EN

Case No COMP/M.6280 - PROCTER & GAMBLE / TEVA OTC BUSINESS

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REGULATION (EC) No 139/2004
MERGER PROCEDURE

Article 6(1)(b) NON-OPPOSITION
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PUBLIC VERSION

MERGER PROCEDURE

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 Where possible the information omitted has been replaced by ranges of figures or a general description.

To the notifying party:

Dear Sir/Madam,

Subject: Case No COMP/M.6280 - PROCTER & GAMBLE / TEVA OTC BUSINESS
Commission decision pursuant to Article 6(1)(b) of Council Regulation No 139/2004[1]

1. On 26 August 2011, the European Commission received a notification of a proposed concentration pursuant to Article 4 of Council Regulation (EC) No 139/2004 by which the undertaking "The Procter & Gamble Company" (USA) (hereafter: "P&G") acquires within the meaning of Article 3(1)(b) of the Merger Regulation control of parts of the OTC business of Teva Pharmaceutical Industries Ltd. (Israel) (hereafter: "Teva") by way of acquiring shares in a newly created company to which both parties will contribute assets. P&G and Teva are hereinafter referred to as "parties".

I. THE PARTIES

2. P&G is the parent company of an international group active in a wide range of consumer products, including consumer health.

3. Teva is an international pharmaceutical company headquartered in Israel with a wide portfolio of generic and a limited number of originator pharmaceuticals. It is, according to internal documents, the world's largest manufacturer of pharmaceuticals.

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

II. THE OPERATION

4. P&G and Teva agreed to form a new entity (the "Company") to which they will contribute their international (excluding the US, Canada and Puerto Rico) over-the-counter ("OTC") pharmaceutical businesses.[2]

5. The OTC Business of Teva consists of a wide range of OTC products ranging from vitamins to pain relief treatments. [Description of another unrelated transaction][3] P&G will acquire at least 51% of the equity interests in the joint venture and Teva up to 49%.

III. CONCENTRATION

6. The transaction will result in Procter & Gamble acquiring sole control over the Company and consequently over Teva's contributed OTC Business and therefore constitutes a concentration within the meaning of Article 3(1)(b) and Article 3(2)(a) of EC Regulation No 139/2004. The acquisition of control over Teva's OTC Business is a concentration as it constitutes a part of Teva's assets with market presence, to which a market turnover can be attributed.[4] Following the Jurisdictional Notice, sole control is normally acquired on a legal basis where an undertaking acquires a majority of the voting rights or when one shareholder, even if holding a minority stake, has the power to veto strategic decisions.[5]

IV. EU DIMENSION

7. The undertakings concerned have a combined aggregate world-wide turnover of more than EUR 5 000 million[6] (P&G EUR 59 544 million, OTC Business of Teva EUR […] million). Each of them has an EU-wide turnover in excess of EUR 250 million (P&G EUR […] million, OTC Business of Teva EUR […] million), but they do not achieve more than two-thirds of their aggregate EU-wide turnover within one and the same Member State. The acquisition of sole control by P&G over Teva's OTC Business therefore has EU dimension.

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2 For North America, the parties will set up a separate joint venture (the "NA JV"), which will be controlled by P&G under similar arrangements, and will essentially market P&G's products in the NA. The creation of NA JV constitutes part of the same concentration, as it is envisaged under the same transaction agreements.

3 Should the sale of such assets to the Company take place within the two-year period laid down in Article 5(2) of the Merger Regulation, the proposed transaction would need to be re-notified once that sale takes place.

4 Para 17 and 24 of the Commission Consolidated Jurisdictional Notice under council Regulation (EC) No. 139/2004 on the control of concentrations between undertakings (OJ C95, 16.04.2008, p. 1), hereafter referred to as "Jurisdictional Notice".

5 The Board will have six members, three appointed by each, Teva and P&G. The Chairman will be appointed by P&G and will have a casting vote over strategic decisions, including the business plan, the budget, decisions on purchase, sale, or lease of any assets, decisions with respect to new business opportunities, approval of dividend policies, and over issuing or incurring any debt. Finally, P&G will have the casting vote regarding the appointment of senior management, except for the COO, who will be appointed by Teva, but will report to the CEO appointed by P&G. The Company's statutes do not foresee any other requirements that may contradict these provisions.

6 Turnover calculated in accordance with Article 5(1) of the Merger Regulation and the Commission Consolidated Jurisdictional Notice (OJ C95, 16.04.2008, p. 1) ("JN").

V. AFFECTED MARKETS

8. The proposed transaction primarily concerns the supply of pharmaceutical OTC products. Teva will contribute its entire OTC pharmaceutical businesses outside the US, Canada and Puerto Rico, including in the areas where P&G is already active. In addition to pharmaceutical OTC products, both P&G and Teva OTC business supply confectionary throat drops (registered as food products) and certain other products not licensed as pharmaceuticals but as medical devices (e.g., ovulation tests) and as general consumer products (e.g. baby wipes).

9. In previous pharmaceutical decisions, the Commission has applied the ATC (Anatomical Therapeutical Chemical) classification devised for marketing purposes by EphMRA (European Pharmaceutical Marketing Association) as a basis for market definition, and has taken the ATC3 level as an appropriate starting point on the basis of the therapeutic use of the products in question. Where appropriate, the Commission has also looked at narrower ATC4 or molecule levels, or across classes.[7] For OTC pharmaceuticals and consumer healthcare products, the Commission has also looked at the classification used in the International Medical Statistics (IMS) Consumer Health's OTC Review reports ("IMS OTC" report).[8]

10. The Commission has often distinguished between OTC and prescription products. In the case at hand, the concentration is limited to OTC products and the parties have defined markets on a conservative basis by excluding prescription drugs (except for laxatives, as explained below). With respect to the OTC products discussed below, the Commission has generally not further segmented the markets in accordance with the galenic form.

11. In accordance with prior pharmaceuticals cases, the parties have relied on the IMS ATC-based "Midas" database ("IMS ATC"), which generally covers sales to pharmacies and hospitals. For completeness, the parties also analysed the figures based on IMS OTC data which covers the grocery channel and includes the products that are not licensed as pharmaceuticals. According to the parties, the IMS OTC data largely corresponds to the ATC classification in the vast majority of the markets concerned by the proposed transaction and does not materially differ from IMS ATC figures (except for cough relievers, as described below). For the markets where sales through mass sales channels were not considered in the IMS OTC database (i.e. the UK), the parties used IRI data. The parties have also explained that Nielsen or IRI data covering for example sales of confectionary throat drops through drug stores would not show any affected markets other than those identified based on IMS (except for one affected non-pharmaceutical market for baby wipes in Hungary).

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7 See, e.g., M.1846 Glaxo/Smithkline, decision of 8.5.2000; M.2192 Smithkline Beecham/Block Drug, decision of 11.1.2001; M.3354 Sanofi-Synthelabo/Aventis, decision of 26.4.2004; M.3853 Solvay/Fournier, decision of 18.7.2005; M.5865 Teva/Ratiopharm, decision of 3.8.2010; M.5953 Reckitt Benckiser/SSL, decision of 25.10.2010. For cold, cough preparations, chest rubs see, e.g., M.4007 Renckitt Benkiser/Boots Healthcare International, decision of 6.1.2006; M.4314 J&J/Pfizer Consumer Healthcare, decision of 11.12.2006.

8 See, e.g., M.4314 Johnson&Johnson/Pfizer Consumer Health Business, decision of 11.12.2006; M.5530 GSK/Stiefel, decision of 17.7.2009; M.6162 Pfizer/Ferrosan Consumer Healthcare Business, decision of 9.6.2011. The IMS OTC database takes into account registered and unregistered medicines and differentiates between prescription and OTC sales of non-prescription bound products.

12. In the area of finished pharmaceutical products, the Commission has consistently held that the markets for finished pharmaceutical products, including OTC and consumer health care products are national in scope.[9] This conclusion has generally been reached because of (i) varying regulatory controls for pharmaceutical products; (ii) perceived differences in price setting and purchasing patterns/reimbursement by Member States; (iii) differences in national clinical guidelines, medical views and patient preferences; (iv) differences in brand, pack size and distribution systems; and (v) because competition between pharmaceutical companies generally takes place at the national level. The parties did not challenge this approach and provided their market shares on a national basis.

13. In the present case, based on the market definition approach discussed above, there are under any market definition not more than seven potentially affected markets in five ATC3/ATC4 categories, i.e. for (i) laxatives (ATC class A6A3) in the Netherlands (ii) chest rubs and other inhalants (ATC class R4A) in Austria, (iii) antitussives/plain antitussives (ATC class R5D/R5D1) in Austria and Germany, (iv) topical nasal preparations/nasal decongestants (ATC class R1A/R1A7) in Finland and Germany, and (v) cold preparations (ATC class R5A) in Germany.

14. In Austria, the affected markets would also arise under the following alternative market definitions: ATC groups R4A and R5A; ATC groups R5D and R5C; ATC groups R5D and R5C and R5A and ATC groups R5A and R1B and R1A7 and R1A9 and R4A and R5C and R5D.[10] The parties also overlap to a small extent in the supply of baby wipes in Hungary (18%).[11]

VI. COMPETITIVE ASSESSMENT

15. In accordance with previous Commission precedents[12], the market investigation focuses on those markets where the transaction leads to combined market shares of 35% or over with an increment of 1% or over (so called "Group 1" markets), those being A6A3 in the Netherlands and R5D in Austria, which are described hereafter. The other affected markets would belong to "Group 2" with a combined share of over 35% but an increment of 1% or less[13] or markets with a combined share in the range of 15% to 35% ("Group 3" markets)[14]. Unless specific issues in such markets are raised during the market investigation, markets which fall within group 2 or 3 for all possible market definitions have not been considered in detail individually and they

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9 See, e.g., M.3751 Novartis/Hexal, decision of 27.5.2005; M.4007 Renckitt Benkiser/Boots Healthcare International, decision of 6.1.2006; M.5253 Sanofi-Aventis/Zentiva, decision of 4.2.2009; M.5295 Teva/Barr, decision of 19.12.2008; M.5479 Teva/Lonza, decision of 14.5.2009; M.5530 Glaxo Smith Kline/Stiefel Laboratories, decision of 17.7.2009; M.5736 TPC/IMS Health, decision of 2.2.2010; M.5953 Reckit Benckiser/SSL, decision of 25.10.2011; M.6162 Pfizer/Ferrosan Consumer Healthcare Business, decision of 9.6.2011.

10 See, e.g., M.4007 Renckitt Benkiser/Boots Healthcare International, decision of 6.1.2006 and M.4314 Johnson&Johnson/Pfizer Consumer Healthcare, decision of 11.12.2006.

11 See, e.g., M.4865 Siemens/Dade Behring, decision of 25.10.2007, where the Commission concluded that the narrowest possible market would be baby wipes.

12 See, e.g., M.5865 Teva/Rathiopharm, decision of 3.8.2010 and M.6162 Pfizer/Ferrosan Consumer Healthcare Business, decision of 9.6.2011.

13 Chest rubs and other inhalants (ATC class R4A) in Austria.

14 Antitussives/plain antitussives (ATC class R5D/R5D1) Germany, topical nasal preparations/nasal decongestants (ATC class R1A/R1A7) in Finland and Germany, and (v) cold preparations (ATC class R5A) in Germany

fall within the general conclusions of no serious doubts. Third parties did not indicate that competition would be significantly impeded on any of these markets.

VI.1. OTC Laxatives – bulk producers (A6A3) in the Netherlands

16. The A6A (laxatives) ATC class includes all products for the treatment of constipation. At ATC4 level, this class includes softeners and emollients (A6A1), contact laxatives (A6A2), bulk producers (A6A3), enemas (A6A4), oral saline preparations (A6A5) and other laxatives (A6A6). In its previous decisions, the Commission considered that all laxatives constitute one relevant product market[15]. The parties argue that markets should be defined at ATC3 level and include both prescription and dual-status products, which can be bought without a prescription (OTC) but which are reimbursed if bought on prescription.[16] The parties submit that in the present case the legal framework, marketing, distribution and rules on reimbursement in the Netherlands do not differ considerably between those dual status laxatives and pure prescription products. Under this market definition, the parties have a combined market share of [10-20]%.

17. Should the relevant product market be defined at ATC4 level and prescription medicines be excluded, the proposed transaction would result in a Group 1 market, comprising OTC bulk producers (A6A3) in the Netherlands. Here, the parties would achieve a combined market share of [50-60]% (Teva's Psylliumvezels-Pch with a market share of [10-20]%, and P&G's Metamucil with [40-50]%).

18. The parties argue even under this scenario, they would still be constrained by existing competitors (Eurocept with a market share of [10-20]%, Novartis ([5-10]%), Norgine ([0-5]%) and other competitors accounting for [0-5]%). They also point to the existence of parallel traders which directly import, repackage and trade in P&G's Metamucil and in products of other competitors. Those parallel traders collectively hold [10-20]% of the market following the parties.

19. The market investigation indicated that the parties' bulk producers are very close substitutes at ATC3 and ATC4 level. The market investigation results revealed that various laxatives belonging to different ATC4 groups are not the closest substitutes although it was indicated that some degree of substitutability between those products does exist and sometimes they can be used interchangeably. In particular, bulk producers can, to a certain degree, be substituted with the other laxatives within ATC3 group A6A (laxatives). Since it is likely that the relevant product market is broader than bulk producers and that bulk producers still face at least some competitive constraint from other types of laxatives such as certain emollients (A6A1), contact laxatives (A6A2), enemas (A6A4), oral saline preparations (A6A5). In any event, in this case, the product market definition in regard of bulk producers and laxatives can be left open as no serious doubts arise under any plausible market definition because of the following reasons.

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15 M.3853 Solvay/Fournier, decision of 18.07.2005; M.4314 Johnson&Johnson/Pfizer Consumer Healthcare, decision of 11.12.2006, para. 28 and M.4007 Reckitt Benckiser/Boots Healthcare International, decision of 6.1.2006.

16 So called "Semi-ethical products". The appraisal of a general market for prescription drugs and semi-ethical product is also in line with Commission precedents for laxatives (M.3853 Solvay/Fournier, decision of 18.07.2005) and also for other products such as topical antihaemorrhoidal in Case M.4314 J&J/Pfizer Consumer Healthcare, decision of 11.12.2006.

20. First, the market investigation suggests that any attempts by the parties to raise the prices would not be sustainable as customers could easily switch to competing undertakings with equally effective products. The majority of competitors already active in the Netherlands indicated that they would be able to increase their supply in the short term and without significant investment in order to attract some of the demand from the parties' products should they became more expensive. Furthermore, potential competitors (active outside bulk producing agents in the Netherlands) indicated that it would be commercially attractive for them to enter the market in the Netherlands within one or two years if a persistent increase in prices of bulk producers would be observed.

21. Next, the market investigation looked into the role of parallel traders and to which degree they can exert a competitive pressure on the parties.[17] The market investigation did not aim to reconstruct the market shares but it showed that parallel trade in bulk producers in the Netherlands does actually not play a significant role..

22. Finally, the market investigation also showed that market participants are not expecting a negative impact of the transaction on patients or competition.

23. As a result, competition concerns can be excluded even for a narrow hypothetical market for OTC bulk producers in the Netherlands.

VI.2. OTC Antitussives (R5D) in Austria

24. The ATC3 class R5D consists of pharmaceutical preparations used to treat dry cough, called antitussives. Plain antitussives are classified in the R5D1 ATC4 sub-category. Combinations of antitussives with expectorants and other products (e.g. antihistamines, herbal tinctures, ephedrine) are classified in the R5D2 sub-category.[18] Productive (or chesty) cough is treated with expectorants, classified in the R5C class. In its previous decisions, the Commission has left open whether antitussives and expectorants belong to the same or separate product markets[19]. In certain decisions, the Commission's investigation also indicated that the markets could be broader, including other preparations against cold and flu, but left the market definition open.[20]

25. For antitussives, P&G in Austria sells dextromethorphan under the brand "Wick Formel44 Plus" (syrup and lozenges). Teva also sells dextromethorphan branded as "Tussastop".

26. The proposed transaction results in Group 1 markets in Austria on both (i) ATC3 class R5D (antitussives) with a combined market share of [90-100]% (Teva [10-20]%, P&G [70-80]%) and (ii) ATC4 level (class R5D1- plain antitussives) with a combined share of 100% relying on IMS ATC. Following this database, apart from the parties, only Nycomed ([5-10]%) and Gall Reidlinger ([0-5]%) supply OTC antitussives in Austria.

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17 Such an approach largely follows the one adopted in the case M.5778 Novartis/Alcon, decision of 9.8.2010.

18 The R5D2 category excludes combinations with analgesics, antipyretics and anti-infectives.

19 M.1846 Glaxo/Smithkline, decision of 8.5.2000; M.1878 Pfizer/Warner-Lambert, decision of 22.5.2000, M.4314 Johnson&Johnson/Pfizer Consumer Health, decision of 11.12.2006; M.4367 APW/APSA/Nordic Capital/CAPIO, decision of 16.3.2007.

20 See, e.g., M.1878 Pfizer/Warner-Lambert, decision of 22.5.2000 and M.4314 Johnson&Johnson/Pfizer Consumer Healthcare, decision of 11.12.2006.

27. The parties argue that the relevant market for Austria should be defined on a broader than R5D level together with certain other competing products classified under different ATC3 classifications namely R5C (expectorants) and R5F (other cough and cold preparations), as combination products are of significant importance in Austria.

28. According to the parties, the Austrian market has traditionally been characterised by the presence of OTC preparations combining both antitussives and expectorants (e.g., Bronchostop by Kwizda, Prospan by Engelhard, Tussimont by Pharmonta, Hustensaft by Weleda) and certain products that are not licensed as medicines (such as Klosterfrau's Broncholind) and which compete with plain antitussives. Whereas the IMS ATC database on antitussives does not take into account these preparations, they are considered in the IMS OTC database. This other database contains one classification for all cough relief medicines (01A1) and another for pure expectorants (01A2). The parties therefore consider that the IMS OTC classification provides a better view of the competitive landscape in Austria, as dual indication (i.e. antitussive and expectorant effects) products play a significant role.

29. The investigation into the Austrian market confirmed the parties' view that there is a national particularity. Contrary to other countries, products with dual indications (antitussives and expectorants, i.e. treating dry and chesty cough) exist[21] and are popular as their market presence and shares show. Furthermore, although the replies were somewhat heterogeneous as regards the different combination products' effectiveness, the overall majority confirmed that these products "often" or "in most cases" compete with the parties (single indication) antitussives. There is also evidence that the dual indication products are actually advertised in traditional and digital media as treating both, dry and chesty cough.[22] Thus, dual indication products put competitive constraints on the parties and have to be considered as belonging to the relevant market; the respective market shares are illustrated in the following table.

Austria ATC 3: Antitussives (R5D), Market shares in value 2010

Procter & Gamble	[10-20]%
Teva	[0-5]%
Combined	[10-20]%**%**
Kwizda	[40-50]%
Engelhard	[20-30]%
Pharmonta	[5-10]%
Klosterfrau	[5-10]%
Weleda	[0-5]%
Nycomed	[0-5]%
Gall Reidlinger	[0-5]%

30. The closeness of competition depends not only on their characteristic as a single or dual indication medicine but also on the active ingredient (being the same in P&G's

21 Bronchostop, Tussimont and Hustensaft-Weleda are not sold outside Austria. On the other hand, P&G, which sells cough preparations across the EU under the Vicks/Wick brand, did not develop a 2 in 1 specifically to enter the Austrian market and mirror the product offering of local suppliers but chose to compete with 'pure' antitussives and expectorants as it did in all other EU countries.

22 E.g. "*Bronchostop. Zaubert den Husten weg! Hustenlöser + Hustenstiller in einem!*" and "*Tussimont Hustensaft wirkt hustenstillend und schleimlösend.*"

Wick Formel44 Plus and in Teva's Tussastop), the brand reputation and the respective marketing support. Regarding the last aspects, Teva's generic product Tussastop is sold only in Austria with little advertising support whilst P&G considers Vick/Wicks to be a […] brand advertised and sold globally across various products.

31. It follows from the above that not only Nycomed (Scottopect) and Gall Reidlinger (St. Severin), which offer single indication products (i.e. antitussives), constrain the parties' competitive behaviour in the market but also undertakings such as Kwizda (with Bronchostop), Engelhard (Prospan), Pharmonta (Tussimont), Weleda (Hustensaft) and perhaps certain non-registered products (such as Klosterfrau's Broncholid) compete with plain antitussives in Austria. Under these circumstances, the combined market shares of the parties are between [10-20]% and [10-20]% under alternative market definitions[23].

32. Therefore, also having in mind that no respondent to the market investigation raised concerns regarding the transaction, competition concerns can be excluded in this market.

23 R5D: [10-20] % as shown in the table above; R5D + R5C: [10-20]%; R5D + R5C + R5A: [10-20]%; OTC classification for cough relief medicines (01A1): [10-20]%.

VII. CONCLUSION

33. For the above reasons, the European Commission has decided not to oppose the notified operation and to declare it compatible with the internal market and with the EEA Agreement. This decision is adopted in application of Article 6(1)(b) of the Merger Regulation.

For the Commission

(signed)
Joaquín ALMUNIA
Vice-President