJ L 311, 28.11.2001, p. 67).

so-called "generic companies". In this case, Hexal B.V./Sandoz B.V. is considered as a generic company. These so-called "generic medicines" contain an active ingredient identical to the reference (originator) medicinal product. When bringing a medicine to the market both originator products and generic products need a marketing authorisation.

- (28) In the Netherlands, the marketing authorisation for J&J's fentanyl depot patches was granted on 17 July 1995.<sup>24</sup> The marketing authorisation for J&J's fentanyl matrix patches,<sup>25</sup> based on the application for a modification of the existing marketing authorisation for the depot patches ("Type II variation"), was granted on 10 August 2004 in the Netherlands.<sup>26</sup>

### 3.2.2. *Marketing authorisation for generic medicines and data exclusivity*

- (29) Generic companies<sup>27</sup> wanting to sell in the EEA in the period concerned could make several national applications for marketing authorisation (which were formally independent of each other), either simultaneously or consecutively.<sup>28</sup> In such a case Directive 2001/83/EC<sup>29</sup> provided that a Member State had to complete the procedure for granting a marketing authorisation within 210 days of the submission of a valid application.<sup>30</sup> Alternatively, generic companies could use the mutual recognition procedure. In the latter case, they would make an application to a single Member State first, the so-called reference Member State. After granting the authorisation, that reference Member State would prepare an assessment report within 90 days of the receipt of the request. The marketing authorisation would then in principle be mutually recognised within 90 days by other Member States where such recognition was requested by the company in question.<sup>31</sup>
- (30) Directive 2001/83/EC also provided with respect to generic medicines, which contain the same active pharmaceutical ingredient as the originator product, that once the period of "data exclusivity" for the pre-clinical toxicological and pharmacological tests and clinical trials originally performed by the originator company had expired, generic companies were allowed to submit an abridged application for a marketing authorisation. Data exclusivity refers to the period during which the data of the original marketing authorisation holder relating to (pre)-clinical testing cannot be used by a generic company for a marketing authorisation via a simplified abridged application.

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<sup>24</sup> ID0507. See also Recital (82).

<sup>25</sup> 25, 50, 75 and 100µg/hour versions.

<sup>26</sup> ID0404, p. 3. See also Recital (79).

<sup>27</sup> A "generic company" can be defined as a company that sells generic medicines.

<sup>28</sup> Article 17(2) of Directive 2001/83/EC provided that where a Member State noted that an application for a marketing authorisation was already under active examination in another Member State, it could suspend its own examination in order to await the assessment report prepared by the other Member State.

<sup>29</sup> In the version applicable in the period concerned. As from 30 October 2005, the amendments introduced by Directive 2004/27/EC started to apply.

<sup>30</sup> Article 17 of Directive 2001/83/EC.

<sup>31</sup> Unless one or more of those other Member States considered that granting a marketing authorisation entailed a risk to public health. In that case, Directive 2001/83/EC foresaw if necessary a procedure leading to a binding decision at EC level.

- (31) The abridged application could be submitted via a national application or via a mutual recognition procedure, relying for this purpose on the relevant data as originally submitted by the originator company. In the period concerned, the period of data exclusivity was six or ten years, depending on the Member State.<sup>32</sup> In the Netherlands, this period of data exclusivity was ten years. As soon as the data exclusivity expired, generic companies could apply for a marketing authorisation via the simplified abridged application, even if the originator reference product was still protected by a patent.
- (32) As stated in the Report on the pharmaceutical sector inquiry (hereafter "sector inquiry report"), litigation may take place between originator companies and generic companies or between originator companies and marketing authorisation bodies regarding marketing authorisations that have been granted to generic companies.<sup>33</sup>
- (33) The data exclusivity of J&J's fentanyl depot patch in the Netherlands expired on 4 March 2004.<sup>34</sup> The marketing authorisation for J&J's matrix patch was a modification of the previous marketing authorisation for the depot patch (see Recital (28)) and did not trigger any new data exclusivity period.
- (34) Hexal B.V. applied in the Netherlands for a marketing authorisation for its fentanyl depot patches through the mutual recognition procedure and the marketing authorisation was granted on 17 March 2005 (see Recital (93)).
- (35) On 24 August 2006, Janssen-Cilag B.V. transferred to Hexal B.V. "duplex registrations"<sup>35</sup> of marketing authorisations of Janssen-Cilag B.V.'s fentanyl matrix patches.<sup>36</sup> Those duplex registrations were used by Hexal B.V./Sandoz B.V. in the framework of the supply agreement with Janssen-Cilag B.V. (see section 6.3).
- (36) In addition to the duplex registrations transferred to Hexal B.V. by Janssen-Cilag B.V. (see Recital (35)), Hexal B.V. also attempted to get the marketing authorisations for its fentanyl matrix patches through the so-called "Type II variation"<sup>37</sup> procedure for which it used its marketing authorisations for the fentanyl depot patch.<sup>38</sup> Hexal B.V. applied for the Type II variation in September 2005 and

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<sup>32</sup> Article 10(1)(a)(iii) of Directive 2001/83/EC. A period of ten years was used by Belgium, Germany, France, Italy, the Netherlands, Sweden, the United Kingdom and Luxemburg. A period of six year was used by Austria, Denmark, Finland, Ireland, Portugal, Spain, Greece, Norway, Liechtenstein and Iceland. See European Commission, DG Competition: Report on the pharmaceutical sector inquiry, 8 July 2009, p. 143, footnote 326.

<sup>33</sup> European Commission, DG Competition: Report on the pharmaceutical sector inquiry, 8 July 2009, section 2.2. and 2.5. For this case, see section 5.2.2.2. regarding litigation between the originator company J&J and generic company Ratiopharm regarding the marketing authorisation of Ratiopharm's generic fentanyl patches.

<sup>34</sup> ID0136, p. 159 and ID0682, p. 9.

<sup>35</sup> Duplex registrations are registrations of products for which the (marketing authorisation) file is identical to that of an already registered product. See ID0861, [http://www.cbg-meb.nl/NR/rdonlyres/0976D8BA-26C5-41B8-8996-E049CA890570/0/cbg16v5\\_0.pdf](http://www.cbg-meb.nl/NR/rdonlyres/0976D8BA-26C5-41B8-8996-E049CA890570/0/cbg16v5_0.pdf)

<sup>36</sup> ID0471, p. 6. and ID1542, p. 5.

<sup>37</sup> Commission Regulation (EC) No 1234/2008 (the "Variations Regulation") defines a major variation of type II as a variation that is not an extension and that may have a significant impact on the quality, safety or efficacy of a medicinal product.

<sup>38</sup> ID0471, p. 5.

the marketing authorisations for Hexal B.V.'s fentanyl matrix patches under this "Type II variation" procedure were granted on 1 October 2007.<sup>39</sup>

### 3.3. Loss of exclusivity and generic entry

- (37) The situation where a pharmaceutical product is no longer subject to data exclusivity (see Recitals (30) and (31)) and at the same time no longer falls under the protection period provided by a patent is referred to as "loss of exclusivity".
- (38) As the Commission has analysed in its sector inquiry report, generic entry into a pharmaceutical market *"can have a profound effect as it changes the market from one in which only one firm could sell the product(s) concerned (possibly via licensees) into one where more sources of supply become available for the product. The most direct effect is likely to be on the average price level of the product(s) concerned and the sales volumes of the originator."*<sup>40</sup> The Commission found in its report that in the period 2000-2007 in the Union one year after generic entry, on average the prices (including originator and generic companies' prices) for its sample of 75 major products had fallen by almost 20% and by about 25% after two years.<sup>41</sup> The Commission also found for the same sample of 75 major products that within one year and two years after generic entry, generic companies had acquired on average a share of sales by volume of 30% and of 45% respectively.<sup>42</sup>
- (39) In the Netherlands, J&J's fentanyl depot patch lost exclusivity on 4 March 2004 (see Recital (33)). Nevertheless, no generic company has ever entered the Dutch market with the depot patch. The first generic entry with fentanyl (matrix) patches took place in January 2007 (see Recital (107)).

### 3.4. Pricing, reimbursement and substitution

- (40) Pursuant to Article 168(7) of the Treaty, Member States are responsible for the organisation of their healthcare system and for the delivery of health services and medical care, including the allocation of resources assigned to them. In this framework, each Member State can take measures to manage the consumption of medicines, regulate their prices or establish the conditions of their public funding.
- (41) Regarding pricing and reimbursement, Member States are free to adopt their own pricing and reimbursement decisions, as long as these comply with the procedural requirements of the Council Directive 89/105/EEC.<sup>43</sup> That Directive lays down a series of procedural requirements to ensure the transparency of pricing and reimbursement measures adopted by the Member States. Member States measures

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<sup>39</sup> ID0471, p. 5.

<sup>40</sup> European Commission, DG Competition: Report on the pharmaceutical sector inquiry, 8 July 2009, p. 98.

<sup>41</sup> European Commission, DG Competition: Report on the pharmaceutical sector inquiry, 8 July 2009, p. 99.

<sup>42</sup> European Commission, DG Competition: Report on the pharmaceutical sector inquiry, 8 July 2009, p. 108.

<sup>43</sup> Council Directive 89/105/EEC of 21 December 1988 relating to the transparency of measures regulating the prices of medicinal products for human use and their inclusion in the scope of national health insurance systems (OJ L 040 , 11.2.1989, p. 8).

must be free of discrimination against imported medicinal products and based on objective and verifiable criteria which are independent from the origin of the products.

- (42) As this case concerns the Netherlands (see Recital (2)), the focus of this section will be on the Dutch pricing and reimbursement system. In the Netherlands, in the period concerned, a company which intended to market a medicinal product (whether an originator or generic product) needed a maximum price to be set and the level of reimbursement from public funds to be established for that product.

#### 3.4.1. Pricing

- (43) When a pharmaceutical company applied for a price for a pharmaceutical product in the Netherlands, the government imposed a maximum wholesale price (or "pharmacy purchase price") at the level of sales to pharmacies. That maximum price was calculated as the average pharmacy purchase price (or wholesale price) of "comparable" medicines in four reference Member States: Belgium, France, Germany and the United Kingdom.<sup>44</sup> That maximum price formed the upper limit above which prices at the purchase level of the pharmacies were not allowed to rise. Those maximum prices were re-calculated every six months. Taking that maximum price into account, the price at which the product was to be sold to pharmacies was introduced in the "Taxe" which was a list containing the recommended pharmacy purchase prices for all pharmaceuticals that were available on the Dutch market and which were monthly published by Z-index<sup>45</sup>. The prices in the Taxe (hereafter "list prices") were regularly updated by wholesalers and manufacturers, and had to be equal to or below the maximum price defined by the government.<sup>46</sup> At the retail level, the pharmacy sold the product at a price (the pharmacy retail price) which included the pharmacy purchase price (that is to say, the maximum wholesale price) and an additional fixed fee for the pharmacist's services.
- (44) However, as generic products were often sold at a significant discount to pharmacies (which were not necessarily passed on to the patient), in 2004 the government decided to transform those discounts into structural price drops. Therefore, in February 2004, a voluntary agreement in respect of converting those discounts and bonuses to structural price reductions (hereafter "the covenant") was concluded between the Ministry of Health, Welfare and Sport (VWS), the Royal Dutch Pharmaceutical Society (KNMP), the Netherlands Health Insurers (Zorgverzekeraars Nederland, ZN) and the Dutch Federation for Generics Manufacturers (BOGIN).
- (45) In the covenant, the generic industry agreed to reduce the official list prices of generics, which were already on the market at that time. That reduction aimed at achieving an overall 40% decrease in sales from their 2003 level. For new generic products, coming on the market in the future, the generic industry agreed to set the list prices on average at least 40% below the list prices of the corresponding

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<sup>44</sup> ÖBIG, *Surveying, Assessing and Analysing the Pharmaceutical Sector in the 25 EU Member States*. ID0711, p. 13.

<sup>45</sup> Z-index B.V. is an organisation originally founded by pharmacists. [www.z-index.nl](http://www.z-index.nl).

<sup>46</sup> ÖBIG, *Surveying, Assessing and Analysing the Pharmaceutical Sector in the 25 EU Member States*. ID0711, p. 12.

originator product in the last month before the patent expiry.<sup>47</sup> However, generic companies were left free to decide for which products they would reduce the price and by how much, in order to achieve those overall savings.<sup>48</sup>

- (46) The initial covenant covered only the year 2004. In October 2004, the covenant was extended until 1 January 2006 and Nefarma, the originator industry association in the Netherlands, had also become a party to the covenant. The obligations of the generic companies remained in force and new provisions concerning pricing of originator products were included. In particular, the list prices of originator products, whose generic versions were already on the market at that time, had to be reduced in order to achieve a 40% reduction on the total sales revenues across all of those originator medicines, from their 2003 level. For the originator products for which there was no generic version at that time, the list price had to be reduced once a first generic product entered the market at least by 40% on average in comparison to the list price in the last month before the patent expiry.<sup>49</sup> The originator companies were also left free to decide for which products they would reduce the price and by how much, in order to achieve those overall savings.<sup>50</sup>
- (47) The covenant was later extended for 2006 and 2007. Both the originator industry and the generic industry agreed to the additional price reduction during those two years in order to achieve additional overall 8.5% savings on the sales revenues in comparison to the sales revenues in 2005.
- (48) In the period concerned there was therefore a general pressure on both the originator and the generic companies to considerably reduce the wholesale prices once a generic product entered the market. The companies kept some discretion concerning the exact price reductions within their product portfolio. But even if a company decided not to significantly reduce a price of a given product, its competitors were likely to do so due to the general requirement for all companies to achieve the overall 40% savings. Once a competitor reduced the price, the company was put under pressure to follow the trend and match the price reductions introduced by its competitor for the given product, in particular in order to avoid patient's co-payments<sup>51</sup> on its product due to the applicable rules on reimbursement (see Recital (52)).
- (49) The facts of this case may provide an illustration of how that general framework worked in practice. For fentanyl patches, Janssen-Cilag B.V. expected that if Novartis/Sandoz entered the Dutch market in August 2005, Novartis/Sandoz would set the price approximately 33% below the pharmacy purchase price of the originator Janssen-Cilag B.V.'s product. In that case, Janssen-Cilag B.V. foresaw that "*Janssen-Cilag price has to be reduced to 67% of current PPP [Pharmacy Purchase Price] as of August 2005.*"<sup>52</sup> A similar price reduction in case of Hexal B.V./Sandoz B.V.'s

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<sup>47</sup> ÖBIG, *Surveying, Assessing and Analysing the Pharmaceutical Sector in the 25 EU Member States*, p 509. ID0711, p. 16.

<sup>48</sup> ID0829, p. 3.

<sup>49</sup> Article 5 of Convenant inzake het omzetten van kortingen en bonussen voor geneesmiddelen in structurele prijsverlagingen 2005. ID0771, p. 3.

<sup>50</sup> ID0800, p. 3.

<sup>51</sup> That is to say, paying the extra cost above the price of the cheapest generic version.

<sup>52</sup> ID0135, p. 152.



launch was also foreseen by Janssen-Cilag B.V. in other internal documents that are described in detail in section 6.

### 3.4.2. *Reimbursement*

- (50) In order for patients to obtain a reimbursement for an authorised medicine in the Netherlands, pharmaceutical companies have to submit reimbursement applications to the Ministry of Health, Welfare and Sport ("VWS"). The Ministry of VWS determines within 90 days after receiving the application, whether a pharmaceutical will be included in the pharmaceutical reimbursement system or not. Reimbursable pharmaceuticals are identified on a list, which is divided into the following three categories:

Annex 1A: Pharmaceutical products for which therapeutically interchangeable pharmaceuticals exist.

Annex 1B: Unique pharmaceutical products for which no therapeutically interchangeable pharmaceuticals exist.

Annex 2B: Special pharmaceutical products which are only reimbursed under specific circumstances.

- (51) Unique pharmaceutical products (Annex 1B), which cannot be grouped together with other pharmaceuticals, are often originator products for which there are no generic products yet on the market. Those unique pharmaceuticals are fully reimbursed, with no reimbursement limit (the only cap is the maximum wholesale price, see Recital (43)).<sup>53</sup>
- (52) If a new pharmaceutical (for example, a generic product) is added to the reimbursement list and it is interchangeable with a unique Annex 1B pharmaceutical (for example, the corresponding originator product), both products will enter into the Annex 1A category and will be reimbursed according to a reference price system. For each cluster of such interchangeable/substitutable medicines, the maximum reimbursement level is set as the average of the list prices of the pharmaceuticals in the cluster. As a result, the maximum reimbursement level will normally lie above the price level of generic medicines, and below the price level of the originator medicine. This means that at least one product in each cluster is always fully reimbursed.<sup>54</sup> Generic products will normally be fully reimbursed. However, already since 2004, health insurance funds have been permitted to reimburse only one (the lowest priced generic) version of an active ingredient.<sup>55</sup>

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<sup>53</sup> ÖBIG, *Surveying, Assessing and Analysing the Pharmaceutical Sector in the 25 EU Member States*, p. 513. ID0711, p. 20.

<sup>54</sup> ÖBIG, *Surveying, Assessing and Analysing the Pharmaceutical Sector in the 25 EU Member States*, p. 516-517. ID0711, p. 23-24.

<sup>55</sup> ÖBIG, *Surveying, Assessing and Analysing the Pharmaceutical Sector in the 25 EU Member States*, p. 515. ID0711, p. 22.

### 3.4.3. Substitution

- (53) In the Netherlands, if the prescription of the physician refers to the international non-proprietary name (INN) of a medicine, the pharmacist is, in principle, free to choose the brand of the medicine to be dispensed, whether the originator product or a generic version of it.<sup>56</sup>
- (54) Actual substitution, that is to say replacing what has been prescribed by an equivalent, may occur when a prescription does refer to a specific brand of a medicine, for instance to the originator brand, but without an indication on the prescription that there is a medical necessity for that particular brand to be used by the patient. In that case, the pharmacist may substitute the prescribed medicine with a cheaper one having the same active ingredient. This could be a generic version of the originator product or a parallel import of the originator product. The prescriber must approve the substitution in advance when issuing the prescription (by refraining from indicating that the brand prescribed is medically necessary) and the patient must also approve the substitution.<sup>57</sup>
- (55) To the extent that the health insurer reimburses only the price of the cheapest product, the pharmacist will normally substitute to that product, to avoid that the patient is not fully reimbursed. However, if several products have the same lowest price, the pharmacist is able to choose. To the extent that in the period concerned pharmacists still had genuine freedom to offer several generic products to the patient<sup>58</sup>, all of which would be fully reimbursed, the manufacturers/distributors of those generic products would try to convince the pharmacies to sell their product by offering discounts and bonuses to the pharmacies. That type of competition is called margin-competition. In the period concerned, when the covenant with industry was in force in which considerable price reductions for generic medicines had been agreed (see Recital (44)), the scope for such discounts and bonuses was reduced, but was still significant.
- (56) In the Netherlands, the Dutch Medicines Evaluation Board (MEB) considered both types of fentanyl patches, reservoir and matrix, as substitutable.<sup>59</sup> It was therefore possible for pharmacists to substitute between the fentanyl reservoir and matrix patches.<sup>60</sup> As confirmed by J&J, the MEB declared that both types of patches were bio-equivalent<sup>61</sup> and even rejected a proposal for variation of the Summary Product

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<sup>56</sup> However, in the relevant period it was not possible for pharmacists to substitute a product prescribed by a physician by a product which had a different active substance. Pharmacists were required by law to dispense a product with the prescribed active substance. See ID0825, p. 2.

<sup>57</sup> ÖBIG, *Surveying, Assessing and Analysing the Pharmaceutical Sector in the 25 EU Member States*, p 518. ID0711, p. 25. In theory, the patient could refuse substitution, but whenever only the cheapest generic medicine is reimbursed by his or her health insurer, the Dutch patient will be inclined to accept substitution and therefore not opt for (the more expensive) originator product for which he or she will have to make a co-payment (see footnote 51).

<sup>58</sup> ID0825, p. 2.

<sup>59</sup> ID0564, p. 3.

<sup>60</sup> ID0564, p. 3.

<sup>61</sup> ID1542, p. 11 and ID1544.

Characteristics which had been submitted by J&J due to invoked potential risks when switching between the two types of patches.<sup>62</sup>

#### 4. THE MARKET PLAYERS

##### 4.1. Undertakings subject to the present proceedings

(57) This Decision concerns the Co-promotion agreement between the Dutch company Janssen-Cilag B.V., a subsidiary of Johnson & Johnson, and the Dutch pharmaceutical companies Hexal B.V. and Sandoz B.V. The latter, Hexal B.V. and Sandoz B.V. were both, at the time of the alleged infringement, subsidiaries of Novartis AG.

###### 4.1.1. Johnson & Johnson

(58) **Johnson & Johnson** is the ultimate parent company of the Johnson & Johnson group of companies. It is a US-based pharmaceutical, medical devices and consumer packaged goods manufacturer that is one of the largest originator undertakings in the Union and worldwide. The corporation's headquarter is located in New Brunswick, New Jersey, United States of America.<sup>63</sup> Johnson & Johnson has more than 250 operating companies (including Janssen-Cilag B.V.) conducting business in virtually all countries of the world. In 2005, Johnson & Johnson achieved a worldwide consolidated turnover of more than EUR 40 billion. Its annual turnover generated with prescription medicines for human use in the 27 Member States in 2005 was over EUR 3 billion.<sup>64</sup> The worldwide consolidated turnover of Johnson & Johnson in 2012 was over USD 67 billion.<sup>65</sup>

(59) In the Netherlands, the undertaking Johnson & Johnson is active through its subsidiary **Janssen-Cilag B.V.**, registered in Tilburg, the Netherlands. Johnson & Johnson is the ultimate parent company of Janssen-Cilag B.V., indirectly owning 100% of the latter's shares through several intermediate companies.<sup>66</sup> In 2005, Janssen-Cilag B.V. had a turnover of over EUR 120 million of which transdermal fentanyl patches accounted for over EUR 24 million.<sup>67</sup>

###### 4.1.2. Novartis AG

(60) **Novartis AG** based in Basel, Switzerland, is the ultimate parent company of the Novartis group of companies.<sup>68</sup> The undertaking is a large pharmaceutical player, both for originator products and generic products, which it markets through its Sandoz division. In 2005, Novartis achieved worldwide consolidated net sales of

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<sup>62</sup> ID1542, p. 11 and 13.

<sup>63</sup> ID0307, p. 3.

<sup>64</sup> ID0531, p. 1.

<sup>65</sup> ID1616, p. 2 and Johnson & Johnson Annual Report 2012:  
<https://www.jnj.com/sites/default/files/pdf/JNJ2012annualreport.pdf>.

<sup>66</sup> ID0307, p. 2.

<sup>67</sup> ID0532, p. 1.

<sup>68</sup> ID0311, p. 3.

more than USD 32 billion<sup>69</sup> of which USD 12 billion were generated in Europe.<sup>70</sup> The worldwide consolidated turnover of Novartis AG for the financial year 2012 was EUR 44 billion.<sup>71</sup>

- (61) In 2005, Novartis AG acquired Hexal AG, a generic company established under German law. The acquisition was announced in February 2005 and completed on 6 June 2005. Hexal AG was active in the Netherlands through **Hexal B.V.**, a company with its registered office in Hillegom. Until 6 June 2005, Hexal B.V. was 100% owned by Hexal AG. From 6 June 2005, following the acquisition of Hexal AG by Novartis AG, Novartis AG became the ultimate parent company of Hexal B.V. From 6 June 2005 until 18 July 2005 Novartis AG indirectly owned 95% of Hexal B.V.'s shares and since 18 July 2005 Novartis AG has indirectly owned 100% of Hexal B.V.'s shares through several intermediate companies. On 12 September 2007, Hexal B.V. was merged into Sandoz B.V. and since then it no longer exists as a separate legal entity.<sup>72</sup>
- (62) **Sandoz B.V.** is a Dutch company offering healthcare products in pharmaceuticals, vaccines and diagnostics, generics, and consumer health sectors. Sandoz B.V. has its registered office in Almere, the Netherlands. The ultimate parent company of Sandoz B.V. is and has been at least since 1 January 2005 Novartis AG.<sup>73</sup> In the period concerned Novartis AG indirectly owned 100% of the shares of Sandoz B.V. through several intermediate companies.<sup>74</sup>

## 4.2. Other market players

- (63) Besides J&J and Novartis/Sandoz, there were other companies marketing fentanyl in the Netherlands in the period concerned or thereafter.

### 4.2.1. [Third party]\*

- (64) [...] \* [Third party]\* develops, produces and sells various pharmaceutical products as well as services. Its portfolio includes generic and innovative drugs, over-the-counter and hospital products as well as food supplements and skin care products.<sup>75</sup> [Third party]\* was [a strong]\* generic company on the Dutch market in the 2004-2009 period.<sup>76</sup>

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<sup>69</sup> ID0865, p. 2. Novartis Annual Report 2005, p. 16:

<http://www.novartis.com/downloads/newsroom/corporate-publications/Novartis-20-F-2005.pdf>.

<sup>70</sup> ID0866, p. 2. Novartis Annual Report 2005, p. 22:

<http://www.novartis.com/downloads/newsroom/corporate-publications/Novartis-20-F-2005.pdf>.

<sup>71</sup> ID1625, p. 2 and Novartis Annual Report 2012:

<http://www.novartis.com/downloads/investors/reports/novartis-annual-report-2012-en.pdf>.

<sup>72</sup> ID0311, p. 5.

<sup>73</sup> ID0311, p. 5.

<sup>74</sup> ID0311, p. 5.

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

<sup>75</sup> ID0869. [...]\*

<sup>76</sup> [...]\*

#### 4.2.2. *Ratiopharm Nederland B.V.*

(65) Ratiopharm Nederland B.V. is a Dutch subsidiary of Germany-based generic pharmaceutical company Ratiopharm GmbH (both companies are hereafter jointly referred to as "Ratiopharm"). Founded in 1987 as Magnafarma B.V., it was renamed in 2004, due to its acquisition by Ratiopharm GmbH. Ratiopharm GmbH has been itself since 2010 a subsidiary of Teva Pharmaceuticals Ltd.<sup>77</sup>

#### 4.2.3. *Nycomed B.V.*

(66) Nycomed B.V. (now Takeda Nederland B.V.) is a subsidiary of generic pharmaceutical company Nycomed, which has its headquarters in Switzerland. It is a pharmaceutical company that provides medicines for hospitals, specialists and general practitioners, as well as – on selected markets – over-the-counter products. Nycomed, the parent company, was acquired by Takeda Company Ltd in 2011. In June 2012, Nycomed B.V. was renamed Takeda Nederland B.V.<sup>78</sup>

#### 4.2.4. *Actavis B.V.*

(67) Actavis B.V. is a subsidiary of the Swiss-based generic pharmaceutical company Actavis Group HF. It has its registered office in Baarn, the Netherlands, and sells generic products for retail and hospital, branded- and over-the-counter products.<sup>79</sup> The company is one of the top three generic suppliers in the Netherlands. It joined the Actavis Group in 2005 as a result of Actavis' acquisition of Alpharma's generic business.<sup>80</sup>

## 5. DESCRIPTION OF THE MARKET

(68) This section describes the product concerned, the fentanyl patch, and sets out the development of the Dutch market for fentanyl patches, including the main players active on the market in the period concerned or shortly thereafter.

### 5.1. The product

(69) Fentanyl is the generic, international non-proprietary name of a synthetic opioid which is 80 to 100 times stronger than morphine. It is used to treat chronic pain. Chronic pain is defined as a pain episode with duration of over 3 months. The most widespread chronic pain conditions are cancer-associated pain, low back pain and osteoarthritis.<sup>81</sup> Fentanyl was initially approved for cancer pain only, but after clinical studies in the non-cancer pain setting, it was approved for chronic intractable pain in many countries.

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<sup>77</sup> ID0867. <http://www.ratiopharm.de/index.php?id=340>  
<sup>78</sup> ID0868. <http://www.nycomed.com/nl/about-nycomed/>  
<sup>79</sup> ID0860. <http://www.actavis.nl/nl/default.htm>  
<sup>80</sup> ID0860. <http://www.actavis.nl/nl/default.htm>  
<sup>81</sup> ID0143, p. 85.

- (70) Fentanyl was introduced as an intravenous anaesthetic by J&J in the 1960's. The fentanyl compound patent expired already in 1982.<sup>82</sup>
- (71) Fentanyl is used in the hospital sector and is also prescribed for personal use out of hospitals. In the latter case it is dispensed to patients by pharmacies. One can therefore distinguish between the hospital channel and the retail channel.<sup>83</sup>
- (72) Fentanyl sales in the Union in 2005 amounted to EUR 641 million and in the Netherlands to EUR 27 million.<sup>84</sup> In 2006, fentanyl sales in the Union amounted to EUR 668 million and in the Netherlands to EUR 28 million.
- (73) In many countries fentanyl is classified as a narcotic and, as such, its distribution is subject to even stricter rules than ordinary prescription medicines. In the Netherlands, the legal and regulatory framework is provided by the Opium Act ("*Opiumwet*").<sup>85</sup> Fentanyl falls under the list of substances that are considered to be hard drugs in the Opium Act. In addition to the general requirements that apply to medicines, there are some additional requirements that apply to Fentanyl such as that pharmacist and physicians operating pharmacies have to save the prescriptions separately from the other prescriptions and have to obtain an acknowledgement of receipt upon delivery of which a copy will be kept.<sup>86</sup>
- (74) The European Pharmaceutical Market Research Association (EphMRA) maintains a classification of molecules<sup>87</sup>, in which fentanyl belongs to the subgroup of narcotics (N2A), which contains "*all analgesics classified as narcotics in accordance with the legal definition of narcotics analgesics in each country*".<sup>88</sup> The N2A subgroup of narcotics, in the EphMRA classification, contains a number of molecules, among which the following:
- natural opium alkaloids such as morphine, hydromorphone or oxycodone;
  - pencylpiperidine derivates such as fentanyl, pethidine;
  - diphenylpropylamine derivatives such as dextromoramide, piritramide or methadone;
  - benzomorphan derivatives such as pentazocine;
  - oripavine derivatives such as buprenorphine;
  - morphinan derivates such as nalbuphine; and

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<sup>82</sup> ID0141, p. 126.

<sup>83</sup> Over 90% of the fentanyl sales in the Netherlands were retail sales out of hospitals. See ID0404, p. 6.

<sup>84</sup> ID0955, p. 2, including forms of fentanyl such as "*intranasal variant (nose spray)*", "*oral variant (tablets)*" and "*intravenous variants*".

<sup>85</sup> Law of 12 May 1928, containing regulations concerning opium and other narcotic substances (*Wet van 12 mei 1928, tot vaststelling van bepalingen betreffende het opium en andere verdoovende middelen*). ID0554, p. 3.

<sup>86</sup> ID0529, p. 2-5 and ID0554, p. 3-4.

<sup>87</sup> ID0862. [http://www.whocc.no/atc\\_ddd\\_methodology/the\\_ephmra\\_classification\\_system/](http://www.whocc.no/atc_ddd_methodology/the_ephmra_classification_system/)

<sup>88</sup> ID1064, p. 5. <http://www.ephmra.org/pdf/WHO-ATC%202012.pdf>, p. 52.

- narcotics in combination with antispasmodics.

(75) Fentanyl<sup>89</sup> is, to date, available in the form of transdermal patches, which is the most commonly used form, but also intravenous injection, oral buccal tablet or a lollipop, and, as of 2009, a nose spray.<sup>90</sup>

(76) The transdermal patch containing fentanyl was launched in the mid-1990's by J&J. Two main types of the transdermal patches have been introduced until today: the depot (reservoir) patch and the matrix patch.

#### 5.1.1. *Depot patch*

(77) The depot patch (also called reservoir patch) has a small reservoir containing an inert alcohol gel infused with selected fentanyl doses. The reservoir containing the gel is fixed on the skin to provide constant administration of the opioid over a period of 48 to 72 hours. This means that a patient with chronic pain who needs strong analgesia only needs to replace the patch every three days. The delivery system also helps to reduce breakthrough pain, which can occur between doses of more frequently taken painkillers.

#### 5.1.2. *Matrix patch*

(78) The follow-on product (so-called "second generation product"), the matrix patch, comprises two thin layers: a translucent polyethylene film and an adhesive matrix containing the active ingredient (fentanyl). The active ingredient fentanyl is thus contained in the adhesive matrix rather than in a gel-reservoir as with the depot patch. According to J&J, the matrix patch provides additional patient benefits in adhesion, wearability and discretion and allows the technical opportunity to develop a smaller (in size and also potency) version of the patch, which was not possible with the depot patch.<sup>91</sup> In its reply to the Statement of Objections Novartis/Sandoz also

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<sup>89</sup> According to the statements quoted in J&J's presentation on Durogesic from 10 January 2005, "[t]here is broad clinical and preclinical experience from worldwide application in all patient and age groups. It seems that the transdermal application of transdermal fentanyl is more advantageous than other opioids." (ID0136, p. 458). "Based on data from studies [...] transdermal Fentanyl is the superior treatment available at this time." (ID0136, p. 458) "The transdermal fentanyl has some advantages over slow release morphine. ... eg. less constipation. In addition, the rate of nausea and vomiting is less under transdermal fentanyl. Patients who are treated with a stable dose of transdermal fentanyl could participate actively at road traffic." (ID0136, p. 458).

<sup>90</sup> In J&J's document entitled "EMEA and Western Europe Quarterly Business Update for Johnson & Johnson Investor Relations. Fourth Quarter 2006" (ID0145, p. 46), Durogesic is placed amongst "Pain (LA [long-acting] Opioids)". The Report provides data on a quarterly basis and covers the period from the fourth quarter 2005 to the third quarter of 2006. The following average shares of sales are provided for that period for the products covered:

Durogesic – 56.4% by value and 43.8% by volume;  
 Buprenorphine – 10.6% by value and 10.0% by volume;  
 Oxycodone – 16.8% by value and 13.3% by volume;  
 Hydromorphone – 5.3% by value and 3.4% by volume;  
 Dihydrocodeine – 1.0% by value and 6.9% by volume; and  
 Morphine – 9.9% by value and 22.6% by volume. (ID0145, p. 75-76).  
 See also Recital (107).

<sup>91</sup> ID0143, p. 86 and ID1542, p. 10-11.

claimed the "*newer fentanyl matrix patches exhibited numerous superior features when compared to the older fentanyl depot patches*".<sup>92</sup>

- (79) In the Netherlands, the MEB considered the two types of patch, reservoir and matrix, as substitutable (see section 3.4.3).

## 5.2. Development of the Dutch market

- (80) This section describes activities of the main players marketing fentanyl patches in the Netherlands in particular in the period concerned.<sup>93</sup>

### 5.2.1. Originator

#### 5.2.1.1. J&J

- (81) J&J has been active in the area of pain relief for many years. Fentanyl patches marketed under the brand name Durogesic are still one of the most important blockbuster products in J&J's portfolio, accounting for USD 589 million worldwide revenues in 2011.<sup>94</sup> In 2005, J&J's sales of Durogesic amounted to more than EUR 575 million in the Union<sup>95</sup> and to USD 1.6 billion worldwide.<sup>96</sup>
- (82) The depot patch was developed by J&J's partner Alza Corporation (hereafter "Alza") in the mid-1980's. As Alza was acquired by J&J in 2001, ownership of the depot patch was transferred to J&J.<sup>97</sup> The first marketing authorisation for Durogesic in the

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<sup>92</sup> ID1537, p. 4.

<sup>93</sup> This section concentrates on originator and generic companies. Regarding parallel trade, Novartis/Sandoz argued in its reply to the Statement of Objections that "*fentanyl's status as a controlled substance under Schedule 1 of the Dutch Opium Act (Opiumwet) was a significant factor in the economic context because it acted as a hurdle for parallel traders*" (ID1537, p. 9.). This statement is not in line with the evidence on the file. Contemporaneous documents indicate that parallel trade with fentanyl patches was taking place in the Netherlands in the period before or around the entry into force of the Co-promotion agreement despite the specific regulatory requirements. The Commission refers, for example, to Janssen-Cilag B.V.'s "*Durogesic Business Plan 2005*" (ID0635, p. 2), which provides information and data on the level of "*parallel imports*" of fentanyl patches to the Netherlands prior to the entry into force of the Co-promotion agreement. Moreover, in its reply to the Statement of Objections J&J submitted an expert paper "*Transdermal Fentanyl Systems: Potential Risks Of Inadvertent Changing Between Different Transdermal Fentanyl Systems*"<sup>93</sup> prepared in 2005 which mentions parallel trade with fentanyl depot patches: "*It is estimated that, at the time of switching between DUROGESIC® reservoir and DUROGESIC® D.TRANS formulations, both products will co-exist in the market for a short period of time, even though Janssen-Cilag intends to solely market DUROGESIC® D.TRANS in Europe owing to parallel importation of the DUROGESIC® reservoir.*" (ID1546, p. 5). J&J also annexed to its reply the Dutch MEB's Press Release from 4 March 2005 entitled "*Gelijke werkzaamheid bij fentanyl bevattende pleisters (Durogesic)*" (translation: Equal efficacy in patches containing fentanyl (Durogesic)) which states: "*De parallel geïmporteerde Durogesic pleisters kunnen nog bestaan uit een reservoir systeem.*" (translation: The parallel imported Durogesic patches may still consist of a reservoir system.) (ID1544, p. 1).

<sup>94</sup> ID0863, p. 2. Johnson & Johnson's Form 8-K, Current Report Pursuant to Section 13 or 15(d) of the Securities Exchange Act of 1934, dated 24 January 2012, p. 24.

<http://files.shareholder.com/downloads/JNJ/2121757214x0xS1445305-12-96/200406/filing.pdf>

<sup>95</sup> ID0531, p. 1.

<sup>96</sup> ID0864, p. 2. Johnson & Johnson 2005 Annual Report, p. 27.

<http://files.shareholder.com/downloads/JNJ/2123370872x0xS950123-06-3129/200406/filing.pdf>

<sup>97</sup> ID0334, p. 7.



EEA was obtained in March 1994 in the United Kingdom.<sup>98</sup> Later the depot patch was also launched in the other Member States, including the Netherlands in 1995. According to J&J, in July 2005 the depot patch lost patent protection "*in the main (G5) European markets*" except for Spain, that is to say in Germany, France, the United Kingdom and Italy.<sup>99</sup> However, "*Durogesic patches were not protected by a patent in the Netherlands. Initially, Alza Corporation filed a patent application for the reservoir patch in the Netherlands in 1985. [...] According to Janssen-Cilag's information, Alza's patent application for the reservoir patch in the Netherlands was abandoned by Alza in the course of 1993.*"<sup>100</sup>

- (83) Depending on the Member State, data exclusivity expired either on 4 March 2000 or, as is the case for the Netherlands, on 4 March 2004.<sup>101</sup> In the Netherlands therefore the depot patch lost exclusivity on 4 March 2004.
- (84) In 2004, J&J introduced the follow-on product, the matrix patch (D-Trans or Durogesic SMAT). In 2002, three patent applications relating to the matrix patch were filed with the European Patent Office (EPO). For further details regarding the patent situation and the final revocation of the Matrix Patch Patent, see Recital (23).
- (85) Following the introduction of the matrix patch, J&J stopped marketing the depot patch in most Member States between August 2004 (for Sweden and Finland) and January 2010 (for Malta), and replaced it with its matrix patch.<sup>102</sup> In the Netherlands, the matrix patches were launched in August 2004 and, according to J&J, J&J sold the last batches of its reservoir patches in November 2004, which was followed by the product stocks at wholesaler, hospital and pharmacy level being depleted over time.<sup>103</sup>
- (86) Initially, the depot patch and later the matrix patch were marketed in various strengths, based on the release rate of the active ingredient to the skin, namely 25 µg/hour, 50 µg/hour, 75 µg/hour and 100 µg/hour. As from the beginning of 2005, J&J also launched the 12.5 µg/h dosage of the matrix patch in several Member States as a line extension. For the Netherlands, J&J launched the 12.5 µg/h dosage of the matrix patch in January 2005.<sup>104</sup>
- (87) As regards pricing, between January 2004 and February 2007 Janssen-Cilag B.V. had to change the price of its Durogesic product (both depot and matrix) several times, following the revisions of the maximum pharmacy purchase price by the Dutch Ministry of Health, Welfare and Sport.<sup>105</sup>

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<sup>98</sup> ID0136, p. 159.

<sup>99</sup> ID0682, p. 10.

<sup>100</sup> ID0682, p. 10.

<sup>101</sup> ID0136, p. 159 and ID0682, p. 9.

<sup>102</sup> ID0530, p. 1-27.

<sup>103</sup> ID0530, p. 20 and ID0529, p. 2. According to Novartis/Sandoz, the older depot patches were no longer marketed in the Netherlands by February 2005 (see ID1537, p. 4.). In any event, the depot patches were therefore not marketed in the Netherlands by the time the Co-promotion agreement was concluded.

<sup>104</sup> ID0530, p. 20.

<sup>105</sup> ID0800, p. 2.

(88) In January 2007, when the permanent entry of an independent generic competitor (Ratiopharm) became inevitable, J&J launched its "own generic" of the matrix patch in order to be able to run a "two-price strategy" (see section 5.2.2.3). At that point in time, Janssen-Cilag B.V. entered into a supply agreement with Hexal B.V./Sandoz B.V. [...] which enabled Hexal B.V./Sandoz B.V. [...] to market J&J's matrix patches under their respective names.

### 5.2.2. Generics

(89) Well before the depot patch lost exclusivity in the Union and J&J replaced it with the matrix patch, several generic companies tried to develop their own fentanyl patches with varying success as the production of transdermal patches is technically complex. After the loss of exclusivity, generic players entered the national markets in the Union and in 2007, fentanyl was already number 3 of the top selling prescription medicines in the generic segment with sales of generic fentanyl products accounting for more than EUR 108 million in the Union.<sup>106</sup>

(90) The following generic players have been active on the national markets in the Union with fentanyl transdermal patches and especially in the Netherlands.

#### 5.2.2.1. Novartis/Sandoz

(91) Hexal AG and its subsidiaries started to develop a generic fentanyl patch already in March 1999. It was the first generic company that managed to develop its own fentanyl transdermal depot patch (hereinafter "Novartis/Sandoz depot patch").

(92) The Novartis/Sandoz depot patch was marketed under the brand "Fentanyl-Hexal TTS". In handwritten notes, J&J's [employee]\* stated that "*Tests appeared to show that Hexal reservoir was equivalent to our matrix*"<sup>107</sup>, that is to say, J&J's second generation product.

(93) Hexal AG, including its subsidiaries, obtained the first marketing authorisation within the Union for its depot patch in July 2004 in Finland, followed by marketing authorisations in other Member States in the course of 2005.<sup>108</sup> According to Novartis/Sandoz, the Novartis/Sandoz depot patch was launched first in June 2005 in Sweden, and following the expiry of J&J's depot patch patents in the main Union markets in July 2005, also in Germany, the United Kingdom, Poland, Finland, Hungary and Ireland in August 2005.<sup>109</sup>

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<sup>106</sup> See European Commission, DG Competition: Report on the pharmaceutical sector inquiry, 8 July 2009, p. 60.

<sup>107</sup> ID0138, p. 272. "*Hexal reservoir blijkt uit testen [...] equivalent @ onze matrix*".

<sup>108</sup> ID0472, p. 1-2.

<sup>109</sup> ID0555, p. 1-2. In its reply to the Statement of Objections (ID1542, p. 18), as well as in its comments on the Letter of Facts (ID1702, p. 2), J&J submitted that J&J's contemporaneous market intelligence indicates that Novartis/Sandoz launched its generic fentanyl depot patch in (late) August 2005 only in Germany and the United Kingdom and in the other five countries only on 1 September 2005. Hence there could be a discrepancy of up to 30 days in the information invoked by the parties concerning the launch dates of Novartis/Sandoz's depot patch in those five Member States. Given that the product was launched by Novartis/Sandoz, the Commission, in case there were any discrepancy in the information provided, relies on the information provided by Novartis/Sandoz in its reply to the Commission's

- (94) In the Netherlands, the marketing authorisation for the Novartis/Sandoz depot patch was granted in March 2005<sup>110</sup> and the pricing and reimbursement status in April 2005.<sup>111</sup> However, although the marketing authorisation and the pricing and reimbursement decision were granted, the Novartis/Sandoz depot patch was never actually launched in the Netherlands. Instead, Novartis/Sandoz entered into the Co-promotion agreement with J&J. Novartis/Sandoz abstained from launching its depot patch in the Netherlands for the whole duration of the Co-promotion agreement, which lasted from 11 July 2005 until 15 December 2006 (addendum included).
- (95) In parallel to the depot patch, Novartis/Sandoz also developed its own fentanyl matrix patches. In fact, Novartis/Sandoz had two development projects for matrix patches: (i) the first development project used J&J's depot Durogesic as the reference product and resulted in "Fentanyl Hexal MAT" (also known as FTY TTS); (ii) the second development project used J&J's matrix Durogesic as the reference product and resulted in "Fentanyl Hexal S" (also known as FLY TTS).<sup>112</sup>
- (96) Fentanyl Hexal MAT was first launched in the Union in Germany in December 2005 and later also in other Member States.<sup>113</sup> The other version of Novartis/Sandoz's matrix patch, Fentanyl Hexal S, was then launched in November 2008 in Germany.<sup>114</sup> As regards the Netherlands, Novartis/Sandoz launched a matrix patch under its own brand only in January 2007, after the Co-promotion agreement with J&J was terminated. However, J&J supplied that matrix patch to Novartis/Sandoz in the framework of a supply agreement signed in October 2006 and valid for the period from 1 January 2007 to 31 December 2008.<sup>115</sup> The supply agreement was terminated by the end of 2008<sup>116</sup> and as of January 2009 Novartis/Sandoz started to market its own fentanyl matrix patch.<sup>117</sup>

#### 5.2.2.2. Ratiopharm

- (97) Ratiopharm was considered by J&J as a less imminent potential competitor.<sup>118</sup> But despite the fact that Novartis/Sandoz had the marketing authorisation in the Netherlands since March 2005, after it had entered into the Co-promotion agreement it was Ratiopharm that was the first company to actually attempt to enter the market with a generic fentanyl patch (matrix) in the Netherlands on 1 February 2006, almost two years after the loss of exclusivity and almost seven months after the Co-promotion agreement between Janssen-Cilag B.V. and Hexal B.V./Sandoz B.V. was signed. Ratiopharm's presence on the market was only very short. In February 2006

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request for information under the obligation set out in Article 18 rather than on J&J's market intelligence. In any event, the difference in timing of the launch of the product claimed by J&J is only minor and does not have any significance for the legal assessment of the infringement at hand.

<sup>110</sup> ID0471, p. 3 and ID0472, p. 2.

<sup>111</sup> ID0472, p. 2.

<sup>112</sup> ID0471, p. 5.

<sup>113</sup> ID0555, p. 1-2.

<sup>114</sup> ID0555, p. 1-2.

<sup>115</sup> ID0135, p. 103-120 and ID0161, p. 317.

<sup>116</sup> ID0554, p. 5.

<sup>117</sup> With the exception of Novartis/Sandoz's 12.5 µg/h version, which was sold in the Netherlands already from August 2008. See ID0554, p. 6 and ID0555, p. 1-2.

<sup>118</sup> See, for example, Recital (134) and Recital (178).

Janssen-Cilag B.V. filed a complaint with the Dutch Medicines Evaluation Board ("MEB") for the alleged circumvention of the mutual recognition procedure for marketing authorisation by Ratiopharm and in parallel Janssen-Cilag B.V. filed summary administrative court proceedings. On 15 March 2006 Janssen-Cilag B.V. obtained a positive interim court decision that led to the suspension of the marketing authorisation of the Ratiopharm's generic fentanyl matrix patch. Ratiopharm therefore had to leave the market on 15 March 2006. Ratiopharm's presence on the Dutch market in this period therefore lasted only from 1 February 2006 to 15 March 2006.<sup>119</sup>

- (98) In the same proceedings, the Dutch Medicines Evaluation Board (MEB) adopted a new decision on 9 June 2006. With that MEB decision Ratiopharm could attempt to enter the market again. Ratiopharm re-launched its generic fentanyl matrix patch in the Netherlands, but J&J filed an appeal and obtained another positive court decision on 28 July 2006 that again suspended the marketing authorisation for Ratiopharm's generic fentanyl matrix patch until the decision on the merits. Ratiopharm's second short presence on the market therefore lasted from 9 June 2006 to 28 July 2006. The case was finally closed after Ratiopharm's withdrawal of the marketing authorisation in the last quarter of 2006.<sup>120</sup>
- (99) As the two temporary entries by Ratiopharm were very short they did not trigger the termination of the Co-promotion agreement between Janssen-Cilag B.V. and Hexal B.V./Sandoz B.V.<sup>121</sup>
- (100) In the meantime, Ratiopharm submitted a new marketing authorisation application and, on that basis, obtained a new marketing authorisation for a generic fentanyl matrix patch in the Netherlands on 21 December 2006. Shortly thereafter, in February 2007, Ratiopharm re-launched a generic fentanyl matrix patch on the Dutch market, this time on a permanent basis.

#### 5.2.2.3. J&J's own generic

- (101) Beside its Durogesic brand, J&J launched the same fentanyl matrix patch in the Netherlands as its "own generic" under a second brand name "Fentanyl Matrix J-C" in January 2007, to be able to run a two-price-strategy in order to better compete with generic prices after it was clear that independent generic entry was inevitable.<sup>122</sup>

#### 5.2.2.4. [Third party]\*

- (102) While being the [strong]\* generic market [player]\* and interested in the Fentanyl business, [third party]\* has not developed any own fentanyl transdermal patches.<sup>123</sup>

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<sup>119</sup> See ID0161, p. 19, ID0137, p. 287, ID0141, p. 132 and ID0334 p. 13.

<sup>120</sup> See ID0137, p. 332, ID0141, p. 132 and ID0334 p. 13.

<sup>121</sup> See for example J&J's internal email from April 2006: *"On March 15 [2006], JC NL [Janssen-Cilag B.V.] won the court case against MEB with the implication that Ratiopharm had to stop immediately selling their patch and that Durogesic could return to its original price. As a consequence, Durogesic sales in the NL are again up to speed."* ID0137, p. 287. See also Recital (166).

<sup>122</sup> ID0135, p. 622.

<sup>123</sup> It has never applied for a marketing authorisation for the depot patch in any EEA Member State. ID0408, p. 2-3.

As regards the matrix patch, [third party]\* relied on the rights owned by other companies, namely [...] and its partner [...]\*, rather than developing its own fentanyl matrix patches in-house. However, [...] was granted a marketing authorisation for fentanyl matrix patches in Denmark [...] almost two years after Novartis/Sandoz had obtained its first marketing authorisation for the generic fentanyl depot patch in Finland.

- (103) [Third party]\* then initiated a Mutual Recognition Procedure ("MRP") [...] based on the [...] marketing authorisation in Denmark. The MRP procedure included, inter alia, an application to the MEB in the Netherlands. However, the procedure was severely delayed, because some Member States raised major public health issues during the Mutual Recognition Procedure. In [...] 2008 the Committee for Medicinal Products for Human Use (CHMP) recommended the refusal of the granting of marketing authorisation and the suspension of already granted marketing authorisations where appropriate.<sup>125</sup> [Third party]\* therefore did not have its own marketing authorisation for transdermal fentanyl patches in the Netherlands.
- (104) Already in October 2005, J&J reported internally that [third party]\* was searching for a partner, notably for a duplex registration for fentanyl patches for the Dutch market.<sup>126</sup> J&J considered [third party]\* as a strong generic market player in the Netherlands, even stronger than Hexal B.V.<sup>127</sup> As [a strong]\* generic market [player]\* in the Netherlands, [third party]\* had a sales force with experience in generic and even "innovative"<sup>128</sup> medicines. [...] <sup>129</sup> [...]\*.<sup>130</sup>
- (105) [...] The supply agreement between J&J and [third party]\* was then finalised and signed in [...]\*.<sup>131</sup> [Third party]\* launched the transdermal fentanyl patches in the Netherlands under the brand name [...]\*.<sup>132</sup>

#### 5.2.2.5. Nycomed, Actavis

- (106) Both companies entered the Dutch market with generic fentanyl transdermal matrix patches later. The first sales of transdermal fentanyl patches marketed in the Netherlands by Nycomed took place in June 2007, but its sales were marginal.<sup>133</sup> The first sales of transdermal fentanyl patches marketed in the Netherlands by Actavis took place only in January 2009.<sup>134</sup>

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<sup>124</sup> ID0408, p. 12.

<sup>125</sup> ID0408, p. 12.

<sup>126</sup> ID0137, p. 339.

<sup>127</sup> ID0137, p. 339.

<sup>128</sup> ID0163, p. 91.

<sup>129</sup> [...]\*.

<sup>130</sup> ID0408, p. 13.

<sup>131</sup> ID0135, p. 121-137.

<sup>132</sup> ID0933, p. 3.

<sup>133</sup> ID0933, p. 3.

<sup>134</sup> ID0933, p. 3.

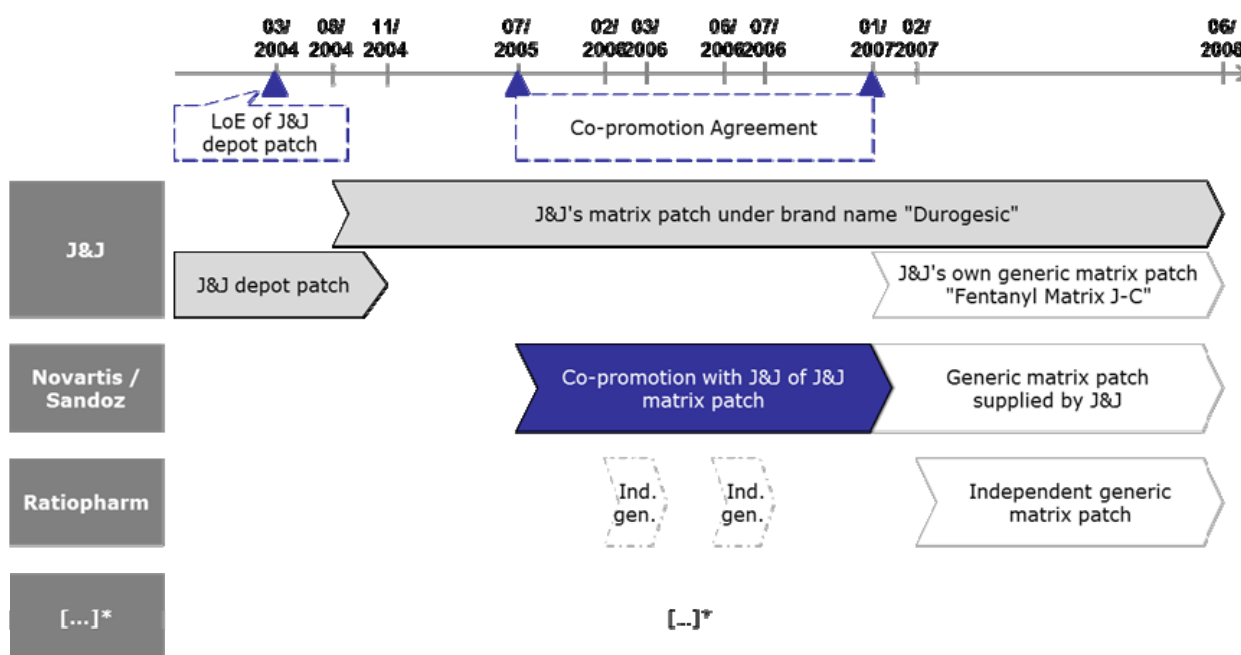
### 5.2.3. Summary of the development of the Dutch market

(107) On the basis of the information of sections 5.2.1 and 5.2.2, the development of the Dutch market can be summarised as follows.

- The only undertaking that has ever launched the fentanyl depot patch in the Netherlands is J&J. J&J sold the last batches of its depot patches in the Netherlands in November 2004.
- Between November 2004<sup>135</sup> and January 2007 J&J's matrix patch was the only fentanyl product marketed in the Netherlands, except for two short temporary failed attempts to enter by Ratiopharm in 2006.
- In January 2007 Novartis/Sandoz [...] launched, under their respective names, the generic matrix patch [...]\*. J&J also launched its own generic matrix patch in January 2007. Ratiopharm, the first independent generic, launched its matrix patch in the Netherlands in February 2007.
- [...]\*

(108) The graph below provides a summary overview of the market entry and presence of the main players marketing transdermal fentanyl patches in the Netherlands between the beginning of 2004 and June 2008.

**Graph: Launch of fentanyl patches in the Netherlands**



Source: Commission

<sup>135</sup> See also Recital (85) and footnote 93.

## 6. THE CO-PROMOTION AGREEMENT

### 6.1. The negotiations

- (109) This section describes, based on the available evidence and in particular on the contemporaneous documents, the initial preparations of J&J for the negotiations with Hexal B.V./Sandoz B.V. concerning the co-operation on fentanyl patches in the Netherlands, the actual negotiations, the finalisation of the Co-promotion agreement and its signature.
- (110) After the loss of exclusivity of the fentanyl depot patch in the Netherlands in March 2004, any generic company could have entered the Netherlands market with its own fentanyl patches. J&J was aware that Hexal B.V. was in an advanced stage of development of its generic fentanyl depot patch and may be capable of launching the product in the Netherlands in the foreseeable future. In June 2004 Janssen-Cilag B.V. prepared an internal note "*Action list, Business Plan Presentations, 14-17 June 2004*" which provided a "to do" list per molecule. For Durogesic it stated: "*After the launch of matrix conduct market research among general practitioners and pharmacies concerning their willingness to still switch from matrix to generic reservoir. [...] Work out a project on how to position the depot patch of Hexal as inferior. Research the possibility of cooperation with Hexal as a pre-emptive strategy for the arrival of the matrix generic.*"<sup>136</sup>
- (111) The following email from July 2004, exchanged within the management of Janssen-Cilag B.V., summarised market intelligence concerning generic fentanyl patches and further stated: "*What does this mean for our upcoming talk with Hexal? - Introduction of generic matrix not before July 2005. If bio-equivalence and/or patent issues pose problems then maybe only in 2006. - Hexal knows they are running behind with the matrix and are probably attempting to make a deal with us so that they can launch at the same time. As possible means to put pressure on us they have the reservoir patch (from Finland). It is in our interest that the reservoir patch does not come on the market before the other matrix patches because of possible price drops. We should come to an agreement that we give a duplex registration as soon as another matrix comes onto the market, in return the reservoir patch is not to be introduced.*"<sup>137</sup>

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<sup>136</sup> ID0155, p. 22-23. "*Voer na introductie van de matrix marktonderzoek uit bij huisartsen en apothekers naar de bereidheid om dan nog te switchen van matrix naar generiek reservoir. [...] Werk project uit hoe de depot-pleister (Hexal) als inferieur te positioneren. Onderzoek de mogelijkheid van samenwerking met Hexal als pre-emptive strategie voor de komst van matrix generiek.*"

<sup>137</sup> ID0155, p. 46. "*Wat betekent dat voor ons en aanstaande gesprek met Hexal: - introductie van generieke matrix niet voor juli 2005, mochten bio-equivalente en/of patent issues nog roet in het eten gooien dan misschien pas in 2006. - Hexal weet dat ze achterlopen met de matrix en proberen waarschijnlijk met ons een deal te maken zodat ze gelijktijdig kunnen introduceren. Als mogelijk dwangmiddel hebben ze de reservoir patch (verg. Finland). Het is in ons belang om de reservoir patch niet voor de andere matrixpleisters op de markt te hebben vanwege mogelijke prijsdaling. We zouden tot een afspraak kunnen komen dat we hen een matrix duplex registratie geven zodra een andere matrix op de markt komt, tegenprestatie is geen reservoir introduceren.*"

- (112) As part of J&J's "comprehensive strategic response to the generic challenge"<sup>138</sup>, the "Project Team Durogesic Generics" was established in the Netherlands. The minutes of the Project Team Durogesic Generics meeting on 7 October 2004 stated:

*"Assumptions Launch Generics in NL:*

- *Launch Fentanyl Reservoir Patch (probably only Hexal) Q2 2005*
- *Launch Fentanyl Matrix patches (>3) Q1 2006*
- *Price reduction Durogesic D-Trans after introduction of generic fentanyl: -21%*
- *Introduction "covenant": expected general price reduction of generics: 33%"<sup>139</sup>*

At that time J&J therefore expected Hexal B.V. to launch the depot patch in the Netherlands in the second quarter of 2005, well in advance of other potential generic entrants, which were preparing launch of matrix patches. The same document stated: "*Cooperation with Hexal: Aim: to block generic fentanyl reservoir patch in 2005*"<sup>140</sup>

- (113) Further market intelligence on Hexal's fentanyl patches was gathered by Janssen-Cilag B.V. in November 2004: "*Hexal realised four registrations in Finland to be able to cover the generic registration in Europe. [...] Hexal has certainly already started a European registration procedure. [...] This means that if everything goes well, Hexal can have its registration in the Netherlands at the end of January 2005 and as the best case (for them!) after a quick reimbursement [decision] it could come on the market on 1 March 2005. [...] According to the insite information, Hexal has sufficient production capacity for patches. [...] Our strategy can be only a strategy of delay. Generic will in any event come. Pharmacokinetic differences between our reservoir and the matrix patch cannot be used in promotional activities because we argue that there are no clinical differences between the two forms.*"<sup>141</sup>
- (114) In the same chain of emails from November 2004, the [employee]\* of Janssen-Cilag B.V. concluded that Hexal's position was strong and that different scenarios should

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<sup>138</sup> ID0135, p. 414-415.

<sup>139</sup> ID0161, p. 338. "*Assumptions Launch Generics in NL:*  
- *Launch Fentanyl Reservoir patch (waarschijnlijk alleen Hexal) Q2 2005*  
- *Launch Fentanyl Matrix patches (>3) Q1 2006*  
- *Prijzdaling Durogesic D-TRANS na introductie generiek fentanyl: -21%*  
- *Invoering 'convenant': verwachte algemene prijsdaling generieken: -33%.*"

<sup>140</sup> ID0161, p. 339. "*Samenwerking Hexal. Doestelling: blokkeren Generiek Fentanyl Reservoir patch in 2005.*"

<sup>141</sup> ID0161, p. 324-326. "*Hexal heeft vier registraties in Finland gerealiseerd om generieke registratie in Europa te kunnen dekken. [...] heeft Hexal al zeker een Europese registratie procedure gestart. [...] Dit betekent dat als alles goed verloopt Hexal eind januari 2005 zijn registratie in Nederland kan hebben en als best case (voor hen!) na een snelle vergoeding per 1 maart 2005 op de markt zouden kunnen komen. [...] Volgens insite informatie heeft Hexal voldoende productie capaciteit voor pleisters. [...] Onze strategie kan alleen maar een strategie van vertraging zijn. Generiek gaat er toch komen. Farmacokinetische verschillen tussen onze reservoir en matrix pleister mogen promotioneel niet uitgedragen worden want we stellen dat er geen klinische verschillen tussen de twee vormen zijn.*"



be developed to face this challenge: "*The position of Hexal is thus strong. [...] could you please already prepare a base-line scenario (Hexal with own patch on the market by March 2004 [sic; 2005 is meant] (worst) and by June (best)) and a scenario with a construction whereby Hexal does not launch and gets a part of our cake.*"<sup>142</sup>

- (115) In December 2004, an email exchange within Janssen-Cilag B.V.'s management reported that the available data was not sufficient to produce an expert report demonstrating differences between Durogesic D-Trans (matrix) and the depot patch regarding effects on the skin.<sup>143</sup> The reply in the same chain of emails read as follows: "*Can you think up an alternative. We have very little time! Impact 7-8 million euro.*"<sup>144</sup> The following reply in the same chain of email stated: "*Alternative 1 is to frustrate registration. There is not much chance of this, as we see from the Board's latest messages. The most realistic approach is to make a deal with Hexal to survive 2005 in any event. We are preparing scenarios. A decision will be taken next week.*"<sup>145</sup>
- (116) On 22 December 2004, an internal email with various scenarios was sent by the [employee]\* of Janssen-Cilag B.V. to other members of Janssen-Cilag B.V.'s management. Two main scenarios were considered: (1) "*Competition situation*", that is to say the launch of a generic depot patch by Hexal B.V. either in March 2005 or in July 2005; (2) "*Cooperation*" with Hexal B.V.<sup>146</sup>
- (117) In case of competition, the effect was estimated to amount to loss of market share for Janssen-Cilag B.V. by 50% in case of Hexal B.V.'s launch in March 2005 or by 40% (that is to say, Janssen-Cilag B.V. would keep 60% market share) in the event of launch in July 2005. The financial loss for Janssen-Cilag B.V. due to a decline of the price level was estimated to amount to EUR 4.9 million (Hexal B.V.'s launch in March 2005) or EUR 2.1 million (launch in July 2005). This price effect was anticipated to be even worse if the generic price was set at 40% of the originator price ("*worst case*").<sup>147</sup>
- (118) As regards the cooperation scenario, the document states: "*General aim of cooperation: Until the arrival of the generic matrix (expected by beginning 2006) not to have a depot generic on the market and in that way to keep the high current price level and to ensure BP [Business Plan]. The cooperation means that Hexal is to introduce the original JC [Janssen-Cilag] packages on the (Dutch) market (cf. co-selling). An own generic (also duplex) must be prevented. [...] Additional parameters in the cooperation scenario: Discounts to the market by JACNL [Janssen-Cilag B.V.]*

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<sup>142</sup> ID0161, p. 324. "*De positie van Hexal is dus sterk.[...] zou jij alvast een base-line scenario kunnen opzetten (Hexal met eigen pleister in de markt per maart 2004 (worst) en per juni (best)) en een scenario met een constructie waarbij Hexal niet introduceert en een deel van onze koek krijgt.*"

<sup>143</sup> ID0161, p. 323.

<sup>144</sup> ID0161, p. 323. "*Willen jullie een alternatief bedenken. We hebben zeer weinig tijd! Impact 7-8 miljoen euro.*"

<sup>145</sup> ID0161, p. 323. "*Alternatief 1 is registratie frusteren. Dit heeft niet veel kans als we de laatste berichten van het College zijn [sic]. Meest reële initiatief is deal met Hexal maken om in ieder geval 2005 door te komen. We zijn hier mee bezig om scenario's uit te werken. Volgende week besluitvorming.*"

<sup>146</sup> ID0161, p. 39.

<sup>147</sup> ID0161, p. 39.

*stay at 2004 level. Prices stay at 2004 level. [...] Points to be discussed with Hexal in the cooperation scenario: [...] Purchase price of Durogesic for Hexal (e.g. 10 to 25% GIP?<sup>148</sup>). Possible additional compensation for co-selling by Hexal (e.g. 100.000 – 1.000.000?). Possibilities for extending the cooperation for 2006 (further co-selling or Duplex registration). Starting date of co-selling (March -> July?)."*<sup>149</sup>

- (119) These scenarios were further elaborated in J&J's internal presentation of 22 December 2004 concerning Janssen-Cilag's business plan for Durogesic in the Netherlands for 2005. A slide in the presentation with the title "*Supply deal. What's in it for*" contained the following points explaining the interests of both companies in the deal:

*"JANSSEN CILAG:*

- *no price (PPP<sup>150</sup>) reduction;*
- *additional NTS<sup>151</sup> for the Durogesic sold to Hexal;*
- *possible trade out with Itraconazol.*

*HEXAL PHARMA*

- *no price (PPP)reduction;*
- *incremental net profit;*
- *no 'loss' of market share;*
- *matrix in stead of depot patch."*<sup>152</sup>

The point of interest that was common to both parties was therefore "*no price reduction*" if the parties agreed on a co-operation deal, instead of competition.

- (120) In February 2005 the acquisition of Hexal AG and its subsidiaries by Novartis AG was announced.<sup>153</sup> It was effectively completed on 6 June 2005 and this acquisition eventually led to the merger of Hexal B.V. into Sandoz B.V. on 12 September 2007.

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<sup>148</sup> GIP means wholesalers' purchase price.

<sup>149</sup> ID0161, p. 39-40. "*Algemene doelstelling voor samenwerking: Tot aan komst van matrix generiek (verwachting begin 2006) geen depotgeneriek op de markt op te hebben en daarmee huidige hoge prijsniveau te handhaven en BP zeker te stellen. Samenwerking houdt in dat Hexal originele JC verpakkingen op de (Nederlandse) markt brengt (verg. co-selling). Eigen generiek (ook duplex) moet worden voorkomen. [...] Overige parameters in het samenwerkingsscenario: - Discounts naar de markt door JACNL blijven op niveau 2004 – Prijzen blijven op niveau 2004. Te onderhandelen punten met Hexal in samenwerkingsscenario: [...] - Inkoopprijs Durogesic voor Hexal (bv 10 tot 25% van GIP?) – Eventueel aanvullende vergoeding voor co-selling door Hexal (bv 100.000 – 1.000.000?) – De mogelijkheden voor verlenging van het samenwerkingstraject voor 2006 (verdere co-selling of Duplex registratie) – Start datum van co-selling (maart ->juli?)".*

<sup>150</sup> PPP means "Pharmacy purchase price", see Recital (43).

<sup>151</sup> NTS means "Net trade sales".

<sup>152</sup> ID0160, p. 13.

<sup>153</sup> ID0832, p. 1.

- (121) At that time, in February 2005, Hexal B.V. continued preparations for the launch of its own generic fentanyl patches in the Netherlands. This is illustrated by two internal documents prepared by Hexal B.V. in February 2005.
- (122) The first document<sup>154</sup> is a one-page analysis of three potential scenarios, which stated the following:

***"No cooperation***

*In this case Hexal B.V. will introduce its own depot patch in July.*

*In the case of more providers, AIP [Pharmacy Purchase Price] -/- 23%*

*Reduction of AIP [Pharmacy Purchase Price] market value by 4.4 mill. Euro (23% of 19.2 mill. Euro)*

*Plus additional reduction due to the covenant +/- 10%: € 1.9 mill. Euro*

*Hexal will give a discount of +/- 40% on the AIP [Pharmacy Purchase Price]. JC [Janssen-Cilag] a discount of 25%.*

*The generics will take over a market share of the trademarked product.*

*On a yearly basis:*

*Profit for HEXAL: €3,720,293*

*Loss for JC [Janssen-Cilag]:*

*Fall in price: € 3.747.548 (23% AIP + 10% covenant)*

*Extra discounts to be given: € 562.132 (-15%)*

*Loss of market share: € 2.747.735 (going up to 50%)*

***€ 7,057,415***

***Cooperation***

*In this case Hexal B.V. will bring launch JC's patches in July.*

*In this case there is no reduction of the AIP [Pharmacy Purchase Price]*

*Discounts can be also be kept lower.*

*Profit for Hexal: €2,991,328*

*Loss for JC [Janssen-Cilag]:*

*Loss of market share: € 4.168.244*

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<sup>154</sup> ID0172, p. 17.

*Profit from supplying Hexal:* € 490,382

*Difference:* €3,677,862

### **Proposal Hexal**

*In this case Hexal B.V. will launch JC's patches in March.*

*In this case there is no reduction of the AIP [Pharmacy Purchase Price].*

*Discounts can also be kept lower.*

*Profit for Hexal:* €3,935,958

*Loss for JC [Janssen-Cilag]:*

*Loss of market share:* € 5,484,531

*Profit from supplying Hexal:* € 648,239

*Difference:* €4,839,292<sup>155</sup>

<sup>155</sup>

ID0172, p. 17.

#### **"Geen Samenwerking:**

*In dit geval zal HEXAL B.V. haar eigen Depot pleister in juli introduceren op de markt.*

*Bij meerdere aanbieders AIP +/- 23%*

*Daling AIP waarde markt met 4,4 mln Euro (23% van 19,2 mln Euro)*

*Plus nog eens extra daling ivm convenant +/- 10%: € 1,9 mln Euro*

*Hexal zal een korting gaan geven van +/- 40% op de AIP. JC een korting van 25%.*

*Generiek zal marktaandeel overnemen van het specialite.*

#### **Op jaarbasis:**

*Dit levert HEXAL op €3.720.293*

*Dit kost JC:*

*Prijsverlaging: € 3.747.458 (23% AIP + 10% convenant)*

*Extra te geven korting: € 562.132 (15%)*

*Verlies marktaandeel: € 2.747.735 (oplopend tot 50%)*

**€7.057.415**

#### **Met Samenwerking**

*In dit geval zal HEXAL B.V. de Matrix pleisters van JC in juli op de markt brengen.*

*In dit geval is er geen daling van de AIP.*

*De te geven korting kan ook lager gehouden worden.*

*Dit levert HEXAL op: € 2.991.328*

*Dit kost JC:*

- (123) According to Hexal B.V.'s analysis, Hexal B.V. therefore expected to make an annual profit of EUR 3 720 293 under the option "*No cooperation*", in which case Hexal B.V. would bring its own depot patch on to the market in July 2005. Under that option, Janssen-Cilag B.V. was expected to incur a loss of EUR 7 057 415. Under the option "*With Cooperation*", in which case Hexal B.V. would bring the matrix patch of Janssen-Cilag B.V. on to the market in July 2005, Hexal B.V. was expected to make a profit of EUR 2 991 328, whilst Janssen-Cilag B.V. was expected to incur a loss of EUR 3 677 862.
- (124) The second document prepared by Hexal B.V. in February 2005 under the instructions of the [employee of]\* Hexal B.V.<sup>156</sup> was an internal presentation called "*Fentanyl patches*"<sup>157</sup> and dated 1 February 2005. Two alternative scenarios were considered: "*1. Depot patch – under own name (from July 2005), to be replaced with Matrix by Hexal in due course*" (that option is further referred to as "*Depot*") and "*2. Matrix patch – to bring the matrix patches on the market in cooperation with JC [Janssen-Cilag]*" (that option is further referred to as "*Matrix*").<sup>158</sup> The presentation mentioned estimated profits of Hexal B.V. under those two scenarios. The estimates were identical to the calculations in the document mentioned in Recital (122).
- (125) Pros and cons of both scenarios were summarised as follows:

***"Depot***

- + *new introduction*
- + *exclusive product*
- + *increasing market share*

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*Verlies marktaandeel* € 4.168.244  
*Winst op doorlevering Hexal* € 490.382  
*Verschil:* € **3.677.862**

***Voorstel HEXAL:***

*In dit geval zal HEXAL B.V. de Matrix pleister van JC in maart op de markt brengen.*

*In dit geval is er geen daling van de AIP.  
 De te geven korting kan ook lager gehouden worden.*

*Dit levert HEXAL op € 3.935.958*

*Dit kost JC:*

*Verlies marktaandeel:* € 5.484.531  
*Winst op doorlevering Hexal* € 648.239  
 € **4.839.292"**

<sup>156</sup>

ID0832, p. 3.

<sup>157</sup>

ID0172, p. 19. "*Fentanyl pleisters*"

<sup>158</sup>

ID0172, p. 24. "*1. Depot pleister – Onder eigen naam (vanaf juli 2005), Zal bij Hexal op termijn door Matrix vervangen worden 2. Matrix pleister – In samenwerking met JC de matrix pleisters op de markt brengen.*"

+ profit with a discount of 40% and a market share going up to 50% is €3.720.293.

+ less discounts on the label deals (agreement is increase in coverage means less discounts)

- AIP<sup>159</sup> -/- 23%

- Market is now Matrix

### **Matrix**

+ No switch problems

+ New relationship

- no market share

- JC [Janssen-Cilag] packaging

- Registration costs of Depot

- Profit with discounts of 15% and market share going up to 30% is € 2.991.328

**Difference** [between scenario Depot and scenario Matrix] is **€728.965.**<sup>160</sup>

- (126) The "Depot" scenario, that is to say the launch of Hexal B.V.'s own product, therefore seemed more beneficial for Hexal B.V. at that stage, at least from the financial point of view. However, the presentation also considered some "extra options". One of the extra options was the following: "Due to Hexal's launch, the PPPs [Pharmacy Purchase Price] have to be decreased by 23%. Annual turnover of 20 million Euro in AIP [Pharmacy Purchase Price] decreases by 4,6 million Euro.

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<sup>159</sup> AIP means "Apotheek Inkoop Prijs", which is translated into English as the "Pharmacy purchase price (PPP)". See Recital (43).

<sup>160</sup> ID0172, p. 37. "Depot  
+ Nieuwe introductie  
+ Exclusief product  
+ Groei marktaandeel  
+ Winst met een korting van 40% en een marktaandeel oplopend naar 50% is €3.720.293.  
+ Minder korting op labeldeals (afpraak is stijging in dekking is minder korting)  
- AIP -/- 23%  
- Markt is nu Matrix.

### *Matrix*

+ Geen switch problemen

+ nieuwe relatie

- Geen marktaandeel

- JC-verpakkingen

- Registratiekosten Depot

- Winst met korting van 15% en marktaandeel oplopend naar 30% is €2.991.328.

**Vershil is €728.965."**

*How much is it worth for JC [Janssen-Cilag] that Hexal does not launch?"*<sup>161</sup> In other words, Hexal B.V. was aware that due to the generic entry by Hexal B.V. the pharmacy purchase price of fentanyl patches in the Netherlands would have to be decreased by 23%, which would result in the decrease of the total annual fentanyl sales in the Netherlands by EUR 4.6 million. If Hexal B.V. did not enter the market, there would be no price decrease and the pharmacy purchase prices would stay at the same level. In that context, the question was raised "how much is it worth" for Janssen-Cilag B.V. that Hexal B.V. does not enter the market.

- (127) Sandoz B.V. planned the launch of the Novartis/Sandoz's fentanyl patch in the Netherlands for summer 2005. This is illustrated by its internal strategic presentation "Targets 2005" concerning the Netherlands prepared in March 2005 by the [employee]\* of Sandoz B.V. and the [employee]\* of Sandoz B.V. It included among the "Key Launch Assumptions" for 2005 the following statement: "Fentanyl – NL - launch date 02/07/2005".<sup>162</sup>
- (128) On J&J's side, in February 2005 the [employee]\* of Janssen-Cilag B.V. created a "Planning form 2005" which contained "Objectives" for various Janssen-Cilag B.V.'s products and for Durogesic it stated: "Durogesic: Meet BP [Business Plan] Durogesic NTS [Net Trade Sales] by delaying/preventing Hexal generic introduction in 2005."<sup>163</sup>
- (129) In March 2005, emails were exchanged internally within J&J (including J&J's subsidiaries in the Netherlands and Germany), trying to put together up to date background information on the fentanyl market and potential generic entrants, which would be used for preparation of the upcoming meeting between Janssen-Cilag B.V. and Hexal B.V. As part of that email exchange, the following question was also raised: "Would Hexal refrain from launching Reservoir if you agree on a co-selling deal?"<sup>164</sup>
- (130) In April 2005, different scenarios were considered again by Hexal B.V. A table entitled "Fentanyl Calculation"<sup>165</sup> dated 15 April 2005 contained two scenarios: "Scenario 1: Hexal introduces depot patch" and "Scenario 2: Hexal purchases Durogesic matrix patch from Janssen Cilag with early entry in July 2005". In that document the "net profit" of scenario 1, Hexal's launch of its own depot patch, was estimated at between EUR 2.2 and EUR 3.0 million, depending on the level of discounts to be offered and market share potentially acquired by Hexal B.V. in the Netherlands. From that presentation, scenario 2, that is to say not launching Hexal B.V.'s own depot patch and instead co-operating with Janssen-Cilag B.V., seemed to be more attractive from the financial point of view. The "positive difference" of scenario 2 compared to scenario 1 was estimated to be between EUR 1.6 and 2.4 million. The "pros and cons" of both scenarios were summarised as follows:

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<sup>161</sup> ID0172, p. 38. "Door introductie Hexal moeten de AIP's dalen met 23%. Jaaromzet in AIP van 20 miljoen Euro daalt met 4.6 miljoen Euro. Hoeveel is het JC waard, dat Hexal niet introduceert?"

<sup>162</sup> ID0174, p. 181.

<sup>163</sup> ID0160, p. 23.

<sup>164</sup> ID0161, p. 376.

<sup>165</sup> ID0172, p. 41.

***"Depot patch Hexal Development, sold under Hexal label/tradename***

*Pros*

- *New introduction (reputation)*
- *Competitive purchase price*
- *Portfolio coverage increases*
- *Exclusive generic (reputation)*
- *Sales visible in IMS/Farminform*

*Cons*

- *Market declines with at least 35% because of covenant*
- *Depot patch more difficult to switch because market is used to matrix patch.*

***Matrix patch from Janssen Cilag (Durogesic) originator product***

*Pros*

- *Higher net profit*
- *No switching problems*
- *Short lead time, low stock levels can be maintained*
- *When other generic companies register Fentanyl patches, we have access to a duplex registration from the matrix-patch from Janssen Cilag.*
- *Possibilities of access to other Janssen Cilag products such [as] Itraconazole, etc.*
- *During cooperation with Janssen Cilag, Hexal has time to develop a matrix Fentanyl Patch.*

*Cons*

- *Sales not visible in IMS/Farminform (because originator product is sold)<sup>166</sup>*

- (131) Janssen-Cilag B.V. prepared its own new version of various scenarios in May 2005. An earlier version is dated 13 May 2005 and it was slightly amended by a version dated 17 May 2005. Two scenarios were analysed in that document: "*Base Case: No Deal*" and "*Hexal deal as of August 2005*", in which case "*Hexal sells Durogesic matrix from Janssen-Cilag as of August 2005*". The "*Base Case: No Deal*" scenario contained the following assumptions for 2005 and 2006:

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<sup>166</sup> ID0172, p. 41.



"Assumptions 2005:

1 Hexal enters market in August 2005 with own depot patch

2 Hexal sets price at approx. PPP [Pharmacy Purchase Price] +/- 33% (all put-ups except 12.5mg)

3 Hexal has no Duro 12 [12µg/hour version of Durogesic]

4 Hexal gains marketshare starting in August with 10%; going up to 30% in December 2005

5 Janssen-Cilag price has to be reduced to 67% of current PPP as of August 2005

6 Janssen-Cilag applies 21% additional discount as of August

Assumptions 2006:

1 No deal with Hexal in 2006

2 Generic matrix competition as of January 2006

3 Competition does not have Duro 12

4 Market share Janssen-Cilag goes from 70% in January to 40% in December 2006

5 Janssen-Cilag applies 40% discount as of January 2006"<sup>167</sup>

(132) This version of the two scenarios was sent on 17 May 2005 by the [employee]\* of Janssen Cilag B.V. to the [employee]\* of Janssen-Cilag, to the [employee]\* of Johnson & Johnson and to the [employee]\* of Janssen Cilag B.V. The cover email included the following statement: "*Making deal with Hexal is crucial for us in the life cycle of Durogesic: If there is no deal then Hexal will enter the market (expected for August 2005) with their fentanyl patch:*

- *the government will force us to lower our price by 33%;*
- *loss of market share by JAC [Janssen-Cilag] (between 30% and 40% within 5 months)*
- *high rebates to be given by JAC [Janssen-Cilag]"<sup>168</sup>*

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<sup>167</sup> ID0135, p. 152.

<sup>168</sup> ID0161, p. 146. "*Het maken van deal met Hexal is voor ons cruciaal in de lifecycle van durogesic: >indien er geen deal is dan komt Hexal op de markt (verwacht per augustus 2005) met hun fentanyl pleister:*  
- *dienen we de prijs van overheidswege te verlagen met 33%*  
- *marktaandeel verlies voor JAC (tussen de 30-40% binnen de 5 maanden)*  
- *hoge korting te geven door JAC"*.

So in mid-May 2005, J&J expected Hexal B.V. to launch the generic patch in the Netherlands in August 2005, which would result in a significant decrease in price of J&J's product, a significant loss of market share for J&J and the need to offer higher discounts to pharmacies.

- (133) In handwritten notes of 1 June 2005, J&J's [employee]\*, made the following observations regarding the Dutch market for fentanyl:

*"-24% (legal decrease) + 10 (due to covenant -> agreement between all pharmacies) -> as of product is on the list.*

*Dutch market is margin driven (price); pharmacies might  $\Delta$  [substitute] matrix by reservoir to keep margin.*

*Expected move of market share to depot Hexal*

*Expected needed price discount of 20%*

*2nd generic: timing?*

*Hexal deal is only delaying mechanism*

*Competition*

*- reservoir (currently only Hexal) -> Aug 05*

*- 2nd generation nov/dec 05? (Hexal limited by production capacity rather than registration)*

*[...]*

*Reasoning for deal for Hexal*

- *Gain as much as possible before 2<sup>nd</sup> gx [generics] (protect price)*
- *No advantage for gaining market share"<sup>169</sup>*

This quote shows that J&J was aware of the threat of the potential generic entry by Hexal B.V. with its depot patch, which would result in an expected price decrease for J&J's fentanyl patch of 34% ("*24% + 10*"). As the matrix patch was substitutable by the generic depot patch at that time, J&J expected that Hexal B.V. would gain an important market share. Moreover, J&J would need to offer additional "*price discounts*" to pharmacies estimated at "*20%*". The quote also explains why the cooperation with J&J would be interesting for Hexal B.V. As long as there was no other generic product on the market, it was in the interest of Hexal B.V. to co-operate with J&J and "*protect price*" to "*[g]ain as much as possible before 2<sup>nd</sup> [generic]*".

- (134) At the beginning of June 2005 J&J perceived Novartis/Sandoz as being capable of launching its generic fentanyl patch in the near future. The internal note from J&J,

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<sup>169</sup> ID0138, p. 249-250.

dated 6 June 2005 and written by the [employee]\* of Janssen-Cilag EMEA, contained the following statement: "*Since the Durogesic patent expires by late July<sup>170</sup> we believe Hexal at the earliest will launch by mid August 2005. However, it is unclear whether Hexal will launch simultaneously in all countries (where they hold registrations), or whether they will take a staged approach and initially launch in selected key countries only.*"<sup>171</sup> In the table "*Estimated Launch Timing: Fentanyl Gx in EMEA*", which is part of the same internal note, the following information was provided for the Netherlands: "*Hexal Reservoir: 15.08.05; 1.Matrix: 15.10.05 [Ratiopharm]; 2.Matrix: 22.06.06 [Nycomed]; 3.Matrix: 23.10.06 [Hexal]*"<sup>172</sup> This shows again that J&J expected Novartis/Sandoz to launch the depot patch in the Netherlands in August 2005, in advance of other potential generic entrants, which were focusing on matrix patches.

- (135) On the same day, 6 June 2005, J&J decided to enter into negotiations with Novartis/Sandoz on the terms of an agreement for the Netherlands and prepared a list of conditions for those negotiations:

*"As discussed with [employee of Johnson & Johnson]\*, we will enter the negotiations with Hexal under the following conditions:*

- *Janssen-Cilag would enter in a co-promotion deal with Hexal as of July/August 2005;*
- *Length of the agreement : 1-1.5 year with a rescission clause under which both parties can end the contract if economic circumstances change dramatically (eg enterance of generic)*
- *Janssen-Cilag will keep the NTS and distribution of Durogesic;*
- *Hexal will provide selling services towards the market in close collaboration with Janssen-Cilag;*
- *To be agreed upon # of rep's promoting to pharmacies and which tasks will be done by Hexal and which tasks will be done by J-C [Janssen-Cilag];*
- *Hexal will receive a royalty (exact % to be determined);*
- *The contract also ends if Hexal enters the market with its own fentanyl-patch or -matrix*
- *The contract also ends if the Durogesic sales are below to be determined threshold*

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<sup>170</sup> As explained by J&J, the reference to the patent expiry is probably meant as a reference to the main European markets. However, in the Netherlands the depot patch was not protected by any valid patent at that time. See ID0688, p. 11-12.

<sup>171</sup> ID0138, p. 476.

<sup>172</sup> ID0138, p. 477.

- *If needed, J-C [Janssen–Cilag] will offer to Hexal the right of having a duplex registration at the moment a generic competitor will enter the market. J-C [Janssen–Cilag] will deliver semi-finished product (e.g. patches) or finished product (to be agreed upon). The duplex registration will be given back to J-C [Janssen–Cilag] by Hexal if Hexal/Sandoz enters the market with its own product.*<sup>173</sup>

(136) On 13 June 2005, a meeting took place between representatives of Janssen-Cilag B.V. and of Hexal B.V. and Sandoz B.V. to discuss details of the potential cooperation on fentanyl. During that meeting the conditions prepared by J&J on 6 June 2005 (see Recital (135)) were shared with Hexal B.V./Sandoz B.V. partly in writing (a hard copy handed over), partly verbally.<sup>174</sup> In an internal email of 14 June 2005 which was circulated within J&J, the outcome of the meeting was summarised as follows: *"They [Hexal B.V./Sandoz B.V.] agreed in principle with the conditions as stipulated earlier (see attachment). In the coming weeks (preferable before July 1 2005), we need to work out the details. In the mean time could you please send me a draft:*

- *Secrecy agreement*
- *Letter of intent*<sup>175</sup>

(137) The new proposal from Janssen-Cilag B.V. thus referred to a *"co-promotion deal"* whereby Janssen-Cilag B.V. should keep the distribution/sales of Durogesic for itself and pay a royalty to Hexal B.V./Sandoz B.V. for promotion services only. The new proposal was clearly understood also by Novartis/Sandoz. An internal email circulated within Novartis/Sandoz on 17 June 2005 stated: *"Janssen will not supply the product as a generic (Hexal or Sandoz), their adapted proposal concerns "co-marketing & royalty payment".*<sup>176</sup>

(138) On 15 June 2005 the three Hexal B.V./Sandoz B.V. documents mentioned in Recitals (122), (124) and (130) of this Decision were sent to the [employee]\* of Sandoz B.V., the [employee]\* of Hexal B.V. and the [employee]\* of Sandoz B.V. The cover email mentioned that the same documents were also sent to two [employees]\* of Hexal AG and discussed with the [employee]\* of Sandoz AG.<sup>177</sup> This shows that those documents were still considered as a valid basis for Novartis/Sandoz's decision-making. According to the cover email, the first attachment, the presentation referred to in Recital (124), was *"used internally to evaluate all possibilities"*.<sup>178</sup> The second attachment, the document with calculations from April 2005 referred to in Recital (130), was, according to the cover email, *"the result of the latest talks with Janssen-Cilag"*.<sup>179</sup> The third attachment was the analysis referred to in Recital (122).

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<sup>173</sup> ID0136, p. 264.

<sup>174</sup> ID0134, p. 117.

<sup>175</sup> ID0136, p. 266.

<sup>176</sup> ID0172, p. 7.

<sup>177</sup> ID0172, p. 16.

<sup>178</sup> ID0172, p. 16. *"is intern gebruikt om alle mogelijkheden te evalueren."*

<sup>179</sup> ID0172, p. 16 *"de resultante van de laatste besprekingen met Janssen Cilag."*

- (139) The same document, the analysis referred to in Recital (122), was originally prepared by Hexal B.V., but was later also in the possession of Janssen-Cilag B.V. The document was attached to an internal fax sent within J&J on 17 June 2005, as described in the following Recital (140).
- (140) On 17 June 2005, a fax was sent from the [employee]\* of Janssen-Cilag B.V. to the [department]\* of Johnson & Johnson, including a cover page and two attachments: one page with three different scenarios and some handwriting on it; and a spreadsheet with sales calculations. The cover page of the fax contained the following statement: "*The page with my handwriting was provided to us by Hexal. According to their calculation they could make approximately €4.0 million profit in year 1 if they launch their depot patch in July 2005. The spreadsheet was given to Hexal by us, in the case that Hexal would buy Durogesic from Janssen-Cilag. We then calculated a profit for Hexal of ± €4 million.*"<sup>180</sup> The attachment, mentioned to be provided by Hexal B.V., is the document mentioned in Recital (122), analysing the three scenarios: "*No cooperation*"; "*Cooperation*"; and "*Proposal Hexal*". Under the scenario "*No cooperation*", that it to say in the event of Hexal B.V.'s launch in July 2005, Hexal B.V. was expected to make a profit, on an annual basis, of EUR 3 720 293 and Janssen-Cilag B.V. was expected to incur a loss of EUR 7 057 415.<sup>181</sup>
- (141) On 23 June 2005, the [department]\* of Johnson & Johnson prepared a draft secrecy agreement and a draft letter of intent to be sent, on behalf of Janssen-Cilag B.V., to Hexal B.V./Sandoz B.V.<sup>182</sup> The two documents were formally transmitted to Sandoz B.V. on 29 June 2005.<sup>183</sup>
- (142) On the following day, 30 June 2005, Novartis/Sandoz started its internal decision-making procedure on the proposal from Janssen-Cilag B.V. Emails were exchanged on 30 June and 1 July 2005 between managers of Hexal B.V./Sandoz B.V. in the Netherlands and a [employee]\* of Hexal AG ([holding senior positions at Sandoz B.V. and Sandoz International GmbH]\*)<sup>184</sup> who was requested to make a decision on the new proposal from Janssen-Cilag B.V. That internal email exchange provides explanations of the new proposal from Janssen-Cilag B.V., which may help to better understand the rationale of the Agreement and it is therefore reproduced in full below (Recitals (143) to (145)).
- (143) The first email was sent on 30 June 2005 from the [employee]\* of Sandoz B.V. to the [employee]\* of Hexal AG. The [employee]\* of Sandoz B.V. and the [employee]\* of Hexal B.V. were also in copy. The overview of the two different scenarios prepared by Hexal B.V. on 15 April 2005 (see Recital (130)) was attached as an annex. The email read as follows:

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<sup>180</sup> ID0134, p. 119. "*Het blad met mijn gekribbel op werd door Hexal aan ons bezorgd. Volgens hun berekeningen zouden zij in jaar 1 ruim € 4.0 miljoen winst kunnen maken indien zij in juli 2005 hun depot Pleister op de market zouden brengen. De spreadsheet werd door ons aan Hexal gegeven waarbij Hexal Durogesic van Janssen-Cilag zou kopen. We berekenden toen een profit voor Hexal van ±€4.0 miljoen.*"

<sup>181</sup> ID0134, p. 120.

<sup>182</sup> ID0136, p. 267.

<sup>183</sup> ID0179, p. 57-64.

<sup>184</sup> ID0819, p. 1-3.

*"We would like to draw your attention to the current status of Fentanyl patches for Sandoz/Hexal NL.*

*1. Hexal NL discussed different scenarios with Janssen/Cilag with respect to the launch of their Fentanyl patches. Based on these discussions, two scenarios (hexal launch of own developed depot patch or Hexal selling the Durogesic matrix patch) were presented to you by [the [employee]\* of Hexal B.V.]. We've attached these scenarios for your convenience.*

*We've heard from [the [employee]\* of Hexal B.V.] that you approved by telephone to go on with scenario 2.*

*2. During the follow up meetings, Janssen/Cilag indicated that instead of Hexal selling the Durogesic matrix patch in Durogesic packaging, they propose – based on an [...] assessment that they performed – to pay for a co-promotional payment when Hexal is not launching their own depot patch. Hexal would then [sic] receive an amount of € 3,700,000 on an annual basis, paid on a monthly basis. When another competitor gets a registration for this product, the contract can be terminated and Hexal can launch their own depot patch immediately in order to be the first generic company to launch the generic version. Hexal launch of the depot patch would result in an annual profit of € 2.246.989 (see attached excel sheet)*

*Although the new proposal from Janssen/Cilag is interesting from a financial point of view, [...] we would suggest continuing with the preparations for the launch of the Hexal product.*

*[...] and after that inform us on which scenario we should execute."<sup>185</sup>*

- (144) On 1 July 2005 the [employee]\* of Hexal AG replied to the [employee]\* of Sandoz B.V. and to the [employee]\* of Sandoz B.V.:

*"Could you please tell me, what PRACTICALLY has changed in the contract of Fentanyl, I really do not understand, what is different now. Do you agree with the difference??"<sup>186</sup>*

- (145) On the same day, 1 July 2005, the [employee]\* of Sandoz B.V. sent a reply to the [employee]\* of Hexal AG with the [employee]\* of Sandoz B.V. in copy:

*"First idea of the JC [Janssen-Cilag] proposal was to give Hexal additional margin for physical distribution of the JC [Janssen-Cilag] product. The [employee]\* of JC [Janssen-Cilag] however estimates – from an anti competition strategy point of view – the legal risk to [sic] high to go for this first proposal."<sup>187</sup> Therefore they now suggest a royalty payment for non-*

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<sup>185</sup> ID0332, p. 5.

<sup>186</sup> ID0332, p. 3.

<sup>187</sup> J&J explained in its reply to the Statement of Objections that the [department]\* was concerned that such arrangement could lead to alignment in terms of pricing and positioning on the market. ID1542, p. 4.

*specified co-promotional activities. This would cover the legal risk from their side.*

*Our idea about these proposals is;*

- *Both scenarios are designed for the non-introduction of the Hexal Fentanyl patch.*
- *From a financial point of view both scenarios are similar. They are only willing to pay less than the first proposal, based on additional research results at pharmacist and doctors in favour of the JC [Janssen-Cilag] product. The financial difference itself is acceptable, since the gain compared to the introduction of the own Hexal product is still substantial.*

*[...] There is no justification for any money from co-promotional activities.<sup>188</sup>*

- (146) On 8 July 2005, a fax was sent from Hexal B.V. to Janssen-Cilag B.V. and later forwarded to the [department]\* of Johnson & Johnson, with a draft (entitled "Concept") of the calculation of costs of the Fentanyl co-marketing (or co-promotion) services. The following items were included in the draft calculation:

***"Fentanyl Co-marketing Calculation***

<i>Duration:</i>	<i>1 year</i>
<i>No. of sales representatives (Sandoz/Hexal)</i>	<i>8</i>
<i>Sales representatives cost (60% Fentanyl promotion)</i>	<i>€ 1.104.000</i>
<i>Training cost for sales representatives</i>	<i>€ 158.400</i>
<i>Mid management incl support to sales reps</i>	<i>€ 278.400</i>
<i>Mid management training costs</i>	<i>€ 100.000</i>
<i>Backoffice support</i>	<i>€ 422.400</i>
<i>Software adjustments (backoffice &amp; reporting)</i>	<i>€ 70.000</i>
<i>Opportunity costs alternative time sales reps (missed sales/profit)</i>	<i>€ 814.567</i>
<i>Market analysis and data acquisition</i>	<i>€ 125.000</i>
<i>Compensation for promotion of fentanyl 12 patch (20% of est margin)</i>	<i>€ 483.000</i>
<i>Other</i>	<i>€ 145.000</i>

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<sup>188</sup> ID0332, p. 3.

Total amount

€3.700.767"<sup>189</sup>

It should be noted, however, that that document never became part of the actual Co-promotion agreement.

- (147) On 10 July 2005, just one day before the entry into force of the Co-promotion agreement, an email was sent from the [employee]\* of Johnson & Johnson's [department]\* to the [employee]\* of Janssen-Cilag B.V. In that email the [employee]\* reported that Sandoz's [employee]\* confirmed that Hexal B.V./Sandoz B.V. had received the letter of intent from Janssen-Cilag B.V., that the letter of intent would now be turned into a term sheet by Hexal B.V./Sandoz B.V., and that the term sheet would be sent for approval to Janssen-Cilag B.V. and thereafter turned into the actual contract. In that context the member of Johnson & Johnson's [department]\* made the following request: *"As discussed on the phone can you please, in view of the actual contract, provide us with something concerning the commercial rationale of the deal (in particular the increasing importance of pharmacies)?"*<sup>190</sup>
- (148) The reply from the [employee]\* of Janssen-Cilag B.V., sent on the same day, 10 July 2005, stated that it was important to sign the contract with Hexal B.V. in the following week and provided the following explanations concerning the co-operation:

*"In The Netherlands the pharmacist plays a key roll [sic] towards general practitioners and patients. Pharmacists together with general practitioner determine often for which disease which drug should be prescribed. These guidelines are often an obligation for all members involved in the discussion ("FTO: farmacotheapeutich overleg").*

*At the same time more and more patient compliance becomes a hot topic. A gain the pharmacist plays a key roll as he advises patients how to use drugs and how to deal with side effects.*

*Clinical research studies show that around 30% of patients on Durogesic stop due to side effects within a few weeks after starting the treatment. Main reason is side effects like obstipation and nausea. Since January 2006 Durogesic 12 is available. This low dose version of Durogesic together with proper advise of pharmacists on how to deal with side effects give a real opportunity to reduce the drop out of patients considerably and thus increase further the Durogesic sales.*

*Hexal has a team of 8 pharmacy representatives available. These people have excellent relations with pharmacists and can play an important role in visiting phamacists and promoting Durogesic.*"<sup>191</sup>

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<sup>189</sup> ID0151, p. 59.

<sup>190</sup> ID0143, p. 329. *"Kan jij, zoals telefonisch besproken, ons met het oog op het eigenlijke contract iets bezorgen omtrent de commerciële rationale van de deal (i.h.b. het groeiend belang van de apotheken)?"*

<sup>191</sup> ID0143, p. 328.



The same document stated that "Janssen-Cilag will pay Hexal 308333 (three hundred and 8 thousand and three hundred thirty three) Euro's per month. Janssen-Cilag will pay Hexal within 30 days after the month ended."<sup>192</sup> However, the services to be provided by Hexal B.V./Sandoz B.V. were described only very briefly and in a very general manner: "Obligation Hexal: Hexal will have a team of 8 pharmacy representatives, promoting Durogesic. Remark: name here all services of Hexal."<sup>193</sup> Finally, it should be noted that that document never became part of the actual Co-promotion agreement either.

- (149) The Letter of intent prepared by J&J was then sent to Hexal B.V./Sandoz B.V. for possible comments. On 11 July 2005, a fax was sent from Hexal B.V. to Sandoz B.V. with Hexal B.V./Sandoz B.V.'s proposed modifications (in track changes) of the Letter of Intent. One of the new proposed provisions was the following: "Hexal/Sandoz will provide to Janssen-Cilag the services listed under Annex 1 hereto ("Services") towards the market in close cooperation with Janssen-Cilag. Hexal Sandoz will keep records of all the Services provided to Janssen-Cilag."<sup>194</sup> The new draft Annex 1 was also attached to that fax and read as follows:

**"CONCEPT**

***Fentanyl Co-marketing activities***

*Duration* *1 year*

*No. of sales representatives (Sandoz/Hexal)* *8*

*Target market:*

*- Pharmacies non-hospital* *1.880*

*- Pharmacies hospital* *120*

*- Self-dispensing doctors* *550*

*- Wholesalers* *10*

*Visit frequency:* *5-6 times per year*

*Total visits per year (80% score):* *11.264*

*Total visits per day (230 working days):* *49*

*Main topics visit:*

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<sup>192</sup> ID0143, p. 329

<sup>193</sup> ID0143, p. 328. "Opmerking: benoem hier alle services van Hexal."

<sup>194</sup> ID0179, p. 66.

- *General product + company information*

- *Usage*

- *Samples*

- *Conditions*

- *Reports will be transmitted to headquarters*

*Sales meetings with (mid)management*      *1x per month*

- *Discuss actual sales figures, estimates and trends*

*Joint visits with manager*      *1x per month per rep*

*Telephone calls by manager to inform customer satisfaction after visit*

*Product knowledge training for sales representatives*      *5 times per year*

*Product knowledge training for mid management*      *5 times per year*

*Backoffice activities:*

*Receive and process orders from pharmacies and wholesalers*

*Sales forecast and sales monitoring*

*A summarizing report will be provided to management on a monthly basis*<sup>195</sup>

- (150) On 13 July 2005 a draft of the Co-promotion agreement was sent by email from the [department]\* of Johnson & Johnson to Janssen-Cilag B.V. "*for internal discussion purposes*".<sup>196</sup> In the email reply, the [employee]\* of Janssen-Cilag B.V. made several comments on the draft, including the following: "*I would suggest you include as an attachment all the elements that determine the amount. I am pretty sure their [employee]\* also want to have this part of the contract.*"<sup>197</sup>
- (151) Nevertheless, on 14 July 2005 the second version of the draft Co-promotion agreement was sent from the [department]\* of Johnson & Johnson to Janssen-Cilag

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<sup>195</sup> ID0179, p. 68.

<sup>196</sup> ID0137, p. 355.

<sup>197</sup> ID0137, p. 355.

B.V. and the cover email included also the following statement: "*In particular, as discussed today, we do not believe it is worth annexing a schedule with a list of services.*"<sup>198</sup> The description of the services to be provided or the elements for calculation of the amount to be paid for those services were therefore not defined in the final version of the Co-promotion agreement. In its reply to the Statement of Objections J&J explained that the reason for not adding the schedule with a list of services was because the Co-promotion agreement "*was expected to be straightforward and of a short duration, and that it contained all the necessary parameters*".<sup>199</sup>

- (152) The final Co-promotion agreement was signed by Janssen-Cilag B.V. on 15 July 2005 and sent to Hexal B.V. and Sandoz B.V.<sup>200</sup> Hexal B.V. signed the Agreement on 20 July 2005 and Sandoz B.V. signed the Agreement on 22 July 2005.<sup>201</sup> It came into force retro-actively on 11 July 2005.<sup>202</sup>

## 6.2. The Agreement

### 6.2.1. The Initial Agreement

#### 6.2.1.1. General provisions

- (153) The Co-promotion agreement was concluded between Janssen-Cilag B.V. on the one hand and Hexal B.V. and Sandoz B.V. on the other hand (the Agreement refers to them jointly as "the Company").

- (154) The preamble states that:

*"In the Territory [the Netherlands] the pharmacists play an increasing key role in determining, together with general practitioners, for which disease which drug should be prescribed, and in advising patients how to use the drugs and how to deal with side effects;"* (Preamble, letter B)<sup>203</sup>

*"There is an increasing need for Janssen-Cilag to detail the Product [Durogesic] towards pharmacists;"* (Preamble, letter C)<sup>204</sup>

*"Company has a Sales Force (as defined below) that has built strong expertise in promoting drugs with pharmacists;"* (Preamble, letter D)<sup>205</sup>

*"The parties hereby want the Company's [Hexal B.V./Sandoz B.V.'s] Sales Force to promote the Product in accordance with this Agreement, especially the monthly forecast in the Schedule."* (Preamble, letter E).<sup>206</sup>

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<sup>198</sup> ID0137, p. 359.

<sup>199</sup> ID1542, p. 4.

<sup>200</sup> ID0179, p. 87.

<sup>201</sup> ID0179, p. 30.

<sup>202</sup> ID0179, p. 15.

<sup>203</sup> ID0179, p. 15.

<sup>204</sup> ID0179, p. 16.

<sup>205</sup> ID0179, p. 16.

<sup>206</sup> ID0179, p. 16.

- (155) The "*Product*" is defined as "*the pharmaceutical product more particularly known as Durogesic®, existing in the following galenic forms: Durogesic 12, patches for transdermal use 12 µg/hour; Durogesic 25, patches for transdermal use 25 µg/hour; Durogesic 50, patches for transdermal use 50 µg/hour; Durogesic 75, patches for transdermal use 75 µg/hour; Durogesic 100, patches for transdermal use 100 µg/hour.*" (Article 1).<sup>207</sup>
- (156) The "*Sales Force*" is defined as "*Company's [Hexal B.V./Sandoz B.V.'s] sales force consisting of 8 representatives detailing the Product.*" (Article 1).<sup>208</sup>
- (157) The "*Territory*" is defined as the Netherlands. (Article 1).<sup>209</sup>

#### 6.2.1.2. Hexal B.V./Sandoz B.V.' duties

- (158) Janssen-Cilag B.V. "*confirms Company [Hexal B.V./Sandoz B.V.] as its co-promotion partner in the Territory and Company agrees to act in that capacity subject to the terms and conditions of this Agreement.*" (Article 2.1).<sup>210</sup> However, Company's [Hexal B.V./Sandoz B.V.'s] duties with regard to the co-promotion activities are described in a rather general way. The Agreement states in Article 3 that:

*"3.1. Company [Hexal B.V./Sandoz B.V.] shall use its reasonable endeavours to assist Janssen-Cilag in the promotion of the Product to the Pharmacists through the Sales Force, [...] but Company shall not be entitled to sell or enter into any negotiations for the sale of the Product on behalf of Janssen-Cilag, or to bind Janssen-Cilag in any way.*

*3.2. Company [Hexal B.V./Sandoz B.V.] shall be responsible for training at its own cost*

*3.3*

*3.3.1. Company [Hexal B.V./Sandoz B.V.] shall conduct the promotion and marketing by the Sales Force of the Product to the Pharmacists with all due care and diligence and shall cultivate and maintain good relations with the Pharmacists in accordance with sound commercial principles.*

*3.3.2. Company [Hexal B.V./Sandoz B.V.] shall conduct the promotion and marketing by the Sales Force of the Product to the Pharmacists in compliance with all the applicable laws and regulations relating to the promotion and marketing of the Product, as well as the CGR Code and all related Janssen-Cilag instructions as indicated by Janssen-Cilag from time to time in writing.*

*3.4. Company [Hexal B.V./Sandoz B.V.] shall procure that its representatives on the Sales Force:*

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<sup>207</sup> ID0179, p. 16. At the time of the agreement the Durogesic depot patch was not on the Dutch market anymore (see Recital (85) and the only fentanyl product available was the Durogesic matrix patch.

<sup>208</sup> ID0179, p. 17.

<sup>209</sup> ID0179, p. 17.

<sup>210</sup> ID0179, p. 17.

3.4.1. *If considered reasonable shall at the expense of Janssen-Cilag attend meetings with representatives of Janssen-Cilag and such Pharmacists as may be necessary in Janssen-Cilag's reasonable opinion for the performance of its duties under this Agreement;*

3.4.2. *Shall make such calls upon Pharmacists for the purpose of promoting the Product;*

3.5 *Company shall in relation to the Product*

3.5.1 *describe itself as "co-promotion partner" for Janssen-Cilag;*

3.5.2 *not hold itself out, or permit any person to hold it out, as being authorised to bind Janssen-Cilag in any way;*

3.5.3 *not do any act which might reasonably create the impression that it is so authorised.*

3.6 *Company [Hexal B.V./Sandoz B.V.] shall maintain a list of Pharmacists who are customers or prospective customers for the Product and shall at the request of Janssen-Cilag supply it with a copy of that list. Janssen-Cilag shall not use such list for any other purpose than set forth herunder.*

3.7 *Company [Hexal B.V./Sandoz B.V.] shall from time to time keep Janssen-Cilag fully and detailed informed in writing of Company's [Hexal B.V./Sandoz B.V.'s] promotional and marketing activities by the Sales Force in respect of the Product and shall promptly at request of Janssen-Cilag deliver a detailed written report of such call activities. [...]"<sup>211</sup>*

- (159) The above description (Recital (158)) of Hexal B.V./Sandoz B.V.'s duties and the co-promotion activities in the Agreement is rather general. On the other hand, the Agreement is clear about the fact that Hexal B.V./Sandoz B.V. should not be involved in the sales of the Product. The Agreement states explicitly that "*[a]ll sales of the Product in the Territory shall be made by Janssen-Cilag on such terms and conditions as Janssen-Cilag in its absolute discretion may from time to time determine*" (Article 4.1).<sup>212</sup> Moreover, "*[u]nless otherwise agreed in writing, Company [Hexal B.V./Sandoz B.V.] shall not be entitled to receive payments on Janssen-Cilag's behalf in respect of sales of the Product.*" (Article 4.2).<sup>213</sup>

#### 6.2.1.3. Janssen-Cilag B.V.'s duties

- (160) As far as the rights and duties of the parties are concerned, the most important and also quite specific part of the Agreement therefore seems to be the section on payments. Article 7 of the Agreement related to the payments state the following:

- *"In consideration of the obligations undertaken by Company [Hexal B.V./Sandoz B.V.] in respect of the members of the Sales Force, Company*

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<sup>211</sup> ID0179, p. 17-19.

<sup>212</sup> ID0179, p. 20.

<sup>213</sup> ID0179, p. 20.

*shall be entitled to receive from Janssen-Cilag a monthly amount of € 308,333, starting from July, 11, 2005. The first and last monthly instalments will only be pro rata the number of days the Agreement is actually in effect." (Article 7.1.)<sup>214</sup>*

- *"Company [Hexal B.V./Sandoz B.V.] shall invoice to Janssen-Cilag on a monthly basis. All invoices shall be paid within 30 days of the end of the month from receipt of the invoice." (Article 7.2.)<sup>215</sup>*

(161) For the twelve month duration of the initial agreement (see section 6.2.1.5.), the total amount to be paid by Janssen-Cilag B.V. to Hexal B.V./Sandoz B.V. was thus EUR 3.7 million in monthly instalments. That amount corresponds to the profit Hexal B.V./Sandoz B.V. told Janssen-Cilag B.V. it could have made in the first year if it had launched its own fentanyl patch (see Recital (140)). It should be also noted that the duration of the Agreement was later extended and thereby the total amount paid also increased (see section 6.2.3.).

(162) Besides payments to Hexal B.V./Sandoz B.V., the main duties of Janssen-Cilag B.V. stemming from the Co-promotion agreement, are in particular:

- *"Be responsible for obtaining all licenses, permits and approvals, which are necessary or advisable for the sale of the Product in the Territory and for the performance of its duties hereunder." (Article 6.1.1.)<sup>216</sup>*
- *"To the extent they are relevant for the purposes of this Agreement, notify Company of any changes in the laws and regulations in the Territory relating to the nature, method of manufacture, packaging, labelling or sale of the Product, and shall forthwith notify Company if it becomes aware that Janssen-Cilag or the Product are or may be in breach of any of those laws or regulations." (Article 6.1.2.)<sup>217</sup>*
- *"At its own expense promptly supply Company with such catalogues, advertising, promotional and selling materials, literature and information as Company may from time to time reasonably require for the purpose of complying with its obligations under this Agreement." (Article 6.2.1.)<sup>218</sup>*
- *"Promptly and efficiently deal with any after sale or medical information enquiry relating to the Product raised by a customer and prospective customer in the Territory." (Article 6.2.2.)<sup>219</sup>*
- *"Comply with all the applicable laws and regulations relating to the nature, method of manufacture, packaging and labelling of the Product." (Article 6.2.3.)<sup>220</sup>*

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<sup>214</sup> ID0179, p. 22.

<sup>215</sup> ID0179, p. 22.

<sup>216</sup> ID0179, p. 21.

<sup>217</sup> ID0179, p. 21.

<sup>218</sup> ID0179, p. 22.

<sup>219</sup> ID0179, p. 22.

- *"Ensure that all materials and activities requested of those selling Durogesic comply with the CGR Code."* (Article 6.2.4.).<sup>221</sup>

(163) The obligations of Janssen-Cilag B.V., except for the payments to Hexal B.V./Sandoz B.V., also seem to be rather general and many of them would be reasonably expected even without any agreement (for example, the duty to comply with the applicable laws).

#### 6.2.1.4. Possibility for Duplex Registration

(164) The Agreement also included a provision on discussions concerning the possibility for further cooperation between the parties once a third party would launch the fentanyl matrix patch on the Dutch market:

*"Parties will in good faith discuss the possibility for Company or one of its Affiliates to use a duplex registration<sup>222</sup> of the matrix-formulation of the Product at the moment a Third Party launches such matrix formulation of the Product in the Territory. The terms and discussions of a duplex registration will be discussed during the term of this Agreement. For the avoidance of doubt, such possible use of a duplex registration shall not pertain to the 12 µg/hour version of the Product."* (Article 10bis).<sup>223</sup>

#### 6.2.1.5. Duration and Termination of the Agreement

(165) The initial agreement *"was entered into as of 11<sup>th</sup> day of July, 2005 (the "Effective Date")"*.<sup>224</sup> It was due to expire, without further notice, on 10 July 2006, unless extended by mutual agreement and in writing at the latest one month before expiry (Article 10.1.).<sup>225</sup>

(166) Earlier termination was possible only on the specific grounds listed in the Agreement. This included the situation where (i) Hexal B.V./Sandoz B.V. or an affiliate<sup>226</sup> or (ii) any third party had a fentanyl patch (matrix or depot) listed on the Dutch pharmacy TAXE list, known as Z-index<sup>227</sup> (Article 10.2.1.).<sup>228</sup> In the earlier case the Agreement could have been terminated immediately, in the latter case with 10 days' notice.

(167) In the event of early termination of the Agreement, the Agreement provided for certain consequences, in particular the termination of the payments at the date of the

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<sup>220</sup> ID0179, p. 22.

<sup>221</sup> ID0179, p. 22.

<sup>222</sup> For "duplex registration" see footnote 35.

<sup>223</sup> ID0179, p. 26-27.

<sup>224</sup> ID0179, p. 15.

<sup>225</sup> ID0179, p. 24.

<sup>226</sup> An "Affiliate" is defined in the Agreement as *"any company which owns or controls at least fifty per cent (50%) of the voting stock of such given company, or any other company at least fifty per cent (50%) of whose voting stock is owned or controlled by such owning or controlling company or by the given company."* ID0179, p. 16.

<sup>227</sup> See Recital (43).

<sup>228</sup> ID0179, p. 24.

written notice (or at the end of the notice period if applicable) (Article 10.10.).<sup>229</sup> In other words, in the event of early termination for example due to the launch of Hexal B.V./Sandoz B.V.'s own generic depot patch in the Netherlands, Hexal B.V./Sandoz B.V. would stop receiving the monthly payments with immediate effect.

#### 6.2.2. Events during Implementation of the Agreement

- (168) According to the information provided by Novartis/Sandoz, "[b]ased on available information, after initial preparations, which included training and the drafting of a questionnaire, Hexal/Sandoz Netherlands commenced a market survey of pharmacies in the Autumn of 2005 through its own sales representatives who personally visited and interviewed on the basis of a questionnaire a large proportion of pharmacies across all regions of the Netherlands. Amongst other things, the purpose of these visits was to gauge how pharmacists perceived the newer fentanyl matrix patches and the 12 mcg/h formulation. In addition to obtaining this valuable knowledge, the survey questions were also aimed at raising pharmacists' awareness of Janssen-Cilag's Durogesic by promoting the benefits of the newer matrix patches (Janssen-Cilag's Durogesic was the only fentanyl matrix patch available at that time), reinforcing their superiority over the older depot patches and reminding pharmacists of the benefits of the 12 mcg/h strength."<sup>230</sup>
- (169) J&J confirmed that the list of 13 questions "were put to the pharmacists by the Hexal/Sandoz sales force during the face to face visits, to support the promotion of the Durogesic ® matrix patch."<sup>231</sup> Novartis/Sandoz then further stated that "[o]f the broader number of pharmacies visited, 140 pharmacists completed and returned a questionnaire form that was provided during the market survey. The pharmacists either completed the questionnaire forms with the assistance of a sales representative during the visit or on their own after a sales representative's visit. The forms completed during visits were typically collected by sales representatives on the spot while forms completed by pharmacists after the visit were typically returned by fax or mail. [...] Based on the information available, three reports were prepared by Hexal/Sandoz Netherlands that summarised and analysed the questionnaire forms that were completed by pharmacists. [...] A draft summary of the outcome of the market survey of pharmacies was then shared between Hexal/Sandoz Netherlands and Janssen-Cilag on 25 July 2006."<sup>232</sup>
- (170) On 12 December 2005, the first report was sent by email from Sandoz B.V. to Janssen-Cilag B.V., covering the period "October – December 2005". The report is based on the replies from 124 pharmacies to the questionnaire containing 10 basic questions (most of them "yes-or-no" questions) and 3 supplementary questions. The report is just a statistical overview of the replies. The questions asked in the questionnaire are the following:

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<sup>229</sup> ID0179, p. 26.

<sup>230</sup> ID0701, p. 4.

<sup>231</sup> ID0688, p. 7. Reference is made to 13 "questions", although strictly speaking the list contains 12 questions and 1 space for "Other comments." See Recital (170).

<sup>232</sup> ID0701, p. 4.



- *"Can you estimate how many patients in the catchment area are being treated for serious chronic pain?"*
- *Can you provide percentage shares of the prescriptions divided between Morphine, Fentanyl, Tramadol and others?"*
- *Is there attention paid to pain management in the FTO [Pharmacotherapeutic consultations amongst general practitioners and pharmacists]?"*
- *Are guidelines used for that?"*
- *Is the pharmacist asked for advice by the doctor/specialist in case of pain management for serious chronic pain?"*
- *Is the matrix patch regarded as an improvement?"*
- *Is the "12" patch regarded as a welcome complement of the product range?"*
- *Would a (generic) depot patch be still acceptable? If so, under which conditions?"*
- *Would a product range of Fentanyl patches without the "12" patch be still acceptable? If so, under which conditions?"*
- *In the case of Fentanyl patches, is it still an argument that the product is the original?"*
- *Other comments: "*<sup>233</sup>

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<sup>233</sup> ID0135, p. 196-197. *"Kunt u inschatten hoeveel patiënten in het verzorgingsgebied worden behandeld voor ernstige chronische pijn?"*

*Kunt u een procentuele verdeling geven van het voorschrift, te verdelen onder Morfine, Fentanyl, Tramadol en Overig?"*

*Is er aandacht (bested) in het FTO voor pijnbestrijding?"*

*Worden hierbij richtlijnen gehanteerd?"*

*Wordt de apotheker wel om advies gevraagd door de arts/specialist in het geval van pijnbestrijding bij ernstige chronische pijn?"*

*Wordt de matrixpleister ervaren als een verbetering?"*

*Wordt de "12" (opstap) pleister ervaren als een welkome aanvulling op het assortiment?"*

*Zou een (generieke) depotpleister nog acceptabel zijn? Zo ja, onder welke voorwaarden?"*

*Zou een assortiment Fentanyl pleisters zonder de "12" opstapleister acceptabel zijn? Zo ja, onder welke voorwaarden?"*

*Is in het geval van Fentanyl pleisters origineel fabriekaart nog een argument?"*

*Verdere opmerkingen: "*

- (171) On 2 February 2006, the second report was sent by email from Sandoz B.V. to Janssen-Cilag B.V.<sup>234</sup> Again, this is just a short statistical overview of the replies. Moreover, the questions asked for the purpose of the second report were exactly the same as in the first questionnaire. The results (replies to the 13 questions) also seem to be very similar to the results of the first questionnaire. Interestingly, the report indicates that it covers the period April - July 2006 (sic)<sup>235</sup> despite the fact that it was submitted already in February 2006.
- (172) On 28 April 2006, the third (and last) report was sent by email from Sandoz B.V. to Janssen-Cilag B.V., this time covering the period January – April 2006.<sup>236</sup> The report is again in the same simple format as the previous ones, with the same 13 questions in the questionnaire and with very similar results obtained.
- (173) On 25 July 2006, a one-page draft Evaluation Report of the co-promotion project was sent by email from Janssen-Cilag B.V. to Sandoz B.V.<sup>237</sup> That one page report, with the three abovementioned reports attached to it as annexes, was the only substantive document that the parties submitted to the Commission when requested to provide "*all the documents evaluating the co-promotion activities during the term of the co-promotion agreement and also ex post, i.e. once the co-promotion agreement was terminated*".<sup>238</sup>
- (174) The Evaluation Report stated the following:

**"EVALUATION CO-PROMOTION PROJECT DUROGESIC**

*The introduction of Durogesic-matrix-patches (fentanyl TTS) in the strengths of 25 uq, 50 uq, 75 uq and 100 uq on the Dutch market, made it necessary to visit the pharmacist as well as the general practitioner to make a case for the use of Durogesic within the treatment of severe chronic pains where opiates are necessary. The introduction of the 12 uq Durogesic matrix patch created the possibility to use opiates with a relative low initial dosage especially for benign pain, such as slight dorsal pain, vertebral compression fractures or arthrosis. This strength also made it possible to increase the dosage of 12 uq in small steps. This message is very important for the doctor as well as for the pharmacist.*

*The sales force of Janssen-Cilag aimed mainly at the promotion of Durogesic among general practitioners and pain specialists. Due to the limited size of this sales force, it was not possible to visit the above-mentioned doctors as well as the pharmacists with the message on the treatment of severe chronic pains with the new matrix-patches and the initial and titrated dosage of 12 uq.*

*That's why a partnership was sought with an organisation that has sales force capacities to target pharmacists.*

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<sup>234</sup> ID0135, p. 202.

<sup>235</sup> ID0135, p. 204.

<sup>236</sup> ID0135, p. 219-220.

<sup>237</sup> ID0135, p. 235.

<sup>238</sup> ID0404, p. 6.

*Besides the promotional aspect concerning the positioning of the Durogesic-matrix-patches, the so-called product message, this co-promotion created the possibility of carrying out a market enquiry among pharmacists, which gave more insight into the treatment of severe chronic pain, and made an assessment feasible of possible problems that might arise due to the simultaneous marketing of the new matrix patches and the old reservoir patches.*

*On 21 October 2005 the sales force of Sandoz-Hexal was trained in the product message of Durogesic. On Monday 24 October, the co-promotion targeting pharmacists actually started.*

*The sales support unit of Sandoz-Hexal drew up a questionnaire that was discussed with the pharmacists after verification by Janssen-Cilag. Each quarter, a report on the outcomes of the market enquiry was made and discussed between [employee of]\* Sandoz/Hexal and [employee]\* of Janssen-Cilag Nederland.*

*The evaluations for the three quarters are enclosed in the attachment to this document.*

*With the arrival of generic fentanyl patches on the Dutch market, the co-promotion will be terminated”<sup>239</sup>.*

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ID0135, p. 236.

**"EVALUATIE CO-PROMOTIE-PROJECT DUROGESIC**

*Met de introductie op de Nederlandse markt van de Durogesic-matrix-pleisters (fentanyl TTS) in de sterktes 25 uq, 50 uq, 75 uq en 100 uq ontstond de behoefte om naast de huisarts ook de apotheker te bezoeken met de boodschap over de plaatsbepaling van Durogesic bij de behandeling van ernstige chronische pijn, waarbij opiaten nodig zijn. Met de introductie van de de Durogesic-matrix-pleister met een sterkte van 12 uq werd de mogelijkheid geschapen om met een relatief lage startdoserings bij m.n. benigne pijn, zoals bij lage rugpijn, wervelingzakkingen, artrose, opiaten in te zetten. Tevens gaf deze sterkte de mogelijkheid om de dosering van Durogesic in kleine stappen van 12 uq te verhogen. Deze boodschap is zeer belangrijk voor zowel arts als apotheker.*

*De salesforce van Janssen-Cilag richtte zich m.n. op promotie van Durogesic bij de huisarts en de pijnspecialist. Door de beperkte grootte van deze salesforce was het niet mogelijk om naast bovengenoemde artsen ook de apothekers te bezoeken met de boodschap over behandeling van ernstige chronische pijn met de nieuwe matrix-pleisters en de start –en titreerdosis met de 12 uq. Om die reden werd een partnership gezocht met een organisatie met salesforce-capaciteit naar de apotheker.*

*Naast het promotionele aspect m.b.t. de positionering van de Durogesic-matrix-pleisters, de z.g. productboodschap, gaf deze co-promotie de mogelijkheid om bij de apotheker marktonderzoek te doen, waardoor meer inzicht in de behandeling van ernstige chronische pijn kon worden verkregen en waarbij ook een inschatting kon worden gemaakt van de evt. problemen die konden ontstaan door het tegelijkertijd op de markt aanwezig zijn van de nieuwe matrixpleisters en de oude reservoir-pleisters.*

*Op 21 oktober 2005 is de salesforce van Sandoz-Hexal getraind in de productboodschap van Durogesic. Maandag 24 oktober is de co-promotie bij de apotheker daadwerkelijk gestart.*

*Vanuit de afdeling sales-support van Sandoz-Hexal is een enquette opgesteld die na verificatie door Janssen-Cilag bij de apothekers is besproken.*

*Per kwartaal is er een rapportage over de uitkomsten van het marktonderzoek opgesteld en besproken tussen [employee]\* van Sandoz-Hexal en [employee]\* van Janssen-Cilag Nederland.*

*In de bijlagen aan dit document zijn de 3 kwartaal-evaluaties toegevoegd.*

- (175) Shortly after concluding the Co-promotion agreement for the Netherlands with J&J, Novartis/Sandoz launched in August and September 2005 the generic fentanyl reservoir patch in at least 7 other Member States. In those other Member States the generic entry caused substantial price reductions of J&J's Durogesic. On 30 November 2005 an internal email was circulated within J&J with some market intelligence and stating that "*Reservoir patch: launched by Hexal in 7 countries.*"<sup>240</sup> This is further confirmed by an internal presentation of J&J "*DUROGESIC Life Cycle Management*"<sup>241</sup> from 12 December 2005, which included the following table:<sup>242</sup>

**Fentanyl Reservoir: Generic patches (25µg - 100µg/h)**

Country	Company	Launch	Price reduction/reimbursement vs. Durogesic (retail)
Germany	Hexal	August 18, 2005	16% to 21%
Finland	Hexal	September 1, 2005	30% - first step 50% - as of Oct 1. 05
Sweden	Hexal	September 1, 2005	31% to 34%
Norway	Hexal	September 1, 2005	100% reimbursement, but substantial rebates
Poland	Hexal	September 1, 2005	20 to 23%
Ireland	Hexal	September 1, 2005	20%
United Kingdom	Hexal, (branded) Hillcross, Ivax (unbranded)	August 23, 2005	0.3% to 1.9%
Italy	Hexal	Expected soon	35%

- (176) The fact that there was no generic fentanyl patch on the Dutch market in 2005 was appreciated by the Janssen-Cilag B.V.'s management. For example, the internal annual evaluation report, created in December 2005 and evaluating the performance of the [employee]\* of Janssen-Cilag B.V. for 2005, states: "*Business results: [...] [The [employee]\*] prepared delay of generic entry Durogesic (year end: +11 Mio Euro against worst case).*"<sup>243</sup>
- (177) Novartis/Sandoz in fact did not launch its generic product in the Netherlands during the whole term of the Co-promotion agreement, including the addendum which was in force until 15 December 2006 (see Recital (193)). In January 2006, the [employee]\* of Sandoz B.V. sent an internal email in which he clearly explained Novartis/Sandoz's reasoning behind the Co-promotion agreement with J&J:

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*Met de komst van generieke fentanyl-pleisters op de Nederlandse markt zal de co-promotie worden beëindigd."*

<sup>240</sup> ID0137, p. 314.

<sup>241</sup> ID0135, p. 526 and 528.

<sup>242</sup> See also Recital (93) and footnote 109.

<sup>243</sup> ID0160, p. 213.

*"In July [2005] we had to make the decision locally to either launch the product Fentanyl (which was included in target 2005) or go for the co-marketing option. In the end it was decided to go for the last option. We also locally paid for the destruction of packaging material which was already produced and the filling [sic; meant is filing] of the registration of this product. So we choose [sic; meant is chose] to go for Oper. Inc. [Operating Income] in stead of Sales/Market share (which was in the target 2005). I didn't record the missed sales and contribution on Fentanyl as a forgiveness item, since the decision was taken locally not to launch the product and go for the more profitable solution."*<sup>244</sup>

- (178) Eventually, it was another generic player, Ratiopharm, which launched the first generic fentanyl patch, a matrix patch, in the Netherlands on 1 February 2006. According to J&J's internal documents, *"Ratiopharm took everybody by surprise and entered the Dutch market with their Gx [Generic] Fentanyl matrix patches (25-100mg) as of February 1st, 2006. Ratiopharm has set their Pharmacy Purchase Price (PPP) at the expected (compulsory) level of 35 % below our actual Durogesic prices. Ratiopharm sells to the largest wholesalers (OPG, Interpharm, Brocacef and Mosadex) with an additional discount of 70%(!)."*<sup>245</sup> J&J was considering how to react quickly to the generic entry of Ratiopharm. The proposed actions included significant discounts and also launch of Janssen-Cilag B.V.'s own generic product, *"Fentanyl JC"*.<sup>246</sup>
- (179) However, Ratiopharm's presence on the market was short-lived and it left the market on 15 March 2006. Ratiopharm had to leave the market due to an interim injunction based on a complaint by Janssen-Cilag B.V. for the alleged circumvention of the mutual recognition procedure for marketing authorisation.<sup>247</sup>
- (180) Janssen-Cilag B.V., nevertheless, continued with preparations for a successful generic entry by a third party. It followed up on the previously floated idea of duplex registrations being given to other generic companies. On 5 April 2006, Janssen-Cilag B.V. requested from the [department]\* of Johnson & Johnson a [...] assessment concerning the proposal to extend the duration of the Co-promotion agreement with Hexal B.V./Sandoz B.V. and, at the same time, to proceed with transferring the duplex registration to Hexal B.V./Sandoz B.V.<sup>248</sup> The duplex registration, however, could only be used once a third party launched its generic fentanyl patch in the Netherlands. The proposal is explained as follows:

*"If J-C [Janssen-Cilag] were to grant the duplex registration to Sandoz, then I would argue in favour of extending the co-promotion contract and preparing a contract regarding the duplex registration. [...]"*

*Co-promotion agreement extension (addendum):*

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<sup>244</sup> ID0172, p. 9.

<sup>245</sup> ID0161, p. 19-20.

<sup>246</sup> ID0161, p. 388.

<sup>247</sup> See section 5.2.2.2 and also, for example, ID0172, p. 85.

<sup>248</sup> ID0150, p. 45.

*The following aspects are restated here:*

*Rationale: In line with the recent strategy Sandoz has the possibility of further increasing the turnover of Fentanyl patches. Sandoz has an account team that can continue to concentrate on Fentanyl (originating from Janssen-Cilag) and in this way increase the turnover at the same pharmacies by replacing other opioids used for pain with Fentanyl.*

*Reference to 10b: Duplex registration. Janssen-Cilag will grant a duplex registration of Fentanyl matrix formulation to Sandoz.*

*Fee per month: still to be decided, but lower than today, because Sandoz can buy the Fentanyl matrix from Janssen-Cilag at a much cheaper price.*

*Duration of the extension: 1 year. After that possible again on an annual basis. (if this makes sense to both parties).*

*Duplex registration contract*

*Conditions:*

*Janssen-Cilag grants Sandoz the right to launch the Fentanyl matrix (25-100) originating from Janssen-Cilag bv on the Dutch market after at least one generic company physically distributed its Fentanyl matrix formulation on the Dutch market.[...]”<sup>249</sup>*

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<sup>249</sup> ID0150, p. 45-46. "Mocht J-C overgaan om een duplex registratie te geven aan Sandoz, dan pleit ik voor een verlenging van het co-promotie contract en het opstellen van een contact aangaande de Duplex registratie. [...]"

*Co-promotie agreement verlenging (addendum) :*

*Hierin worden de volgende aspecten nog eens aangegeven:*

*Rationale: in lijn met de huidige strategie heeft Sandoz de mogelijkheid om de omzet van de Fentanyl pleisters verder te laten groeien. Sandoz heeft immers een account team dat aandacht kan blijven geven aan Fentanyl (afkomstig van Janssen-Cilag) en daardoor meer omzet te creëren bij dezelfde apothekers dmv omzetting van andere opiaten, gebruikt bij pijn, naar Fentanyl.*

*Verwijzing naar 10 bis: Duplex registratie. Janssen-Cilag zal aan Sandoz een Duplex registratie van Fentanyl matrix formulering geven.*

*Fee per maand: nog te bepalen, maar lager dan tot op heden, want Sandoz kan bij Janssen-Cilag Fentanyl matrix tegen een veel lagere prijs inkopen.*

*Duur van de verlenging: 1 jaar daarna opnieuw mogelijk met een jaar etc (als dit zinvol wordt geacht door beide partijen.).*

*Duplex registratie contract*

*Conditioes:*

*Sandoz krijgt van Janssen-Cilag het recht om de Fentanyl matrix (25-100) afkomstig van Janssen-Cilag*

- (181) J&J's plan was therefore to allow Novartis/Sandoz ([...])\* to sell the generic fentanyl patches supplied by Janssen-Cilag B.V. as soon as at least one generic company could not be stopped from selling generic matrix patches on the Dutch market. In the meantime, before the process of the "duplex" transfer was completed and in particular, until a third party launched its generic fentanyl patch, the term of the existing Co-promotion agreement with Novartis/Sandoz would be extended by an addendum.
- (182) On 17 May 2006, Sandoz B.V. sent Janssen-Cilag B.V. a signed Letter of Intent concerning the transfer of the duplex registration to Sandoz B.V.<sup>250</sup>
- (183) In June 2006, Ratiopharm entered the Dutch market (for the second time) with its generic matrix patch. The events are described in the internal email sent by the [employee]\* of Janssen-Cilag B.V. on 13 June 2006:

*"[A]s of June 9th, the MEB (Medicines Evaluation Board) renounced the claim of Janssen-Cilag regarding the registration of fentanyl matrix by Ratiopharm. Hence, Ratiopharm is allowed back on the Dutch pharma market, effective immediately.*

*In order to manage Durogesic sales & profitability after generic product entrance, we received earlier agreement to provide Sandoz with a duplex registration of Fentanyl matrix. This process is well on its way and most likely Sandoz will be able to launch by August 1, 2006.*

*At the same time, we also indicated that we would like to give a 2nd duplex registration to [third party]\* (holding presently 35% volumeshare of the generic market) under the same conditions as Sandoz.<sup>251</sup>*

- (184) The issue that was still to be decided upon was the compensation to Hexal B.V./Sandoz B.V. for the period before they effectively came on the market with the "duplex product". In the internal email of Janssen-Cilag B.V. from 12 July 2006, the following compensation was proposed:

*"I propose:*

*Not to pay any additional compensation in July – this month Sandoz still receives the last payment of €109,408 under the current contract.*

*Sandoz is to receive a compensation of €25,000 in the month of August;*

*Sandoz is to receive a compensation of €25,000 in September if they do not launch their duplex because the court judgment of 24 July is positive for*

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*by te introduceren in de Nederlandse markt nadat tenminste een generica firma haar Fentanyl matrix formulering fysiek in de nederlandse markt heeft gedistribueerd [...]"*

<sup>250</sup> ID0151, p. 151.

<sup>251</sup> ID0137, p. 332.

*Janssen-Cilag, and Ratiopharm may no longer be active on the NL market.*<sup>252 253</sup>

- (185) Ratiopharm was indeed eventually forced to leave the market again as of 28 July 2006.<sup>254</sup> This meant that there was no generic fentanyl patch on the Dutch market. Therefore the parties decided to proceed with the extension of the Co-promotion agreement by the addendum<sup>255</sup> instead of immediately transferring the duplex registration from Janssen-Cilag B.V. to Hexal B.V./Sandoz B.V. and launching the "duplex product" by Hexal B.V./Sandoz B.V. [...] as previously anticipated (see Recital (183)).

### 6.2.3. *Addendum to the Agreement*

- (186) In August 2006, Janssen-Cilag B.V., on the one hand, and Hexal Pharma Nederland B.V.<sup>256</sup> and Sandoz B.V., on the other, concluded an addendum to the initial co-promotion agreement. Sandoz B.V. signed the addendum on 16 August 2006 and Janssen-Cilag B.V. on 17 August 2006.<sup>257</sup>
- (187) The addendum came into force retroactively on 11 July 2006 and extended the initial agreement for a period of one year, until 10 July 2007, except if terminated earlier by either party giving the other not less than 10 days' notice (Article 5 of the addendum).<sup>258</sup>
- (188) The only other substantial modification of the initial agreement concerned the payment. The monthly amount to be paid by Janssen-Cilag B.V. to Hexal B.V./Sandoz B.V. was changed to EUR 250 000 (instead of the initial EUR 308 333), starting from 1 August 2006 (Article 4 of the addendum).<sup>259</sup> In the period covered by the addendum, Hexal B.V./Sandoz B.V. received in total at least EUR 1 250 000 from Janssen-Cilag B.V.
- (189) The addendum thus provided for an additional payment of EUR 3 000 000 in total to Hexal B.V./Sandoz B.V. had the Agreement continued to run for the whole additional period of 12 months.

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<sup>252</sup> ID0161, p. 355 *"ik stel voor om:*  
*In juli geen bijkomende compensatie te storten – deze maand ontvangt Sandoz nog een laatste betaling van €109,408 onder het huidige contract.*

*Sandoz krijgt een vergoeding van €25'000 in de maand augustus;*

*Sandoz krijgt een vergoeding van €25'000 in september indien zij niet op de markt komen met hun duplex omdat de uitspraak van de rechtbank op 24 juli positief is voor Janssen-Cilag en Ratiopharm niet langer op de NL markt actief mag zijn."*

<sup>253</sup> See section 6.2.1.4.

<sup>254</sup> See Recital (98).

<sup>255</sup> See ID0135, p. 240-244.

<sup>256</sup> According to Sandoz, "*Hexal B.V. used Hexal Pharma Nederland as a trade name*" (see ID0311, p. 3). Therefore hereafter no distinction is made between Hexal B.V. and Hexal Pharma Nederland B.V.

<sup>257</sup> ID0179, p. 33-38.

<sup>258</sup> ID0179, p. 35.

<sup>259</sup> ID0179, p. 35.



- (190) The addendum did not contain any provision that further specified or modified the co-promotion activities to be provided by Hexal B.V./Sandoz B.V. When requested to describe specific promotion activities that Hexal B.V./Sandoz B.V. sales force actually performed during the period covered by the addendum, Novartis/Sandoz replied that "*[a]t this time, Sandoz is not aware of contemporaneous supporting evidence and is not in a position to provide a specific description of activities performed during the period July 2006 to December 2006.*"<sup>260</sup> J&J in its reply to the same question stated that "*Janssen-Cilag is not aware of any responsive documents in addition to those which are already part of the Commission's file.*"<sup>261</sup> The Commission observes that there are no documents in the Commission's file that would indicate that any specific co-promotion activities were performed by Hexal B.V./Sandoz B.V. sales force in the period from July to December 2006.
- (191) The only reference to the potential duplex registration in the addendum is in Recital C. of the Preamble: "*In accordance with Article 10bis of the [Co-promotion] Agreement, parties have started discussions on a duplex-registration and are close to reaching an agreement in that respect.*"<sup>262</sup> At the time the addendum was signed, on 17 August 2006, the parties therefore were still in the course of discussions on a duplex registration and had not yet reached the final agreement.
- (192) The duplex marketing authorisations of J&J's fentanyl matrix patches were transferred to Hexal B.V./Sandoz B.V. by Janssen-Cilag B.V. only later, on 24 August 2006.<sup>263</sup>

#### 6.2.4. Termination of the Agreement

- (193) The Co-promotion agreement was eventually terminated on 15 December 2006. An email, sent from Janssen-Cilag B.V. to Sandoz B.V. on 4 December 2006, stated the following:

*"As discussed, Janssen-Cilag wishes to terminate the co-promotion agreement of 11 July 2005 concerning Durogesic as of 15 December 2006.*

*Accordingly, Sandoz will send us the last invoice of €125,000 for the activities performed in December 2006 (until 15 December).*

*We would hereby like to thank you for the constructive co-operation during the last one and half years.*"<sup>264</sup>

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<sup>260</sup> ID0701, p. 4.

<sup>261</sup> ID0688, p. 8.

<sup>262</sup> ID0179, p. 34.

<sup>263</sup> See Recital (35).

<sup>264</sup> ID0161, p. 348. "*zoals besproken wenst Janssen-Cilag de co-promotie overeenkomst van 11 juli 2005 met betrekking tot Durogesic stop te zetten per 15 december 2006.*

*Overeenkomstig zal Sandoz ons een laatste factuur toesturen van €125,000 voor de activiteiten verricht in december 2006 (tot 15 december).*

*Bij deze wensen wij u tevens te bedanken voor de constructieve samenwerking tijdens het laatste anderhalf jaar."*

- (194) The Co-promotion agreement between Janssen-Cilag B.V. on the one hand and Hexal B.V. and Sandoz B.V. on the other was therefore terminated and replaced by the supply agreement as described below (section 6.3).

### 6.3. The supply agreement and generic entry

- (195) The supply agreement was entered into by Janssen-Cilag B.V. (signed on 18 September 2006) on the one hand and by Sandoz B.V. and Hexal Pharma Nederland B.V. (both companies signed on 13 October 2006) on the other.<sup>265</sup> The supply agreement entered into force on 1 January 2007 and had an initial duration of 2 years.<sup>266</sup>
- (196) In parallel, Janssen-Cilag B.V. engaged in negotiations with [third party]\* with a view to concluding a similar supply agreement. On [...]\*, the supply agreement with [third party]\* was signed. It entered into force on [...]\*, with the launch date foreseen for [...]\*.<sup>267</sup> It had an initial duration of 2 years from the launch date.<sup>268</sup>
- (197) Via the supply agreements, Janssen-Cilag B.V. granted Hexal B.V./Sandoz B.V. and [third party]\* a non-exclusive right to purchase, promote and sell the transdermal fentanyl patches in the Netherlands under the generic companies' respective brand. The right to purchase, promote and sell the 12 µg/hour version was conditional upon the entry into the Dutch market of a competing generic of such version.
- (198) The supply agreements permitted Hexal B.V./Sandoz B.V. [...] to introduce their generic versions once an independent generic player was present on the market. Given that Ratiopharm started a new marketing authorisation procedure for a generic matrix patch (Ratiopharm had eventually obtained the marketing authorisation on 21 December 2006), Janssen-Cilag B.V. anticipated that Ratiopharm would enter the market either in December 2006 or in January 2007.<sup>269</sup> Janssen-Cilag B.V. therefore decided to launch its own generic version of fentanyl matrix patches as of 1 January 2007.<sup>270</sup> At the same time, Hexal B.V./Sandoz B.V. [...] also entered the market with matrix fentanyl supplied by Janssen-Cilag B.V. as of 1 January 2007 (though without the 12 µg/hour patch).<sup>271</sup>
- (199) It turned out however that Ratiopharm actually only came onto the market on 1 February 2007.<sup>272</sup> Janssen-Cilag B.V. internally commented that given Ratiopharm's launch as of 1 February 2007, the authorisations for Hexal B.V./Sandoz B.V. [...] were one month too early (that is to say, at a time when no other independent generic was yet on the market).<sup>273</sup>

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<sup>265</sup> ID0135, p. 115.

<sup>266</sup> ID0135, p. 103-120. See also ID0161, p. 317 and ID0161, p. 318-322.

<sup>267</sup> ID0135, p. 122.

<sup>268</sup> ID0135, p. 121-137.

<sup>269</sup> ID0161, p. 317 and ID0161, p. 318-322.

<sup>270</sup> ID0161, p. 317.

<sup>271</sup> ID0161, p. 317 and ID0161, p. 318-322.

<sup>272</sup> Ratiopharm launched all the product strengths except for the 12 µg/hour version.

<sup>273</sup> ID0161, p. 317

- (200) The cooperation between Janssen-Cilag B.V. and Hexal B.V./Sandoz B.V. was eventually terminated by Sandoz B.V. by a letter of 27 June 2008 and the termination was effective as of 1 January 2009.<sup>274</sup>
- (201) Overall, the cooperation through the Co-promotion agreement together with the subsequent supply agreement between Janssen-Cilag B.V. and Hexal B.V./Sandoz B.V. was perceived as successful by J&J. In a presentation of November 2007 entitled "*Partnering deals - Lessons learned from the Netherlands*", prepared by the [employee]\* of Janssen-Cilag B.V., the partnering deals with Hexal B.V./Sandoz B.V. and [third party]\* were evaluated *ex-post*. Regarding the Co-promotion agreement with Hexal B.V./Sandoz B.V., the effects for Janssen-Cilag B.V. were assessed as follows:

*"No price reduction Durogesic*

*Ex-factory Price effect on annual basis (2006): 5.9 MIO*

*Retain market share*

*Loss of 25% MS [Market Share], would mean an additional loss of: 4.6 MIO*

*No additional discounts*

*30% additional discount would be needed; less: 4.2 MIO"<sup>275</sup>*

This means<sup>276</sup> that thanks to the Co-promotion agreement, there was no reduction in the price of Janssen-Cilag B.V.'s fentanyl patch in the Netherlands in the period concerned due to generic entry and this had a positive price effect for Janssen-Cilag B.V. estimated at EUR 5.9 million on an annual basis.<sup>277</sup> In addition, J&J retained its market share as sole supplier<sup>278</sup> for the duration of the Co-promotion agreement and avoided the expected loss of 25% of its market share in the event of generic entry. Janssen-Cilag B.V. therefore saved an additional EUR 4.6 million for "a full year".<sup>279</sup> Finally, as long as the Co-promotion agreement was in place and no generic was on the market, Janssen-Cilag B.V. did not have to pay any additional discounts to pharmacies and saved EUR 4.2 million for "a full year" in comparison to the scenario of the generic entry.<sup>280</sup>

- (202) For the entire period of the Co-promotion agreement, including the addendum, Janssen-Cilag B.V. paid a total of approximately EUR 5 million to Hexal

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<sup>274</sup> ID0173, p. 55

<sup>275</sup> ID0138, p. 121.

<sup>276</sup> This understanding of the presentation was not contested by the Parties in their replies to the Statement of Objections.

<sup>277</sup> J&J explained that "[t]he 5.9 million figure was derived from the required price reduction upon entry of the generic version as a consequence of applying the Covenant". ID0933, p. 4.

<sup>278</sup> Where reference is made to J&J as the sole or only supplier of fentanyl patches in the Netherlands, it is meant that the only fentanyl patches available in the Netherlands in the given period were produced by J&J.

<sup>279</sup> ID0933, p. 4.

<sup>280</sup> J&J explained that this bullet point concerns the extra margin to be given to pharmacists. ID0933, p. 4.

B.V./Sandoz B.V.<sup>281</sup> According to the *ex-post* evaluation mentioned in Recital (201), Janssen-Cilag B.V. saved in total EUR 14.7 million by concluding the Co-promotion agreement with Hexal B.V./Sandoz B.V. whereby the launch of Hexal B.V./Sandoz B.V.'s generic product in the Netherlands was prevented.

- (203) Regarding the supply agreement, J&J described the effects for Janssen-Cilag B.V. in the same presentation from November 2007 as follows:

*"Market share still substantial (90%)*

*5 generic labels on the market*

*MS generic partners: 25%*

*MS Nycomed + Ratiopharm: 10%*

*Profitable prices*

*Actual NTS [Net Trade Sales] 2007: 15.5 MIO*

*Comparison with worst case scenario*

*Worst case NTS 2007[Net Trade Sales]: 7.1 MIO<sup>282</sup>*

According to that presentation, Janssen-Cilag B.V. still supplied approximately 90% of the Dutch market with its fentanyl patches even after the generic entry, thanks to the supply agreements with Hexal B.V./Sandoz B.V. and [third party]\*. Janssen-Cilag B.V.'s fentanyl patches were marketed either by Janssen-Cilag B.V. itself or through its generic partners Hexal B.V./Sandoz B.V. and [third party]\*, which supplied approximately 25% of the Dutch market. Janssen-Cilag B.V. also estimated to have maintained profitable prices for the duration of the supply agreements with Hexal B.V./Sandoz B.V. and [third party]\*, despite the generic entry. Actual Net Trade Sales of Janssen-Cilag B.V.'s fentanyl patches in 2007 were therefore EUR 8.4 million higher than under the worst expected scenario.

## **7. THE NATURE OF THE INFRINGEMENT**

### **7.1. Application of Article 101 of the Treaty**

- (204) This Decision examines the application of Article 101 of the Treaty to the Co-promotion agreement between J&J and Novartis/Sandoz.<sup>283</sup> The product concerned was the fentanyl transdermal patch, including both the depot patch and the matrix patch, and the territorial scope of the Agreement was the Netherlands.<sup>284</sup>

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<sup>281</sup> See Recitals (161) and (188).

<sup>282</sup> ID0138, p. 121.

<sup>283</sup> As mentioned in Recital (392), the Co-promotion agreement was applicable not only to the contractual parties, but also to their "*Affiliates*", including companies established outside the Netherlands.

<sup>284</sup> For the regulatory specificities of the Netherlands, see section 3.

- (205) In this case the Commission is the competent authority to apply Article 101 of the Treaty since the infringement in question had an appreciable effect on trade between Member States (for the detailed assessment of the effect on trade see section 7.6.). As the infringement did not affect trade with the Contracting Parties of the EEA Agreement, the EEA Agreement does not apply.
- (206) The following sections outline the requirements of Article 101(1) of the Treaty and the legal concepts used therein, including "agreements between undertakings", "restriction of competition" and "restriction of competition by object". This is followed by the application of those general principles to the specific facts of this case and the assessment whether the parties' practices under examination amounted to a restriction "by object" of competition within the meaning of Article 101(1) of the Treaty. Thereafter it is analysed whether the practices affected trade between Member States. Finally, the application of Article 101(3) of the Treaty is discussed.

## 7.2. Article 101(1) of the Treaty

- (207) Article 101(1) of the Treaty prohibits as incompatible with the internal market "*all agreements between undertakings [...] which may affect trade between Member States and which have as their object or effect the prevention, restriction or distortion of competition within the common market, and in particular those which:*

[...]

*(b) limit or control production and markets;*

*(c) share markets or sources of supply.*

[...]"

provided the conduct does not meet the conditions for an exemption pursuant to Article 101(3) of the Treaty. The Court of Justice of the European Union has clarified that the types of agreements covered by Article 101(1)(a) to (e) of the Treaty do not constitute an exhaustive list of prohibited collusion.<sup>285</sup>

- (208) The conclusion of the legal assessment below is that the Co-promotion agreement that is the subject of this Decision had the object of restricting competition within the internal market or a substantial part thereof, in that it contained a transfer of considerable value from the originator J&J to a close potential generic competitor, Novartis/Sandoz, with the objective that the latter would not enter the Dutch market with generic fentanyl patches for the duration of the Agreement.

## 7.3. Agreements between undertakings

- (209) Article 101(1) of the Treaty prohibits "*agreements between undertakings*". As the Court of Justice held in Case C-97/08, *Akzo Nobel v Commission*, "*the concept of an undertaking covers any entity engaged in an economic activity, regardless of its legal*

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<sup>285</sup> Case C-209/07, *Competition Authority v Beef Industry Development Society Ltd (BIDS) and Barry Brothers (Carrigmore) Meats Ltd*, [2008] ECR I-08637, paragraph 23.

*status and the way in which it is financed [...] even if in law that economic unit consists of several persons, natural or legal.*"<sup>286</sup> An "agreement" can be said to exist when there is a concurrence of wills between two or more parties.

- (210) The Commission considers that the infringement in this case presents all the characteristics of an agreement<sup>287</sup> between undertakings in the sense of Article 101 of the Treaty, as all the parties to the Co-promotion agreement were engaged in an economic activity and they adhered to a common plan which limited or was likely to limit their individual commercial conduct.

#### **7.4. Restriction of competition**

- (211) In the pharmaceutical sector, once the SPC period has expired and the active ingredient is no longer protected, that active ingredient can in principle be used by generic companies to produce and sell generic medicines containing the identical active ingredient in question (see section 3.3). In that situation, the originator undertaking and the generic undertaking(s) involved in the development of the generic version of the same product may be at least potential competitors, if not already actual ones. They should therefore, in principle, show independent commercial conduct. In this case<sup>288</sup>, the fentanyl depot patch had never been protected by a valid patent in the Netherlands and data exclusivity had expired, as explained in Recitals (22) and (33).
- (212) Generic entrants will tend to price their product lower, often considerably lower, than the originator's product, as otherwise distributors, pharmacies, prescribers, patients and health insurers would have little reason to choose their product, given that the generic product uses the same active ingredient as the original product. In principle, the only significant way for generic undertakings to compete with the originator's product and with each other's product is therefore on price. The more generic companies enter, the stronger the price competition will normally tend to become and the faster prices will normally tend to fall.
- (213) In the Netherlands, at the time the Co-promotion agreement was concluded, the introduction of a first generic medicine on the market would have had as a consequence considerable loss of turnover and profits for the originator product. Moreover, due to the pricing and reimbursement rules in force the new generic products were to be introduced at a pharmacy purchase price on average at least 40% below the price of the corresponding originator product and the price of the originator product was also to be reduced on average by 40% once a first generic entered the market (see section 3.4.1). Those substantial price decreases would have been to the benefit of the Dutch health system and, ultimately, Dutch consumers. Moreover, competition would have come into existence between the originator

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<sup>286</sup> Judgment of 10 September 2009, paragraphs 54-55.

<sup>287</sup> The concept of agreement within the meaning of Article 101(1) of the Treaty "centers around the existence of a concurrence of wills between at least two parties, the form in which it is manifested being unimportant so long as it constitutes the faithful expression of the parties' intention", Case T-41/96 *Bayer AG v Commission* [2000] ECR II-3383, paragraph 69. This paragraph was quoted by the Court of Justice in the appeal against the General Court's judgment in the Bayer cases in Cases C-2/01P and C-3/01P *Bundesverband der Arzneimittel-Importeure e V v Bayer AG* [2004] ECR I-23, paragraph 97. It is clear that a legally enforceable contract qualifies as an agreement.

product and the generic version, which could have led to further price decreases, for instance by health insurers reimbursing only the lowest-priced product, and/or larger discounts to pharmacists.<sup>288</sup>

- (214) Under those circumstances, the originator may prefer trying to delay or avert generic entry by creating a decisive incentive for the generic not to enter, by sharing with it the supra-competitive profits resulting from the non-existence of generic competition. At the same time the generic undertaking may prefer to stay out of the market in exchange for a considerable value transfer, which may correlate to or possibly be even higher than the profit the generic undertaking would have made had it launched its own generic product. Moreover, the generic undertaking would receive that value without the need to undergo all the risks of competition.
- (215) Consumers, however, will be considerably worse off in this situation, as they fail to benefit from the competition and lower prices that would have followed generic entry. Therefore this type of agreement merits particular scrutiny.

## 7.5. Restriction of competition by object

### 7.5.1. Principles

- (216) The Court of Justice recalled in *GlaxoSmithKline Services v Commission* that the anti-competitive object and effect of an agreement are not cumulative but alternative conditions for assessing whether such an agreement comes within the scope of the prohibition laid down in Article 101 of the Treaty. It is not necessary to examine the effects of an agreement once its anticompetitive object has been established.<sup>289</sup> The distinction between "*infringement by object*" and "*infringement by effect*" arises from the fact that certain forms of collusion between undertakings can be regarded, by their very nature, as being "*injurious to the proper functioning of normal competition*".<sup>290</sup> An agreement is a restriction of competition by object if it reveals a "sufficient degree of harm to competition".<sup>291</sup>
- (217) In particular, the Commission considers that, depending on the specific circumstances of the case, an agreement by which a generic competitor accepts restrictions on its commercial freedom in return for a significant value transfer can be a restriction by object contrary to Article 101 of the Treaty. In this respect, Case C-209/07, *Irish Beef*, is of particular relevance to the facts examined in this Decision. That case dealt with a mechanism, the so-called BIDS arrangements, to reduce perceived overcapacity in the Irish beef sector. As part of the BIDS arrangements, the undertakings that stayed in the market paid financial compensation to those who agreed to leave the market. The Court stated, in this respect:

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<sup>288</sup> See Recital (55).

<sup>289</sup> Case C-501/06, C-513/06, C-515/06, C-519/06 [2009] ECR I-9291, paragraph 55.

<sup>290</sup> Case C-209/07 *Competition Authority v Beef Industry development Society and Barry Brothers*, [2008] I-8637, paragraph 17; C-8/08 *T-Mobile*, [2009] ECR I-4529, paragraph 29; Communication from the Commission: Guidelines on the applicability of Article 101 of the Treaty on the Functioning of the European Union to horizontal co-operation agreements, OJ C 11, 14.1.2011, p. 8, points 21 and 24.

<sup>291</sup> C-501/06, C-513/06, C-515/06, C-159/06 *GlaxoSmithKline Services v Commission*, paragraph 55. Case T-111/08, *MasterCard*, not yet reported, paragraph 139. See also Case C-226/11 *Expedia Inc. v Autorité de la concurrence*, not yet reported, paragraph 36.

*"The BIDS arrangements are intended therefore, essentially, to enable several undertakings to implement a common policy which has as its object the encouragement of some of them to withdraw from the market and the reduction, as a consequence, of the overcapacity which affects their profitability by preventing them from achieving economies of scale.*

*That type of arrangement conflicts patently with the concept inherent in the EC Treaty provisions relating to competition, according to which each economic operator must determine independently the policy which it intends to adopt on the common market. Article 81(1) EC [now 101(1) of the Treaty] is intended to prohibit any form of coordination which deliberately substitutes practical cooperation between undertakings for the risks of competition.*

*In the context of competition, the undertakings which signed the BIDS arrangements would have, without such arrangements, no means of improving their profitability other than by intensifying their commercial rivalry or resorting to concentrations. With the BIDS arrangements it would be possible for them to avoid such a process and to share a large part of the costs involved in increasing the degree of market concentration [...]"<sup>292</sup>*

- (218) The Court of Justice in *Irish Beef* concluded that the arrangements in question were a restriction by object.<sup>293</sup> The facts in this Decision show important similarities to the situation in *Irish Beef*, in that in the Agreement covered by this Decision two (potential) competitors agreed on a common plan whereby a close, or the most advanced, generic undertaking was given the incentive not to enter the market with its own generic product by a substantial payment which would be lost in case of entry. The main difference is that in the case at hand, there is no question of reducing any overcapacity in the market, but rather of preserving and sharing the supra-competitive profits of the incumbent undertaking and thus restricting competition between them, compared to the situation that most probably would have arisen in the absence of the agreement in question. Moreover, the generic company accepted to delay the launch of its own product in exchange for attractive monthly payments knowing that it would be facing the interruption of the payments if it entered into the market.
- (219) On the basis of the above and in order to identify whether the Co-promotion agreement had the potential to restrict competition by its very nature, the analysis below (section 7.5.2) will in particular take into account whether:
- the generic undertaking and the originator undertaking were at least potential competitors;
  - due to the Agreement, the generic undertaking limited, for the duration<sup>294</sup> of the Agreement, its independent efforts to enter the market with its generic product; and

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<sup>292</sup> Case C-209/07, *Competition Authority v Beef Industry Development Society Ltd and Barry Brothers (Carrigmore) Meats Ltd*, judgment of 20 November 2008, paragraphs 33 to 35.

<sup>293</sup> Ibidem, paragraph 40.

<sup>294</sup> The term "duration" refers to the period during which the Agreement was in force.



- the Agreement was related to a transfer of value from the originator undertaking which substantially reduced the incentives of the generic undertaking to independently pursue its efforts to enter the market with its generic product.

(220) In the present case other important factors will also be taken into consideration, namely the fact that the amount paid to Hexal B.V./Sandoz B.V. considerably exceeded what Hexal B.V./Sandoz B.V. itself expected, at the time it concluded the Agreement, to make if it had launched its own fentanyl depot patch in the Netherlands, and that it matched the amount Janssen-Cilag B.V. was made to believe Hexal B.V./Sandoz B.V. would have made if it had entered the Dutch market with its own fentanyl depot patch. In addition, in this context, particular factual features of the present case, as described in detail in the section below, will in view of their significance against the backdrop of the principles hereby identified, further inform the Commission's finding as to whether the Co-promotion agreement had the above referred potential. The particular factual features of the present case include the fact that during the period covered by the initial co-promotion agreement, Hexal B.V./Sandoz B.V. carried out only limited promotion activities, of limited usefulness to Janssen-Cilag B.V., while for the period covered by the addendum, there is no evidence that any promotion activities were carried out by Hexal B.V./Sandoz B.V. whatsoever.

#### 7.5.2. *Application to the present case*

(221) In accordance with well-established case law of the Court of Justice<sup>295</sup>, the analysis in this section first examines the economic and legal context leading up to the Agreement's conclusion as it emerges from the facts described in this Decision. This analysis leads to the conclusion that the undertakings in question were at least potential competitors at the time when they concluded the Agreement.

(222) In a second step, the analysis examines the actual content and objectives of the Agreement. This analysis identifies (i) the payments from J&J (ii) the counter-performance of Novartis/Sandoz. To the extent that the implementation of the Agreement throws any further light on these questions, this is also analysed.<sup>296</sup> This analysis leads to the conclusion that the Co-promotion agreement included a non-entry mechanism, whereby for the duration of the Agreement strong incentives were provided for Novartis/Sandoz not to enter the Dutch market. If Novartis/Sandoz entered the Dutch market it would have lost the considerable monthly payments from J&J, which considerably exceeded what Novartis/Sandoz expected to make if it

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<sup>295</sup> Case C-501/06P, C-241/06P, C-515/06P and C-519/06P, *GlaxoSmithKline*, [2009] ECR I-9291, paragraph 58 and the jurisprudence cited therein. See also Case C-403/08 a.o., *Football Association Premier League*, judgment of 4 October 2011, paragraph 136, [2011] ECR I-09083, and Case C-8/08, *T-Mobile Netherlands BV* a.o., judgment of 4 June 2009, [2009] ECR I-4529, paragraph 27.

<sup>296</sup> The Court recalled in Case T-491/07 *Groupement des cartes bancaires*, paragraph 251, that while determining restriction by object, the content of the agreement as well as its origin and the circumstances of its implementation can be taken into account. The way in which an agreement is actually implemented may reveal a restriction by object even where the formal agreement does not contain an express provision to that effect, see Guidelines on the application of Article 81(3) (OJ C 101, 27.4.2004, p. 97, recital 22).

launched the product and which was considerably less than what J&J expected to lose if Novartis/Sandoz entered the market.

- (223) In a third step, the analysis examines each party's intentions regarding the Agreement to see whether they match the analysis of the objective elements of the first two steps, even if demonstration of such subjective is not legally required. The analysis of the parties' intentions confirms the objective elements of the analysis and shows that both parties acted in full knowledge of the objective of the Agreement which was designed to ensure that Novartis/Sandoz was kept out of the market and J&J could maximise its profits for sales of the originator product as long as the Agreement was in force and share these supra-competitive profits with Novartis/Sandoz.
- (224) The Commission also analyses the parties' arguments on the existence of justifications for the agreements under Article 101(3) of the Treaty and finds that the conditions of that provision are not met.
- (225) Overall, the Commission concludes that the Agreement between Janssen-Cilag B.V. and its close potential generic competitor, Hexal B.V./Sandoz B.V., containing transfers of value amounting in total to approximately EUR 5 million which induced the generic undertaking in question not to pursue its independent efforts to enter the market for the duration of the Agreement constituted an infringement of Article 101 of the Treaty.

#### 7.5.2.1. Legal and economic context of the Agreement

- (226) In 2005, Janssen-Cilag B.V. was the only undertaking marketing fentanyl transdermal patches on the Dutch market and the Co-promotion agreement with Hexal B.V./Sandoz B.V. signed in July 2005 helped Janssen-Cilag B.V. to effectively maintain its position as the sole provider of the fentanyl patches on the Dutch market until January 2007.<sup>297</sup> In this section, the legal and economic context of the Agreement will be analysed and in particular it will be assessed whether Janssen-Cilag B.V. and Hexal B.V./Sandoz B.V. were, at the time the Co-promotion agreement was concluded, at least potential competitors. The generic company is a potential competitor if there are "real concrete possibilities" for the generic company to enter the market and to compete with the originator.<sup>298</sup> This entails an analysis of whether the undertaking was pursuing an "economically viable strategy".<sup>299</sup> The generic company's intention to enter the market, which may result from its development work, is a relevant factor. However, the ability to enter the market is the essential factor.<sup>300</sup> A potential competitor does not have to have a readily marketable product as long as the company is able to enter within a "short period of time".<sup>301</sup>

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<sup>297</sup> Save for short periods of temporary failed entries by Ratiopharm; see section 5.2.2.2.

<sup>298</sup> Case T-461/07 *Visa Europe, Visa International Service v Commission*, paragraph 166.

<sup>299</sup> *Ibidem*, paragraph 167.

<sup>300</sup> Case T-416/07 *Visa Europe Visa International Service v Commission*, paragraphs 168 and 174.

<sup>301</sup> See also Case T-461/07 *Visa Europe, Visa International Service v Commission*, paragraph 189 where the General Court stated that the potential entry must "take place with sufficient speed to form a constraint".

The perception of a threat by the current market players is also an element which can be taken into account for the assessment of potential competition.

- (227) For that purpose, it will be analysed, in particular, whether: (i) there were any regulatory obstacles for Novartis/Sandoz to launch its fentanyl patch in the Netherlands at the time it concluded the Co-promotion agreement; (ii) Novartis/Sandoz was actively preparing the launch of its own fentanyl patch in the Netherlands at the time it concluded the Co-promotion agreement; and (iii) J&J perceived Novartis/Sandoz as a (at least) potential competitor in the Netherlands.
- (a) Potential regulatory obstacles
- (228) In the Netherlands J&J's fentanyl depot patch has never been protected by a valid patent. The market exclusivity for the depot patch was only based on the regulatory data exclusivity period for the purposes of a marketing authorisation. When, on 4 March 2004, the data exclusivity expired, the depot patch also lost exclusivity<sup>302</sup>.
- (229) After the fentanyl depot patches in the Netherlands had lost exclusivity, Hexal B.V. applied for the marketing authorisation for its fentanyl depot patch in August 2004. The marketing authorisation was granted on 17 March 2005, four months before the Co-promotion agreement was concluded.<sup>303</sup>
- (230) The pricing and reimbursement status, which is also a regulatory precondition for marketing the product in the Netherlands, was granted to Hexal B.V. in April 2005<sup>304</sup>, approximately three months before the Co-promotion agreement was concluded. By that time Hexal B.V. therefore fulfilled all the key regulatory requirements for launch of its fentanyl depot patches.
- (231) Regarding the applicable rules on substitution in the Netherlands, the two types of patches (depot and matrix) were at that time considered as substitutable by the MEB.<sup>305</sup> Pharmacists had the right to substitute an originator product with its generic version (see section 3.4.3). Because of the position taken by the MEB on the fentanyl patches, such substitution was therefore not only possible between originator and generic versions of the matrix patch, but also between the originator version of the matrix patch and the generic version of the depot patch.<sup>306</sup> In other words, if Hexal B.V./Sandoz B.V. had launched its generic fentanyl depot patch in the Netherlands, it could have been substituted by the pharmacies for Janssen-Cilag B.V.'s matrix patch. This meant that by giving larger discounts to pharmacists than Janssen-Cilag B.V., Hexal B.V./Sandoz B.V. could have persuaded many pharmacists to sell its product rather than Janssen-Cilag B.V.'s.

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<sup>302</sup> See Recitals (82) and (83).

<sup>303</sup> See Recital (94).

<sup>304</sup> See Recital (94).

<sup>305</sup> See Recital (79).

<sup>306</sup> See also ID0564, p. 3.

- (232) Therefore Hexal B.V./Sandoz B.V. was so advanced in its preparations that there were no significant regulatory hurdles for it to launch its fentanyl depot patch in the Netherlands in July 2005 or shortly thereafter.<sup>307</sup>
- (b) Novartis/Sandoz's preparations and readiness for the generic product launch
- (233) Novartis/Sandoz's contemporaneous documents, including internal estimates and calculations, demonstrate that shortly before concluding the Co-promotion agreement with Janssen-Cilag B.V., Hexal B.V./Sandoz B.V. was still actively preparing the launch of its own product (generic depot patch)<sup>308</sup> and that it was actually very close to launching the product in July or August 2005. In the absence of the Co-promotion agreement, the launch in July or August 2005 would have been a very realistic and plausible option, as shown below.
- (234) For example, Hexal B.V.'s internal presentation, dated 1 February 2005 estimated: "*Depot patch under own name (from July 2005)*".<sup>309</sup> Sandoz B.V.'s internal strategic presentation entitled "*Targets 2005*" concerning the Netherlands prepared in March 2005 included among the "*Key Launch Assumptions*" for 2005 the following line: "*Fentanyl – NL - launch date 02/07/2005*".<sup>310</sup>
- (235) Hexal B.V.'s presentation mentioned in Recital (234) was circulated within Novartis/Sandoz's management by email on 15 June 2005, together with two other documents analysing different scenarios.<sup>311</sup> All those documents circulated on 15 June 2005 included as a first option (scenario) launch of Novartis/Sandoz's own depot patch in July 2005. Those documents calculate the annual potential revenue from the launch at EUR 3.72 million<sup>312</sup>, based on an estimate made in February 2005, and the "*net profit*" for the 12 months period at EUR 2.2 to 3.0 million<sup>313</sup>, based on an estimate made in April 2005.<sup>314</sup> On 29 June 2005 the [employee]\* of Sandoz B.V. wrote to the [employee]\* of Sandoz B.V. concerning those documents: "*not formally approved, but discussed*".<sup>315</sup> This shows that less than two weeks before the Co-promotion agreement with Janssen-Cilag B.V. entered into force, Novartis/Sandoz attributed a concrete and considerable value to the option of entering the market with its own product in July or in August 2005.
- (236) On 30 June 2005 the new proposal from Janssen-Cilag B.V. "*to pay for a co-promotional payment when Hexal is not launching their own depot patch*"<sup>316</sup> was explained and submitted for decision in an email to a [employee]\* of Hexal AG. The

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<sup>307</sup> This was not questioned by the parties in their replies to the Statement of Objections.

<sup>308</sup> In its reply to the Statement of Objections, "*Sandoz does not deny that Hexal made preparations towards a possible launch of a generic depot patch. Hexal received a marketing authorisation. Hexal had also applied for a reimbursement limit, which had been granted.*" ID1537, p. 17.

<sup>309</sup> See Recital (124).

<sup>310</sup> See Recital (127).

<sup>311</sup> See Recital (138).

<sup>312</sup> See Recitals (122) and (124).

<sup>313</sup> See Recital (130).

<sup>314</sup> According to Novartis/Sandoz, the estimates differ, because they rely on various hypotheses. ID0832, p. 3.

<sup>315</sup> ID0172, p. 16. "*niet formeel accoord, wel besproken.*"

<sup>316</sup> See Recital (143).

proposed interim actions in that email were the following: *"Although the new proposal from Janssen/Cilag is interesting from a financial point of view [...] we would suggest continuing with the preparations for the launch of the Hexal product."*<sup>317</sup> So, less than two weeks before entry into force of the Co-promotion agreement, the top management of Novartis/Sandoz still recommended continuing with preparations for the launch of Novartis/Sandoz's own generic product.

- (237) The fact that Hexal B.V./Sandoz B.V. felt itself capable of launching the generic fentanyl patch in the Netherlands in August 2005 at the latest is further confirmed by an internal email of 10 January 2006 sent by the [employee]\* of Sandoz B.V., which describes the events *ex-post*: *"In July [2005] we had to make the decision locally to either launch the product Fentanyl (which was included in target 2005) or go for the co-marketing option. In the end it was decided to go for the last option. We also locally paid for the destruction of packaging material which was already produced and the filling of the registration of this product. So we choose to go for Oper. Inc. [Operating Income] in stead of Sales/Market share (which was in the target 2005). I didn't record the missed sales and contribution on Fentanyl as a foregone item, since the decision was taken locally not to launch the product and go for the more profitable solution."*<sup>318</sup>
- (238) From the abovementioned documents it is clear that at the time the Co-promotion agreement was concluded, in July 2005, Novartis/Sandoz was not only capable but also on the verge of launching its own generic fentanyl patch in the Netherlands, including having already produced the packaging material, but Novartis/Sandoz deliberately decided not to launch and engage in competition, but instead to *"go for the more profitable solution"*.
- (239) By August 2005, Novartis/Sandoz had launched its generic fentanyl depot patch in at least seven other Member States (Germany, Finland, Hungary, Ireland, Poland, Sweden and the United Kingdom)<sup>319</sup>. The production of Novartis/Sandoz's fentanyl depot patches for all Union markets has always taken place [...]\*.<sup>320</sup> The fact that Novartis/Sandoz in the Netherlands had already had the packaging material prepared shows that Novartis/Sandoz had every intention of entering the Dutch market as well.
- (240) Novartis/Sandoz argued in the reply to the Statement of Objections that there was no "perfect" substitutability between the matrix and the depot patch.<sup>321</sup> Novartis/Sandoz further stated that because it was clear by July 2005 that Janssen-Cilag B.V. had succeeded in moving the market exclusively to the matrix patch and by that time the market for fentanyl depot patches had effectively disappeared, Hexal B.V.'s

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<sup>317</sup> See Recital (143).

<sup>318</sup> See Recital (177).

<sup>319</sup> ID0555, p. 1-2. In comparison to the total size of the markets in those other seven Member States, the size of the total fentanyl market in the Netherlands was modest.

<sup>320</sup> ID0471, p. 4.

<sup>321</sup> *"The Commission's assessment seems to a large extent to rely on the assumption that there was "perfect" substitutability between the matrix patch and the depot patch" which would not be correct, "because at the time the Co-promotion agreement was signed, Janssen-Cilag had already converted the market to matrix patches."* ID1537, p. 14.

perception was that the only generic patch that could effectively compete against Janssen-Cilag B.V.'s product in the Netherlands was a generic matrix patch.<sup>322</sup>

- (241) A similar argument was advanced by J&J in its reply to the Statement of Objections. J&J argued that *"because the matrix patch was superior to the depot patch, [...] any new launch of such a depot patch was unlikely to be successful"*.<sup>323</sup> To support its argument, J&J refers notably to two internal Novartis/Sandoz documents<sup>324</sup> predating the conclusion of the Co-promotion agreement to demonstrate that Hexal B.V./Sandoz B.V. itself anticipated *"switch problems" if it introduced a depot patch on the Dutch market*.<sup>325</sup> At the same time, J&J acknowledged that both J&J and Novartis/Sandoz in their projections expected that if Novartis/Sandoz introduced its own generic depot patch *"it would rapidly gain market share, reaching a market share of 50% a year after launch"*.<sup>326</sup> In this respect, J&J argued that *"these projections were wildly optimistic and should be discounted significantly based on the penetration of Hexal's depot patch in countries where the depot patch was launched"*.<sup>327</sup>
- (242) It is not disputed that before the Co-promotion agreement was entered into, J&J started to market its matrix patches and stopped marketing its depot patches in the Netherlands (see, for example, Recital (85)). However, there were no significant regulatory hurdles for Hexal B.V./Sandoz B.V. to launch its fentanyl depot patch in the Netherlands in July 2005 or shortly thereafter. This included the decision of the MEB that both types of patches are bioequivalent and substitutable (see Recitals (228) to (232)). This is not contested either by Novartis/Sandoz<sup>328</sup> or by J&J.<sup>329</sup> In J&J's own words *"the Dutch Medicines Evaluation Board (MEB) saw both types of*

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<sup>322</sup> *"Janssen-Cilag's successful conversion strategy created a significant hurdle to generic entry, and, in particular, to generic entry with a depot patch because Janssen-Cilag had influenced doctors and patients to view the depot patch as being technically inferior to the matrix patch and the 12 mcg strength as a key management tool. [...] Obviously, Janssen-Cilag's deliberate attempt to fence off any competition in the market by withdrawing its depot patch, launching the matrix patch and broadening its portfolio with a 12 mcg version created an economic context in which it was not viable, or at least not commercially rational, to launch a depot patch without a 12 mcg version on the Dutch market at the time the Co-promotion agreement was negotiated."* ID1537, p. 15. See also ID1537, p. 16.

<sup>323</sup> ID1542, p. 7. J&J also submitted with its reply a published study (ID1543) and an internal white paper (ID1546) on the topic of switching between types of patches. Reference is made to Recital (242) and the opinion of the MEB in that respect.

<sup>324</sup> These documents are mentioned in Recitals (124) and (130).

<sup>325</sup> ID1542, p. 8. The two internal Novartis/Sandoz's documents submitted by J&J read as follows:

*"Depot patch (2) Disadvantages (...) – The market has just been transformed to a matrix patch. (...)*

*Matrix patch (1) Advantages – No switch problem for the patient."* (ID0172, p. 27 and 30)

*"Depot patch more difficult to switch because market is used to matrix patch."* (ID0179, p. 88).

<sup>326</sup> ID1542, p. 8.

<sup>327</sup> ID1542, p. 8. To support its argument, J&J submits a table based on the IMS data, according to which the market shares of the generic depot patches on the N2A Narcotic Analgesics market in the countries where the depot patch was launched (see Recital (93)) were between 1% and 9% one year after launch. According to J&J, *"[t]hese figures confirm that the uptake of the Hexal depot patch was consistently low, irrespective of the specific regulatory environment in each of those Member States. There is no reason to believe that the outcome would have been (very) different in the Netherlands."* (ID1542, p. 9.) A similar position is taken by Novartis/Sandoz in its observations on J&J's reply to the Statement of Objections (ID1612, p. 1).

<sup>328</sup> ID1537, p. 14.

<sup>329</sup> ID1542, p. 11.

*patch [reservoir and matrix] as substitutable*<sup>330</sup> and "*because of the position taken by the MEB [...], such substitution was possible between reservoir and matrix*"<sup>331</sup>. This means that in the Netherlands the reservoir patch was a real and equivalent alternative to the matrix patch. Moreover, the Dutch MEB took a clear position on the bio-equivalence and substitutability of different fentanyl patches and it even rejected a proposed variation of the Summary Product Characteristics, submitted by J&J concerning alleged potential risks of switching between different types of patches.<sup>332</sup> Therefore in the MEB's view, contrary to J&J's claim, there were no potential risks of switching between them. This issue is discussed in further detail in Recitals (408) to (411).

- (243) Furthermore, the two documents invoked by J&J and mentioned in Recital (241) speak of "*disadvantages*" of the depot patch due to the switch and that switching back is "*more difficult*". However, they do not state that a new launch of a generic fentanyl depot patch was unrealistic or even impossible or that it was perceived as such by the parties at the time the Co-promotion agreement was entered into. The contemporaneous evidence on the file clearly contradicts the arguments advanced by the parties that it was the parties' perception that the only generic patch that could effectively compete against Janssen-Cilag B.V.'s product in the Netherlands was a generic matrix patch.
- (244) In this respect, the contemporaneous documents show that in the summer 2005 Novartis/Sandoz was not only capable but also on the verge of launching its own generic fentanyl depot patch in the Netherlands and at that time Novartis/Sandoz expected to gain a significant market share with its depot patch. Novartis/Sandoz had already produced the packaging material. Moreover, in internal documents circulated within the Novartis/Sandoz management in June 2005, the annual potential revenue from the launch of fentanyl depot patches was estimated at EUR 3.72 million and the "*net profit*" for the 12 months period at EUR 2.2 to 3.0 million (see Recital (235)). On 30 June 2005, so less than two weeks before entry into force of the Co-promotion agreement, the top management of Novartis/Sandoz still recommended to continue with preparations for the launch of Novartis/Sandoz's own generic depot patch (see Recital (236)).<sup>333</sup> The contemporaneous documents further show that J&J perceived Novartis/Sandoz as the only potential competitor capable of launching its generic version of fentanyl depot patches by August 2005 and also as a potential competitor capable of gaining a significant market share with its depot patch (see, for example, Recitals (117), (131) to (133) and (248) to (255)). As formulated by J&J in its reply to the Statement of Objections, "*each of them [J&J and Novartis/Sandoz] expected that if Hexal introduced its own generic depot patch it would rapidly gain market share, reaching a market share of 50% a year after launch*".<sup>334</sup> This evidence contradicts the parties' argument that Novartis/Sandoz's and/or J&J's perception at the time of concluding the Co-promotion agreement was that the only generic patch that could effectively compete against Janssen-Cilag B.V.'s product in the Netherlands was a generic matrix patch.

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<sup>330</sup> ID0564, p. 3. See also Recital (79).

<sup>331</sup> ID0564, p. 4.

<sup>332</sup> See Recital (56).

<sup>333</sup> See also, for example, Recitals (125), (130) and (237) to (239).

<sup>334</sup> ID1542, p. 8. See also, for example, ID0161, p. 39 and ID0172, p. 41.

- (245) With regard to the parties' reference to the low penetration of Hexal's depot patch in countries where the depot patch was launched, the Commission observes, for example, that Novartis/Sandoz launched its fentanyl depot patch in 15 Member States in total.<sup>335</sup> In some Member States Novartis/Sandoz launched its fentanyl depot patch as early as summer 2005<sup>336</sup>, whilst in other Member States it was launched much later (for example, in Romania it was launched in April 2008).<sup>337</sup> In those Member States where Novartis/Sandoz launched its fentanyl depot patch later, it was not deterred from launching by sales results in other Member States, such as those invoked by J&J. Furthermore, in some Member States Novartis/Sandoz withdrew its fentanyl depot patch from the market at some point, whilst in at least four Member States Novartis/Sandoz's fentanyl depot patch was still on the market at least until March 2012,<sup>338</sup> again despite or regardless of the sales results in other Member States, such as those invoked by J&J. The information on the uptake on other national markets is therefore not conclusive or helpful for the assessment of the specific situation in the Netherlands.
- (246) Moreover, even if the information on the uptake of Novartis/Sandoz's depot patch on other national markets were of importance for the assessment whether Novartis/Sandoz was likely to enter the Dutch market, no such information on the uptake of generic depot patches in other Member States was available to the parties at the time the parties negotiated and entered into the Co-promotion agreement, as the launch of the Novartis/Sandoz's depot patch in the other Member States took place only after the Co-promotion agreement was entered into (with the exception of Sweden where Novartis/Sandoz launched the depot patch in June 2005, so only shortly before the Co-promotion agreement entered into force on 11 July 2005).<sup>339</sup> The contemporaneous documents mentioned in the preceding paragraphs (see for instance Recital (244)) confirm that at the time of entering into the Co-promotion agreement, according to the parties, Novartis/Sandoz was capable of rapidly gaining a substantial market share with its generic depot patch and posed a real threat for the sales of J&J's matrix patch in the Netherlands.
- (247) The arguments of the parties summarised in Recitals (240) and (241) therefore cannot alter the conclusion that at the time of concluding the Co-promotion agreement or shortly before Hexal B.V./Sandoz B.V. was still actively preparing the launch of its own generic depot patch in the Netherlands and was on the verge of launching it, including the packaging material being already produced.
- (c) J&J's perception of Novartis/Sandoz as potential competitor
- (248) Already in November 2004 Janssen-Cilag B.V. reported that "*if everything goes well Hexal can have its registration in the Netherlands at the end of January 2005 and as the best case (for them!) after a quick reimbursement [decision] it could come on the*

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<sup>335</sup> Austria, Belgium, Czech Republic, Finland, Germany, Hungary, Ireland, Italy, Poland, Portugal, Romania, Slovakia, Slovenia, Sweden, United Kingdom. See ID0555. J&J, in both its reply to the Statement of Objections (ID1542, p. 8-9) and its comments on the Letter of Fact (ID1702, p. 2), mentioned only 7 Member States.

<sup>336</sup> Finland, Germany, Hungary, Ireland, Poland, Sweden, United Kingdom. See ID0555.

<sup>337</sup> ID0555.

<sup>338</sup> Austria, Germany, Italy, United Kingdom. See ID0555.

<sup>339</sup> ID0555.



market on 1 March 2005. [...] According to the insite information Hexal has sufficient production capacity for patches. [...]"<sup>340</sup>

- (249) On 17 May 2005, less than two months before the entry into force of the Co-promotion agreement, the [employee]\* of Janssen-Cilag B.V. wrote in an internal email: "*Making deal with Hexal is crucial for us in the life cycle of Durogesic: If there is no deal then Hexal comes on the market (expected for August 2005) with their fentanyl patch*".<sup>341</sup> That email also refers to the expected price decrease after Hexal B.V.'s entry due to the regulatory framework, which suggests that Hexal B.V. was perceived by Janssen-Cilag B.V. as the first generic company to possibly enter the Dutch market.
- (250) In the attachment to that internal J&J email, which was sent, amongst others, to the [employee]\* of Janssen-Cilag and in which different scenarios were analysed, for the option "*Base Case: No Deal*" the following was assumed: "*Hexal enters market in august 2005 with own depot patch*".<sup>342</sup>
- (251) J&J perceived Novartis/Sandoz as the only generic company capable of launching the generic fentanyl patch (depot) in the immediate future. In the handwritten notes of 1 June 2005, the [employee]\* wrote: "*Dutch market is margin driven (price); pharmacies might  $\Delta$  [substitute] matrix by reservoir to keep margin. Expected move of market share to depot Hexal. Expected needed price discount of 20% [...] Hexal deal is only delaying mechanism. Competition - reservoir (**currently only Hexal**) -> Aug 05 [...]*".<sup>343</sup>
- (252) On 6 June 2005, less than one month before the entry into force of the Co-promotion agreement, the [employee]\* of Janssen-Cilag EMEA wrote in an internal note circulated within J&J that the launch of Novartis/Sandoz's reservoir patch in the Netherlands was estimated as being 15 August 2005. Based on the information in that note, Novartis/Sandoz was expected to be the first generic to enter the Dutch market and other generic competitors would follow only later.<sup>344</sup>
- (253) J&J therefore perceived Novartis/Sandoz as the most advanced potential generic competitor in the Netherlands.
- (254) The Statement of Objections<sup>345</sup> and also Recital (251) of this Decision refer to J&J's perception of Hexal B.V./Sandoz B.V. shortly before the Co-promotion agreement was concluded "*as the only generic company capable of launching the generic fentanyl patch (depot) in the immediate future*." This fact is not contested by the parties. However, J&J<sup>346</sup> and Novartis/Sandoz<sup>347</sup> argued in their replies to the

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<sup>340</sup> See Recital (113). See also Recitals (111), (112) and (114).

<sup>341</sup> See Recital (132).

<sup>342</sup> See Recital (131).

<sup>343</sup> See Recital (133); emphasis added.

<sup>344</sup> See Recital (134).

<sup>345</sup> Statement of Objections, Recital (231).

<sup>346</sup> "*JC [Janssen-Cilag] might have regarded Hexal as the only probable generic competitor with a depot patch, but one cannot then make the jump to deduce that JC believed that there were no others that might enter soon with a matrix patch [...]. Indeed the file clearly shows that JC expected other companies to enter with a matrix patch, starting from late 2005/early 2006. The reality is that JC*

Statement of Objections that Ratiopharm and Nycomed were also expected to enter the Dutch market with a generic matrix patch.

- (255) Obviously, there may have been other potential competitors perceived by J&J to be able to enter the market at a later stage (that is to say, not in the immediate future) with their matrix patches. For example, Ratiopharm's entry was, according to the internal documents invoked by J&J, expected to take place three months after the entry into force of the Co-promotion agreement and the actual generic entry (on a permanent basis) by Ratiopharm took place only in February 2007, i.e. more than 18 months after the Co-promotion agreement entered into force. Nycomed's entry was expected by J&J almost one year after the Co-promotion agreement was concluded and the actual generic entry by Nycomed took place only in June 2007, i.e. approximately 23 months after the Co-promotion agreement entered into force. This is recognised by J&J itself.<sup>348</sup> But the parties did not submit any evidence to show or did not even claim that there was any other company perceived to be capable of launching generic fentanyl patches in the Netherlands by August 2005. Therefore the Commission concludes that Novartis/Sandoz was, shortly before concluding the Co-promotion agreement, perceived by J&J as the only potential competitor capable of launching its generic version of fentanyl patches by August 2005 at the latest (see Recitals (250) to (252)).
- (d) Conclusions on the legal and economic context of the Agreement
- (256) On the basis of the above, it must be concluded that around the time of concluding the Co-promotion agreement, Hexal B.V./Sandoz B.V. was so advanced that there were no significant regulatory hurdles preventing it from launching its fentanyl depot patch in the Netherlands, Hexal B.V./Sandoz B.V. was still actively preparing the launch of its own product in the Netherlands and it was on the verge of launching it, including the packaging material being already produced, and Hexal B.V./Sandoz B.V. was perceived by J&J as its most advanced potential generic competitor in the

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*expected Hexal to be the first to enter, but with Ratiopharm and Nycomed following closely behind. In a letter dated 6 June 2005 (a month before the co-promotion deal was signed) from [name of the employee], then [employee]\*, the following launch estimates regarding the Netherlands were stated: Ratiopharm: 15.10.05; Nycomed 22.06.06." ID1542, p. 7. J&J further submitted that Novartis/Sandoz had a similar expectation that other companies would enter with a matrix patch shortly after Hexal B.V.'s entry with a depot patch and referred in this respect to two Novartis/Sandoz's country performance reports (ID0179, p. 115 and 120).*

<sup>347</sup> *"The characterization of Hexal as the "most advanced generic competitor in the Netherlands" is difficult to reconcile with the fact that, as the Commission itself admits, Ratiopharm was a potential competitor of Janssen-Cilag, and was the first company to actually attempt to enter the market with a generic matrix fentanyl patch. Indeed, Ratiopharm twice launched a matrix patch in the Netherlands, the first time from 1 February 2006 to 15 March 2006 and the second time from 9 June 2006 to 28 July 2006. In light of these facts, as well as those set forth above, it is difficult to understand why the Commission considers that Hexal was the most advanced generic competitor of Janssen-Cilag." ID1537, p. 17.*

<sup>348</sup> ID1542, p. 7. In relation to J&J's argument that Novartis/Sandoz had similar expectations (see footnote 346), it must be noted that (i) the expected launch dates of other potential generic competitors were still significantly later than the expected entry of Novartis/Sandoz, (ii) the two country performance reports invoked by J&J seem to be from 2006 (see ID0179, p. 4.), not from 2005 as assumed by J&J, and that they hence refer to Ratiopharm's expected entry in December 2006 or January 2007, so at least 17 months after the Co-promotion agreement entered into force, and (iii) as explained in this Recital (255), the actual entry of these potential generic competitors took place much later than that.

Netherlands capable of launching by August 2005. Therefore, for all the reasons set out above, Hexal B.V./Sandoz B.V. was a close potential competitor, and probably the closest competitor, of Janssen-Cilag B.V. on the Dutch market for transdermal fentanyl patches.

#### 7.5.2.2. Content, objectives and implementation of the Agreement

- (257) This section examines the actual content and objectives of the Agreement. The Agreement provided for considerable payments from J&J to a close potential generic competitor on the Dutch market, Novartis/Sandoz. In exchange for the monthly payments, Novartis/Sandoz agreed to provide non-specified co-promotion activities. The Agreement also contained a Termination Clause whereby, in the event of market entry by Novartis/Sandoz, the Agreement - including the monthly payments - could have been terminated immediately by J&J. This created strong incentives for Novartis/Sandoz to stay out of the market (see Recitals (311) to (328)). That arrangement will therefore be referred to as the "non-entry mechanism" in the Agreement. To the extent that the implementation of the Agreement throws any further light on these questions, it will, in addition, be mentioned.
- (258) The Agreement between the originator undertaking, J&J, and Novartis/Sandoz raises competition concerns. Firstly, the Agreement kept a close potential competitor, furthermore, at the moment when its market entry threat was imminent, out of the market. Secondly, despite the *prima facie* mentioning of co-promotion services, its peculiar features reveal that the Agreement was in fact a "pay for delay" deal whereby J&J maintained its position as the sole supplier of the fentanyl patches on the Dutch market for the duration of the Agreement and Novartis/Sandoz accepted to stay off the market in exchange for considerable payments. Therefore, it will be found that the Agreement constitutes a restriction of competition.
- (259) This section first analyses the payments from J&J to Novartis/Sandoz. Then, the counter-performance of Novartis/Sandoz, will be examined. Two elements will be considered in particular, namely the co-promotion services and the "non-entry mechanism", and each will be assessed against the payment from J&J to Novartis/Sandoz. Thereafter, the main objectives of the Agreement will be identified and conclusions will be drawn.
- (a) Payments from J&J to Novartis/Sandoz
- (260) Article 7 of the initial co-promotion agreement provided for considerable<sup>349</sup> payments from Janssen-Cilag B.V. to Hexal B.V./Sandoz B.V. "*in consideration of the obligations undertaken by Company [Hexal B.V./Sandoz B.V.] in respect of the members of the Sales Force.*"<sup>350</sup> Hexal B.V./Sandoz B.V. was entitled "*to receive from Janssen-Cilag a monthly amount of € 308,333, starting from July, 11, 2005.*"<sup>351</sup> For the whole duration of the initial co-promotion agreement (until 11 July 2006) this amounted in total to approximately EUR 3.7 million.

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<sup>349</sup> See Recitals (317) to (328).

<sup>350</sup> See Recital (160).

<sup>351</sup> See Recital (160).

- (261) In August 2006, the addendum changed the monthly amount to be paid by Janssen-Cilag B.V. to Hexal B.V./Sandoz B.V. to EUR 250 000 (instead of the initial EUR 308 333), starting from 1 August 2006.<sup>352</sup> The extended Co-promotion agreement was eventually terminated on 15 December 2006.<sup>353</sup> For the duration of the addendum (from 11 July 2006 to 15 December 2006), the value transferred from J&J to Hexal B.V./Sandoz B.V. amounted in total to approximately EUR 1.3 million.
- (262) The total value transferred from J&J to Novartis/Sandoz in monthly instalments during the term of the Co-promotion agreement, including the addendum, was therefore approximately EUR 5 million. In the following sections 7.5.2.2 (b) and (c) the value transfer will now be compared with the counter-performance of Novartis/Sandoz, that is to say the co-promotion services to be provided under the Co-promotion agreement and the compliance with the "non-entry mechanism".
- (b) Co-promotion activities
- (263) Hexal B.V./Sandoz B.V. agreed under the Agreement to promote Janssen-Cilag B.V.'s fentanyl matrix patch in the Netherlands. According to the initial co-promotion agreement, Hexal B.V./Sandoz B.V.'s duties were, in particular, to:
- *"use its reasonable endeavours to assist Janssen-Cilag in the promotion of the Product [Durogesic] to the Pharmacists through the Sales Force" (Article 3.1.).<sup>354</sup> The "Sales Force" was "consisting of 8 representatives detailing the Product." (Article 1)<sup>355</sup>*
  - *"conduct the promotion and marketing by the Sales Force of the Product to the Pharmacists with all due care and diligence and [...] cultivate and maintain good relations with the Pharmacists in accordance with sound commercial principles" (Article 3.3.1.)<sup>356</sup>*
  - *"conduct the promotion and marketing by the Sales Force of the Product to the Pharmacists in compliance with all the applicable laws and regulations relating to the promotion and marketing of the Product [...]" (Article 3.3.2.).<sup>357</sup>*
- (264) However, the specific services to be provided by Hexal B.V./Sandoz B.V. are not defined in any further detail in the version of the initial co-promotion agreement which was eventually signed.<sup>358</sup>
- (265) Based on the content of the Agreement, the description of services to be provided by Hexal B.V./Sandoz B.V. under the Co-promotion agreement was very limited, these

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<sup>352</sup> See Recital (188).

<sup>353</sup> See Recital (193).

<sup>354</sup> See Recital (158).

<sup>355</sup> See Recital (156).

<sup>356</sup> See Recital (158).

<sup>357</sup> See Recital (158).

<sup>358</sup> The parties did not add any annex describing the co-promotion services, as had been at some point envisaged (see Recital (148)). J&J's explanation as to why such an annex was not added (see Recital (151) and ID1542, p. 4) is not convincing insofar as the need to identify these co-promotion services does not depend on the duration of the agreement.

services were non-specified and described only in a very general manner at the time the initial co-promotion agreement was concluded.

- (266) In addition, this assessment based on the content of the Agreement is corroborated by the way the Agreement was implemented. As regards the co-promotion activities actually performed by Hexal B.V./Sandoz B.V. during the term of the initial co-promotion agreement, the activities invoked by the parties are limited. During the term of the initial co-promotion agreement, only occasional contacts took place between Janssen-Cilag B.V. and Hexal B.V./Sandoz B.V.<sup>359</sup> The co-promotion targeting pharmacists actually started only on 24 October 2005, so more than three months after the Co-promotion agreement entered into force.<sup>360</sup> The monthly payments were also provided during that initial period.
- (267) The only contemporaneous documents on co-promotion activities which the parties were able to provide include three questionnaires containing replies of approximately 140 pharmacies to 13 multiple-choice questions (identical questions for each questionnaire) and a one-page final evaluation report, which were at the time submitted by Hexal B.V./Sandoz B.V. to Janssen-Cilag B.V.<sup>361</sup> As explained by J&J, "*[t]his questionnaire was used in the face to face discussions between the Hexal/Sandoz sales force and the pharmacists*",<sup>362</sup> but no further details on or proof of these face to face discussions or any other specific promotion activities were provided as "*[g]iven the length of time that has passed, Janssen-Cilag can no longer provide details here*".<sup>363</sup>
- (268) Novartis/Sandoz explained that "*[b]ased on available information, after initial preparations, which included training and the drafting of a questionnaire, Hexal/Sandoz Netherlands commenced a market survey of pharmacies in the Autumn of 2005 through its own sales representatives who personally visited and interviewed on the basis of a questionnaire a large proportion of pharmacies across all regions of the Netherlands. Amongst other things, the purpose of these visits was to gauge how pharmacists perceived the newer fentanyl matrix patches and the 12 mcg/h formulation. In addition to obtaining this valuable knowledge, the survey questions were also aimed at raising pharmacists' awareness of Janssen-Cilag's Durogesic by promoting the benefits of the newer matrix patches (Janssen-Cilag's Durogesic was the only fentanyl matrix patch available at that time), reinforcing their superiority over the older depot patches and reminding pharmacists of the benefits of the 12 mcg/h strength.*

*Of the broader number of pharmacies visited, 140 pharmacists completed and returned a questionnaire form that was provided during the market survey. The pharmacists either completed the questionnaire forms with the assistance of a sales representative during the visit or on their own after a sales representative's visit. The forms completed during visits were typically collected by sales representatives on the*

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<sup>359</sup> See section 6.2.2

<sup>360</sup> See Recital (174)

<sup>361</sup> See Recitals (170) to (174).

<sup>362</sup> ID0688, p. 8.

<sup>363</sup> ID0688, p. 7.

*spot while forms completed by pharmacists after the visit were typically returned by fax or mail.*"<sup>364</sup>

- (269) Although the co-promotion activities were not specified in detail in the Co-promotion agreement, the Commission notes that the Co-promotion agreement included certain rights and obligations of the parties relating to the co-promotion activities. For example, according to Article 3.2 of the Co-promotion agreement, Hexal B.V./Sandoz B.V. was "*responsible for training at its own cost.*"<sup>365</sup> J&J and Novartis/Sandoz indicated that Hexal B.V./Sandoz B.V.'s sales force was trained by Hexal B.V./Sandoz B.V.'s [employee]\* at a meeting on Friday 21 October 2005. When the information concerning implementation of that provision was requested by the Commission, the parties were not able to identify any training material provided and no further training was mentioned.<sup>366</sup>
- (270) According to Article 3.3.2 of the Co-promotion agreement, Hexal B.V./Sandoz B.V. was obliged to conduct the promotion and marketing in compliance with, amongst others, "*instructions as indicated by Janssen-Cilag from time to time in writing.*"<sup>367</sup> Novartis/Sandoz stated in its reply to a Commission request for information that it was not aware "*that Janssen-Cilag considered it was necessary to send written instructions in accordance with the possibility provided for under Article 3.3.2 of the co-promotion agreement.*"<sup>368</sup> Both parties identified only one document that might possibly be considered as such written instructions. It is a short email from Janssen-Cilag B.V.'s [employee]\* to the Hexal B.V./Sandoz B.V.'s [employee]\* providing short comments on the draft questionnaire to be submitted to the pharmacies.<sup>369</sup> No other specific documents were mentioned by the parties in this respect when specifically requested by the Commission.<sup>370</sup>
- (271) Article 3.4.1 of the Co-promotion agreement envisaged that Hexal B.V./Sandoz B.V.'s sales force would, at the expense of Janssen-Cilag B.V., attend meetings with representatives of Janssen-Cilag B.V. and pharmacists.<sup>371</sup> Novartis/Sandoz stated that, besides one meeting of Janssen-Cilag B.V.'s employee and Hexal B.V./Sandoz B.V.'s [employee]\* on 20 September 2005, Novartis/Sandoz was "*not aware that Janssen-Cilag considered it was necessary to rely on the possibility provided for under Article 3.3.2 of the co-promotion agreement to organise any direct meetings with sales representatives of Hexal/Sandoz Netherlands.*"<sup>372</sup> When the information concerning implementation of that provision was requested by the Commission, J&J did not invoke that any such meetings took place.<sup>373</sup>
- (272) According to Article 3.6 of the Co-promotion agreement, Hexal B.V./Sandoz B.V. was obliged to maintain a list of pharmacists who were actual or prospective

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<sup>364</sup> ID0701, p. 4.

<sup>365</sup> See Recital (158).

<sup>366</sup> ID0846, p. 2 and ID0841, p. 2.

<sup>367</sup> See Recital (158).

<sup>368</sup> ID0841, p. 2.

<sup>369</sup> ID0135, p. 190.

<sup>370</sup> ID0846, p. 2 and ID0841, p. 2.

<sup>371</sup> See Recital (158).

<sup>372</sup> ID0841, p. 3.

<sup>373</sup> ID0846, p. 3.

customers of Durogesic patches and supply Janssen-Cilag B.V., on its request, with a copy of that list.<sup>374</sup> Novartis/Sandoz stated that it was "*not aware that Janssen-Cilag considered it was necessary to rely on the possibility provided for under Article 3.6 of the co-promotion agreement to request Hexal/Sandoz Netherlands to supply a list of pharmacists who are customers or prospective customers for Durogesic.*"<sup>375</sup> J&J invoked that Hexal B.V./Sandoz B.V. provided "*a list of pharmacies visited*" together with the three questionnaires<sup>376</sup> submitted to Janssen-Cilag B.V. in December 2005, February 2006 and April 2006.<sup>377</sup> However, those lists do not indicate any customers or prospective customers as mentioned in Article 3.6. J&J has not been able to identify any lists other than the three lists mentioned in this Recital.<sup>378</sup>

- (273) According to Article 6.2.1 of the Co-promotion agreement, Janssen-Cilag B.V. was obliged to supply, at its own expense, Hexal B.V./Sandoz B.V. with "*catalogues, advertising, promotional and selling materials, literature and information*" for the promotion activities.<sup>379</sup> Concerning this subject, for J&J "*it has not been possible to identify and retrieve supporting evidence in addition to the documents already in the file.*"<sup>380</sup> According to Novartis/Sandoz, "*Janssen-Cilag provided Hexal/Sandoz Netherlands with promotional leaflets for Durogesic around the time of the meeting on or about 20 September 2005*".<sup>381</sup> When the information concerning implementation of that provision was requested by the Commission, no further contacts and other supplies of the promotional materials were mentioned.<sup>382</sup>
- (274) On the basis of the above, all evidence of co-promotion activities available for the duration of the initial co-promotion agreement can be summarised as follows: the supply of promotional leaflets on a single occasion; a single training session of the sales force which took place more than three months after the Co-promotion agreement entered into force and for which no training material could be identified; the only written instruction from Janssen-Cilag B.V. possibly being a single email with short comments on the draft questionnaire; three questionnaires (13 identical multiple-choice questions each) submitted to Janssen-Cilag B.V. and containing the replies of pharmacies, accompanied with a list of pharmacies visited; and the one-page evaluation report mentioned in Recital (267).<sup>383</sup>
- (275) Even more striking are the facts concerning the period covered by the addendum (July 2006 – December 2006). The addendum itself does not contain any specific provision that would supplement or modify the initial co-promotion agreement with respect to the co-promotion activities to be performed by Hexal B.V./Sandoz B.V. Moreover, for the period covered by the addendum the parties are "*not in a position*

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<sup>374</sup> See Recital (158).

<sup>375</sup> ID0841, p. 3.

<sup>376</sup> See Recitals (170) to (173).

<sup>377</sup> ID0846, p. 3.

<sup>378</sup> ID0846, p. 3.

<sup>379</sup> See Recital (162).

<sup>380</sup> ID0846, p. 3.

<sup>381</sup> ID0841, p. 3.

<sup>382</sup> ID0841, p. 3 and ID0846, p. 3.

<sup>383</sup> The Commission observes that during this period alone, Hexal B.V./Sandoz B.V. received approximately EUR 3.7 million.

to provide a specific description of activities performed" (Novartis/Sandoz)<sup>384</sup> and are "not aware of any responsive documents in addition to those which are already part of the Commission's file" (J&J).<sup>385</sup> The Commission observes that the contemporaneous documents on the Commission's file, including those submitted by the parties, refer, as far as any co-promotion activities are concerned, exclusively to the period preceding the addendum.

- (276) The available evidence indicating any specific promotion activities during the initial co-promotion agreement is therefore limited and there is no available evidence at all that any specific promotion activities were performed by Hexal B.V./Sandoz B.V. during the period covered by the addendum. Moreover, there is no available evidence showing that any specific promotion activities for the period covered by the addendum were even planned or discussed by the parties.<sup>386</sup>
- (277) Although the promotion services provided by Hexal B.V./Sandoz B.V. appear to be limited, Janssen-Cilag B.V. paid a considerable amount for those co-promotion services and it is therefore relevant to analyse the importance those co-promotion services had for Janssen-Cilag B.V. at the time it concluded the Agreement.
- (278) J&J argued that "*the agreements gave Janssen-Cilag the opportunity to promote effectively and efficiently its new patch to the pharmacy channel, which was of great importance once exclusivity on the reservoir patch expired and generic versions could enter.*"<sup>387</sup> However, it is doubtful whether and how, in the period covered by the Co-promotion agreement, Hexal B.V./Sandoz B.V.'s co-promotion services targeting the pharmacies, for which Janssen-Cilag B.V. paid EUR 5 million, could have been useful for Janssen-Cilag B.V. Below the alleged importance of Hexal B.V./Sandoz B.V.'s co-promotion services for Janssen-Cilag B.V. is examined with regard to the following:
- Promotion of matrix patch against the depot patch;
  - Promotion of originator product against generics;
  - Need for experienced sales force visiting pharmacists;
  - Promotion of fentanyl against other painkillers;
  - Educating pharmacists and patients;
  - Possibility of duplex registration and supply agreement.
- (i) Promotion of matrix patch against the depot patch

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<sup>384</sup> ID0701, p. 4.

<sup>385</sup> ID0688, p. 8. None of the documents on the Commission's file directly concern co-promotion activities in the period covered by the addendum.

<sup>386</sup> The Commission observes that the payments from Janssen-Cilag B.V. to Hexal B.V./Sandoz B.V. were still being provided on a regular monthly basis during the period covered by the addendum and amounted to a total of EUR 1.3 million for that period alone.

<sup>387</sup> ID0564, p. 1.



- (279) Hexal B.V./Sandoz B.V. was to promote the matrix patch against the depot patch. Janssen-Cilag B.V. argued that "*it was deemed important for pharmacists to understand properly the superiority of the matrix patch over the reservoir [depot] patch*".<sup>388</sup> However, the Commission observes that there has not been any depot patch on the Dutch market since November 2004.<sup>389</sup> The only potential competitor of Janssen-Cilag B.V. that was developing a depot patch for the Dutch market and was capable of launching it in 2005 was Hexal B.V./Sandoz B.V.<sup>390</sup> However, Hexal B.V./Sandoz B.V. agreed to the non-entry mechanism for the duration of the Co-promotion agreement with Janssen-Cilag B.V.<sup>391</sup> Hexal B.V./Sandoz B.V. indeed did not launch its depot patch in the Netherlands and no other generic depot patches have ever been launched in the Netherlands by any other company.<sup>392</sup> The purpose of the co-promotion activities, as argued by Janssen-Cilag B.V., was therefore to make the pharmacists understand the superiority of the matrix patch over a product that was no longer on the market.
- (280) In its reply to the Statement of Objections, J&J submitted in this respect that "*[i]n 2005, JC [Janssen-Cilag] management had good reasons to believe that Nycomed would launch its micro-reservoir patch imminently. [...] The Nycomed patch (under the trade name Matrifen®) was promoted by Nycomed as a matrix patch but consisted in fact of a multitude of micro-reservoirs.*"<sup>393</sup>
- (281) However, J&J recognised that Nycomed's patch was marketed as a matrix patch and itself referred internally to the Nycomed patch as "*matrix*" in some contemporaneous documents.<sup>394</sup>
- (282) Moreover, according to J&J's internal contemporaneous documents, the entry of Nycomed in the Netherlands was expected at the earliest only in June 2006,<sup>395</sup> so almost one year after the entry into force of the Co-promotion agreement, and not already in 2005. At the same time, J&J argued in its reply to the Statement of Objections that the Co-promotion agreement was expected to be of a short duration, no more than a couple of months.<sup>396</sup> This would mean that even if J&J considered Nycomed's fentanyl patch as a micro-reservoir rather than a matrix patch, J&J expected Nycomed to enter the Dutch market only several months after the Co-promotion agreement was allegedly expected to be terminated. In that case, as a logical consequence, no co-promotion activities by Novartis/Sandoz would therefore have been expected to take place at that time.
- (283) Furthermore, even if Nycomed's patch was considered by J&J as a micro-reservoir patch and not as a matrix patch, there is another contradiction in J&J's arguments. It was claimed by J&J that any new launch of a depot patch was unlikely to be

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<sup>388</sup> ID0564, p. 4.

<sup>389</sup> See Recital (85).

<sup>390</sup> See Recital (251).

<sup>391</sup> See Recital (257)

<sup>392</sup> ID0564, p. 5.

<sup>393</sup> ID1542, p. 14.

<sup>394</sup> See, for example, Recital (134).

<sup>395</sup> ID0138, p. 477. See also ID1542, p. 14.

<sup>396</sup> ID1542, p. 2 and 4.

successful after the switch of the market.<sup>397</sup> According to J&J the Dutch market was already switched to the matrix patch long before June 2006 when the potential launch of Nycomed's patch was expected by J&J. In the logic of J&J's argument, Nycomed's product would have been therefore unlikely to succeed and to pose any threat to J&J's sales.

- (284) In addition, the first sales of transdermal fentanyl patches marketed in the Netherlands by Nycomed took place only in June 2007, that is almost two years after the Co-promotion agreement entered into force and six months after the Co-promotion agreement was terminated.

(ii) Promotion of originator product against generics

- (285) Concerning potential promotion activities against generic fentanyl patches in the Netherlands, the Commission observes that at the time the Co-promotion agreement was concluded (and also for the entire duration of the Co-promotion agreement), there was no generic fentanyl patch launched on the Dutch market. If a patient was prescribed a fentanyl patch by their treating physician at that time, the pharmacists had no choice and had to dispense to the patient Janssen-Cilag B.V.'s Durogesic (matrix) fentanyl patch. The promotion of Janssen-Cilag B.V.'s matrix patch towards pharmacists at that time was therefore of little or no importance in that respect. Interestingly, the co-promotion towards pharmacies was terminated at the very moment when generic fentanyl patches actually entered the Dutch market in January 2007.

(iii) Need for experienced sales force visiting pharmacists

- (286) J&J argued that "*Janssen-Cilag needed access to an experienced and comprehensive sales force that would visit the pharmacists to promote Durogesic®. [...] Sandoz had a well-regarded sales force and was deemed the right choice by the Janssen-Cilag Dutch management.*"<sup>398</sup>
- (287) J&J is a large pharmaceutical company with a broad portfolio of prescription medicines on the Dutch market. However, J&J was not able to identify any other co-promotion agreement that it entered into for any other product in the Netherlands, either before or after the Co-promotion agreement that is the subject of this Decision.<sup>399</sup> For the whole EEA, J&J was able to identify only one other agreement with a generic company involving the co-promotion element, but even that agreement was not considered by J&J to be similar to the Co-promotion agreement.<sup>400</sup> This shows that the Co-promotion agreement was unique and quite unusual. For all other products in the Netherlands and even other EEA markets J&J was able to manage without engaging a co-promotion partner.

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<sup>397</sup> See Recital (240) and ID1542, p. 7 and 8.

<sup>398</sup> ID0564, p. 4-5.

<sup>399</sup> ID0688, p. 4.

<sup>400</sup> ID0688, p. 5. In its reply to the Statement of Objections J&J stated that while it did not enter into similar co-promotion agreements with generic companies in the EEA, J&J did have some co-promotion agreements with originator companies (ID1542, p. 4).

(288) Moreover, J&J chose directly as its co-promotion partner a close potential competitor in the Netherlands that, furthermore, was on the verge of entering the market for fentanyl patches with its generic product. J&J indeed confirmed that it did not approach any other generic company prior to the Agreement with Hexal B.V./Sandoz B.V.<sup>401</sup> This was in a situation where the [strong]\* generic market [player] in the Netherlands, [third party]\*, was still looking for a partner that would enable it to enter the fentanyl market.<sup>402</sup> Moreover, there were other, more remote generic companies interested in entering the Dutch market with fentanyl patches.

(iv) Promotion of fentanyl against other painkillers

(289) J&J argued that *"the co-promotion agreement was part of Janssen-Cilag's strategy to approach both the prescriber (Janssen-Cilag) and the pharmacists (Hexal/Sandoz) in order to grow the sales of fentanyl patches (at the time only Durogesic® matrix patches) as much as possible, in competition with other strong painkillers, such as Tramadol, MSContin and Oxycodon. To compete with other painkillers, Janssen-Cilag had the Durogesic® matrix patch, as well as the new, 12.5mcg strength. But, in order to guarantee their commercial success, it also needed to promote these products to pharmacists, i.e. inform them of the advantages and safety profile of this strong opioid and ensure the good accompaniment of patients under Durogesic®. This could not satisfactorily be done through sending letters or placing advertisements. Personal detailing to the pharmacists was therefore necessary."*<sup>403</sup>

J&J further argued that *"[i]f there is no generic version of a product, it is important for the pharmacist to understand the properties and benefits of the proprietary product (which is in competition with other proprietary products). The reason for this is that in the Netherlands the pharmacist plays a key role towards general practitioners and patients. Pharmacists together with general practitioners often determine which product should be prescribed for which disease. These guidelines are often an obligation for all members involved in the discussion ("FTO: farmacotherapeutisch overleg")."*<sup>404</sup>

(290) As acknowledged by J&J itself, at the time of the Co-promotion agreement, in the period 2005-2006, *"[i]t was not possible for pharmacists to substitute a product prescribed by a physician by a product which had a different active substance. Pharmacists were required by law to dispense a product with the prescribed active substance."*<sup>405</sup> This means that as long as the treating physician prescribed patches containing fentanyl, the activities targeted at pharmacies and promoting fentanyl patches against other painkillers containing different active substance, such as Tramadol, MSContin and Oxycodon, had no direct effect as the pharmacists had no

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<sup>401</sup> ID0688, p. 4.

<sup>402</sup> See section 5.2.2.4 As the [strong]\* generic market [player]\* in the Netherlands, [third party]\* had a sales force with experience in generic and even "innovative" medicines. See Recital (104).

<sup>403</sup> ID0688, p. 6-7. Similarly, the preamble of the Co-promotion agreement states: *"In the Territory [the Netherlands] the pharmacists play an increasing key role in determining, together with general practitioners, for which disease which drug should be prescribed, and in advising patients how to use the drugs and how to deal with side effects;"* *"There is an increasing need for Janssen-Cilag to detail the Product [Durogesic] towards pharmacists;"* *"Company has a Sales Force (as defined below) that has built strong expertise in promoting drugs with pharmacists;"* (See Recital (154)).

<sup>404</sup> ID0688, p. 8.

<sup>405</sup> ID0825, p. 2.

possibility to substitute fentanyl patches by those other products containing a different active substance anyway.

- (291) In this respect J&J argued in its reply to the Statement of Objections that "*Durogesic® competes with other long-acting opioids, such as Tramadol, Oxycodone, Morphine and Buprenorfine*"<sup>406</sup> and that "*the co-promotion sought to promote the use of matrix fentanyl patches vs. other long-acting opioids. Again, the Commission seems to ignore or underestimate the need to do this. [...] In the Netherlands, pharmacists gather with general practitioners in the pharma[co]therapeutic consultation ("FTO" or "Farmacotherapeutisch Overleg"). The FTO is organized on a regional basis and is a forum at which general practitioners and pharmacists exchange views, inform and educate each other, and agree on specific protocols or actions in order to ensure that patients are best helped. [...] Within the FTO, it was possible and proper for pharmacists and physicians to exchange ideas about treating long-lasting and chronic pain. Pharmacists play a role in informing physicians and agreeing with them on proper therapy protocols. That means that pharmacists can influence the prescription behaviour of physicians.*"<sup>407</sup>
- (292) In its reply to the Statement of Objections J&J stated that at the time the Agreement was entered into "*the co-promotion agreement was expected to be straightforward and of a short duration*"<sup>408</sup> and that "*the delay in generic competition that was implied in Hexal's co-operating with JC*", in other words the duration of the Co-promotion agreement, "*was expected to amount to **no more than a couple of months***".<sup>409</sup> At the same time, according to the available information, any substantive activities of Hexal B.V./Sandoz B.V. under the Co-promotion agreement had not started before late October 2005, that is to say more than three months after the Co-promotion agreement entered into force.<sup>410</sup> So the Co-promotion agreement was expected to be in place only for a couple of months, but no activities targeting the pharmacists were planned (and executed) for more than three months after the entry into force. This is difficult to reconcile with the claimed purpose of the Co-promotion agreement to efficiently promote the use of matrix fentanyl patches versus other long-acting opioids by targeting the pharmacists.
- (293) Moreover, as stated by J&J, in general terms pharmacists may, in pharmacotherapeutic consultations, play a role in informing physicians and "*agreeing with them on proper therapy protocols*". Furthermore, in this respect reference is made to the document, submitted by J&J in its reply to the Statement of Objections,<sup>411</sup> published by the *Koninklijke Nederlandse Maatschappij ter bevordering der Pharmacie*<sup>412</sup> and entitled "*Guideline for generic substitution*"<sup>413</sup>.

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<sup>406</sup> ID1542, p. 15.

<sup>407</sup> ID1542, p. 14-15.

<sup>408</sup> ID1542, p. 4, footnote 4. Emphasis added.

<sup>409</sup> ID1542, p. 2-3. Emphasis added.

<sup>410</sup> Recital (266).

<sup>411</sup> ID1545.

<sup>412</sup> Royal Dutch Pharmacists Association.

<sup>413</sup> *Handleiding Geneesmiddelssubstitutie*. English translation available online: <http://www.knmp.nl/downloads/producten-diensten/farmacotherapie/handleiding.geneesmiddelssubstitutie.engels.201202.pdf>

According to that document "[f]or example, agreements can be reached (e.g. within the FTO and FTTO<sup>414</sup>) concerning which medicinal products may or may not be substituted, in the case of both new and existing medication. **It is recommended that these agreements be set out in writing.**"<sup>415</sup> However, none of the parties submitted any evidence that any therapy protocols or agreements on prescribing or substituting of fentanyl patches were produced in writing as a result of the co-promotion activities under the Co-promotion agreement or even attempted or planned as the document which J&J produced recommended.<sup>416</sup> Moreover, regarding pharmacotherapeutic consultations, J&J in its comments on the Letter of Facts stated that "*JC [Janssen-Cilag] and J&J do not know whether these topics were discussed*".<sup>417</sup>

- (294) The whole co-promotion project, for which Janssen-Cilag B.V. paid approximately EUR 5 million in total, was evaluated by the parties in the final Evaluation Report.<sup>418</sup> The Evaluation Report did not mention any tangible results achieved (or even attempts to achieve those results), such as for example any guidelines or written agreements on prescribing of fentanyl between pharmacists and physicians being agreed as a result of the promotion activity. In this respect the claimed aim of Janssen-Cilag B.V. to approach the pharmacists in order to indirectly influence what product was to be prescribed by the physicians is not substantiated by the way the Co-promotion agreement was negotiated, implemented and evaluated.
- (295) Furthermore, as mentioned in Recital (287), Janssen-Cilag B.V. has never used a co-promotion partner to promote its products towards pharmacies before or after the Co-promotion agreement with Hexal B.V./Sandoz B.V. for fentanyl patches and has been able to successfully market all its other products in the Netherlands without engaging in co-promotion partnerships. This included marketing of its own products against other originator products.
- (296) J&J also submitted in its reply to the Statement of Objections that "*JC [Janssen-Cilag] also informed physicians about the various alternatives to treat pain*"<sup>419</sup> and

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<sup>414</sup> Pharmacotherapeutic Transmural Consultation (*Farmacotherapeutisch transmuraal overleg*).  
<sup>415</sup> ID1545, p. 29. Emphasis added. "*Er kunnen bijvoorbeeld afspraken worden gemaakt (bijvoorbeeld binnen het FTO en FTTO) welke geneesmiddelen wel en niet mogen worden gesubstitueerd, zowel bij nieuwe als bij bestaande medicatie. Het verdient aanbeveling deze afspraken schriftelijk vast te leggen.*" Novartis/Sandoz argued in its comments on the Letter of Facts (ID1709, p. 4-5) that the Guidelines submitted by J&J were dated 2012 and hence "*would not appear relevant for the assessment of the situation in 2005*". It is noted for completeness' sake that this wording is the same for instance in the publicly available September 2006 version of the Guidelines (ID1724).

<sup>416</sup> It is recalled that in the Statement of Objections (Recital 262) the argument of J&J on pharmacotherapeutic consultations' importance in the context of competition "*with other proprietary products*" was mentioned (see also Recital (289) of this Decision). While Novartis/Sandoz argued that "*at the date of the co-promotion agreement, there was no generic substitute for Janssen-Cilag's matrix patches available on the Dutch market [and that i]t is, consequently, unsurprising if no substitution agreement had been entered into with respect to non-existent products*" (ID1709, p. 5), Novartis/Sandoz has not addressed why it seemingly excludes the possibility of any written therapy protocols or agreements on fentanyl and other proprietary products.

<sup>417</sup> ID1702, p. 3-4.

<sup>418</sup> See Recital (174).

<sup>419</sup> ID1542, p. 15.

referred to a slideshow used for that purpose in Ireland.<sup>420</sup> That slideshow is specific to Ireland and there is no evidence that any similar document or initiative have been prepared or used in the Netherlands. Moreover, this slideshow does not provide any information on the role of pharmacists in the treatment of pain and is therefore of little relevance for the argument under examination.

(v) Educating pharmacists and patients

- (297) J&J also argued that "*the pharmacist plays a key role, since, through good information and counselling of the patient, the chances of an effective (switching to a different strength at the right time) and efficient (preparing the patients for the possible side-effects, such as nausea) treatment are increased. This in return also benefits Janssen-Cilag, since a satisfied patient will continue to take its medication.*"<sup>421</sup> The Commission observes that the old depot patch, which was considered interchangeable with the new matrix patch, was on the Dutch market for almost ten years.<sup>422</sup> During that entire period, Janssen-Cilag B.V. did not need to engage a co-promotion partner to inform the pharmacists about the aspects mentioned in this Recital. Furthermore, once generics entered the Dutch market and the Co-promotion agreement with Hexal B.V./Sandoz B.V. was terminated, there was no new co-promotion partner of Janssen-Cilag B.V. to provide information to the pharmacists anymore.
- (298) Moreover, as mentioned in Recital (292), at the time the Co-promotion agreement was entered into, J&J argued that it expected it to be in place only for a couple of months, but no activities targeting the pharmacists were planned (and carried out) for more than three months after the entry into force. This is difficult to reconcile with the claimed purpose of the Co-promotion agreement to efficiently educate the pharmacists in respect of J&J's fentanyl patches. This issue is also further dealt with in section 7.7.2.

(vi) Possibility of duplex registration and supply agreement

- (299) Hexal B.V./Sandoz B.V. subsequently entered into the supply agreement with Janssen-Cilag B.V., the possibility of which was mentioned in the initial co-promotion agreement. J&J argued that "*[i]mportantly, the agreement provided that Janssen-Cilag would discuss in good faith the grant to Sandoz of a duplex registration for the matrix formulation, to be used as soon as another generic company entered with a matrix patch. This duplex registration would allow Sandoz to sell fentanyl matrix patches under its own trade name and label.*"<sup>423</sup> Allegedly, this was beneficial for Janssen-Cilag B.V. as the "*supply agreement allowed Janssen-Cilag to derive income from sales in the generic market through supplies to Sandoz.*"<sup>424</sup>

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<sup>420</sup> ID1553.

<sup>421</sup> ID0688, p. 8.

<sup>422</sup> As for the 12.5 µg version of the matrix patch, it had already been on the Dutch market for ten months when the limited co-promotion activities were initiated. See Recitals (86) and (266).

<sup>423</sup> ID0564, p. 3.

<sup>424</sup> ID0564, p. 5.

- (300) This argument is further dealt with in section 7.7.3. It is nevertheless already noted that there is nothing in the provisions of the Co-promotion agreement or the addendum that would guarantee Hexal B.V./Sandoz B.V. the said duplex registration and/or supplies of the matrix patches from Janssen-Cilag B.V.<sup>425</sup> To "*discuss the possibility*" is clearly far from actually granting the duplex registration and the supplies of the product.
- (301) J&J argued in its reply to the Statement of Objections that "*[t]he Commission relies on the wording in the letter of intent, and in the co-promotion agreement itself, to assert that there was no guarantee that Hexal would receive a duplex registration which would allow it to enter the market with a matrix patch. In so doing, the Commission fails to have proper regard for the content and the scope of the negotiations between JC [Janssen-Cilag] and Hexal in respect of the fentanyl patches, as well as the factual context in which these negotiations took place.*"<sup>426</sup> J&J referred to two internal J&J documents<sup>427</sup> to demonstrate that "*[a]t the time that JC entered into the co-promotion agreement, it was understood that JC intended to grant Hexal access to the matrix patch on terms still to be negotiated (as indeed they were in due course). [...] In the co-promotion agreement that was concluded in July 2005, the right for Hexal to obtain a duplex registration was not formally included because the terms were not settled at the time. However, the agreement provided that the parties would discuss in good faith the grant of such a duplex registration and the conditions of such a grant during the term of the co-promotion. And that is indeed what happened. In April 2006, JC sent Hexal a draft Letter of Intent in respect of the duplex registration annex supply deal (sic) and the Letter of Intent was signed in May 2006. As early as May 2006, Hexal started with the necessary steps for launching its JC-supplied matrix patch. The duplex registration was transferred in August 2006. [...] The negotiations concerning the co-promotion agreement show that there was a mutual expectation that Hexal would be granted an early entry deal. Subsequent events confirm this.*"<sup>428</sup>
- (302) In its reply to the Statement of Objections, J&J also argued that "*when it comes to considering the duplex registration and supply deal, the Commission rejects its relevance merely because the terms of the right had not yet been settled at the precise time that the co-promotion agreement was entered into.*"<sup>429</sup> However, J&J confirmed the Commission's finding that in the Co-promotion agreement itself, "*the right for Hexal to obtain a duplex registration was not formally included*" and the alleged understanding "*is not written down explicitly in the agreement.*" Therefore, not only "*the terms of the right had not yet been settled*" at the time of concluding the Agreement, but also the very existence of the right itself had not been settled. Furthermore, Novartis/Sandoz confirmed that it "*has never claimed that Hexal was*

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<sup>425</sup> The addendum was signed by the parties in August 2006 and entered into force retroactively as of 11 July 2006. The supply agreement was a separate contract that was signed only in September and October 2006 and entered into force as of 1 January 2007.

<sup>426</sup> ID1542, p. 4-5.

<sup>427</sup> See Recital (135) and footnote 174, which are further analysed in footnote 433. Regarding the importance for Hexal B.V./Sandoz B.V. of access to the J&J's matrix, J&J referred only to two documents from February and April 2005 (see Recitals (124) and (130)) presenting the supply from J&J as a potential scenario.

<sup>428</sup> ID1542, p. 5-6.

<sup>429</sup> ID1542, p. 6. See also ID1702, p. 2-3.

*guaranteed a duplex registration and/or supplies of the matrix patches from Janssen-Cilag*".<sup>430</sup>

- (303) Nor was the right for Hexal B.V./Sandoz B.V. to obtain a duplex registration formally included in the addendum extending the duration of the initial co-promotion agreement. The only short reference to the duplex registration in the addendum, which was signed by the parties respectively on 16 and 17 August 2006, that is more than 13 months after the Co-promotion agreement entered into force, is in the Preamble and reads as follows: "*In accordance with Article 10bis of the [Co-promotion] Agreement, parties have started discussions on a duplex-registration and are close to reaching an agreement in that respect.*"<sup>431</sup> Therefore, at the time the initial co-promotion agreement and the addendum were entered into, the supply agreement was not signed, and there was no legal guarantee in the provisions of the initial co-promotion agreement or the addendum for Hexal B.V./Sandoz B.V. to receive the duplex registration and/or supplies of the matrix patches from Janssen-Cilag B.V.<sup>432</sup>
- (304) It is not contested that there might have been discussions between J&J and Novartis/Sandoz concerning the duplex registrations in the relevant period. However, as already stated, to "*discuss the possibility*", as mentioned in the Co-promotion agreement, is far from actually providing a legal right to receive the duplex registration.<sup>433</sup> Moreover, the fact that no legal right to receive the duplex registration was guaranteed to Novartis/Sandoz is further confirmed by contemporaneous documents. For example, in February 2006 Hexal B.V./Sandoz B.V. was aware that

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<sup>430</sup> ID1709, p. 3.

<sup>431</sup> See Recital (191). Novartis/Sandoz argued that "*the expression 'in accordance with' in Recital C of the addendum confirms that there was an obligation or commitment to negotiate in Article 10bis*" (ID1709, p. 4). Firstly, the reference to Article 10bis confirms only a commitment of parties to "*discuss the possibility [...] to use a duplex registration [...]*". Secondly, negotiating leaves scope for uncertainty as to the outcome of the negotiation.

<sup>432</sup> In its reply to the Statement of Objections (ID1542, p. 6) and its comments on the Letter of Facts (ID1702, p. 3), J&J submitted that despite the wording of the agreement the Commission should regarding the supply deal "*draw inferences about the parties' intentions from documents and statements not found in the agreement*". J&J refers to Case C-74/04 *Commission v Volkswagen*, [2006] ECR I-6585, paragraph 39, which states that "*the will of the parties may result from both the clauses of the dealership agreement in question and from the conduct of the parties, and in particular from the possibility of there being tacit acquiescence [...]*". However, firstly the rule "*in claris non fit interpretatio*" applies (see Opinion of Advocate General Mengozzi in Case C-511/06 *Archer Daniels Midland v Commission*, paragraph 169). Secondly, "tacit acquiescence" is not even alleged by J&J and the conduct of the parties at the time of the agreement shows neither an indisputable community of wills on a supply agreement at this time nor an unconditional commitment to enter into such an agreement in the future. Moreover, the documents mentioned in J&J's reply to the Statement of Objections (ID1542, p. 5) were exchanged during the negotiation leading up to the Co-promotion agreement: they cannot replace or supersede the clear wording of the Co-promotion agreement itself. The cautious language of the Co-promotion agreement vouches for J&J's refusal to accept a frank commitment.

<sup>433</sup> J&J relied on two internal documents of June 2005 (referred to in Recital (301)), one concerning the preparation and the other the internal minutes of the meeting with Hexal B.V./Sandoz B.V. The first document stated: "***If needed, J-C [Janssen-Cilag] will offer to Hexal the right of having a duplex registration at the moment a generic competitor will enter the market.***" (see ID1542, p. 5, which quotes the document ID0136, p. 264, emphasis added). The second document described what was "*discussed*". Eventually what emerged from the negotiations was the Co-promotion agreement, whose Article 10bis confirms only a commitment of parties to "*discuss the possibility [...] to use a duplex registration [...]*".



Ratiopharm might try to enter the market within a short time. Hexal B.V./Sandoz B.V.'s internal email of 2 February 2006, almost seven months after the Co-promotion agreement entered into force, set out two possible scenarios how to react to the potential generic entry by Ratiopharm: either to launch Hexal B.V./Sandoz B.V.'s own depot patch or to launch a matrix patch to be supplied by J&J. However, concerning the latter option Hexal B.V./Sandoz B.V. stated that the disadvantage was that this was "*depending on the consent by JC [Janssen-Cilag]*"<sup>434</sup>. In the same email, it is also stated that the preference is for the scenario with the matrix patch supplied by J&J, "*but this is not yet agreed with Janssen*".<sup>435</sup> Therefore J&J's statement that "*[t]he negotiations concerning the co-promotion agreement show that there was a mutual expectation that Hexal would be granted an early entry deal*" and that "*[s]ubsequent events confirm this*" cannot be accepted.

- (305) Nor is it contested either that J&J and Novartis/Sandoz signed the Letter of Intent concerning the transfer of the duplex registration to Sandoz B.V. in May 2006, so during the period when the Co-promotion agreement was still in force (see Recital (182)). However, the terms of the Letter of Intent were not strictly followed by the parties. For example, the Letter of Intent provided that "*within 45 (forty five) days after signature date of the Letter of Intent, the Parties shall negotiate in good faith and sign a final License and Supply Agreement for the duplex registration for Sandoz' Product which Sandoz shall purchase from Janssen-Cilag [...]*".<sup>436</sup> But the supply agreement was actually signed by Hexal B.V. and Sandoz B.V. only on 13 October 2006, more than 140 days after signature of the Letter of Intent. The supply agreement had therefore not been signed during the effective period of the initial co-promotion agreement and not even by the time the addendum to the Co-promotion agreement entered into force on 11 July 2006, but more than 90 days later. Moreover, the supply agreement entered into force only after the permanent generic entry of a third party, Ratiopharm, became imminent in January 2007. This was only after the Co-promotion agreement (including the addendum) was terminated.
- (306) The duplex registration had not been transferred to Hexal B.V./Sandoz B.V. during the effective period of the initial co-promotion agreement or by the time the addendum to the Co-promotion agreement entered into force either. The addendum did not include any substantive provision concerning the duplex registration or supplies of J&J's fentanyl patches other than a short reference mentioned in Recital (304) of this Decision, that "*parties have started discussions on a duplex-registration and are close to reaching an agreement in that respect*". Eventually, the duplex registration was transferred to Hexal B.V./Sandoz B.V. on 24 August 2006, so only after the addendum was signed and entered into force.
- (307) All these considerations confirm that the Co-promotion agreement and the supply agreement were two distinct agreements based on self-standing, formally independent and separate legal contracts. The Commission recalls that this Decision pursues the Co-promotion agreement between the parties, not the separate supply agreement which entered into force only after the Co-promotion agreement was terminated.

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<sup>434</sup> ID0178, p. 8. "*Nadeel afhankelijk toestemming JC*"

<sup>435</sup> ID0178, p. 7. "*maar dit is nog niet accoord bij Janssen*".

<sup>436</sup> ID0151, p. 153.

- (308) Moreover, in this respect the Commission observes that Janssen-Cilag B.V. also signed a similar supply agreement for fentanyl patches with [third party]\*, which entered the Dutch market with the product supplied by Janssen-Cilag B.V. [...]\*.<sup>437</sup> [Third party]\* was not previously involved in the co-promotion of Janssen-Cilag B.V.'s originator product. Therefore the previous engagement in or experience with the promotion of fentanyl patches towards pharmacies was clearly not a necessary pre-condition for concluding the supply agreement with Janssen-Cilag B.V. and the claimed potential benefits of the supply agreement are unrelated to the co-promotion services performed under the Co-promotion agreement. More details on this issue are provided in section 7.7.3.
- (309) In addition to the considerations under (i) to (vi) (Recitals (279) to (308)), it should also be noted that at the time of the Co-promotion agreement Janssen-Cilag B.V. did not demonstrate that it would attach any real importance to the co-promotion activities, for which it paid approximately EUR 5 million in total. In particular, Janssen-Cilag B.V. did not seize the rights which were granted to it under the Agreement, such as giving written instructions to Hexal B.V./Sandoz B.V. concerning the promotion activities, organising any meetings with sales representatives of Hexal B.V./Sandoz B.V. or their management or requesting regularly a list of pharmacists who were customers or prospective customers for Durogesic. Janssen-Cilag B.V. was not even able to establish whether it provided any promotion materials to its co-promotion partner.<sup>438</sup>
- (310) The Commission therefore notes that for the period covered by the initial co-promotion agreement, the limited promotion services provided by Hexal B.V./Sandoz B.V., for which Janssen-Cilag B.V. paid approximately EUR 3.7 million, were of only marginal importance for Janssen-Cilag B.V. For the period covered by the addendum, Janssen-Cilag paid approximately EUR 1.3 million to Hexal B.V./Sandoz B.V. and there is no evidence of any promotion services being provided in return in that period at all.
- (c) "Non-entry mechanism": Termination in case of entry
- (311) Article 10 of the initial co-promotion agreement provided for the right of either party *"to terminate the agreement immediately, by written notice, if Company [Hexal B.V./Sandoz B.V.] or a Company Affiliate has a fentanyl patch listed on the Dutch pharmacy TAXE list (known as Z-index)."*<sup>439</sup>
- (312) Listing of a product on the TAXE list, which is public, means launching the product in the Netherlands (see section 3.4.1). That Termination Clause therefore effectively meant that if Hexal B.V./Sandoz B.V. were to launch its own product in the Netherlands, Janssen-Cilag B.V. would immediately become aware of it and could terminate the Agreement immediately and in that case the payments of the monthly instalments from Janssen-Cilag B.V. to Hexal B.V./Sandoz B.V. would be stopped immediately.

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<sup>437</sup> See Recital (196).

<sup>438</sup> See Recitals (270) to (274).

<sup>439</sup> See Recital (166).

- (313) The prospect of termination ending the monthly payments was a strong disincentive for Hexal B.V./Sandoz B.V. to launch its own fentanyl patch in the Netherlands as analysed in detail in Recitals (317) to (328). At the time of concluding the Co-promotion agreement, Janssen-Cilag B.V. was the sole supplier of the fentanyl matrix patch in the Netherlands<sup>440</sup> and the value transferred to Hexal B.V./Sandoz B.V. considerably exceeded the profit Novartis/Sandoz expected to make for the same period if it launched its own generic product.<sup>441</sup> Because the substantial payments in monthly instalments to Hexal B.V./Sandoz B.V. could have been terminated immediately by Janssen-Cilag B.V. in the event of the generic entry,<sup>442</sup> that provision brought a close potential generic competitor to abstain from market entry, thus installing a "non-entry mechanism".
- (314) Termination clauses can be part of any agreement. However, in this case Janssen-Cilag B.V. concluded the Agreement with a close potential competitor which, furthermore, was on the verge of launching its own product. Moreover, the non-entry mechanism was designed in such a way that it rendered the potential entry by Hexal B.V./Sandoz B.V. financially completely unattractive. Hence, the non-entry mechanism was the prominent feature of the Agreement.
- (315) In addition, once the Co-promotion agreement entered into force, Hexal B.V./Sandoz B.V. indeed stayed out of the market with its fentanyl depot patch for the whole term of the initial agreement (from July 2005 to July 2006). It stayed out of the market during the period covered by the addendum (from July 2006 to December 2006), until the (permanent) launch of the independent generic fentanyl patch by a third party became imminent. Janssen-Cilag B.V. and Hexal B.V./Sandoz B.V. then terminated the Co-promotion agreement in December 2006 and reverted to co-operation in the form of a supply agreement (see section 6.3).
- (316) In the light of the central role that the "non-entry mechanism" played in the Agreement, the monthly payments from Janssen-Cilag B.V. to Hexal B.V./Sandoz B.V. should be analysed with regard to the incentives that they provided to Hexal B.V./Sandoz B.V. for not-entering the Dutch market. Such analysis will show that such payments were computed in a way to remunerate Hexal B.V./Sandoz B.V. for staying out of the market rather than for any co-promotion services.
- (317) Before the Agreement was concluded, Novartis/Sandoz internally analysed, on several occasions, the pros and cons of different scenarios, namely (i) market entry with its own depot patch or (ii) refraining from the launch of its own depot patch and cooperation with Janssen-Cilag B.V.
- (318) In February 2005, an internal presentation called "*Fentanyl patches*" prepared by Hexal B.V., under the instructions of the [employee]\* of Hexal B.V., concluded that if Hexal B.V. were to launch its own depot patch in the Netherlands in July 2005, the annual profit for Hexal B.V./Sandoz B.V. would be approximately EUR 3.7 million.<sup>443</sup> The same presentation also included the following: "*Due to*

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<sup>440</sup> See Recital (285).

<sup>441</sup> See Recitals (317) to (322).

<sup>442</sup> See Recitals (166) to (167).

<sup>443</sup> See Recitals (124) and (125).

*Hexal's launch, the AIPs [Pharmacy purchase price] have to be decreased by 23%. [...] How much is it worth for JC [Janssen-Cilag] that Hexal does not launch?"<sup>444</sup>*

- (319) In April 2005, the scenarios were considered again by Hexal B.V. in a table entitled "*Fentanyl Calculation*", which was prepared under the instructions of the [employee]\* of Hexal B.V.<sup>445</sup> In that document the net profit (over a 12 month period) for Hexal B.V. resulting from the option of Hexal B.V.'s launch of its own depot patch in August 2005 was estimated at between approximately EUR 2.2 and EUR 3.0 million, depending on the level of discounts to be offered and market share potentially acquired by Hexal in the Netherlands.<sup>446</sup> The difference in comparison to the calculation from February 2005 mentioned in Recital (318) was explained by Novartis/Sandoz as due to the fact that the calculations rely on various hypotheses.<sup>447</sup> In June 2005, the calculations mentioned in Recitals (318) and (319) were circulated and discussed among the top management of Novartis/Sandoz.<sup>448</sup> Novartis/Sandoz's internal decision-making process on the proposal from Janssen-Cilag B.V. to enter into the Co-promotion agreement was launched and on 30 June 2005, a few days before the Co-promotion agreement entered into force, it was specified in an internal email amongst Novartis/Sandoz's management that "*Hexal launch of the depot patch would result in an annual profit of € 2.246.989*".<sup>449</sup>
- (320) This shows that only a few days before the Co-promotion agreement entered into force, Novartis/Sandoz believed that the launch of its own fentanyl depot patch would bring Hexal B.V./Sandoz B.V. an annual profit of approximately EUR 2.2 million. Under the initial co-promotion agreement with Janssen-Cilag B.V., Hexal B.V./Sandoz B.V. was effectively guaranteed EUR 3.7 million on an annual basis, as long as the Co-promotion agreement was in force and Hexal B.V./Sandoz B.V. stayed out of the market. This was a very strong incentive for Hexal B.V./Sandoz B.V. not to launch its own product, because, as confirmed by Novartis/Sandoz's management at that time, "*the gain compared to the introduction of the own Hexal product is still substantial*".<sup>450</sup> If Hexal B.V./Sandoz B.V. launched its generic product during the term of the Agreement Janssen-Cilag B.V. would have the right to terminate the Agreement and stop the monthly payments immediately. In financial terms, Hexal B.V./Sandoz B.V. would be therefore considerably worse off if it launched its generic product and competed with Janssen-Cilag B.V.
- (321) For the period covered by the addendum, from 11 July 2006 to 15 December 2006, Hexal B.V./Sandoz B.V. received approximately EUR 1.3 million from Janssen-Cilag B.V. Given that the annual profit for Hexal B.V./Sandoz B.V. in the scenario of the launch of its own fentanyl depot patch was estimated at approximately EUR 2.2 million, the expected profit for the 5 months duration of the addendum

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<sup>444</sup> See Recital (126)

<sup>445</sup> ID0832, p. 3.

<sup>446</sup> See Recital (130).

<sup>447</sup> See Recital (235). From the documents it appears that, for example, the expected level of discounts to be given to the pharmacies or the expected market share to be acquired by Hexal B.V./Sandoz B.V. in case of entry were estimated differently in both calculations.

<sup>448</sup> See Recitals (125) and (143).

<sup>449</sup> See Recital (143).

<sup>450</sup> See Recital (145).

could be roughly estimated at EUR 0.9 million.<sup>451</sup> The amount received by Hexal B.V./Sandoz B.V. from Janssen-Cilag B.V. for the period covered by the addendum, when no generic fentanyl patch was on the Dutch market, therefore exceeded the amount that Hexal B.V./Sandoz B.V. expected to make for the same period if it launched its own generic product.

(322) The Commission therefore concludes that for the duration of the whole Co-promotion agreement, including the addendum, the amount that Novartis/Sandoz received from J&J, approximately EUR 5 million, considerably exceeded the profit Novartis/Sandoz expected to make for the same period if it launched its own generic product.

(323) The analysis will now turn to J&J, to assess the importance for Janssen-Cilag B.V. of Hexal B.V./Sandoz B.V.'s non-entry on the Dutch market with fentanyl patches.

(324) Janssen-Cilag B.V. also internally assessed the potential impact of Hexal B.V./Sandoz B.V.'s launch of the depot patch. An overview of the potential scenarios ("*No deal*" and "*Hexal deal as of August 2005*") was circulated on 17 May 2005 among various J&J entities, including Janssen-Cilag B.V. and the [department]\* of Johnson & Johnson.<sup>452</sup> In the cover email, the [employee]\* of Janssen-Cilag B.V. informed his colleagues that if there was no deal with Hexal B.V./Sandoz B.V. and Hexal B.V./Sandoz B.V. would enter the market in August 2005:

- "*the government will force us to lower our price by 33%*;
- *loss of market share by JAC [Janssen-Cilag] (between 30% and 40% within 5 months)*
- *high rebates to be given by JAC [Janssen-Cilag]*".<sup>453</sup>

(325) In November 2007, the Co-promotion agreement with Hexal B.V./Sandoz B.V. was evaluated *ex-post* in the presentation entitled "*Partnering deals - Lessons learned from the Netherlands*" prepared by the [employee]\* of Janssen-Cilag B.V. That *ex-post* evaluation emphasised that concluding the Co-promotion agreement with Hexal B.V./Sandoz B.V. meant that Hexal B.V./Sandoz B.V. did not launch its own fentanyl depot patch on the Dutch market. The Co-promotion agreement had, in comparison to the scenario when Hexal B.V./Sandoz B.V. would have launched its own fentanyl depot patch, a positive effect for Janssen-Cilag B.V. with regard to the price, the potential loss of market share and additional discounts to pharmacies. According to the *ex-post* evaluation, Janssen-Cilag B.V. saved in total at least EUR 14.7 million for "a full year" by concluding the Co-promotion agreement.<sup>454</sup>

(326) The Commission therefore concludes that the positive effects from which Janssen-Cilag B.V. benefited for not having a generic competitor on the market for the whole

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<sup>451</sup> The average monthly profit is calculated from the estimated annual profit and then multiplied by the number of months of the duration of the addendum.

<sup>452</sup> See Recitals (131) and (132).

<sup>453</sup> See Recital (132).

<sup>454</sup> See Recitals (201) and (202).

period of the Co-promotion agreement, including the addendum, considerably exceeded the total value of the payments transferred to Hexal B.V./Sandoz B.V., which amounted to approximately EUR 5 million.

(327) In addition, the Commission observes that on 17 June 2005, shortly before the Co-promotion agreement was concluded, Janssen-Cilag B.V. was made to believe, by a document mentioned to be provided to Janssen-Cilag B.V. by Hexal B.V., that in the scenario of the launch of Novartis/Sandoz's depot patch in July 2005, Hexal B.V. was expected to make an annual profit of approximately EUR 3.7 million.<sup>455</sup> This amount matches the amount that Janssen-Cilag B.V. paid to Hexal B.V./Sandoz B.V. for the first twelve months according to the terms of the initial co-promotion agreement.

(328) The Commission concludes that the Co-promotion agreement and in particular its Termination Clause were structured in a way that Hexal B.V./Sandoz B.V. would be better off by not entering the Dutch market as it would have lost the considerable monthly payments paid by Janssen-Cilag B.V. Such Termination Clause was, in fact, one of the key elements of the agreement and it was designed and implemented in such a way as to put an end to Hexal B.V./Sandoz B.V.'s project of launching a generic depot patch on the Dutch market.

(d) Objectives of the Agreement

(329) The above analysis of the Agreement shows that the main objective of the Agreement was to block the imminent market entry of Hexal B.V./Sandoz B.V. for as long as the Agreement would be in force.

(330) Indeed, on the one side, Hexal B.V./Sandoz B.V. agreed to give up its project of market entry and to co-operate with its competitor in exchange for a considerable amount of money which exceeded the profit with Hexal B.V./Sandoz B.V. expected to result from the market entry.<sup>456</sup> This rendered the launch of Hexal B.V./Sandoz B.V.'s generic product financially unattractive.

(331) On the other side, by providing Hexal B.V./Sandoz B.V., a close potential competitor, with a payment that exceeded its expected profits from market entry but that was still lower than the loss that Janssen-Cilag B.V. would have incurred if a generic had entered,<sup>457</sup> Janssen-Cilag B.V. managed to keep its monopoly and supra-competitive prices and shared its monopoly rent with its close potential competitor.

(332) The main objective pursued by the parties with the Agreement and payments, which was the market exclusion of the generic competitor for the duration of the Agreement, is also clearly illustrated by contemporaneous statements of the parties leading to the signing of the Co-promotion agreement. The parties were aware that "*if there is no deal then Hexal will enter the market (expected for August 2005)*"<sup>458</sup>

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<sup>455</sup> See Recital (140). The cover page of the internal fax within J&J mentions the annual profit for Hexal B.V./Sandoz B.V. of "*approximately €4.0 million*" and refers to the attachment, mentioned to be provided by Hexal B.V./Sandoz B.V., that includes the specific figure of EUR 3.7 million.

<sup>456</sup> See Recitals (140) and (143).

<sup>457</sup> See, for instance, Recitals (115), (117) and (140).

<sup>458</sup> Recital (132). See also, for example, Recital (133).

and that the Agreement is "*designed for the non-introduction of the Hexal Fentanyl patch*".<sup>459</sup>

(e) Conclusions on the content, objectives and implementation of the Agreement

(333) The Commission concludes that:

- Janssen-Cilag B.V. entered into the Agreement with its close potential competitor Hexal B.V./Sandoz B.V., which agreed that instead of launching (likely imminently) its own Fentanyl product it would co-operate with Janssen-Cilag B.V. Janssen-Cilag B.V. did not check for alternatives even if, at the time, for example, the [strong]\* generic market [player]\* in the Netherlands, [third party]\*, was still looking for a partner that would enable it to enter the fentanyl market.
- Moreover, for the duration of the Co-promotion agreement, Janssen-Cilag B.V. paid in total approximately EUR 5 million to Hexal B.V./Sandoz B.V. in monthly instalments. Concerning Hexal B.V./Sandoz B.V.'s obligation to provide co-promotion services, the description of those services in the Agreement was limited and the services were non-specified. In addition, for the duration of the initial co-promotion agreement Hexal B.V./Sandoz B.V. carried out only limited activities and for the duration of the addendum there is no evidence that any promotion activities were carried out by Hexal B.V./Sandoz B.V. whatsoever. The usefulness of those limited services for Janssen-Cilag B.V. was doubtful.
- The Co-promotion agreement included a non-entry mechanism, whereby for the duration of the Agreement strong incentives were provided for Hexal B.V./Sandoz B.V. not to enter the Dutch market. If Hexal B.V./Sandoz B.V. had entered the Dutch market it would have lost the considerable monthly payments from Janssen-Cilag B.V., which considerably exceeded what Hexal B.V./Sandoz B.V. expected to make if it launched the product and which were much less than what Janssen-Cilag B.V. expected to lose if Hexal B.V./Sandoz B.V. entered the market.
- The main objective of the Agreement was to keep Janssen-Cilag B.V.'s close potential competitor out of the Dutch market.

7.5.2.3. Intentions of the parties

(334) Even though the parties' intentions do not constitute a necessary legal element to determine the restrictive aspect of an agreement, the Commission can take them into account.<sup>460</sup> The parties' statements in a number of strategic internal documents from the period of the negotiations as well as the implementation of the Agreement clarify the general objectives and purpose of the co-operation between Janssen-Cilag B.V.

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<sup>459</sup> Recital (145). See also, for example, Recital (143).

<sup>460</sup> Case T-491/07 *Groupement des cartes bancaires*, paragraph 251, not yet published, quoting Case 96/82 *IAZ International Belgium* [1983] ECR 3369 paragraph 23. See also recital 22 of the Guidelines on the application of Article 81(3) of the Treaty, OJ C 101 of 27 April 2004, p. 97.

and Hexal B.V./Sandoz B.V. The parties' intentions regarding the Co-promotion agreement will be examined below and such analysis will show that they confirm the assessment of the objective elements established in the previous two sections.

- (335) The facts described in section 6 show that both parties were well aware of and understood the main objective of the Agreement, which was to keep the generic fentanyl depot patch of Hexal B.V./Sandoz B.V. out of the Dutch market in exchange for a considerable amount of money paid by Janssen-Cilag B.V. to Hexal B.V./Sandoz B.V.
- (336) From the initial stages of the negotiations J&J was looking for the most practical solution and a suitable (legal) instrument which would ensure that Novartis/Sandoz would not enter the Dutch market with its fentanyl depot patch.
- (337) Already in July 2004 Janssen-Cilag B.V. explained its strategy with regard to Hexal B.V.'s fentanyl patches in the internal email as follows: "*What does this mean for our upcoming talk with Hexal? [...] It is in our interest that the reservoir patch does not come on the market before the other matrix patches because of possible price drops. We should come to an agreement that we give a duplex registration as soon as another matrix comes onto the market, in return the reservoir patch is not to be introduced.*"<sup>461</sup>
- (338) The "*Project Team Durogesic Generics*" established by J&J in the Netherlands included then in its minutes of October 2004 the following statement: "*Cooperation Hexal: Aim: to block generic fentanyl reservoir patch in 2005*".<sup>462</sup>
- (339) That general aim is confirmed by an email exchange amongst Janssen-Cilag B.V.'s management from November 2004, in which the management was informed that Hexal B.V. could come on the market already on 1 March 2005 and that "*[o]ur strategy can be only a strategy of delay. Generic will in any event come.*"<sup>463</sup> On that basis the [employee]\* of Janssen-Cilag B.V. instructed his colleagues to prepare "*a scenario with a construction whereby Hexal does not launch and gets part of our cake.*"<sup>464</sup>
- (340) Later, in June 2005, the [employee]\* of Janssen-Cilag's pharmaceutical products in Europe noted: "*Reasoning for deal for Hexal: "[g]ain as much as possible before 2<sup>nd</sup> gx [generics] (protect price)*".<sup>465</sup> In other words, Janssen-Cilag B.V. aimed at convincing Hexal B.V./Sandoz B.V. not to enter the market as long as there was no other generic competitor, by agreeing a strategy which made it possible to (i) avoid the reduction in the price of the originator Janssen-Cilag B.V.'s product and (ii) share the supra-competitive profits among them ("*get part of the cake*").
- (341) In December 2004, Janssen-Cilag B.V. confirmed internally that "*[t]he most realistic approach is to make a deal with Hexal to survive 2005 in any event.*"<sup>466</sup> Internal

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<sup>461</sup> See Recital (111); emphasis added.

<sup>462</sup> See Recital (112); emphasis added.

<sup>463</sup> See Recital (113).

<sup>464</sup> See Recital (114); emphasis added.

<sup>465</sup> See Recital (133); emphasis added.

<sup>466</sup> See Recital (115).



email exchange between the [employee]\* of Janssen-Cilag B.V. and other members of Janssen-Cilag B.V.'s management in the Netherlands from December 2004 further confirmed the general aim of the cooperation between Janssen-Cilag B.V. and Hexal B.V./Sandoz B.V.: "*General aim of cooperation [with Hexal B.V./Sandoz B.V.]: Until the arrival of the matrix generic (expected by beginning 2006) not to have a depot generic on the market and in that way to keep the high current price level and to secure BP [Business Plan].*"<sup>467</sup>

- (342) In May 2005, the [employee]\* of Janssen-Cilag B.V. circulated internally the company's own estimates and calculations of various scenarios. He made a direct link between the Agreement with Hexal B.V./Sandoz B.V. and Hexal B.V./Sandoz B.V.'s non-entry to the Dutch market as he explained that "*if there is no deal then Hexal will enter the market (expected for August 2005)*",<sup>468</sup> and the inevitable consequence of that would be that Janssen-Cilag B.V. would have "*to lower our price by 33%*".<sup>469</sup>
- (343) The fact that Novartis/Sandoz had the same understanding of the rationale behind the possible deal with Janssen-Cilag B.V. is shown by the internal presentation of Hexal B.V. prepared in February 2005 and circulated within Novartis/Sandoz's top management in June 2005, which stated: "*Due to Hexal's launch, the PPPs [Pharmacy purchase price] have to be decreased by 23%. [...] How much is it worth for JC that Hexal does not launch?*"<sup>470</sup> In other words, Novartis/Sandoz knew that it was in the interest of Janssen-Cilag B.V. that Hexal B.V./Sandoz B.V. did not enter the market with its generic product and hence to avoid the price reduction. In order to achieve that Janssen-Cilag B.V. would be willing to share the supra-competitive profits with Hexal B.V./Sandoz B.V.
- (344) Whilst the general aim of the co-operation, that is to say non-entry of Novartis/Sandoz, was clear from the start of the negotiations, the legal tool for achieving that aim was eventually modified in the course of the negotiations. Instead of the initial proposal that in exchange for non-entry, the matrix patch would be supplied by Janssen-Cilag B.V. to Hexal B.V./Sandoz B.V. and would be launched under Hexal B.V./Sandoz B.V.'s brand, a new proposal was submitted by Janssen-Cilag B.V. and described by Novartis/Sandoz on 17 June 2005 as follows: "*Janssen will not supply the product as a generic (Hexal or Sandoz), their adapted proposal concerns "co-marketing & royalty payment"*".<sup>471</sup>
- (345) The email exchange between the [employee]\* of Sandoz B.V., the [employee]\* of Sandoz B.V. and a [employee]\* of Directors of Hexal AG from 30 June and 1 July, that is to say 11 and 10 days before the entry into force of the Co-promotion agreement, further explained that "*[d]uring the follow up meetings, Janssen/Cilag indicated that instead of Hexal selling the Durogesic matrix patch in Durogesic packaging, they propose – based on an [...] assessment that they performed – to pay for a co-promotional payment when Hexal is not launching their own depot patch. Hexal would than [sic] receive an amount of € 3,700,000 on an annual basis,*

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<sup>467</sup> See Recital (118); emphasis added.

<sup>468</sup> See Recital (132); emphasis added.

<sup>469</sup> See Recital (132).

<sup>470</sup> See Recital (126).

<sup>471</sup> See Recital (137).

*paid on a monthly basis. [...] Hexal launch of the depot patch would result in an annual profit of € 2.246.989".*<sup>472</sup>

- (346) The new proposal from Janssen-Cilag B.V. is perhaps even better explained in the following email in the same email chain: *"First idea of the JC [Janssen-Cilag] proposal was to give Hexal additional margin for physical distribution of the JC [Janssen-Cilag] product. [Employee]\* of JC [Janssen-Cilag] however estimates – from a anti competition strategy point of view – the legal risk to [sic] high to go for this first proposal. Therefor they now suggest a royalty payment for non-specified co-promotional activities. [...] Both scenarios are designed for the non introduction of the Hexal Fentanyl patch. [...] The financial difference itself is acceptable, since the gain compared to the introduction of the own Hexal product is still substancial."*<sup>473</sup>
- (347) Those statements show that the new proposal from Janssen-Cilag B.V., which was eventually turned into the Co-promotion agreement under investigation between Janssen-Cilag B.V. and Hexal B.V./Sandoz B.V., was *"designed for the non introduction of the Hexal Fentanyl patch"*, the payment provided by Janssen-Cilag B.V. exceeded considerably the profit Hexal B.V./Sandoz B.V. expected to make if it launched its own product (EUR 3.7 million against EUR 2.2 million annually), the payment was to be provided only *"when Hexal is not launching their own depot patch"* and the payment would be formally provided for *"non-specified co-promotional activities"*. In the same email chain, Hexal B.V./Sandoz B.V. even confirmed that *"there is no justification for any money from co-promotional activities"*.<sup>474</sup> Hexal B.V./Sandoz B.V. therefore clearly understood that the remuneration was not provided for its promotion services but, rather, for non-entry with its generic product.
- (348) The parties negotiated, first, the exact amount of money Hexal B.V./Sandoz B.V. would receive from Janssen-Cilag B.V. and also the condition that Hexal B.V./Sandoz B.V. should not launch its depot patch during the term of the Agreement. A [employee]\* of Directors of Hexal AG is therefore informed that Janssen-Cilag B.V. proposed *"to pay for a co-promotional payment when Hexal is not launching their own depot patch"* and that *"Hexal would than [sic] receive an amount of € 3,700,000 on an annual basis"*. The [employee]\* of Hexal AG is then asked for a decision whether the proposal should be accepted or whether Hexal B.V./Sandoz B.V. should rather launch its own depot patch. However, the content of the promotion services to be provided, that one would expect to be at the heart of the negotiations of a "co-promotion agreement", is not even mentioned in that email, which was sent eleven days before the entry into force of the Agreement. At that time the co-promotion activities were still "non-specified". However, it was already confirmed that the Agreement was designed for the non-introduction of the Novartis/Sandoz's patch and that the specific and concrete amount to be transferred from J&J was acceptable for Novartis/Sandoz even if there was *"no justification for any money from co-promotional activities"*.<sup>475</sup>

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<sup>472</sup> See Recital (143).

<sup>473</sup> See Recital (145).

<sup>474</sup> See Recital (145).

<sup>475</sup> See Recital (145).

- (349) Only on 8 July 2005, so only three days before the Co-promotion agreement became effective, did Hexal B.V./Sandoz B.V. send Janssen-Cilag B.V. a calculation of the remuneration for the planned co-promotion services.<sup>476</sup> The total amount in that calculation matches the amount proposed initially by Janssen-Cilag B.V. at the end of June 2005 "*when Hexal is not launching their own depot patch*" as mentioned in Recital (347). At the same time, it also matches the amount that Janssen-Cilag B.V. was previously made to believe that Hexal B.V./Sandoz B.V. would have made if it entered the Dutch market with its own fentanyl depot patch.<sup>477</sup>
- (350) Only on 11 July 2005, the day the Co-promotion agreement entered into force, did Hexal B.V./Sandoz B.V. propose to Janssen-Cilag B.V. to attach to the Co-promotion agreement a draft "*Annex 1*" with a detailed list of co-marketing activities to be provided by Hexal B.V./Sandoz B.V. and to include in the Agreement the provision that "*Hexal/Sandoz will provide to Janssen-Cilag the services listed under Annex 1 hereto*".<sup>478</sup> However, that proposal was rejected by the [department]\* of Johnson & Johnson.<sup>479</sup> The draft Annex 1 never became part of the Co-promotion agreement and the co-promotion services to be provided by Hexal B.V./Sandoz B.V. are not specifically defined or described in detail in the final version of the Agreement.<sup>480</sup> Moreover, the activities actually performed during the implementation of the Co-promotion agreement differ significantly from what would have been foreseen in that document.
- (351) The parties also commented internally on the Co-promotion agreement *ex-post*, once the Agreement was concluded and signed. In an internal email of 10 January 2006 sent by the [employee]\* of Sandoz B.V. it is confirmed that in July 2005 "*we choose to go for Oper. Inc. [Operating Income] in stead of Sales/Market share (which was in the target 2005) [...] the decision was taken locally not to launch the product and go for the more profitable solution*".<sup>481</sup> In other words, it is confirmed *ex-post* that in July 2005 Novartis/Sandoz deliberately decided not to launch its product in the Netherlands and rather to receive the payments from J&J. It is clear from that statement that the key element of the Agreement was "*not to launch the product*" of Novartis/Sandoz in exchange for the "*Operating Income*" from J&J, which was the "*more profitable solution*".
- (352) In November 2007, an internal presentation "*Partnering deals – Lessons learned from the Netherlands*"<sup>482</sup> was prepared by the [employee]\* of Janssen-Cilag B.V. The fact that Hexal B.V./Sandoz B.V. would not launch its generic product was explicitly mentioned as the first feature of the Co-promotion agreement in that presentation ("*Deal with Hexal to jointly promote Durogesic. Hexal **will not introduce** the (inferior) depot patch*").<sup>483</sup> The co-promotion services provided by Hexal B.V./Sandoz B.V. were not described in detail in the presentation and the

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476 See Recital (146).  
 477 See Recital (327).  
 478 See Recital (149).  
 479 See Recital (151).  
 480 See Recital (151).  
 481 See Recital (177).  
 482 See Recital (201).  
 483 ID0138, p. 121; emphasis added.

presentation did not mention, for example, any tangible results achieved, such as any guidelines agreed between pharmacists and physicians concerning prescribing of fentanyl. This is surprising, as one would expect the concrete promotion activities performed and any tangible results achieved through those promotion activities to be emphasised in an evaluation of a "co-promotion" agreement, if those promotion activities were of any importance. The presentation also suggests that, by concluding the Co-promotion agreement and preventing Hexal B.V./Sandoz B.V.'s generic entry, Janssen-Cilag B.V. saved in total at least EUR 14.7 million for "a full year" in comparison to the scenario in which Hexal B.V./Sandoz B.V. would have launched its own fentanyl depot patch.<sup>484</sup>

- (353) The Commission also notes that in its reply to the Statement of Objections, J&J admitted that "***the Hexal deal was expected by those who negotiated it to lead – in addition to an increased promotion and awareness of the Durogesic® patch with pharmacists - to a short delay in generic entry*** [...]."<sup>485</sup>
- (354) Novartis/Sandoz argued in its reply to the Statement of Objections that Hexal's primary purpose was to accelerate the launch of a generic matrix patch<sup>486</sup> and that "*from Hexal's perspective, the primary purpose of the negotiations was to obtain access to a matrix patch as soon as possible. It is evident that the statement of objections is tainting Hexal with Janssen-Cilag's intent – an intent that Hexal did not share.*"<sup>487</sup>
- (355) The Commission disagrees with this argument. As already mentioned above, already in February 2005, that is to say five months before the Co-promotion agreement was concluded, Novartis/Sandoz knew that it was in J&J's interest that Novartis/Sandoz did not enter the market with its generic product and that J&J may be willing to share the supra-competitive profits with Novartis/Sandoz. Novartis/Sandoz internally asked the question: "*How much is it worth for JC that Hexal does not launch?*"<sup>488</sup> Novartis/Sandoz therefore had already at that time the same understanding of the rationale behind the possible deal as J&J. Furthermore, Novartis/Sandoz's contemporaneous documents quoted in Recitals (344) to (351) show that during the negotiations Novartis/Sandoz acted in full knowledge of the objective of the Agreement, which was to exclude Novartis/Sandoz from the market for the duration of the Agreement. In Novartis/Sandoz's own words, both potential scenarios under negotiation, namely physical distribution of J&J's matrix patch by Novartis/Sandoz

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<sup>484</sup> See Recitals (201) and (325).

<sup>485</sup> ID1542, p. 3; emphasis added.

<sup>486</sup> Novartis/Sandoz argued that "[t]he negotiations with Janssen-Cilag initially started on the basis that Janssen-Cilag would grant a duplex registration to Hexal. At a fairly late point during the negotiations, Janssen-Cilag did not want to offer to Hexal a duplex registration anymore and proposed the Co-promotion agreement instead, with a promise to later re-open discussions on the matrix patch. It was felt at the time that this was the best agreement Hexal could reach with Janssen-Cilag. Although it did not give immediate access to a matrix patch, it allowed Hexal to get familiar with the matrix patch right away through the co-promotion activities, while leaving open the possibility that it would get access to Janssen-Cilag's matrix patch prior to the development of its own matrix patch being finished. Sandoz therefore contests the statement made by the Commission that "whilst the general aim of the co-operation, i.e. non-entry of Novartis/Sandoz was clear from the start of the negotiations, the legal tool for achieving that aim was eventually modified in the course of the negotiations." ID1537, p. 16.

<sup>487</sup> ID1537, p. 17.

<sup>488</sup> See Recital (343).

or royalty payment for non-specified co-promotion activities, were "*designed for the non introduction of the Hexal Fentanyl patch*".<sup>489</sup>

- (356) Novartis/Sandoz further argued that "*the evidence in the file shows that the parties at the time of the negotiations only entered into this agreement after the involvement of their respective legal services which at least indicates that the parties endeavoured to enter into a final agreement that was in compliance with the EU competition law rules. In this respect it is relevant to consider that the Co-promotion agreement does not contain any non-compete provision. Importantly, Hexal performed promotional services and communicated the reports on the survey that it had conducted to the benefit of Janssen-Cilag.*"<sup>490</sup>
- (357) The Commission disagrees with this argument. According to well-established case law of the Courts of the Union, "[f]or an infringement of the competition rules to be regarded as having been committed intentionally, it is not necessary for an undertaking to have been aware that it was infringing those rules; it is sufficient that it could not have been unaware that its conduct was aimed at restricting competition".<sup>491</sup> As established above, Novartis/Sandoz was aware that the Agreement was "*designed for the non introduction of the Hexal Fentanyl patch*".<sup>492</sup> The parties therefore could not have been unaware that their conduct was aimed at restricting competition. The involvement of their respective legal services in the negotiations does not change anything in that respect.<sup>493</sup> Moreover, the notion that agreements which are aimed at market exclusion in exchange for a payment are likely to constitute a restriction by object under Article 101 of the Treaty is well established.
- (358) Concerning the argument that the Co-promotion agreement does not contain any non-compete provision, reference is made to Recitals (311) to (328), where the "non-entry mechanism" embedded in the Co-promotion agreement was described and analysed, and where it was found that the "non-entry mechanism" played a central role in the Co-promotion agreement. The prospect of termination of the monthly payments provided Hexal B.V./Sandoz B.V. with strong incentives not to enter. Concerning the argument that "*Hexal performed promotional services*", the Commission notes that Novartis/Sandoz has not substantiated that statement by any new evidence. Reference is therefore made to Recitals (263) to (310) where the Commission analysed the co-promotion services provided by Hexal B.V./Sandoz B.V. and concluded that for the period covered by the initial co-promotion agreement, only limited promotion services were provided by Hexal B.V./Sandoz B.V. and for the period covered by the addendum, there is no evidence of any co-promotion services being provided at all.

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<sup>489</sup> See Recital (346).

<sup>490</sup> ID1537, p. 16.

<sup>491</sup> Case T-11/06 *Romana Tabacchi Srl v Commission* [2011] ECR II-06681, paragraph 227; Case T-348/94 *Enso Española SA v Commission*, paragraph 277.

<sup>492</sup> See Recital (346).

<sup>493</sup> See ID1542, p. 4. The Commission recalls that in Case C-681/11 *Schenker* [2013], paragraph 43, the Court stated: "*Article 101 TFEU must be interpreted as meaning that an undertaking which has infringed that provision may not escape imposition of a fine where the infringement has resulted from that undertaking erring as to the lawfulness of its conduct on account of the terms of legal advice given by a lawyer [...]*".

(359) Taken together, the intentions of the parties confirm the objective elements of the analysis in that they show that both parties acted in the full knowledge of the objective of the Agreement and that both parties designed the Co-promotion agreement in a way that ensured that Hexal B.V./Sandoz B.V.'s generic product was kept out of the market and Janssen-Cilag B.V. could maximise its profits for sales of the originator product as long as the Agreement was in force and share those supra-competitive profits with Hexal B.V./Sandoz B.V. The payments to Hexal B.V./Sandoz B.V. were made conditional upon not launching of Hexal B.V./Sandoz B.V.'s generic product and substantially exceeded the profits Hexal B.V./Sandoz B.V. could have hoped to make had it entered the market in the Netherlands with its own generic fentanyl patch. At the same time the payments from Janssen-Cilag B.V. were considerably lower than the potential losses Janssen-Cilag B.V. was expected to suffer in case Hexal B.V./Sandoz B.V. launched its own generic fentanyl patch.

### 7.5.3. *Conclusion on restriction by object*

(360) In view of all the elements relating to the Co-promotion agreement of 11 July 2005 between Janssen-Cilag B.V. and Hexal B.V./Sandoz B.V., the following can be concluded.

(361) Firstly, based on the analysis of the economic and legal context, Hexal B.V./Sandoz B.V. was, at the time it concluded the Co-promotion agreement with Janssen-Cilag B.V., a close potential competitor of Janssen-Cilag B.V. The review of the legal and economic context has shown that entry was a plausible assumption. Had it not been for Janssen-Cilag B.V.'s Co-promotion agreement with Hexal B.V./Sandoz B.V., there would have been a strong likelihood that Hexal B.V./Sandoz B.V. would have entered the market in the Netherlands with its generic fentanyl depot patch as the first generic competitor, probably in August 2005.

(362) Secondly, the Co-promotion agreement concluded by Janssen-Cilag B.V. and Hexal B.V./Sandoz B.V. included a non-entry mechanism whereby Janssen-Cilag B.V.'s monthly payments would cease if Hexal B.V./Sandoz B.V. or any third party would undertake to enter the market. Accordingly, Hexal B.V./Sandoz B.V. did stay out of the Dutch market with its own fentanyl depot patch for the entire duration of the Co-promotion agreement (from 11 July 2005 to 15 December 2006).

(363) Thirdly, as a consequence of the Agreement, Janssen-Cilag B.V.'s close potential generic competitor was excluded from the market at a time when the threat of its market entry was imminent. Janssen-Cilag B.V. did not check for alternatives. This was in a situation where, for example, the [strong]\* generic market [player]\* in the Netherlands, [third party]\*, was still looking for a partner that would enable it to enter the fentanyl market<sup>494</sup> and there were other, more remote generic companies interested in entering the Dutch market with fentanyl patches.

(364) Moreover, for the period concerned, Janssen-Cilag B.V. paid in total approximately EUR 5 million to Hexal B.V./Sandoz B.V. in monthly instalments. Those payments were provided for undefined co-promotion services. During the period covered by

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<sup>494</sup> As the [strong]\* generic market [player]\* in the Netherlands, [third party]\* had a sales force with experience in generic and even "innovative" medicines. See Recital (104).

the initial co-promotion agreement (from 11 July 2005 to 11 July 2006), for which Hexal B.V./Sandoz B.V. received approximately EUR 3.7 million, Hexal B.V./Sandoz B.V. carried out only limited promotion activities, of limited usefulness to Janssen-Cilag B.V. During the period covered by the addendum (from 11 July 2006 to 15 December 2006), Hexal B.V./Sandoz B.V. received approximately EUR 1.3 million for undefined co-promotion services. There is no evidence that, for the duration of the addendum, any promotion activities were carried out by Hexal B.V./Sandoz B.V. whatsoever. At the same time, by preventing Hexal B.V./Sandoz B.V. from entering the Dutch market with its own generic fentanyl patches for the duration of the Agreement Janssen-Cilag B.V. avoided significant losses, which would have considerably exceeded the amount Janssen-Cilag B.V. paid to Hexal B.V./Sandoz B.V. under the Co-promotion agreement. Moreover, the amount paid to Hexal B.V./Sandoz B.V. considerably exceeded what Hexal B.V./Sandoz B.V. itself expected, at the time it concluded the Agreement, to make if it had launched its own fentanyl depot patch in the Netherlands<sup>495</sup>. Moreover, it matched the amount Janssen-Cilag B.V. was made to believe Hexal B.V./Sandoz B.V. would have made if it had entered the Dutch market with its own fentanyl depot patch.

- (365) The above objective elements of the analysis were confirmed by the intentions of the parties as they showed that both parties acted in the full knowledge of the objective of the Agreement. Both parties designed the Co-promotion agreement in a way that ensured that Hexal B.V./Sandoz B.V.'s generic product was kept out of the market and Janssen-Cilag B.V. could maximise its profits for sales of the originator product as long as the Agreement was in force. Janssen-Cilag B.V. shared those supra-competitive profits with Hexal B.V./Sandoz B.V.
- (366) The Commission therefore concludes that the Co-promotion agreement between the incumbent originator undertaking and its close potential competitor examined in this Decision constitutes a restriction of competition by object.<sup>496</sup>
- (367) This conclusion cannot be put in question by Novartis/Sandoz's argument in its reply to the Statement of Objections that it is not supported by the *Irish Beef* judgment which the Commission refers to (see Recitals (217) and (218)). First, Novartis/Sandoz argued that, unlike *Irish Beef*, the Co-promotion agreement did not concern all market participants.<sup>497</sup> Second, it argued that the objective of the Co-promotion agreement was not to reduce capacity on the market.<sup>498</sup> Third, unlike *Irish Beef*, the Co-promotion agreement did not aim to ensure that Hexal would actually leave the market and, importantly, there was no provision in the Co-promotion agreement that specifically restricted Hexal's ability to enter the market with its own patch.<sup>499</sup>

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<sup>495</sup> The amount was paid to Hexal B.V./Sandoz B.V. without it having to undergo the risks of competition after market entry.

<sup>496</sup> As explained in Recital (216), it is hence not necessary to examine the effects of the Co-promotion agreement once its anticompetitive object has been established.

<sup>497</sup> ID1537, p. 17.

<sup>498</sup> ID1537, p. 18.

<sup>499</sup> ID1537, p. 18.

- (368) Concerning the first point made by Novartis/Sandoz, at the time the Co-promotion agreement was concluded there was only one competitor actually marketing the fentanyl patches in the Netherlands, J&J, and it entered into the agreement with a close potential competitor, which was perceived by J&J as its most advanced potential competitor and which was capable to enter the market in the immediate future at that time, Novartis/Sandoz.<sup>500</sup> The Agreement therefore concerned the relevant market participants active on the market at the time the Agreement was concluded or capable of entering the market in the immediate future.
- (369) Concerning the second and third point made by Novartis/Sandoz, the Statement of Objections<sup>501</sup> and also this Decision pointed to certain differences between the Irish Beef case and the case at hand (see Recital (218)). The Commission therefore did not claim that the factual setting in this case and in *Irish Beef* was identical. The Commission rather pointed to the underlying principles of the *Irish Beef* judgment and emphasised that the facts in the Fentanyl case "*show important similarities to the situation in Irish Beef, in that in the Agreement covered by this Statement of Objections two (potential) competitors agreed on a common plan which eliminated, for a certain period of time, the incentives for one of them, the generic undertaking, to enter the market with its own generic product.*"<sup>502</sup>
- (370) In any event, even if the facts of this case and *Irish Beef* showed relevant differences (*quod non*), that would not in itself be a reason to conclude that the Co-promotion agreement in this case did not constitute a restriction of competition by object. The conclusion that the Co-promotion agreement in this case constituted a restriction of competition by object is based on an in-depth legal assessment of the specific facts of this case provided above (see in particular sections 7.5.2 and 7.5.3).
- (371) Furthermore, Novartis/Sandoz argued that "under EU competition law there is no obligation upon any company to develop or to launch a product. This is particularly true in a situation where the launch of the product was no longer commercially viable due to subsequent developments in the market".<sup>503</sup> Contrary to what is asserted by Novartis/Sandoz, the Commission does not argue that there is a general obligation on companies to develop or launch a product. However, the Commission recalls that the notion that agreements which are aimed at market exclusion in exchange for a payment are likely to constitute a restriction by object under Article 101 of the Treaty is well established.
- (372) Finally, the restriction of competition is appreciable. The Commission Notice on agreements of minor importance which do not appreciably restrict competition under Article 81(1) of the Treaty establishing the European Community (hereafter referred to as the "*de minimis* Notice") acknowledges that "*the Court of Justice of the European Communities has clarified that this provision [Article 81(1) EC, now Article 101(1) of the Treaty] is not applicable where the impact of the agreement on*

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<sup>500</sup> See section 7.5.2.1 where it is shown, on the basis of contemporaneous documents, that Novartis/Sandoz could likely have launched in August 2005 at the latest.

<sup>501</sup> Statement of Objections, Recital (208).

<sup>502</sup> Statement of Objections, Recital (208).

<sup>503</sup> ID1537, p. 17.



*intra-Community trade or on competition is not appreciable.*"<sup>504</sup> In the *de minimis* Notice the Commission quantifies, with the help of market share thresholds, what is not an appreciable restriction of competition under Article 101 of the Treaty. However, point 11 of the Notice explains that these *de minimis* thresholds "*do not apply to agreements containing any of the following hardcore restrictions: (1) as regards agreements between competitors as defined in point 7, restrictions which, directly or indirectly, in isolation or in combination with other factors under the control of parties, have as their object: [...] (b) the limitation of output or sales; (c) the allocation of markets or customers [...].*" The Agreement covered by this Decision had the object of preventing or stopping the generic undertaking concerned from entering one market in the Union. It also de facto allocated the fentanyl market to Janssen-Cilag B.V., in the sense that Hexal B.V./Sandoz B.V. agreed to refrain from competing with Janssen-Cilag B.V. in the Netherlands. Such agreement cannot benefit from the *de minimis* thresholds in the *de minimis* Notice. The Commission refers, in this respect, also to *Expedia*, in which the Court of Justice stated in a preliminary ruling: "*It must therefore be held that an agreement that may affect trade between Member States and that has an anti-competitive object constitutes, by its nature and independently of any concrete effect that it may have, an appreciable restriction on competition.*"<sup>505</sup>

## 7.6. Effect upon trade between Member States

### 7.6.1. Principles

- (373) Article 101(1) of the Treaty is applicable only in so far as agreements "*may affect trade between Member States*".
- (374) According to well-established case law of the European Court of Justice, an agreement "*may affect trade*" when it is "*possible to foresee with a sufficient degree of probability on the basis of a set of objective factors of law or of fact that the agreement [...] may have an influence, direct or indirect, actual or potential, on the pattern of trade between Member States.*"<sup>506</sup> Therefore, whilst Article 101 of the Treaty "*does not require that agreements referred to in that provision have actually affected trade between Member States, it does require that it be established that the agreements are capable of having that effect*"<sup>507</sup>. The concept of "*trade*" covers all

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<sup>504</sup> Commission Notice on agreements of minor importance which do not appreciably restrict competition under Article 81(1) of the Treaty establishing the European Community, OJ C 368 of 22.12.2001, p. 13. The Commission refers to section 7.6 for its analysis of effect on trade between Member States.

<sup>505</sup> Case C-226/11 *Expedia Inc. v Autorité de la concurrence and Others*, reference for a preliminary ruling, judgment of 13 December 2012, paragraph 37.

<sup>506</sup> Case 56/65 *Société technique minière* [1966] ECR 282, paragraph 7; Case 42/84 *Remia a. o.* [1985] ECR 2545, paragraph 22 and joined Cases T-25/95 *Cimenteries CBR* [2002] ECR II-491.

<sup>507</sup> Case C-306/96 *Javico*, [1998] ECR I-1983, paragraphs 16 and 17; see also Case C-219/95P *Ferriere Nord v Commission* [1997] ECR I-4411, paragraph 19; Case T-374/94, *European Night Services*, [1998] ECR II-3141, paragraph 136.

cross-border economic activity including establishment.<sup>508</sup> "Trade" can take place between different undertakings or between different parts of the same undertaking.<sup>509</sup>

- (375) The concept of "trade" also encompasses cases where agreements affect the competitive structure of the internal market, for instance by eliminating a competitor within the Union.<sup>510</sup> Trade "between Member States" refers to trade between at least two Member States. It is not required that trade between all or most Member States is affected.<sup>511</sup> Trade between Member States may also be affected where the relevant geographic market is national in scope.<sup>512</sup> The Union Courts have held in a number of cases that agreements extending over the whole territory of a Member State by their very nature have the effect of reinforcing the partitioning of markets on a national basis by hindering the economic penetration which the Treaty is designed to bring about.<sup>513</sup>
- (376) Nor is it necessary to establish a link between the alleged restriction of competition and the capacity of the agreement as a whole to affect trade between Member States.<sup>514</sup> Furthermore, it is the continuous course of conduct as a whole that must be capable of affecting trade between Member States. It is not required that each individual practice, each provision of an agreement or each agreement that forms part of a single and continuous infringement is capable of doing so.<sup>515</sup>
- (377) Finally, the effect on trade of the agreement must be "appreciable", i.e. the effect on trade between Member States must not be insignificant.<sup>516</sup>

#### 7.6.2. *Application to the present case*

- (378) In this case, the Co-promotion agreement covered the entire territory of a Member State, namely the Netherlands. The Agreement had the object of preventing the generic undertaking Novartis/Sandoz from selling its generic version of the

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<sup>508</sup> Commission Notice: Guidelines on the effect on trade concept contained in Article 81 and 82 of the Treaty, OJ C 101, 27.4.2004, point 19.

<sup>509</sup> Joined cases 240, 241, 242, 261, 262, 268 and 269/82 *Stichting Sigarettenindustrie and others v Commission*, paragraph 49.

<sup>510</sup> Commission Notice: Guidelines on the effect on trade concept contained in Article 81 and 82 of the Treaty, OJ C 101, 27.4.2004, point 20.

<sup>511</sup> Commission Notice: Guidelines on the effect on trade concept contained in Article 81 and 82 of the Treaty, OJ C 101, 27.4.2004, point 21.

<sup>512</sup> Commission Notice: Guidelines on the effect on trade concept contained in Article 81 and 82 of the Treaty, OJ C 101, 27.4.2004, point 22.

<sup>513</sup> Case C-125/07P, C-133/07P and C-137/07P, *Erste Group Bank* [2009] ECR I-8681 paragraphs 38-40; Case T-61/99, *Adriatica di Navigazione v. Commission* [2003] ECR II-5349, paragraph 163. Commission Notice: Guidelines on the effect on trade concept contained in Article 81 and 82 of the Treaty, OJ C 101, 27.4.2004, point 78. See also, for example, Case C-309/99 *Wouters* [2002] ECR I-1577, paragraph 95.

<sup>514</sup> Commission Notice: Guidelines on the effect on trade concept contained in Article 81 and 82 of the Treaty, OJ C 101, 27.4.2004, point 16.

<sup>515</sup> Commission Notice: Guidelines on the effect on trade concept contained in Article 81 and 82 of the Treaty, OJ C 101, 27.4.2004, points 12 and 14.

<sup>516</sup> Case 306/96, *Javico* [1988] ECR I-1983, paragraphs 12-17; Case T-213/00, *CMA CGM a. o. v. Commission* [2003] ECR II-913. Commission Notice : Guidelines on the effect on trade concept contained in Article 81 and 82 of the Treaty, OJ C 101, 27.042004, points 44ff.

transdermal fentanyl patches and therefore eliminated, for the duration of the Agreement, a potential competitor from the Netherlands' national market.

- (379) In line with the case law of the Court of Justice, as the Agreement in question extended "*over the whole of the territory of a Member State, it has, by its very nature, the effect of reinforcing the partitioning of markets on a national basis, thus impeding the economic interpenetration which the Treaty is designed to bring about.*"<sup>517</sup>
- (380) In its reply to the Statement of Objections Novartis/Sandoz submitted that the Commission should not apply an un rebuttable presumption that trade between Member States is capable of being affected and that the fact that the Co-promotion agreement extended over the whole territory of a Member State is not sufficient to conclude that the agreement would reinforce the partitioning of markets on a national basis and that it was capable of having an appreciable effect on the inter-state trade.<sup>518</sup>
- (381) Contrary to what is asserted by Novartis/Sandoz, the Commission does not apply an un rebuttable presumption that trade between Member States is affected due to the anti-competitive agreement covering the whole territory of a Member State.<sup>519</sup> The Commission, in accordance with the case law of the Court of Justice, takes as the starting point of its reasoning the existence of a strong presumption that trade between Member States is affected.<sup>520</sup> That presumption can only be rebutted if an analysis of the characteristics of the agreement and its economic context demonstrates the contrary.<sup>521</sup>
- (382) As Novartis/Sandoz stated in its reply to the request for information, "[t]he production of Hexal/Sandoz's fentanyl depot patches for all of the European Union has always taken place [in a EU Member State other than the Netherlands]\*".<sup>522</sup> Also the fentanyl matrix patch eventually launched by Novartis/Sandoz in the Netherlands in August 2008 (12.5 µg/h version) and January 2009 (other strengths) would have stemmed from Hexal B.V./Sandoz B.V.'s manufacturing site in [EU Member State other than the Netherlands]\*.<sup>523</sup>
- (383) The Co-promotion agreement between J&J and Hexal B.V./Sandoz B.V. therefore prevented cross-border economic activity which could have come about between the Netherlands, where Hexal B.V. and Sandoz B.V. were located, and [EU Member State other than the Netherlands]\*, where Novartis/Sandoz's manufacturing site as well as [company belonging to]\* the Sandoz group of companies, were located. Moreover, Novartis/Sandoz abstained from launching its depot patch (manufactured in [EU Member State other than the Netherlands]\*) in the Netherlands for the whole

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<sup>517</sup> Case C-125/07P, C-133/07P and C-137/07P, *Erste Group Bank* [2009] ECR I-8681 paragraph 38.

<sup>518</sup> ID1537, p. 6 - 8.

<sup>519</sup> ID1537, p. 8.

<sup>520</sup> See, in particular Case, C-125/07P, C-133/07P and C-137/07P, *Erste Group Bank* [2009] ECR I-8681 paragraphs 39-40.

<sup>521</sup> Case C-125/07P, C-133/07P and C-137/07P, *Erste Group Bank* [2009] ECR I-8681 paragraphs 39-40.

<sup>522</sup> ID0471, p. 4.

<sup>523</sup> ID0471, p. 7.

duration of the Co-promotion agreement.<sup>524</sup> Therefore the Co-promotion agreement disrupted patterns of trade between Member States.<sup>525</sup>

- (384) In this respect Novartis/Sandoz argued that "*the Commission's characterisation of internal transfers of goods as "trade" is incompatible with a coherent application of Article 101(1) TFEU*"<sup>526</sup> and also "*incompatible with the Commission's own Guidelines on the effect on trade between Member States*".<sup>527</sup> Similarly, J&J argued that "[i]nterstate trade arises when products have been put on the market in one Member State and are then sold to another Member State",<sup>528</sup> which, according to J&J, did not happen in this case. The Commission does not accept those arguments.
- (385) As recognised by Novartis/Sandoz, the Court of Justice already clearly stated in the *Stichting Sigarettenindustrie* case that "*an agreement concluded between undertakings established in a Member State and covering only the market of that State affects trade between Member States, within the meaning of Article [101 TFEU], if it concerns, even partly, a product imported from another Member State, even where the parties to the agreement obtain the product from a company belonging to their own group.*"<sup>529</sup> This applies to the factual setting in this case which concerns Novartis/Sandoz's fentanyl patches to be imported to the Netherlands from [EU Member State other than the Netherlands]\* and produced in [EU Member State other than the Netherlands]\* by a company belonging to Novartis/Sandoz's own group.<sup>530</sup> Therefore the Commission's legal assessment in this respect is in line with the Court's application of Article 101(1) of the Treaty.
- (386) Moreover, it is important to clarify the following in view of Novartis/Sandoz's submission: the relevant legal concept in this context is the "*effect on trade between Member States*", and not the concepts of "*agreement*" or "*undertaking*" under Article 101(1) of the Treaty. In the case at hand the behaviour restrictive of competition occurred between two independent undertakings and not within the same group. The fact that internal agreements within the same group may not be covered by certain concepts under Article 101 of the Treaty under certain conditions does not entail that internal sales within a group are not relevant for the assessment of other concepts such as the effect on trade or even fines (see Recitals (388) and (389)).
- (387) Concerning Novartis/Sandoz's argument as to the incompatibility with the Commission's own Guidelines on the effect on trade, the Commission refers in particular to point 82 and footnote 62 of the Guidelines, which refers to paragraphs 49 and 50 of the *Stichting Sigarettenindustrie* judgment already quoted in Recital (385) of this Decision. It is therefore clear that point 82 of the Guidelines concerns products imported from other Member States, "*even where the parties to the*

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<sup>524</sup> See Recital (93)

<sup>525</sup> Joined Cases 209 to 215 and 218/78 *Van Landewyck and others v Commission* [1980] ECR 3125, paragraph 170.

<sup>526</sup> ID1537, p. 11.

<sup>527</sup> ID1537, p. 13.

<sup>528</sup> ID1542, p. 20.

<sup>529</sup> Joined cases 240, 241, 242, 261, 262, 268 and 269/82 *Stichting Sigarettenindustrie and others v Commission*, paragraph 49.

<sup>530</sup> ID1537, p. 12.

*agreement obtain the product from a company belonging to their own group*".<sup>531</sup> The argument that the Commission's characterisation of internal transfers of goods as "trade" is incompatible with the Commission's own Guidelines on the effect on trade therefore cannot be accepted.

- (388) In this regard, the Commission refers by analogy to the *Europa Carton* case<sup>532</sup> where the Court considered that no provision prevented the Commission from taking "*internal supplies within one company [...] into account in order to determine the amount of the fine*". The Court found that "*the applicant's assertion that it did not derive any benefit from the cartel when it supplied its cartonboard to its own factories cannot be upheld*". It pointed out that "*to ignore the value of the applicant's internal cartonboard deliveries would inevitably give an unjustified advantage to vertically integrated companies*".
- (389) Similarly, in order to assess the effect on trade of an agreement the purpose of which is to block market entry of products originating from another Member State, competition law cannot ignore or immunise this agreement for the sole reason that those products have been transferred between undertakings belonging to the same group. Whether the import is a direct one by Hexal AG or an indirect one through its subsidiary Hexal B.V., the purpose of the agreement is the same: blocking market entry of those products in the Netherlands. Any other solution would inevitably give an unjustified advantage to vertically integrated companies.
- (390) Furthermore, Novartis/Sandoz argued that the presumption in this case should be overturned given that the Co-promotion agreement did not contain any provision specifically applicable to situations occurring outside the Netherlands and due to the economic and market realities existing at the time that the Co-promotion agreement was signed.<sup>533</sup>
- (391) The Commission disagrees with this argument. With regard to the provisions of the Agreement, the non-entry mechanism described in Recitals (311) to (328) was designed and implemented in such a way as to put an end to Novartis/Sandoz's efforts to launch a generic depot patch on the whole Dutch market, even though, as Novartis/Sandoz argues, the Agreement allegedly concerned only "*co-promotion services to be rendered at certain Dutch pharmacists*". The Agreement was therefore capable of considerably changing the conditions of competition throughout the whole Member State.

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<sup>531</sup> Joined cases 240, 241, 242, 261, 262, 268 and 269/82 *Stichting Sigarettenindustrie and others v Commission*, paragraph 49.

<sup>532</sup> Case T-304/94 *Europa Carton AG v Commission*, paragraphs 120-129. In this case, a German company that produced carton board and manufactured folding boxes had been fined by the Commission for its participation in a cartel relating to carton board. When setting the fine, the Commission took into consideration the value of both sales of carton board to third parties and internal deliveries of carton board to the folding carton factories owned by Europa Carton. Europa Carton argued that those deliveries were irrelevant and should not have been taken into consideration.

<sup>533</sup> ID1537, p. 8-9. In particular, Novartis/Sandoz submitted that "*the Co-promotion agreement in this case was limited to the Dutch territory (at most) and concerned co-promotion services to be rendered at certain Dutch pharmacists by Hexal*".<sup>533</sup> These co-promotion activities were "*to be performed by Hexal to the benefit of Janssen-Cilag only in the Netherlands*" and "[t]he Co-promotion agreement did not contain any wording that suggested that the parties intended to take into account any factor external to the Dutch market nor that either party was attempting to protect itself against "foreign" competition."

- (392) The text of the Co-promotion agreement also contradicts Novartis/Sandoz's argument that it *"did not contain any wording that suggested that the parties intended to take into account any factor external to the Dutch market nor that either party was attempting to protect itself against "foreign" competition"*. The initial co-promotion agreement was applicable not only to the contractual parties, but also to their *"Affiliates"*.<sup>534</sup> An *"Affiliate"* is defined in the Agreement as *"any company which owns or controls at least fifty per cent (50%) of the voting stock of such given company, or any other company at least fifty per cent (50%) of whose voting stock is owned or controlled by such owning or controlling company or by the given company."*<sup>535</sup> Clearly, this definition also covers companies established outside the Netherlands, for example, Novartis AG and Hexal AG, which during the relevant period controlled at least 50% of the voting stock of Hexal B.V. and Sandoz B.V.<sup>536</sup>, and all subsidiaries of Novartis AG or Hexal AG established in other Member States, of which Novartis AG or Hexal AG owned or controlled at least 50% of the voting stock.
- (393) According to Article 10.2.2 of the initial co-promotion agreement, *"either Party shall have the right to terminate the agreement immediately, by written notice, if Company [Hexal B.V./Sandoz B.V.] or a Company Affiliate has a fentanyl patch listed on the Dutch pharmacy TAXE list (known as Z-index)."*<sup>537</sup> The *"non-entry mechanism"* embedded in the Co-promotion agreement and analysed in Recitals (311) to (328) therefore applied also to all *"Affiliates"* of Hexal B.V. and Sandoz B.V. established in other Member States. In this respect it is recalled that Novartis/Sandoz introduced its fentanyl depot patch in at least seven other Member States around the time the Co-promotion agreement entered into force or shortly thereafter. As mentioned in their comments on the Letter of Facts by both J&J<sup>538</sup> and Novartis/Sandoz<sup>539</sup>, the Dutch regulatory framework for opioids<sup>540</sup> required exemptions *"which could, as a matter of law, only be obtained by a Dutch legal entity"*.<sup>541</sup> However, as recognised by J&J, it *"might theoretically have been possible to use an independent importer"*.<sup>542</sup> Article 10.2.2 of the Co-promotion agreement was therefore capable of preventing potential imports of fentanyl transdermal patches of Novartis/Sandoz's Affiliates from other Member States to the Netherlands.
- (394) It must hence be concluded that the Co-promotion agreement blocking the entry on the Dutch market of Novartis/Sandoz's depot patch, the only depot patch that would have been on the Dutch market at that time, was therefore capable of changing patterns of imports and exports of fentanyl patches to and from the Netherlands. As

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<sup>534</sup> ID0179, p. 16, 23, 24 and 27.

<sup>535</sup> ID0179, p. 16. In its comments on the Letter of Facts, Novartis/Sandoz argued that *"a definition and references to "Affiliates" are standard or "boilerplate" provisions that are typically included in any commercial agreement"* (ID1709, p. 6). However, in this case, Affiliates are specifically mentioned in a limited number of clauses, notably Article 10.2.2 regarding the Termination Clause (see section 7.6.2.2 (c) on the *"non-entry mechanism"*).

<sup>536</sup> See Recitals (61) and (62).

<sup>537</sup> ID0179, p. 24.

<sup>538</sup> ID1702, p. 4.

<sup>539</sup> ID1709, p. 6-8.

<sup>540</sup> Notably the Opium Act. See Recital (73).

<sup>541</sup> ID1702, p. 4.

<sup>542</sup> ID1702, p. 4.

mentioned in Recital (239), around the time the Co-promotion agreement was concluded or shortly thereafter, Novartis/Sandoz's fentanyl depot patches were already on the market in a number of Member States other than the Netherlands. In this respect the Commission recalls that under Union law it is not required that the agreement or practice will actually have or has had an effect on trade between Member States, but it is sufficient that the agreement or practice is "capable" of having such effect.<sup>543</sup>

- (395) On the basis of the above analysis of the characteristics of the Co-promotion agreement and its economic context,<sup>544</sup> it is concluded that the strong presumption that trade between Member States was affected by the Co-promotion agreement is not rebutted in this case.<sup>545</sup>
- (396) The Commission also observes that the potential effects on trade between Member States of the Co-promotion agreement between J&J and Novartis/Sandoz were appreciable. J&J's sales of fentanyl in 2005 in the Netherlands amounted to EUR 24 million<sup>546</sup>. Generic competition generally tends to quickly replace originator sales. Novartis/Sandoz, at the time it concluded the Agreement with J&J, was perceived as the first and only generic company capable of entering in the immediate future the Dutch market with fentanyl patches (depot or matrix) and, as such, capable of competing with J&J.
- (397) J&J argued that it is doubtful whether the potential effects on trade between Member States can be considered appreciable and referred to the "*expected low uptake of Hexal's depot patch*" in other Member States.<sup>547</sup> This argument cannot be accepted. As explained in Recital (245), the information on the uptake on other national markets is not conclusive or helpful for the assessment of the specific situation in the Netherlands.<sup>548</sup> As also mentioned in Recitals (241) and (245), the expected uptake of Hexal's depot patch in the Netherlands at the time the Co-promotion agreement was entered into by the parties was substantial, amounting to a market share of 50% one year after the launch.
- (398) Moreover, the expectation that Novartis/Sandoz would have gained a significant market share with its depot patch in the Netherlands was confirmed by J&J's documents also "ex post", that is to say at the time the Co-promotion agreement was terminated. According to that internal "ex post" evaluation, J&J saved in total EUR 14.7 million by concluding the Co-promotion agreement with Hexal B.V./Sandoz

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<sup>543</sup> Commission Notice: Guidelines on the effect on trade concept contained in Article 81 and 82 of the Treaty, OJ C 101, 27.4.2004, point 26.

<sup>544</sup> See also sections 7.5.2.1 and 7.5.2.2

<sup>545</sup> The case law mentioned by Novartis/Sandoz in its reply to the Statement of Objections (ID1537, p. 7) confirms this analysis. Cases *Belasco* (Case 246/86) and *Tate&Lyle plc* (Case T-202/98) concerned defensive measures against increased competition from foreign undertakings. Similarly, the co-operation agreement deterred the most advanced competitor from entering the market through all possible means, and in particular through imports from affiliates.

<sup>546</sup> ID0532, p. 1.

<sup>547</sup> ID1542, p. 20.

<sup>548</sup> Contrary to what Novartis/Sandoz alleged, the Commission does not point to a "*compartmentalisation of the relevant markets*" (ID1709, p. 1-2), but as explained in Recital (245) to the limited usefulness of the uptake data concerning other Member States provided by J&J to assess the Netherlands.

B.V. whereby the launch of Novartis/Sandoz's generic product in the Netherlands was prevented.<sup>549</sup> The potential effects on trade between Member States of the Co-promotion agreement between J&J and Novartis/Sandoz were therefore appreciable.

### 7.6.3. Conclusion on effect on trade

(399) On the basis of the analysis in section 7.6, the Commission concludes that the Agreement was capable of affecting trade between Member States within the meaning of Article 101(1) of the Treaty.

## 7.7. Article 101(3) of the Treaty

### 7.7.1. Principles

(400) Article 101(3) of the Treaty states that Article 101(1) of the Treaty "*may be declared inapplicable in the case of any agreement [...] which contributes to improving the production or distribution of goods or to promoting technical or economic progress, while allowing consumers a fair share of the resulting benefit, and which does not: (a) impose on the undertakings concerned restrictions which are not indispensable to the attainment of these objectives, (b) afford such undertakings the possibility of eliminating competition in respect of a substantial part of the products in question*". Article 101(3) "*provides a defence to undertakings against a finding of an infringement of Article [101(1) of the Treaty]*".<sup>550</sup> Article 1(2) of Regulation (EC) No 1/2003 provides that agreements caught by Article 101(1) of the Treaty which satisfy the conditions of Article 101(3) of the Treaty shall not be prohibited, no prior decision to that effect being required.

(401) According to Article 2 of Regulation (EC) No 1/2003, parties claiming the benefit of Article 101(3) of the Treaty for an infringement shall bear the burden of proving that each of the four conditions of that paragraph is met for the infringement concerned.<sup>551</sup>

(402) The possibility that an agreement restricting competition may be exempted under Article 101(3) of the Treaty also applies to agreements restricting competition by object.<sup>552</sup> However, severe restrictions of competition such as price fixing or limiting, controlling and sharing markets often do not meet the conditions for an exemption under Article 101(3) of the Treaty, because, as the Commission has explained in its Guidelines on the application of Article 81(3) of the Treaty (now Article 101(3) of the Treaty), usually they "*neither create objective economic benefits nor do they benefit the consumer*".<sup>553</sup> Instead, they may lead to "*transfers*

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<sup>549</sup> See Recital (201).

<sup>550</sup> Communication from the Commission - Notice: Guidelines on the application of Article 81(3) of the Treaty, Official Journal C 101, 27/04/2004, p. 97 – 118, point 1.

<sup>551</sup> See also Communication from the Commission – Notice: Guidelines on the application of Article 81(3) of the Treaty, Official Journal C 101, 27/04/2004, p. 97 – 118, point 11.

<sup>552</sup> Case T-168/01 *GlaxoSmithKline Services Unlimited v Commission* [2006] ECR II—2629, paragraph 233 and Communication from the Commission - Notice: Guidelines on the application of Article 81(3) of the Treaty, Official Journal C 101, 27/04/2004, p. 97 – 118, point 46.

<sup>553</sup> Communication from the Commission – Notice: Guidelines on the application of Article 81(3) of the Treaty, Official Journal C 101, 27/04/2004, p. 97 – 118, point 46. Case T-86/95, *Compagnie générale*



[of] value from consumers to producers [...] without producing any countervailing value to consumers."<sup>554</sup> Whether the conditions of Article 101(3) of the Treaty are met requires a specific analysis for each continuing agreement/infringement of Article 101(1) of the Treaty.

- (403) With respect to the first condition, the existence of an efficiency gain, a party invoking Article 101(3) of the Treaty must substantiate each efficiency claim so that the following can be verified:
- the nature of the claimed efficiency;
  - the link between the agreement and the claimed efficiency;
  - the likelihood and magnitude of the claimed efficiency; and
  - how and when the claimed efficiency would be achieved.<sup>555</sup>

In the case of claimed cost efficiencies, a party must as accurately as reasonably possible calculate or estimate the value of the claimed efficiency gain and describe in detail how the amount has been computed. The party must also describe the method by which the efficiency gain has been achieved. Data submitted must be verifiable.<sup>556</sup>

- (404) The Commission has clarified in the Guidelines on the application of Article 81(3) of the Treaty that, in its analysis of whether parties have succeeded in proving that all four conditions have been met, it may consider the conditions in a different order, without there being any obligation to address all four conditions if one or more of them should not be met.<sup>557</sup>
- (405) In this case, the Commission identified some potential efficiency claims that are described and analysed in more detail in sections 7.7.2 and 7.7.3. However, no party has substantiated the potential efficiency gains within the meaning of Recital (403) above. Without such substantiation of each claimed efficiency gain and submission of sufficient evidence that all four conditions of Article 101(3) of the Treaty have been met for an infringement, the exemption of Article 101(3) of the Treaty cannot apply.

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*maritime v Commission* [2002] ECR II-1011, paragraph 138 and Case T-213/95 and T-18/96, *SCK and FNK v Commission* [1997] ECR II-1739.

<sup>554</sup> Communication from the Commission – Notice: Guidelines on the application of Article 81(3) of the Treaty, Official Journal C 101, 27/04/2004, p. 97 – 118, point 46.

<sup>555</sup> Communication from the Commission – Notice: Guidelines on the application of Article 81(3) of the Treaty, Official Journal C 101, 27/04/2004, p. 97 – 118, point 51.

<sup>556</sup> Communication from the Commission – Notice: Guidelines on the application of Article 81(3) of the Treaty, Official Journal C 101, 27/04/2004, p. 97 – 118, point 56.

<sup>557</sup> Communication from the Commission – Notice: Guidelines on the application of Article 81(3) of the Treaty, Official Journal C 101, 27/04/2004, p. 97 – 118, point 38.

7.7.2. *Claimed efficiency gain from improved promotion of the "new" matrix patch to the pharmacy channel*

- (406) J&J claimed that *"the agreements gave Janssen-Cilag the opportunity to promote effectively and efficiently its new patch to the pharmacy channel."*<sup>558</sup> According to J&J, *"the Durogesic® matrix patch constituted a considerable and objective improvement compared with the reservoir patch."*<sup>559</sup> Similarly, Novartis/Sandoz argued in its reply to the Statement of Objections that *"the newer fentanyl matrix patches exhibited numerous superior features when compared to the older fentanyl depot patches"*.<sup>560</sup>
- (407) Although no party has substantiated the potential efficiency gains within the meaning of Recital (403), the Commission will examine whether there is any potential efficiency gain from improved promotion of the "new" matrix patch to the pharmacy channel under the Co-promotion agreement (the first condition of Article 101(3)). The assessment will focus, in particular, on the parties' arguments concerning (i) the promotion of the "new" matrix patch against the old depot patch, (ii) the claimed positive effect of the Co-promotion agreement on the sales of the "new" matrix patch, (iii) the claimed education of pharmacists and patients on the "new" matrix patch through the promotion services under the Co-promotion agreement. Subsequently, it will be examined whether the other conditions of Article 101(3) are fulfilled.
- (408) Firstly, concerning any potential efficiency gain of promotion of the matrix patch against the depot patch<sup>561</sup>, J&J in its reply to the Statement of Objections argued that the MEB's role was limited to verifying that a generic fentanyl patch was bio-equivalent with Durogesic, but the MEB did not answer the question as to whether it was medically recommended within a single therapy to switch between fentanyl patches.<sup>562</sup> J&J then submitted documents referring to the situation in some other Member States and scientific studies concerning possible risks of switching between different fentanyl patches.<sup>563</sup> On that basis J&J concluded that irrespective of the

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<sup>558</sup> ID0564, p. 1.

<sup>559</sup> ID0564, p. 3 and ID1542, p. 9.

<sup>560</sup> ID1537, p. 4.

<sup>561</sup> In this respect J&J claimed that *"given the crucial role that pharmacists would play once generic fentanyl patches appeared on the market, Janssen-Cilag in 2005 decided that it wanted to start reaching out to pharmacists. It was deemed important for pharmacists to understand properly the superiority of the matrix patch over the reservoir patch as well as the importance of the new 12.5 µg strength patch (a Janssen-only product) in the therapy pattern. By educating pharmacists on those important non-price benefits, Janssen-Cilag hoped to help convince them of the superior benefits of its offering."* (ID0564, p. 4.).

<sup>562</sup> *"The MEB's role was limited to verifying that a generic fentanyl patch was bio-equivalent with Durogesic® [...] If patches were declared bio-equivalent, it was possible for pharmacists to substitute between patches, under the conditions prescribed by Dutch law. But the MEB did not (have to) pronounce itself on the therapeutic wisdom of changing between patches for individual patients; that remained ultimately the decision of the doctor and/or the pharmacist. With its declaration of bio-equivalence, the MEB did not answer the question as to whether it was medically recommended within a single therapy to switch between fentanyl patches manufactured by different suppliers. Indeed the interchangeability between fentanyl patches is a topic on which regulatory and medical authorities continue to disagree and in many EU countries restrictions have been placed on substitution between fentanyl patches."* ID1542, p. 11.

<sup>563</sup> ID1542, p. 11-13, ID1543, ID1546, ID1547 and ID1548.

regulatory treatment by the MEB, there were good grounds for J&J to advocate the view not to treat generic fentanyl patches as ordinary generics.<sup>564</sup> Finally, J&J argued that given the slow uptake of Hexal's depot patch in other countries, although depot patches and matrix patches may have been bio-equivalent, they were not perceived as necessarily substitutable by prescribers and by patients.<sup>565</sup>

- (409) This case concerns the Netherlands. The Dutch MEB took a clear position on the bio-equivalence and substitutability of different fentanyl patches and it even rejected a proposed variation of the Summary Product Characteristics, submitted by J&J concerning alleged potential risks of switching between different types of patches.<sup>566</sup> Therefore in the MEB's view the two types of patches, depot and matrix, were considered bio-equivalent and substitutable and there were no potential risks of switching between them. The decisions of national authorities of other Member States in this respect are not applicable in the Netherlands. The Commission notes that J&J admits that "*the Dutch Medicines Evaluation Board (MEB) saw both types of patch [reservoir and matrix] as substitutable*"<sup>567</sup> and that "*because of the position taken by the MEB [...], such substitution was possible between reservoir and matrix*"<sup>568</sup>. This means that the reservoir patch was a real and equivalent alternative to the matrix patch.
- (410) Furthermore, as mentioned in Recital (285), J&J sold the last batches of its depot patch in the Netherlands in November 2004. Hexal B.V./Sandoz B.V. did not launch its depot patch in the Netherlands and rather entered into the Co-promotion agreement with J&J and no other generic depot patches have ever been launched in the Netherlands by any other company.<sup>569</sup> The purpose of the co-promotion activities, as argued by J&J, therefore seems to be to make the pharmacists understand the potential risks of switching from the matrix patch to the depot patch, a product that was no longer on the Dutch market.
- (411) It should be noted that in November 2004, in an email exchange amongst the J&J management responsible for the Netherlands, the [employee]\* of Janssen-Cilag B.V.

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<sup>564</sup> "*The Dutch regulatory treatment of fentanyl patches was therefore permissive, compared with the majority of EU regulatory authorities and the view expressed in post-marketing clinical studies. It should be obvious that, whatever the regulatory treatment, there were good grounds for JC [Janssen-Cilag] to advocate the view, in the interest of patients, not to treat generic fentanyl patches as ordinary generics. Any suggestion in the SO [Statement of Objections] to the contrary is, in JC's view, factually unsupported and unfair. Because the Dutch MEB was permissive in allowing the switching of fentanyl patches, to the point that even SmPC [Summary Product Characteristics] warnings included in many other countries were not authorized in the Netherlands, there was an appropriate and legitimate reason for the education of pharmacists once it was envisaged that generic fentanyl patches would enter the market.*" ID1542, p. 13

<sup>565</sup> "*[T]he very slow uptake of Hexal's depot patch in countries where it had been launched lends further support to the claim that, while they may have been bio-equivalent, depot patches and matrix patches were not perceived as necessarily substitutable (from a variety of perspectives) by prescribers and by patients, and also that there was a benefit in educating pharmacists who would start to play a key role in deciding (i) which patch would be delivered, and (ii) whether to switch titrated patients in an ongoing therapy.*" ID1542, p. 13-14.

<sup>566</sup> See Recital (56).

<sup>567</sup> ID0564, p. 3. See also Recital (79).

<sup>568</sup> ID0564, p. 4.

<sup>569</sup> Concerning the Nycomed patch see the Commission's reasoning in Recitals (280) to (284).

wrote: "*Pharmacokinetic differences between our reservoir and matrix patch cannot be used in promotional activities because **we argue that there is no clinical difference between the two forms.***"<sup>570</sup> The fact that, according to Janssen-Cilag B.V., there was no clinical difference between the two types of patches, weakens considerably any potential efficiency gain of promotional activities of the matrix patch against the depot patch. In its reply to the Statement of Objections, J&J argued that this statement "*does not address the advantages of using matrix patches over reservoir patches*".<sup>571</sup> J&J, however, did not contest that in the relevant period J&J "*argue[d] that there [was] no clinical difference between the two forms [matrix patches and reservoir patches]*".

- (412) Secondly, J&J also claimed that there was a "*positive effect of the co-promotion agreement on the sales of Durogesic ® in volume; these were 28% higher in the last quarter of the co-promotion agreement (136.365 packs sold in Q4 2006) than in the last quarter before the entry into force of the co-promotion agreement (106,659 packs sold in Q2 2005). [...] The sales increase of Durogesic ® (mainly the impressive growth of sales of the 12.5 mcg strength) shows the benefit of the co-promotion for Janssen-Cilag via a direct approach of the pharmacists.*"<sup>572</sup>
- (413) The Commission observes, first of all, that there is no evidence available that the claimed increase of sales of Durogesic during the term of the Co-promotion agreement can be attributed (exclusively or even partly) to the limited co-promotion activities performed by Hexal B.V./Sandoz B.V. targeting the pharmacies. As mentioned in Recital (279), at the time of the Co-promotion agreement and for its entire duration the only fentanyl patch available on the Dutch market was the Durogesic matrix patch from Janssen-Cilag B.V. Therefore if the physician prescribed a fentanyl patch, the pharmacist had no choice other than to dispense Janssen-Cilag B.V.'s patch. As mentioned in Recital (290), at the time of the Co-promotion agreement and for its entire duration, pharmacists were required by Dutch law to dispense a product with the prescribed active substance. Therefore if the physician prescribed a medicine with an active substance other than fentanyl, the pharmacist was not allowed to substitute that other product and dispense a fentanyl patch instead.
- (414) As analysed in Recitals (290) to (293), the claimed benefits of approaching the pharmacists in order to indirectly influence what product was to be prescribed by the physicians are not substantiated by the way the Co-promotion agreement was negotiated, implemented and evaluated. The services to be provided by Hexal B.V./Sandoz B.V. were not defined in detail in the final version of the Agreement and the co-promotion activities invoked by the parties for the period covered by the Agreement are limited.<sup>573</sup> In particular, there is no available evidence that any specific promotion activities were performed by Hexal B.V./Sandoz B.V. at all in the third and fourth quarters of 2006, which is the period specifically invoked by J&J as the period of the highest Durogesic sales (see Recital (412)). The final Evaluation Report did not mention any tangible results achieved (or attempts to achieve those

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<sup>570</sup> See Recital (113); emphasis added.

<sup>571</sup> ID1542, p. 13.

<sup>572</sup> ID0688, p. 6-7.

<sup>573</sup> See Recitals (268) to (277).

results), such as for example any guidelines or written agreements on prescribing of fentanyl between pharmacists and physicians being agreed as a result of the promotion activity. Similarly, when Janssen-Cilag B.V. evaluated internally ex-post the co-promotion project, no tangible results (or attempts to achieve such results), such as guidelines on fentanyl prescribing or general changes in the physicians' prescribing patterns were mentioned whatsoever.<sup>574</sup>

- (415) The claimed increase of sales of Durogesic at that time therefore could not be achieved through the promotion activities under the Co-promotion agreement targeted at pharmacies.
- (416) Thirdly, as mentioned in Recital (297), J&J also argued that an important element of the promotion towards pharmacies was the following: "[T]he pharmacist plays a key role, since, through good information and counselling of the patient, the chances of an effective (switching to a different strength at the right time) and efficient (preparing the patients for the possible side-effects, such as nausea) treatment are increased."<sup>575</sup> However, the old depot patch, which was considered interchangeable with the new matrix patch, was on the Dutch market for almost ten years. During that entire period, Janssen-Cilag B.V. did not need to engage a co-promotion partner to inform the pharmacists about the aspects mentioned by J&J above. Furthermore, once generics entered the Dutch market and the Co-promotion agreement with Hexal B.V./Sandoz B.V. was terminated, Janssen-Cilag B.V. did not engage a new co-promotion partner in order to continue to provide the abovementioned information to the pharmacists.
- (417) In its reply to the Statement of Objections J&J submitted that "*the Commission may well be right that the need for such education may have existed before and continued afterwards. But that is no reason to reject this benefit as irrelevant.*"<sup>576</sup> J&J referred to the launch of its 12 µg version of the matrix patch on the Dutch market in early 2005 and stated that "*while there had always been good reasons to educate pharmacists on fentanyl patches, with the arrival of the 12.5 µg patch, the timing of starting or increasing such education in 2005 was particularly right.*"<sup>577</sup> In addition, J&J invokes two scientific studies<sup>578</sup> to show that side-effects of fentanyl treatment were a serious concern and that by educating pharmacists the patients drop-out rate due to the side effects could have been reduced.<sup>579</sup>
- (418) However, J&J has not sufficiently substantiated that pharmacists and patients would have benefited from information on pharmaceutical products being provided to the pharmacists by companies' sales representatives as a result of the Co-promotion agreement. The Commission refers, in particular, to the evidence of only limited

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<sup>574</sup> See Recital (201).

<sup>575</sup> The preamble of the Co-promotion agreement states: "*In the Territory [the Netherlands] the pharmacists play an increasing key role in determining, together with general practitioners, for which disease which drug should be prescribed, and in advising patients how to use the drugs and how to deal with side effects;*" "*There is an increasing need for Janssen-Cilag to detail the Product [Durogesic] towards pharmacists;*" (See Recital (154)).

<sup>576</sup> ID1542, p. 14.

<sup>577</sup> ID1542, p. 14.

<sup>578</sup> ID1550 and ID1551.

<sup>579</sup> ID1542, p. 14.

activities being planned and performed under the initial co-promotion agreement and no activities being planned and performed whatsoever under the addendum. The potential efficiency gains of the Co-promotion agreement in that respect therefore seem to be limited at best.

- (419) Moreover, as mentioned in Recital (298), at the time the Co-promotion agreement was entered into J&J argued that it expected it to be in place only for a couple of months, but no activities targeting the pharmacists were planned (and carried out) for more than three months after the entry into force. This is difficult to reconcile with the claimed purpose of the Co-promotion agreement to efficiently educate the pharmacists in respect of J&J's fentanyl patches.
- (420) On the basis of the considerations in Recitals (408) to (419), the Commission concludes that no evidence has been submitted that would substantiate that the claimed efficiency gain from promoting the new matrix patch to the pharmacy channel would result from the Co-promotion agreement in question.
- (421) Even if there were identified and substantiated efficiency gains which would result from promotion of the new matrix patch to the pharmacy channel in the framework of the Co-promotion agreement under investigation (*quod non*), the other conditions of Article 101(3) of the Treaty set out in section 7.7.1 would still need to be fulfilled.
- (422) Regarding the second condition of Article 101(3) of the Treaty mentioned in Recital (400) ("indispensability"), the Commission's view is that this condition is not fulfilled either. In view of attaining any possible improvement or progress, it has not been shown that there would be any link between the claimed efficiency gain from "*educating pharmacists on those important non-price benefits*" of the matrix patch on one hand, and the necessity to impose restrictions of competition that have been found in this Decision.
- (423) Furthermore, to the extent that any of the claimed efficiency gains from promoting the matrix patch would exist, the Commission notes that a party has to show, under the third criterion of Article 101(3) of the Treaty ("fair share for consumers"), that such gains at least compensated consumers for the negative impact caused to them by the restriction of competition.<sup>580</sup> In other words, the pro-competitive effects flowing from the Agreement must outweigh its anti-competitive effects.<sup>581</sup> In this case, any potential efficiency gains for consumers from the claimed improved promotion of the matrix patch would have to outweigh the negative impact for consumers of the elimination of the effective generic competition with the fentanyl patches on the Netherlands market for the duration of the Agreement. Consumers, in this respect, are all direct or indirect users of the fentanyl patches, including final consumers, pharmacies and wholesalers.<sup>582</sup> This has not been shown.

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<sup>580</sup> Communication from the Commission – Notice: Guidelines on the application of Article 81(3) of the Treaty, Official Journal C 101, 27/04/2004, p. 97 – 118, points 85 and 86.

<sup>581</sup> Communication from the Commission – Notice: Guidelines on the application of Article 81(3) of the Treaty, Official Journal C 101, 27/04/2004, p. 97 – 118, point 50.

<sup>582</sup> Communication from the Commission – Notice: Guidelines on the application of Article 81(3) of the Treaty, Official Journal C 101, 27/04/2004, p. 97 – 118, point 84.

(424) Finally, regarding the fourth criterion of Article 101(3) of the Treaty ("no elimination of competition"), the Commission notes, that Hexal B.V./Sandoz B.V., a close potential competitor of Janssen-Cilag B.V., stayed out of the market for the entire duration of the Agreement. Moreover, no other generic product entered the Netherlands market on a permanent basis either before or during the term of the Co-promotion agreement, and J&J was the only undertaking marketing fentanyl transdermal patches in the Dutch market throughout the term of the Agreement (safe for the short temporary entries by Ratiopharm).<sup>583</sup>

7.7.3. *Claimed efficiency gain from the possibility of Novartis/Sandoz to distribute the generic matrix patch in the future*

(425) Although no party has substantiated the potential efficiency gains within the meaning of Recital (403), the Commission will examine in this section whether there is any potential efficiency gain stemming from the Co-promotion agreement concerning the possibility for Novartis/Sandoz to distribute the generic matrix patch supplied by J&J in the future (the first condition of Article 101(3)). Subsequently, it will be examined whether the other conditions of Article 101(3) are fulfilled.

(426) J&J claimed that *"the prospect of a duplex registration / supply agreement gave Sandoz the opportunity to sell the product [the matrix patch] under its own name and label (after it had co-promoted Durogesic ®)"*<sup>584</sup> and that *"[t]here were clear benefits for Sandoz but also for patients, who would have an alternative supplier of fentanyl matrix patches that they would otherwise not have had."*<sup>585</sup>

(427) Furthermore, in its reply to the Statement of Objections J&J argued that the Commission *"fails to balance the pro-competitive effect of the transfer of the duplex registration with the asserted anticompetitive effect of the co-promotion agreement. But contemporaneous documents show that JC had the intention-and Hexal the expectation-that such duplex registration would be transferred, and the product supplied, as soon as any generic (expectedly Ratiopharm or Nycomed in the short term) entered the market. Although the Commission construes the termination mechanism in the co-promotion agreement as anticompetitive, if Ratiopharm or Nycomed had entered earlier, as JC had expected, this mechanism would have brought Hexal into the market with a matrix patch much earlier than it would otherwise have been able to."*<sup>586</sup>

(428) As mentioned earlier in section 7.5.2.2, at the time of entering into the Co-promotion agreement and the addendum, the supply agreement was not signed, and the provisions of the Co-promotion agreement or the addendum do not provide a legal guarantee for Hexal B.V./Sandoz B.V. that it would receive the said duplex registration and/or supplies of the matrix patches from J&J. The only provision of the

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<sup>583</sup> See section 5.2.2.2.

<sup>584</sup> ID0564, p. 5.

<sup>585</sup> ID0564, p. 5.

<sup>586</sup> ID1542, p. 6. Novartis/Sandoz mentioned similarly in its comments on the Letter of Facts that *"further negotiations with Janssen-Cilag allowed Hexal to eventually launch a generic matrix patch [...] much earlier than when it could have launched its internally developed matrix patch for which it continued to take all preparatory steps"* (ID1709, p. 3).

Co-promotion agreement that touches upon this subject is Art.10bis which foresees that "[p]arties will in good faith discuss the possibility to use a duplex registration at the moment a Third Party launches such matrix formulation of the Product in the Territory [the Netherlands]. The terms and discussions of a duplex registration will be discussed during the term of this Agreement." To "discuss the possibility" is clearly far from actually granting the duplex registration and the supplies of the product. This is confirmed by the cautious language of the addendum, which was signed by the parties respectively on 16 and 17 August 2006, more than 13 months after the Co-promotion agreement entered into force. The addendum only states that "[i]n accordance with Article 10bis of the [Co-promotion] Agreement, parties have started discussions on a duplex-registration and are close to reaching an agreement in that respect."<sup>587</sup> So even at the time the addendum was signed, the parties were still only in the course of discussions on a duplex registration and had not yet reached the final agreement. Furthermore, Novartis/Sandoz confirmed that it "has never claimed that Hexal was guaranteed a duplex registration and/or supplies of the matrix patches from Janssen-Cilag".

- (429) As mentioned in Recitals (306) to (308), the evidence on the file confirms that the Co-promotion agreement and the supply agreement were two distinct agreements based on self-standing, formally independent and separate legal contracts. The Commission recalls that this Decision pursues the Co-promotion agreement between the parties, not the separate supply agreement which entered into force only after the Co-promotion agreement was terminated. There is therefore no reason for the Commission to assess the pro-competitive or anti-competitive nature of the supply agreement.
- (430) But even if the Commission were in this case to assess the claimed efficiency gains stemming from the transfer of the duplex registration and the supply agreement (*quod non*) under Article 101(3) of the Treaty, all the conditions set out in section 7.7.1 would need to be fulfilled.
- (431) With respect to the first condition of Article 101(3), the existence of an efficiency gain, the Commission observes that no party has substantiated its claim within the meaning of Recital (403).
- (432) Moreover, the option to "discuss the possibility" of the duplex registration was made conditional upon the fact that a third party launched the matrix patch in the Netherlands.<sup>588</sup> In other words, the possibility of the duplex registration would only be available to Hexal B.V./Sandoz B.V. once there was an alternative supplier of the generic fentanyl matrix patch already on the market. This substantially reduces the claimed gain of having the "alternative supplier of fentanyl matrix patches that they [patients] would otherwise not have."
- (433) Regarding the second condition of Article 101(3) of the Treaty ("indispensability"), the Commission's view is that this condition is not fulfilled either. The Commission

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See Recital (191).

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See, for instance, Recital (428). J&J confirmed this in its comments on the Letter of Facts (ID1702, p. 3): "The reason that the negotiations on the duplex/supply deal were still ongoing in July 2006 [...] was "because Ratiopharm ultimately entered later than expected".



does not see any reason why, if the parties wanted to achieve this efficiency, J&J and Novartis/Sandoz could not have directly concluded a genuine supply agreement in which J&J would grant Novartis/Sandoz immediately the right to the duplex registration and the right to sell the product as a generic in the Netherlands, which they in fact did only later, as of 1 January 2007, only once the Co-promotion agreement was terminated and the (permanent) market entry of another independent generic competitor (Ratiopharm) was imminent. Such agreement would have created the same alleged efficiency gain without the restrictions of competition that have been found in this Decision.

- (434) The Commission recalls again that Janssen-Cilag B.V. signed a similar supply agreement for fentanyl patches also with [third party]\*, which entered the Dutch market with the product supplied by Janssen-Cilag B.V.[...]<sup>589</sup> [Third party]\* was not previously involved in the co-promotion of Janssen-Cilag B.V.'s originator product. Therefore previous engagement in or experience with the promotion of fentanyl patches towards pharmacies was clearly not a necessary pre-condition for concluding the supply agreement with Janssen-Cilag B.V.<sup>590</sup>
- (435) In this respect J&J argued that "*the fact that JC entered into a similar supply deal with another generic supplier in no way precludes the pro-competitive effect of a supply agreement with Hexal. The proper counterfactual to consider here is that without the arrangement Hexal would not have entered with a matrix patch as early as it did under the deal with JC.*"<sup>591</sup> The Commission refers to the similar supply agreement with [third party]\* in order to demonstrate that the previous Co-promotion agreement was not indispensable to achieve the claimed potential efficiency gains of the separate supply agreement.
- (436) Moreover, as J&J explained, "*when a generic version of a product enters the market, the choice of the product that the pharmacist will deliver will also be influenced by the financial incentives (discounts) that the pharmacist receives. This is because in the Netherlands the pharmacist has the right to substitute between similar products, also for fentanyl patches. [...] In such cases, the pharmacist has the financial incentive to sell the generic that gives the highest margin. Hence, in a genericised market the focus tends to shift from the product characteristics to price (e.g. discounts).*"<sup>592</sup> In other words, once the first generic enters, instead of any promotion activities the companies rather engage in competition on discounts. This further confirms that there is no link between the Co-promotion agreement before the generic entry and the supply agreement after the generic entry.
- (437) Regarding the third criterion of Article 101(3) of the Treaty ("fair share for consumers"), the benefit of any alleged efficiency gains for consumers from future

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<sup>589</sup> See Recital (196).

<sup>590</sup> In its reply to the Letter of Facts, Novartis/Sandoz argued that it was "*its strategy to enter into the co-promotion agreement, and familiarise and associate itself with the matrix patch early through the co-promotion activities*" (ID1709, p. 4). In view of the limited or inexistent co-promotion activities (see, for instance, Recitals (274) and (275)), it is unclear how Novartis/Sandoz could benefit from this alleged familiarisation and association. Furthermore, [third party]\* signed a similar supply agreement without any previous involvement (see, for instance, Recital (196)).

<sup>591</sup> ID1542, p. 6.

<sup>592</sup> ID0688, p. 8-9.

distribution of the generic matrix patch by Hexal B.V./Sandoz B.V. would need to outweigh the negative impact for consumers of the elimination of the effective generic competition with the fentanyl patches on the Netherlands market for the duration of the Co-promotion agreement. This has not been shown.

- (438) Finally, regarding the fourth criterion of Article 101(3) of the Treaty ("no elimination of competition"), the Commission notes, that Hexal B.V./Sandoz B.V., a close potential competitor of Janssen-Cilag B.V., stayed out of the market for the entire duration of the Agreement. Moreover, no generic product entered the Netherlands market on a permanent basis either before or during the term of the Co-promotion agreement, and J&J was the only undertaking marketing fentanyl transdermal patches on the Netherlands market during the term of the Agreement (safe for the short temporary entries by Ratiopharm).<sup>593</sup>

#### 7.7.4. Conclusion on application of Article 101(3) of the Treaty

- (439) The Commission concludes that at this stage of the proceedings, no party has submitted the evidence required to demonstrate that:
- the Co-promotion agreement resulted in efficiencies in terms of improved distribution or sales of Janssen-Cilag B.V.'s matrix patches;
  - the restriction of competition found in this Decision was indispensable to create such efficiencies;
  - consumers obtained a fair share of such efficiencies; and
  - the Co-promotion agreement did not eliminate competition for the period of its operation.

Unless and until such evidence is presented, the Agreement cannot be exempted under Article 101(3) of the Treaty.

## 8. ADDRESSEES OF THIS DECISION

- (440) As mentioned in section 7.3, Article 101 of the Treaty addresses undertakings. The concept of "undertaking" has an economic scope and encompasses any entity engaged in an economic activity. The "undertaking" that committed the infringement can therefore be larger than the legal entity whose representatives actually took part in the infringing activities. Again quoting the Court of Justice in Case C-97/08, *Akzo Nobel v Commission*, "*When such an economic entity infringes the competition rules, it falls, according to the principle of personal responsibility, to that entity [that is to say, the undertaking] to answer for that infringement.*"<sup>594</sup>
- (441) At the same time, the infringements of Union competition law in this case must necessarily be imputed to a legal person on which fines can be imposed. This

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<sup>593</sup> See section 5.2.2.2.

<sup>594</sup> Judgment of 10 September 2009, paragraph 56.

Decision must therefore be addressed to legal persons.<sup>595</sup> It is accordingly necessary for the Commission to identify, for each undertaking that is to be held accountable for its infringement of Article 101 of the Treaty in this case, one or more legal entities that represent the undertaking concerned.

- (442) It is well-established case law that the conduct of a subsidiary may be imputed to the parent company in particular where, although having a separate legal personality, that subsidiary does not decide independently upon its own conduct on the market, but carries out, in all material respects, the instructions given to it by the parent company. This is the case because, in such a situation, the parent company and its subsidiary form a single economic unit and therefore a single undertaking.<sup>596</sup>
- (443) The Court has ruled in Case C-97/08, *Akzo Nobel v Commission* that in the specific case where a parent company has a 100% shareholding in a subsidiary which has infringed the Union competition rules, first, the parent company can exercise a decisive influence over the conduct of the subsidiary and, second, there is a rebuttable presumption that the parent company does in fact exercise a decisive influence over the conduct of its subsidiary.<sup>597</sup> In those circumstances, it is sufficient for the Commission to prove that the subsidiary is wholly owned by the parent company in order to presume that the parent exercises a decisive influence over the commercial policy of the subsidiary. The Commission will be able to regard the parent company as jointly and severally liable for the payment of the fine imposed on its subsidiary, unless the parent company, which has the burden of rebutting that presumption, adduces sufficient evidence to show that its subsidiary acts independently on the market.<sup>598</sup> This also applies to situations where the parent company indirectly holds a 100% ownership in a subsidiary, via one or more intermediary companies.<sup>599</sup> In order to ascertain whether a subsidiary determines its conduct on the market independently, account must be taken of all the relevant factors relating to economic, organisational and legal links which tie the subsidiary to the parent company.<sup>600</sup>
- (444) In this case the Commission considers that the parent company which exercised decisive influence on the subsidiary at the time of the infringement should be held liable for the infringement committed by the undertaking. In addition, the Commission may in this case hold jointly and severally liable the subsidiary that actually signed the Agreement or that played a prominent role in its negotiation or implementation.

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<sup>595</sup> Case C-97/08, *Akzo Nobel v Commission*, judgment of 10 September 2009, paragraph 57.

<sup>596</sup> Case C-97/08, *Akzo Nobel v Commission*, judgment of 10 September 2009, paragraphs 58-59 and the jurisprudence cited there.

<sup>597</sup> Case C-97/08, *Akzo Nobel v Commission*, judgment of 10 September 2009, paragraph 60.

<sup>598</sup> Case C-97/08, *Akzo Nobel v Commission*, judgment of 10 September 2009, paragraphs 60-61 and the jurisprudence cited there.

<sup>599</sup> See for instance Case T-190/06, *Total SA and Elf Aquitaine SA v Commission*, judgment of 14 July 2011, paragraph 42.

<sup>600</sup> Case C-97/08, *Akzo Nobel v Commission*, judgment of 10 September 2009, paragraph 74.

### **8.1. Johnson & Johnson and Janssen-Cilag B.V.**

- (445) As the facts in section 6.2 indicate, both the initial co-promotion agreement and the addendum were entered into by Janssen-Cilag B.V.
- (446) Given that Janssen-Cilag B.V. was therefore a party to the Co-promotion agreement, the Commission considers it appropriate to hold Janssen-Cilag B.V. liable for the infringement to which this Decision relates.
- (447) Furthermore, the company Janssen-Cilag B.V. was in the period concerned an indirect 100% subsidiary of the company Johnson & Johnson.<sup>601</sup> In the light of the 100% ownership by Johnson & Johnson of Janssen-Cilag B.V., the Commission presumes that Johnson & Johnson exercised a decisive influence over the commercial policy of Janssen-Cilag B.V. That presumption is enough, in and of itself, to establish the liability of Johnson & Johnson and there is no need to add any further indicia in this regard. Given that the presumption suffices to establish the liability of the parent company, the Commission does not need to examine any further evidence.<sup>602</sup>
- (448) However, for the sake of completeness, the Commission notes that there is further evidence showing that Johnson & Johnson actually exercised decisive influence over its subsidiary, including in respect of the infringement. In particular, the Co-promotion agreement was drafted by and consulted with Johnson & Johnson through its [department]\*. Johnson & Johnson's [department]\* also followed the whole procedure of concluding the Agreement.<sup>603</sup>
- (449) As the company Johnson & Johnson still exists, the Commission considers it appropriate to hold Johnson & Johnson liable for the infringement committed in this case.
- (450) Based on the foregoing, it has been established that Johnson & Johnson and Janssen-Cilag B.V., which are a single economic entity, participated in the infringement and should be held jointly and severally liable.

### **8.2. Novartis AG and Sandoz B.V.**

- (451) As described in section 6.2, the initial co-promotion agreement was entered into by Hexal B.V. and Sandoz B.V. and the addendum was entered into by Hexal Pharma Nederland B.V. and Sandoz B.V.
- (452) As indicated in section 4.1.2, on 6 June 2005 Novartis AG became the ultimate parent company of Hexal B.V.<sup>604</sup> On 12 September 2007, Hexal B.V. was merged into Sandoz B.V. and ceased to exist. Hexal Pharma Nederland B.V. is the same

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<sup>601</sup> See Recital (59).

<sup>602</sup> Joined Cases C-628/10 P and C-14/11 P, judgment of 19 July 2012, paragraph 47.

<sup>603</sup> See, for example, ID0134, p. 97-98, ID0134, p. 99-101, ID0137, p. 355-358, ID0137, p. 359-360.

<sup>604</sup> From 6 June 2005 until 18 July 2005 Novartis AG indirectly owned 95% of Hexal B.V.'s shares and from 18 July 2005 Novartis AG indirectly owns 100% of Hexal B.V.'s shares through several intermediate companies. See Recital (61).

entity as Hexal B.V. According to Novartis/Sandoz, Hexal B.V. used Hexal Pharma Nederland as a trade name.<sup>605</sup>

- (453) The company Sandoz B.V. was in the period concerned and still is an indirect 100% subsidiary of the company Novartis AG. Given that Hexal B.V. was merged into Sandoz B.V., that Sandoz B.V. was itself also a party to the Co-promotion agreement (including the addendum) and that Sandoz B.V. still exists, the Commission considers it appropriate to hold Sandoz B.V. liable for the infringement to which this Decision relates.
- (454) In its reply to the Statement of Objections, Novartis/Sandoz submitted that "[a]t the time the Co-promotion agreement was negotiated and entered into, Hexal in the Netherlands was to a large extent still operating as an autonomous entity over which Novartis AG had no effective influence and no involvement with the matters relating to the Co-promotion agreement and as to which Sandoz only had very limited visibility and even less influence."<sup>606</sup> However, the initial co-promotion agreement and the addendum were both signed by both entities, Hexal B.V. and Sandoz B.V., in their own rights. In view of the fact that Sandoz B.V., which was part of the Novartis group of companies long before entering into the Co-promotion Agreement, also signed the Agreement in its own right, the arguments of Novartis/Sandoz are immaterial.
- (455) As mentioned in Recital (453), Sandoz B.V. was in the period concerned an indirect 100% subsidiary of the company Novartis AG. The Commission therefore presumes that Novartis AG exercised a decisive influence over the commercial policy of Sandoz B.V. That presumption is enough, in and of itself, to establish the liability of Novartis AG and there is no need to add any further indicia in this regard.
- (456) However, for the sake of completeness, the Commission notes that there is further evidence showing that Novartis AG actually exercised decisive influence over its subsidiary. In particular, according to Novartis/Sandoz's internal documents only a few days before concluding the initial co-promotion agreement with Janssen-Cilag B.V., internal calculations and assessments of various scenarios of co-operation with Janssen-Cilag B.V. were submitted to and discussed with Novartis' [employee]\*.<sup>607</sup> The person in question<sup>608</sup> was at that time [holding senior positions at several Novartis and Sandoz entities, including Novartis AG]\*.<sup>609</sup> The same person<sup>610</sup> was, at the time the addendum was concluded, [holding senior positions at several Novartis and Sandoz entities, including Novartis AG]\*.<sup>611</sup>

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<sup>605</sup> See footnote 256.

<sup>606</sup> ID1537, p. 5.

<sup>607</sup> ID1065, p. 2. Novartis Annual Report 2005, p. 131.  
<http://www.novartis.com/downloads/newsroom/corporate-publications/Novartis-20-F-2005.pdf>

<sup>608</sup> See Recital (138).

<sup>609</sup> ID0819, p. 6-7.

<sup>610</sup> This person was informed about internal calculations and assessments of various scenarios of co-operation with Janssen-Cilag B.V. shortly before the initial co-promotion agreement entered into force. See ID0172, p. 16.

<sup>611</sup> ID0819, p. 6-7.

- (457) Moreover, the parent company of Hexal B.V. /Sandoz B.V. was directly involved in the Co-promotion agreement. The Agreement refers to "*Affiliates*", which includes, amongst others, companies which own or control at least 50% of the voting stock of a given company.<sup>612</sup> That definition therefore includes Novartis AG in respect of Sandoz B.V. and also Hexal B.V., which were both parties to the Co-promotion agreement. The Co-promotion agreement provides for certain rights and obligations for the "*Company Affiliates*", including Novartis AG, for example in respect of the confidential information received<sup>613</sup> or allows a party to terminate the Agreement if "*a Company [Hexal B.V./Sandoz B.V.'s] Affiliate has a fentanyl patch listed on the Dutch pharmacy TAXE list (known as Z-index).*"<sup>614</sup>
- (458) As the company Novartis AG still exists, the Commission considers it appropriate to hold Novartis AG liable for the infringement committed in this case.
- (459) Based on the foregoing, it has been established that Novartis AG and Sandoz B.V. are a single economic entity and should be held jointly and severally liable.

### **8.3. Conclusion on the addressees**

- (460) It has been established that the following companies directly participated in the infringement of Article 101 of the Treaty, or bear liability for it:
- Johnson & Johnson
  - Janssen-Cilag B.V.
  - Novartis AG
  - Sandoz B.V.

## **9. DURATION OF THE INFRINGEMENT**

- (461) It is apparent from the facts described in section 6 that the infringement identified in this Decision lasted at least from the date of entry into force of the initial co-promotion agreement on 11 July 2005 until the termination of the Co-promotion agreement (including the addendum) on 15 December 2006.

## **10. REMEDIES**

### **10.1. Article 7(1) of Regulation (EC) No 1/2003**

- (462) Where the Commission finds that there is an infringement of Article 101 of the Treaty it may by decision require the undertakings concerned to bring such infringement to an end in accordance with Article 7 of Regulation (EC) No 1/2003.

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<sup>612</sup> ID0174, p. 163.

<sup>613</sup> ID0174, p. 170.

<sup>614</sup> See Recital (166).

The infringement in this case has ceased.<sup>615</sup> There is, therefore, no need in this case to require the undertakings concerned to bring the infringements to an end. However, there is a need to expressly confirm the addressees' obligation not to enter into new agreements having the same object or effect, given that at least one of the addressees of this Decision have made it known in the course of these proceedings that it does not regard the Agreement under review as anticompetitive.<sup>616</sup> In these circumstances, there is a real danger that the undertakings concerned might commit similar practices as those considered in this Decision.

- (463) The undertakings to which this Decision is addressed should therefore be required to refrain from any agreement, concerted practice or decision of an association which may have the same or a similar object or effect.

## 10.2. Article 23(2) of Regulation (EC) No 1/2003

- (464) Under Article 23(2) of Regulation (EC) No 1/2003, the Commission may by decision impose on undertakings fines where, either intentionally or negligently, they infringe Article 101 of the Treaty. For each undertaking participating in the infringement, the fine shall not exceed 10% of its total turnover in the preceding business year.

- (465) In this case, the Commission considers that, based on the facts described in this Decision and on the assessment contained in section 7, the infringement was committed intentionally. As described in section 6 and legally assessed in section 7, the infringement consisted of an explicit, written agreement between the parties concerned which objectively aimed at preventing the generic undertaking from selling generic fentanyl patches in the Netherlands in exchange for a transfer of value from the originator undertaking. The assessment of the Agreement concluded between the originator undertaking J&J and the generic undertaking Novartis/Sandoz also analysed the stated intentions of the parties to the initial co-promotion agreement and its addendum. The conclusion is that the contractual parties knew, should have known or could not have been unaware<sup>617</sup> that the initial co-promotion agreement and its addendum had the object and necessary consequence of restricting competition.<sup>618</sup> In any event, even if the parties had not deliberately infringed Article 101 of the Treaty, they acted at least negligently in entering into an agreement which so clearly restricted competition.

- (466) The Commission therefore intends to impose fines in this case on the undertakings to which this Decision is addressed.

- (467) Pursuant to Article 23(3) of Regulation (EC) No 1/2003, the Commission shall, in fixing the amount of the fines, have regard to all relevant circumstances and particularly to the gravity and duration of the infringement, which are the two criteria

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<sup>615</sup> See section 6.2.4.

<sup>616</sup> See ID0564, p. 1 and ID1537, p. 5. See in this context e.g. Case 7/82, *GVL v Commission*, [1983] ECR 483, paragraph 27, Case T-456/05 and T-47/05, *Güterman and Zwicky AG v Commission*, [2010] II-1443, paragraphs 66 – 67, Case T-410/03, *Hoechst v 0 and Commission*, [2008] ECR II-881 paragraphs 199-200.

<sup>617</sup> Case T-11/06 *Romana Tabacchi Srl v Commission* [2011] ECR II-06681, paragraph 227; Case T-348/94 *Enso Española SA v Commission*, paragraph 277.

<sup>618</sup> See section 7.5.

explicitly referred to in that Regulation. In doing so, the Commission will set the fines at a level sufficient to ensure deterrence. Moreover, the role played by each undertaking in the infringement will be assessed on an individual basis. The Commission will reflect in the fines imposed any aggravating or mitigating circumstances pertaining to each undertaking.

- (468) In setting the fines to be imposed in this case, the Commission will also refer to the principles laid down in its Guidelines on the method of setting fines imposed pursuant to Article 23(2)(a) of Regulation (EC) No 1/2003 (hereafter referred to as "*the Guidelines on fines*").<sup>619</sup>
- (469) Novartis/Sandoz submitted in its reply to the Statement of Objections that if an infringement is found in this case, there is "*no need for the Commission to impose a fine to reach the competition policy goals that it pursues*".<sup>620</sup> Novartis/Sandoz argued that this Decision is one of the first individual decisions taken after the pharmaceutical sector inquiry, which significantly changed the perception of the legal environment in the industry in particular with regard to the relationship between originators and generic companies and sent a clear and effective signal to the pharmaceutical business community about the Commission's views on potential infringements.<sup>621</sup>
- (470) The purpose of the fines is twofold: to sanction the undertakings concerned (specific deterrence) and to deter other undertakings from infringing Union competition law (general deterrence).<sup>622</sup>
- (471) In this case, as established throughout this Decision, the parties were aware that the Agreement was aimed at excluding the close potential generic competitor from the market. It was the very purpose of J&J in concluding that Agreement. Similarly, given the nature of the Agreement which it entered into, Novartis/Sandoz was fully aware that the aim of the Agreement in question was, for the duration of that Agreement, its exclusion from the market.
- (472) The type of infringement at stake in this case, exclusion from the market in return for a payment, was not new and its illegality was foreseeable for the parties. The literal wording of the prohibition laid down in Article 101 of the Treaty itself suggested that those agreements were infringing Union competition law. In order to ensure deterrence, both specific and general, it is therefore appropriate to impose fines in this case on the undertakings to which this Decision is addressed.

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<sup>619</sup> Guidelines on the method of setting fines imposed pursuant to Article 23(2)(a) of Regulation (EC) No 1/2003, OJ C 210, 1.9.2006, page 2.

<sup>620</sup> ID1537, p. 19.

<sup>621</sup> According to Novartis/Sandoz, "*the entire community [...] will readily adapt its business practices to the concrete guidance that is offered by individual decisions. In such a context, there is no need for an individual decision to impose a fine in order to cause a sufficiently strong deterrence effect.*" ID1537, p. 19.

<sup>622</sup> See the Guidelines on fines, point 4.



### **10.3. The calculation of the fines for Johnson & Johnson and Janssen-Cilag B.V.**

#### *10.3.1. General methodology*

(473) In applying the Guidelines on fines, the basic amount of the fine to be imposed results from the sum of a variable amount and an additional amount. The variable amount results from a proportion of the value of sales to which the infringement directly or indirectly relates multiplied by the number of years of the company's participation in the infringement. The additional amount is calculated as a proportion of the value of sales of the goods or services to which the infringement directly or indirectly relates in a given year (normally, the last year of the infringement). The resulting basic amount can then be increased or reduced for each undertaking if either aggravating or mitigating circumstances are retained.

#### *10.3.2. The value of sales*

(474) The basic amount of the fine to be imposed on the undertakings concerned is to be set by reference to the value of sales<sup>623</sup>, that is, the value of the undertakings' sales of goods or services to which the infringement directly or indirectly related in the relevant geographic area in the EEA.

(475) Through the infringement in question, J&J protected its sales of fentanyl transdermal patches in the Netherlands. The Commission therefore took J&J's sales of fentanyl transdermal matrix patches in the Netherlands into account.

(476) The Commission will normally take into account the sales made by the undertakings concerned during the last full business year of their participation in the infringement.<sup>624</sup> In the case at hand, the Agreement lasted less than two years, which period neither covered the full business year 2005 nor the full business year 2006. The Commission therefore used an annual average value of sales calculated on the basis of J&J's actual sales during the relevant period in the Netherlands.<sup>625</sup>

(477) In view of the above and based on the information provided by J&J<sup>626</sup>, the annual average value of sales to be taken into consideration is: EUR 23 339 250.

#### *10.3.3. Determination of the basic amount of the fine*

(478) The basic amount of the fine to be imposed consists of a variable amount of up to 30% of an undertaking's relevant sales in the relevant geographic area within the EEA, depending on the degree of gravity of the infringement and multiplied by the number of years of the undertaking's participation in the infringement, and – where

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<sup>623</sup> Point 12 of the Guidelines on fines.

<sup>624</sup> Point 13 of the Guidelines on fines.

<sup>625</sup> For this purpose, the Commission has first calculated a monthly average value of J&J's sales of transdermal fentanyl patches in the period of operation of the Co-promotion agreement. This monthly average value of sales has then been multiplied by twelve to arrive at an annual average value of J&J's sales of fentanyl patches for the geographic area covered by the Agreement.

<sup>626</sup> See ID0683.

appropriate – an additional amount, of between 15% and 25% of the value of an undertaking's relevant sales, irrespective of duration.<sup>627</sup>

### Gravity

- (479) The gravity of the infringement determines the percentage of the value of sales taken into account in setting the fine. In assessing the gravity of the infringement, the Commission has regard to a number of factors, such as the nature of the infringement, the geographic scope of the infringement and whether or not the infringement has been implemented.
- (480) For that assessment, the following facts described in this Decision were in particular considered:
- the anti-competitive nature and objective of the infringements, in particular the fact that market exclusion is a very serious infringement of Article 101 of the Treaty;
  - the extent to which the Agreement has been implemented, in particular that J&J maintained its position as the sole supplier during the entire duration of the Agreement and that the Agreement provided for a mechanism so that Novartis/Sandoz received the payments on a monthly basis and only as long as there was no generic product published on the Dutch Taxe list, which was publicly accessible.
- (481) J&J, in its reply to the Statement of Objections, argued that the gravity factor in this case should be at the lower end of the scale, given that: (i) the delay in generic entry was expected to be short, in the range of "*just a few months*"<sup>628</sup>; (ii) the agreement led to earlier, more effective competition from Hexal with matrix patches supplied by J&J<sup>629</sup>; (iii) the Agreement concerned only the Netherlands.<sup>630</sup>
- (482) Concerning the alleged parties' expectation at the time of entering into the Co-promotion agreement that the delay of the generic entry caused by the Agreement would be only of a short duration, the Commission recalls that the scope and duration of a restriction by object are determined irrespective of the potential lack of effects.<sup>631</sup> In this case the total duration of the Agreement, including the addendum was one year and five months. Moreover, the initial co-promotion agreement, agreed and signed by both parties, was concluded for a duration of one year with the possibility of extension. After one year, the parties signed the addendum and thereby

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<sup>627</sup> See points 19 to 26 of the Guidelines on fines.

<sup>628</sup> ID1542, p. 16.

<sup>629</sup> ID1542, p. 17.

<sup>630</sup> ID1542, p. 17. Additionally, J&J argued in its "*conclusion regarding gravity*" that "*the agreement predates the Pharmaceutical Sector Inquiry, after which the competition analysis of so-called "pay-for-delay" agreements has crystallized*" (ID1542, p. 17-18). However, the notion that agreements which are aimed at market exclusion in exchange for a payment are likely to constitute a restriction by object under Article 101 of the Treaty is well established in Union competition law. See also e.g. Recital (472).

<sup>631</sup> See, for example, Case T-360/09, *E.ON Ruhrgas AG and E.ON AG v Commission*, judgment of 29 June 2012, paragraph 252 and the case law cited therein.

extended the duration of the Agreement. It is unclear why the parties extended the Agreement after one year if they intended to delay the generic entry only by "*a few months*" as claimed by J&J.

- (483) Concerning the argument that the agreement led to earlier, more effective competition from Hexal with matrix patches supplied by J&J, it has already been established in Recitals (306) and (308) that the Co-promotion agreement and the supply agreement were two distinct agreements. The supply agreement therefore cannot be taken into account for the assessment of the gravity of the Co-promotion agreement for the purpose of calculation of the fine.
- (484) As to the argument that the Co-promotion agreement concerned only one Member State, the Netherlands, the Commission has already taken the geographic scope of the infringement into account when determining the relevant value of sales.
- (485) Taking into account the factors discussed in Recitals (480) to (484) the proportion of the value of sales to be taken into account should be 16%.

#### Duration

- (486) In its assessment of the duration of the infringement the Commission has taken into consideration that the Co-promotion agreement, including the addendum, lasted one year and five months.<sup>632</sup>
- (487) J&J, in its reply to the Statement of Objections, argued that it is likely that Hexal B.V./Sandoz B.V. would not have entered the Dutch market before September 2005, given that Novartis/Sandoz launched its depot patch in (late) August 2005 only in Germany and the United Kingdom, and in five other Member States only in September 2005. J&J concluded on that basis that, for the purpose of calculating fines, "*any delay in entry caused by the agreement is one year and four months at most*".<sup>633</sup>
- (488) As mentioned in Recital (482), in a case involving a restriction by object, the starting date for the purposes of calculating duration is the date of signature of the anticompetitive agreement, irrespective of the potential lack of effects. In this case the date of entry into force of the Co-promotion agreement is the date to be taken into account. Moreover, J&J's argument that Hexal B.V./Sandoz B.V. would likely not have entered the Dutch market before September 2005, and that, hence, that later date should be taken into account, is not supported by the evidence on the file as already explained in Recital (93) and in section 7.5.2.1.
- (489) J&J also argued that the Commission should, for the purpose of calculating duration, "*consider the actual period of delay*" instead of rounding up the number of months as provided for by point 24 of the Guidelines on fines.<sup>634</sup> The Commission, in the

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<sup>632</sup> The Co-promotion agreement entered into force on 11 July 2005 and was terminated (including the addendum) on 15 December 2006. See Recital (461).

<sup>633</sup> ID1542, p. 18. See also ID1702, p. 2.

<sup>634</sup> ID1542, p. 18.

exercise of its discretion in this case, takes into account the actual duration of participation of J&J in the infringement based on full months.

#### Additional amount

- (490) Given that the infringement consists of horizontal market-exclusion agreements which are restrictions of competition by object, the Commission applies the provisions of the Guidelines on fines on the additional amount.<sup>635</sup> To determine the precise percentage of the value of sales to be used for the additional amount the same factors as mentioned in Recital (480) are taken into account. On that basis an additional amount of 16% of the value of sales should be applied.
- (491) J&J argued in its reply to the Statement of Objections that "*given the pro-competitive aspects included in the overall deal, it is submitted that there is no need for such additional amount.*"<sup>636</sup> As explained in Recital (483), the subject of this Decision is the Co-promotion agreement, not the self-standing, independent and separate supply agreement. The supply agreement therefore cannot be taken into account for the assessment of gravity of the Co-promotion agreement for the purpose of calculation of the fine.

#### Conclusion on the basic amount

- (492) Based on the criteria explained in this section 10.3.3, the basic amount of the fine for J&J is EUR 8 999 000.

#### *10.3.4. Adjustments to the basic amount of the fine*

- (493) The Commission may reflect in the fine imposed any aggravating and/or mitigating factors that result in an adjustment of the basic amount. Those factors are listed, in a non-exhaustive way, in points 28 and 29 of the Guidelines on fines.
- (494) No aggravating or mitigating circumstances have been found in this case.
- (495) J&J in its reply to the Statement of Objections argued that J&J "*have always cooperated fully with the Commission, during the Sector Inquiry, the on-site inspection in July 2010, as well as throughout the subsequent investigation*" and on that ground J&J requested the Commission to grant it a reduction of the fine pursuant to point 29, fourth indent of the Guidelines on fines. J&J invoked in particular that J&J has not substantially contested the facts, did not ask for an oral hearing and cooperated actively to contribute to procedural efficiency, which allowed the Commission to adopt a decision earlier than would otherwise have been the case.
- (496) Firstly, the proceedings in this case are separate from the sector inquiry conducted by the Commission in 2008 and 2009. The Commission cannot take into account any claimed cooperation provided in the course of other proceedings, including a separate sector inquiry.

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<sup>635</sup> See point 25 of the Guidelines on fines.

<sup>636</sup> ID1542, p. 18.

- (497) Secondly, as regards the claimed cooperation provided by J&J in the course of the investigation of this case, point 29, fourth indent of the Guidelines on Fines states: "the basic amount may be reduced where the Commission finds that mitigating circumstances exist, such as: [...] where the undertaking concerned has effectively cooperated with the Commission outside the scope of the Leniency Notice and beyond its legal obligation to do so." Under that provision the Commission has to assess, in accordance with case law, whether a reduction of fines is justified due to the fact that J&J's co-operation would have enabled the Commission to establish the infringements more easily.<sup>637</sup> The Commission considers the award of such a reduction could only be of an exceptional nature.<sup>638</sup>
- (498) Whilst the Commission recognises that J&J did not obstruct the investigation of this case, J&J has gone no further than its duty to cooperate during inspections and subsequent dealings with the Commission as specified in Regulation (EC) No 1/2003. J&J has not voluntarily, for example, submitted information that helped the Commission significantly to establish the infringements and the Commission therefore considers that there are no exceptional circumstances present in this case that could justify granting a reduction of the fine for effective cooperation falling outside the Leniency Notice to J&J. Whilst not disputing the facts was considered as a mitigating circumstance under the old guidelines on fines this is no longer the case under the current Guidelines on Fines, adopted in 2006.

#### 10.3.5. Deterrence

- (499) In order to ensure that fines have a sufficiently deterrent effect, the Commission may increase the fine to be imposed on undertakings which have a particularly large turnover beyond the sales of goods to which the infringement relates.<sup>639</sup>
- (500) Given the total global turnover of the undertaking Johnson & Johnson, which in 2012 amounted to EUR 52 322 million<sup>640</sup> it is appropriate to apply a multiplier of 1.2 to the basic amount.
- (501) Based on the application of the specific increase for the purposes of deterrence described in Recital (500), the amount of the fine after the increase for deterrence to be applied to J&J is EUR 10 798 000.

#### 10.3.6. Application of the 10% turnover limit

- (502) As mentioned in Recital (464), the final amount of the fine shall not, in any event, exceed 10% of the total turnover in the last full business year of the undertaking participating in the infringement preceding the date of adoption of the Commission's decision.<sup>641</sup>

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<sup>637</sup> Case T-48/02 *Brouwerij Haacht v. Commission*, [2005] ECR II-5259 paragraph 104 and the case law cited therein.

<sup>638</sup> Commission Decision of 20.10.2005, Case COMP/38.281 *Italian Raw Tobacco*, paragraphs 385 ff.

<sup>639</sup> See point 30 of the Guidelines on fines.

<sup>640</sup> ID1619. Using an average annual exchange rate for 2012 of 1 EUR = 1.2848, Source European Central Bank, ID1636.

<sup>641</sup> See point 32 of the Guidelines on fines.

- (503) Johnson & Johnson and Janssen-Cilag B.V. belong to the same undertaking Johnson & Johnson and should be held jointly and severally liable (see section 8.1). The amount of the fine in Recital (501), after the increase for deterrence, does not exceed 10% of the total turnover of the undertaking Johnson & Johnson in 2012.

10.3.7. *Conclusion: final amount of fine for Johnson & Johnson and Janssen-Cilag B.V.*

- (504) A fine of EUR 10 798 000 should be imposed jointly and severally on Johnson & Johnson and Janssen-Cilag B.V.

**10.4. The calculation of the fines for Novartis AG and Sandoz B.V.**

- (505) Novartis/Sandoz agreed not to sell generic fentanyl patches in the geographic area concerned by the Co-promotion agreement and therefore did not have any sales in the geographic area concerned during the period of the infringement. The Commission therefore applies point 37 of the Guidelines on fines to Novartis AG and Sandoz B.V. Point 37 of the Guidelines on fines allows the Commission to depart from the normal methodology of the Guidelines on fines because of the particularities of a given case or the need to achieve deterrence in a particular case.

- (506) The Commission takes the following elements into account in calculating the fines to be imposed on Novartis/Sandoz in this case.

10.4.1. *Basis for the calculation*

- (507) As mentioned in Recital (505), the Commission, pursuant to point 37 of the Guidelines on fines, departed from the normal methodology of the Guidelines on fines, taking into account the absence of sales by Novartis/Sandoz in the geographic area concerned during the period of the infringement, and the need to ensure deterrence<sup>642</sup>. It therefore used as a basis for the calculation of the fine the value transferred to Novartis/Sandoz by J&J under the Co-promotion agreement, namely EUR 4 994 350.<sup>643</sup>

- (508) Novartis/Sandoz submitted in its reply to the Statement of Objections that "*the most appropriate proxy to the "value of sales" that is available to the Commission for determining the basic amount would be based on contemporaneous estimates (in April 2005) of the potential yearly sales for Hexal AG in case of the hypothetical introduction of a fentanyl depot patch on the Dutch market.*"<sup>644</sup> Novartis/Sandoz further submitted that "*the potential sales estimate based on the lowest estimated share of 25% in the three hypothetical scenarios (i.e. EUR 2 536 923) should be considered the maximum basis for a proxy.*"<sup>645</sup>

- (509) In this case, the calculation is based on the value transferred to Novartis/Sandoz by J&J under the Co-promotion agreement, matching profits that Novartis/Sandoz communicated J&J it could have made had it launched its own fentanyl patch,<sup>646</sup> and

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<sup>642</sup> See also point 31 of the Guidelines on fines.

<sup>643</sup> See Recital (262).

<sup>644</sup> ID1537, p. 20.

<sup>645</sup> ID1537, p. 20.

<sup>646</sup> See Recitals (161) and (327).

which, as part of the "non-entry mechanism", gave Novartis/Sandoz strong incentives to abstain from such market entry.<sup>647</sup>

#### 10.4.2. Gravity

(510) When assessing the gravity of the infringement, the Commission has usually regard to a number of factors, such as the nature of the infringement, the geographic scope of the infringement and whether or not the infringement has been implemented. Normally the gravity of the infringement determines the percentage of the value of sales taken into account when setting the fine. However, as mentioned in Recital (507), in this case by applying point 37 of the Guidelines on fines, the Commission determines the basic amount for Novartis/Sandoz as corresponding to the value transferred to the generic undertaking by J&J.<sup>648</sup> For the sake of completeness, the following is noted:

- the anti-competitive nature and objective of the infringement, in particular the fact that this type of market exclusion must be considered a very serious infringement of Article 101 of the Treaty;
- the extent to which the Agreement has been implemented, in particular that J&J's close potential competitor, Novartis/Sandoz, stayed out of the market for the entire duration of the Agreement and that J&J maintained its position as the sole supplier for the entire duration of the Agreement. The Agreement provided for a mechanism so that Novartis/Sandoz received the payments on a monthly basis and only as long as there was no generic product published on the Dutch Tax list, which was publicly accessible.

#### 10.4.3. Duration

(511) In its assessment of the duration of the infringement the Commission has taken into consideration that the Co-promotion agreement, including the addendum, lasted one year and five months.<sup>649</sup>

#### 10.4.4. Adjustments to the basic amount of the fine

(512) The Commission may reflect in the fine imposed any aggravating and/or mitigating factors that result in an adjustment of the basic amount. Those factors are listed, in a non-exhaustive way, in points 28 and 29 of the Guidelines on fines.

(513) No aggravating or mitigating circumstances have been found in this case.

#### 10.4.5. Deterrence

(514) As mentioned in Recital (507), the Commission, pursuant to point 37 of the Guidelines on fines departed from the normal methodology of the Guidelines on fines, taking also into account the need to ensure deterrence<sup>650</sup> by using as a basis for

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<sup>647</sup> See Recitals (257) and (313).

<sup>648</sup> See also Recital (262).

<sup>649</sup> See Recitals (461).

<sup>650</sup> See also point 31 of the Guidelines on fines.

the calculation of the fine the value transferred to Novartis/Sandoz by J&J under the Co-promotion agreement, namely EUR 4 994 350.

- (515) The Commission may also take into consideration the need to ensure deterrence and to increase the fine to be imposed on undertakings which have a particularly large turnover beyond the sales of goods to which the infringement relates.<sup>651</sup> Given the total global turnover of the undertaking Novartis AG, which in 2012 amounted to EUR 44 110 million<sup>652</sup>, it is appropriate to apply a multiplier of 1.1 to the basic amount.
- (516) Novartis/Sandoz submitted in its reply to the Statement of Objections<sup>653</sup> that "*the deterrence multiplying factor, if any, to be imposed by the Commission should be set at a very low level.*" Novartis/Sandoz argued that "*the Commission should take into account the size and overall resources of Hexal AG, or, at most Sandoz International GmbH, when it is assessing whether to increase the amount of the fine for an alleged infringement essentially committed by Hexal B.V.*" Novartis/Sandoz referred to the acquisition of Hexal AG by Novartis AG which took place shortly (less than 45 days) before signing of the Co-promotion agreement and as a result, "*at the time the Co-promotion agreement was negotiated and entered into, Hexal B.V. was to a large extent still operating as an autonomous entity over which Novartis AG had in reality no effective influence and no involvement with the issues related to the Co-promotion agreement. Moreover, Novartis AG had no influence whatsoever on Hexal B.V. when discussions with Janssen-Cilag were initiated.*"<sup>654</sup>
- (517) Firstly, as recognised by Novartis/Sandoz itself, the purpose of the increase of the fine pursuant to point 30 of the Guidelines on fines is to ensure that the undertaking concerned is sufficiently affected by the fine, in order to achieve deterrence. This Decision is addressed, among others, to Novartis AG which is, together with Sandoz B.V., held jointly and severally liable for the infringement. In order to ensure deterrence, the Commission needs to ensure that Novartis AG as the addressee of this Decision is sufficiently affected by the fine, in particular in view of its large global turnover beyond the sales of goods to which the infringement relates. In this respect the size and overall resources of Hexal AG and Sandoz International GmbH are not relevant, as those companies are not addressees of this Decision.
- (518) Secondly, it should be recalled that both the initial co-promotion agreement and the addendum were also signed by Sandoz B.V., a company that belonged to the Novartis group of companies and was controlled by Novartis AG long before the acquisition of Hexal B.V. took place in 2005.<sup>655</sup> The date of the acquisition of Hexal B.V. therefore does not change the liability of Novartis AG for the infringement.
- (519) Finally, in July 2006, the Co-promotion agreement was still in force and it was even extended by the addendum. The addendum was again signed by both companies

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<sup>651</sup> See also point 30 of the Guidelines on fines.

<sup>652</sup> ID1625, p. 2. Using an average annual exchange rate for 2012 of 1 EUR = 1.2848, Source European Central Bank, ID1636.

<sup>653</sup> ID1537, p. 21.

<sup>654</sup> ID1537, p. 21.

<sup>655</sup> See Recital (62).



controlled by Novartis AG, Hexal B.V. and Sandoz B.V., at a time when more than one year had elapsed since the acquisition of Hexal B.V. by Novartis AG took effect.

- (520) Based on the application of the specific increase for the purposes of deterrence described in Recital (515), the amount of the fine after the increase for deterrence to be applied to Novartis/Sandoz is EUR 5 493 000.

#### *10.4.6. Application of the 10% turnover limit*

- (521) As mentioned in Recital (464), the final amount of the fine shall not, in any event, exceed 10% of the total turnover in the last full business year of the undertaking participating in the infringement preceding the date of adoption of the Commission's decision.<sup>656</sup>

- (522) Novartis AG and Sandoz B.V. belong to the same undertaking Novartis AG and should be held jointly and severally liable (see section 8.2). The amount of the fine in Recital (520), after the increase for deterrence, does not exceed 10% of the total turnover of the undertaking Novartis AG in 2012.

#### *10.4.7. Conclusion: final amount of fine for Novartis AG and Sandoz B.V.*

- (523) A fine of EUR 5 493 000 should be imposed jointly and severally on Novartis AG and Sandoz B.V.

### **10.5. Inability to pay**

- (524) In exceptional cases, the Commission may, upon request, take account of an undertaking's inability to pay in a specific social and economic context according to point 35 of the Guidelines on fines.

- (525) No application claiming inability to pay the fine under point 35 of the Guidelines on fines was made in this case.

## **11. CONCLUSION**

- (526) In the light of the considerations set out in this Decision, the Commission finds that Johnson & Johnson, Janssen-Cilag B.V., Novartis AG and Sandoz B.V. have infringed Article 101 of the Treaty by concluding and implementing the Agreement to which this Decision relates and that fines should be imposed on them pursuant to Article 23(2) of Regulation (EC) No 1/2003.

HAS ADOPTED THIS DECISION:

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<sup>656</sup> See point 32 of the Guidelines on fines.

### *Article 1*

Johnson & Johnson, Janssen-Cilag B.V., Novartis AG and Sandoz B.V. infringed Article 101 of the Treaty by participating, from 11 July 2005 until 15 December 2006, in an agreement concerning fentanyl transdermal patches in the Netherlands.

### *Article 2*

For the infringement referred to in Article 1, the following fines are imposed:

- (a) Johnson & Johnson and Janssen-Cilag B.V., jointly and severally: EUR 10 798 000;
- (b) Novartis AG and Sandoz B.V., jointly and severally: EUR 5 493 000.

The fines shall be paid in euro within three months of the date of notification of this Decision to the following account held in the name of the European Commission:

BANQUE ET CAISSE D'EPARGNE DE L'ETAT

1-2, Place de Metz

L-1930 Luxembourg

IBAN: LU02 0019 3155 9887 1000

BIC: BCEELULL

Ref.: European Commission – BUFI / COMP / AT.39685

After the expiry of that period, interest shall automatically be payable at the interest rate applied by the European Central Bank to its main refinancing operations on the first day of the month in which this Decision is adopted, plus 3.5 percentage points.

Where an undertaking referred to in Article 1 lodges an appeal, that undertaking shall cover the fine by the due date by either providing an acceptable bank guarantee or making a provisional payment of the fine in accordance with Article 90 of Commission Delegated Regulation (EU) No 1268/2012.<sup>657</sup>

### *Article 3*

The undertakings referred to in Article 1 shall refrain from repeating any act or conduct described in Article 1, and from any act or conduct having the same or similar object or effect.

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<sup>657</sup> Commission Delegated Regulation (EU) No 1268/2012 of 29 October 2012 on the rules of application of Regulation (EU, Euratom) No 966/2012 of the European Parliament and of the Council on the financial rules applicable to the general budget of the Union (OJ L 362, 31.12.2012, p. 1).

*Article 4*

This Decision is addressed to:

**Johnson & Johnson**

One Johnson & Johnson Plaza

New Brunswick, NJ 08933

USA

**Janssen-Cilag B.V.**

Dr. Paul Janssenweg 150

5026 RH Tilburg

Netherlands

**Novartis AG**

Lichtstrasse 35

4056 Basel

Switzerland

**Sandoz B.V.**

Veluwezoom 22

1327 AH Almere

Netherlands

This Decision shall be enforceable pursuant to Article 299 of the Treaty.

Done at Strasbourg, 10.12.2013

*For the Commission*

*Joaquín ALMUNIA  
Vice-President*