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Case No COMP/M.3394 - JOHNSON & JOHNSON / JOHNSON & JOHNSON MSD EUROPE

Only the English text is available and authentic.

REGULATION (EEC) No 4064/89
MERGER PROCEDURE

Article 6(1)(b) NON-OPPOSITION
Date: 29/03/2004

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COMMISSION OF THE EUROPEAN COMMUNITIES

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Brussels, 29.03.2004
SG-Greffe(2004) D/201208

PUBLIC VERSION

MERGER PROCEDURE
ARTICLE 6(1)(b) DECISION

To the notifying party

Dear Sir/Madam,

Subject: **Case No COMP/M.3394 – Johnson & Johnson/Johnson & Johnson MSD Europe**
Notification of 27.02.2004 pursuant to Article 4 of Council Regulation No 4064/89[1]

1. On 27/02/2004, the Commission received a notification of a proposed concentration pursuant to Article 4 of Council Regulation (EEC) No 4064/89, as last amended by Regulation (EC) No 1310/97, by which Johnson & Johnson ("J&J", US) acquires within the meaning of Article 3(1)(b) of the Council Regulation control of the whole of Johnson & Johnson MSD Europe (JV") previously a cooperative joint venture with Merck & Co, by way of purchase of shares.

2. After examination of the notification, the Commission has concluded that the notified operation falls within the scope of the Merger Regulation and does not raise serious doubts as to its compatibility with the common market and with the EEA Agreement.

I. THE PARTIES

3. J&J is the ultimate parent company of a global group of companies whose activities are divided into three business segments: i) Consumer ii) Pharmaceuticals iii) Medical Devices & Diagnostics.

4. Currently, J&J shares control with Merck over the JV, which consist of five entities: i) Laboratoires Martin – J&J MSD SAS, in France ii) Woelm Pharma GmbH & Co., in Germany iii) Centra Medicamenta OTC S.r.l., in Italy iv) Abello Farmacia, S.L., in Spain and v) J&J MSD Consumer Pharmaceuticals Ltd., in the UK.

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[1] OJ L 395, 30.12.1989 p. 1; corrigendum OJ L 257 of 21.9.1990, p. 13; Regulation as last amended by Regulation (EC) No 1310/97 (OJ L 180, 9. 7. 1997, p. 1, corrigendum OJ L 40, 13.2.1998, p. 17).

5. J&J and Merck formed the JV in 1993 to develop, manufacture and sell non-prescription pharmaceutical products. The JV product portfolio was meant to be made up of non-prescription medicines using switch compounds derived from J&J and Merck's prescription medicines. In addition, the JV was expected to grow by licensing or acquiring non-prescription pharmaceutical products from other sources. The JV was the extension of J&J and Merck's cooperation in the U.S.A., where they had established a partnership, J&J Merck Consumer Pharmaceuticals Co., in 1989. The US partnership will continue to exist but will not have an impact on the future business activities of the merged entity.

II. THE OPERATION

6. The JV is jointly controlled by J&J and Merck and they have equal representation and voting rights on the Management Board. The day-to-day management of the JV is currently driven by J&J. There is already significant operational integration between the JV and J&J. Merck, of course, participates in the strategic business decision-making. However, it does not intervene on a day-to-day basis in the JV's affairs but leaves J&J to run the JV operational business.

7. On 26/02/2004, J&J and Merck reached an agreement pursuant to which J&J will acquire Merck's 50% shareholding in the JV entities. As a result, after closing, J&J will hold 100% of the JV businesses.

III. CONCENTRATION

8. The acquisition by J&J of the 50% shareholding in the JV entities results in a change from joint to sole control over the JV which constitutes a concentration within the meaning of Article 3(1)(b) of the Merger Regulation.

IV. COMMUNITY DIMENSION

9. The undertakings concerned have a combined aggregate world-wide turnover of more than EUR 5 billion[2]. The combined turnover of the undertakings concerned is more than EUR 100 million in Germany (EUR […] million), France (EUR […] million) and the UK (EUR […] million). The aggregate turnover of J&J and the JV exceeds EUR 25 million in Germany, France and the UK. They do not achieve more than two-thirds of their aggregate Community-wide turnover within one and the same Member State. The notified operation therefore has a Community dimension.

V. COMPETITIVE ASSESSMENT

A. Product markets

10. The JV and J&J are active in the development, manufacture and sale of pharmaceutical products used for the treatment of human illnesses and diseases. The JV is, however, only active in non-prescription pharmaceutical products.

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

11. The manufacturing process for pharmaceutical products includes three steps: i) the manufacturing of active ingredients ii) the manufacturing of pharmaceutical products and iii) packaging.

12. Medicines may be subdivided into therapeutic classes by reference to the "Anatomical Therapeutic Chemical" ("ATC") classification, devised by the European Pharmaceutical Marketing Research Association ("EphMRA") and maintained by EphMRA and Intercontinental Medical Statistics ("IMS"). The ATC classification is hierarchical and has 16 categories (A,B,C,D,etc.), each with up to four levels. The third level (ATC 3) allows medicines to be grouped in terms of their therapeutic indications, i.e. their intended use. ATC 3 can therefore be used as a starting point for market definition. The parties have followed the Commission's approach in this respect and used the ATC 3 classification as a starting point for their analysis. The market investigation has confirmed this approach.

13. The parties also indicate that pharmaceutical products may be classified according to a variety of criteria besides their intended therapeutical use. Common-and related-classifications are based on the question of whether medicines are available with or without a prescription, whether they are reimbursable or whether they are advertisable to the public at large.

14. In general, J&J sells prescription ("P") pharmaceutical products and the JV non-prescription ("NP") pharmaceutical products. The JV sells the NP version of the medicine originally developed by J&J, with the latter continued to market as a prescription medicine. The parties argue that there are significant differences between P and NP medicines, in particular as to marketing and pricing. NP products, which are generally not reimbursable, may be advertised to the public at large. Doctors do not need to intervene in the purchase of these products and consumers make their own choice. These products are typically formulated for minor or short-term illnesses. Pricing of NP products typically is not regulated by the government because these products are generally not reimbursable. By contrast, P products need to be prescribed by a doctor whose intervention is essential in the choice of the product. Pricing for P products is regulated by the government who pays (part of) the purchase price via reimbursement. P products may not be advertised to the public. Marketing is targeted to prescribers (doctors and hospitals). "Semi-ethical" products are NP products for which reimbursement can be obtained if they are purchased on prescription.

15. The parties believe that there is a lack of competitive interaction between NP and P products, and argue that these belong to different product markets. In previous decisions[3], the Commission has indicated a possible distinction between P and NP pharmaceuticals and that they may belong to different product markets. The market investigation has confirmed this with regard to the products concerned by the present case and has not revealed any new elements with regard to the previous views concerning the relevant product market.

16. J&J is also active in the production of active ingredients. Active ingredients are produced from chemical and biological products and may be manufactured in-house or bought in. For some pharmaceutical products, J&J manufactures itself the active ingredients; for others it buys them from third parties. J&J produces 7 active

[3] M.2922 - Pfizer/Pharmacia, Commission decision 27.02.2003

ingredients, which are: loperamide, levocabastine, ketoconazole, miconazole, domperidone, mebendazole and cinnarizine. In previous cases,[4] the Commission concluded that active ingredients form a separate market which is upstream to the market for the finished pharmaceutical products. This has been confirmed by the market investigation.

B. Geographic markets

17. In previous decisions, the Commission has held that the geographic market for pharmaceutical products is national in scope.

18. In previous cases,[5] the Commission concluded that there are indications that active ingredients markets are larger than markets for finished pharmaceutical products and are likely worldwide in scope. This has been confirmed by the market investigation.

C. Assessment

19. Currently the JV is jointly controlled by J&J and Merck. The JV's day-to-day management already substantially relies on J&J management expertise and already today there is a high level of operational integration between the JV and J&J. In addition the vast majority of the contributed products in the JV portfolio originate from J&J.

20. As J&J is active in the upstream markets for several active ingredients, and the JV sells primarily NP pharmaceutical products which are based on these active ingredients, also these vertical relations are analysed.

Horizontally related markets

21. The countries in which the JV currently operates are France, Germany, Ireland, Italy, Spain and the UK. The products the JV sells are in general NP products. J&J sells P products in the ATC 3 classes where the JV is active. The JV usually sells the NP version of the medicine originally developed by J&J, which the latter continued to market as a P medicine.

22. For the purpose of this case it is considered that P and NP products belong to different product markets. On the basis of this there is hardly any overlap between the pharmaceutical products of J&J and the JV. If there is competition between P and NP products it is limited to "semi-ethical" products. However, in the ATC 3 categories where J&J is active *via* semi-ethical products, the combined market share of the parties is in general below 15%. In one category (D1A in Ireland), the combined share (2002) of the parties was [30-40] % but other competitors such as Bayer [20-30] %, Roche [10-20] %, Boots [0-10] %, Ricesteele [0-10] % and others are active in this market. 23. In addition to the above, the Commission has conducted a market investigation in order to verify whether there might be any competitive interaction between J&J's P products and the NP products of the JV. This focused on those ATC 3 categories where the market share of J&J or the JV is above 40%. These categories are: Mouth antifungals

[4] M.1397- Sanofi/Synthelabo, Commission decision 17.05.99

[5] M.1397- Sanofi/Synthelabo, Commission decision 17.05.99

(A1B) in the UK, Gastroprokinetics (A3F) in Ireland, Motility inhibitors (A7H) in France, Germany, Ireland and UK, Anthelmintics (P1B) in the UK.

24. On the basis of the market investigation it can be concluded that, despite the high market share of the parties in some categories, no competition problems arise on these markets, because competing products from other suppliers are present on the market and generic versions are available. The views of the parties that the transaction (change from joint to sole control over the JV) does not bring about a change in competition and will not have any competitive effect, has been confirmed by the market investigation.

25. It follows from the above, that the proposed concentration does not raise serious doubts as to its compatibility with the common market with regard to any horizontal relation between the products of J&J and the JV.

Vertically affected markets

Loperamide

26. Loperamide is the active ingredient used for products in the category A7H-Motility Inhobitors. J&J produces loperamide for its own products a well as for the JV's loperamide-based products. The parties indicate that J&J's share of the non-captive supply of loperamide is about [10-20] %. Loperamide is off-patent. There are more than 30 suppliers of loperamide throughout the world, of which are more than 10 located in Europe. The JV share of sales in the downstream NP segment of the A7H category in 2003 is about [70-80] % in France, [60-70] % in Germany, [90-100] % in Ireland and [80-90] % in the UK.

Ketoconazole

27. Ketoconazole is the active ingredient used for products in the category D1A-Dermatological Antifungals. J&J produces ketoconzaole for its own products and for the JV's ketoconazole-based products as well as for supply to third parties. J&J's share of the non-captive supply of ketoconazole, which is off-patent, is about [0-10] %. There are more than 45 suppliers throughout the world, 8 of which are located in Europe. In 2002, the downstream share of sales for the ketoconazole-based products of the JV in the NP segment of the D1A category is [10-20] % in Germany, [10-20] % in the UK and [10-20] % in Ireland.

Miconazole

28. Miconazole is the active ingredient used for products in the category D1A-Dermatological Antifungals, A1B-Mouth Antifungals and D7B-Topical Corticosteroid Combinations). J&J produces miconazole for its own products and for the JV's miconazole-based products as well as for supply to third parties. J&J's share of the non-captive supply of miconazole, which is off-patent since 1989, is [70-80] %. There are more than 35 suppliers throughout the world, 10 of which are located in Europe. In 2002, the share of sales of the JV in the NP segment of the D1A category is [10-20] % in the UK and [0-10] % in Ireland. In the NP segment of the D7B category, the JV has a share (2003) of sales of [20-30] % in the UK. In the NP segment of the A1B category in the UK, the JV's share (2003) of sale is [90-100] %.

Domperidone

29. Domperidone is the active ingredient used for products in the category A3F-Gastroprokinetics. J&J produces domperidone for its own products and for the JV's domperidone-based products as well as for supply to third parties J&J's share of the non-captive supply of domperidone, which is off-patent, is [20-30] %. There are more than 20 suppliers throughout the world, of which 5 are located in Europe. The share of sales (2003) of the JV in the NP segment of the A3F category is [90-100] % in Ireland. The only other countries where the JV markets domperidone-based products are Italy and the UK where it had a 2003 share of sales in the NP segment of the A3F category of [0-10] % and [90-100] % respectively.

Mebendazole

30. Mebendazole is the active ingredient used for products in the category P1B-Anthelmintics. J&J currently sources part of its requirements of mebendazole, which is off-patent, from […] and resells some of these quantities to third parties. Today J&J only produces a limited quantity for the US market but will discontinue this shortly. In the near future, J&J will therefore source all its mebendazole requirements from third parties. There are more than 45 suppliers in the world.

Levocabastine

31. Levocabastine is the active ingredient used for products in the category S1G-Preparations for the treatment of non-specific conjunctivitis and R1A-Topical nasal decongestants. Today J&J produces levocabastine, which is still under patent in various countries, both for the manufacture of its own products, for the JV's products and supplies to third parties. J&J is currently the only supplier in the world. In 2003, it produced […] kg out of which […] kg were supplied to third parties ([…] kg to […] and the rest concerned sales of finished products to third parties, mostly outside the EEA).In Germany, the sale of shares of the JV in the NP segment of the R1A category and S1G categories are about [0-10] % and [0-10] % respectively (2002). In Italy the JV's share (2003) of sales in the NP R1A segment is [0-10] %. In the UK its sales are discontinued in 2004.

Cinnarizine

32. Cinnarizine is the active ingredient used for products of the category N7C-Antivertigo products. J&J produces cinnarizine for its own products and for the JV's cinnarizine-based products as well as for supply to third parties J&J's share of the non-captive supply of cinnarizine, which is off-patent, is about [30-40] %. There are about 25 suppliers, 7 of which are located in Europe. In 2003, the share of sales of the JV in the downstream NP segment of the N7C category is [50-60] % in Ireland and [40-50] % in the UK.

Conclusion on vertically affected markets

33. It can be concluded from the above, that J&J has only substantial market shares in the market for levocabastine and miconazole. With regard to the market for levocabastine, it can be concluded that the market shares of the JV in the downstream NP segment of R1A and S1G categories are very low. The products based on levocabastine compete with other products based on other active ingredients within these ATC 3 categories resulting in low downstream market shares of the parties. With regard to the market for miconazole, and despite a high market share of the JV in one downstream NP segment, the market investigation confirmed the views of the parties that the notified

concentration will not change J&J's incentive to supply third parties. There are alternative suppliers present on the market to which third parties can turn to and it is very common for buyers of this active ingredient to have more than one supplier qualified.

34. With regard to the vertically affected markets in general, the parties argue that the notified concentration will not change J&J's incentive to supply third parties, because if J&J stopped supplying third parties or, otherwise sought to act anti-competitively, third parties would turn to other alternative suppliers. Furthermore, there are downstream producers who do not depend currently on J&J for the supply of these active ingredients. The market investigation has confirmed the above mentioned views of the parties and that the transaction, which constitutes a change from joint to sole control, did not pose any competition problems.

35. It follows from the above, that the proposed concentration does not raise serious doubts as to its compatibility with the common market in relation to the vertically affected markets.

VI. CONCLUSION

36. For the above reasons, the Commission has decided not to oppose the notified operation and to declare it compatible with the common market and with the EEA Agreement. This decision is adopted in application of Article 6(1)(b) of Council Regulation (EEC) No 4064/89.

For the Commission

(signed)
Neil Kinnock
Member of the Commission