EN

Case No COMP/M.4402 - UCB / SCHWARZ PHARMA

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REGULATION (EC) No 139/2004
MERGER PROCEDURE

Article 6(1)(b) NON-OPPOSITION
Date: 21/11/2006

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COMMISSION OF THE EUROPEAN COMMUNITIES

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 Where possible the information omitted has been replaced by ranges of figures or a general description.

PUBLIC VERSION

MERGER PROCEDURE
ARTICLE 6(1)(b) DECISION

To the notifying party:

Dear Sir/Madam,

Subject: Case No COMP/M.4402 – UCB/Schwarz
Notification of 13.10.2006 pursuant to Article 4 of Council Regulation No 139/2004

1. On 13/10/2006, the Commission received a notification of a proposed concentration pursuant to Article 4 of Council Regulation (EC) No 139/2004[1] by which the undertaking UCB SA ("UCB", Belgium) together with its German wholly-owned subsidiary UCB SP GmbH acquire within the meaning of Article 3(1)(b) of the Council Regulation sole control of the whole of Schwarz Pharma Aktiengesellschaft ("Schwarz", Germany), by way of purchase of shares through a public tender offer.

I. THE PARTIES

2. UCB is a publicly traded Belgian company active in the pharmaceutical industry. In particular, UCB is active in the research, development and commercialization of innovative pharmaceutical and biotechnology products in three therapeutic areas: Central Nervous System ("CNS"), inflammation and immunology (including allergy) and oncology.

1 OJ L 24, 29.1.2004 p. 1

3. Schwarz is a publicly traded drug development and specialty pharmaceutical company based in Monheim, Germany. Schwarz specializes in the manufacture and supply of mainly generic medicines in the areas of cardiovascular diseases, gastrointestinal diseases, urology and CNS diseases.

II. THE OPERATION

4. The transaction will take place by means of a voluntary public tender offer, launched by UCB and UCB SP GmbH, for all issued and outstanding shares of Schwarz in accordance with the provisions of the German take-over act. The consideration for each share of Schwarz shall be a combination of cash and UCB shares. The combination has been approved by the boards of directors of UCB and Schwarz.

5. Thus, the operation constitutes a concentration within the meaning of Article 3.1(b) of the ECMR.

III. COMMUNITY DIMENSION

6. The transaction has a Community dimension, since it satisfies the thresholds of Article 1(3) of the ECMR. The parties have a combined worldwide turnover of more than EUR 2.5 billion[2]. In each of at least three Member States, the combined aggregate turnover of both undertakings concerned is more than EUR 100 million[3]. In each of at least three Member Sates, the aggregate turnover of each of the undertakings concerned is more than EUR 25 million[4]. The aggregate Community-wide turnover of each of the undertakings concerned is more than EUR 100 million[5]. Neither company achieves more than two-thirds of its aggregate Community-wide turnover within one and the same Member State.

IV. RELEVANT MARKETS

Product Markets

7. The proposed transaction gives rise to six affected product markets and one potentially affected market, covering different Member States: (i) prescription R6A systemic in Germany and in the UK; (ii) prescription N3A antiepileptics in Belgium, Ireland, Spain, Netherlands, Greece, Austria, Germany, Italy, Luxembourg, and the UK; (iii) prescription C1D coronary therapy drugs in Germany; (iv) OTC B3A haematinics, iron and all combinations in Finland; (v) OTC R1B systemic nasal preparations in Spain (vi) prescription C4A cerebral and peripheral vasotherapeutics in Germany; and (vii) prescription R3F combinations of B2- stimulants and corticoids in Germany.

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2 UCB EUR 2 billion; Schwarz EUR 1 billion

3 France: UCB EUR […] and Schwarz EUR […]; Germany: UCB EUR […] and Schwarz EUR […]; and the United Kingdom: UCB EUR […] and Schwarz EUR […]

4 ibidem

5 UCB is EUR […] and Schwarz is EUR […]

ATC-3 level

8. In its previous decisions in the pharmaceutical sector, the Commission has noted that drugs may be subdivided into therapeutic classes by reference to the Anatomical Therapeutic Chemical Classification (ATC), devised by the European Pharmaceutical Marketing Research Association (EphMRA) and maintained by EphMRA and Intercontinental Medical Statistics (IMS). The third level (ATC 3) allows medicines to be grouped in terms of their therapeutic indications, i.e. their intended use, and it can therefore be used as an operational market definition. However, in certain cases it may be necessary to analyse pharmaceutical products at a higher, lower or mixed level or to further subdivide the ATC 3 classes on the basis of demand-related criteria. In the present case, the parties have accepted this view.

Prescribed/non-prescribed (OTC)

9. The Commission has in the past defined separate markets for over the counter ("OTC"), as opposed to prescription, pharmaceuticals because medical indications (as well as side effects), legal framework, marketing and distributing tend to differ between these categories. The parties have followed this subdivision between OTC and prescribed medicines.

Originator medicines/generics

10. In previous decisions, the Commission has never made a distinction between generics and originator drugs. The competitive assessment was generally based on all medicines but when assessing the competitive situation in a given market, the Commission took into account the fact that parties' originator drugs were exposed to generic competition. Generics are in general less expensive copies of the originator drugs. In the present case, the parties have accepted this view.

Future markets/research and development

11. In its previous decisions concerning the pharmaceuticals sector, the Commission has concluded that a full assessment of the competitive position of the parties requires an analysis of products that are not yet on the market but are at an advanced stage of development. In brief, research and development (R&D) projects undergo three different phases of clinical testing. Phase III is the final one, starting in general three years before the product is marketed. In accordance with the Commission's decisional practice, the products undergoing the Phase III trials have been duly analysed.

Geographic Markets

12. The Commission has so far defined the geographic markets for pharmaceutical products as being national markets, despite the trend towards standardisation at a European level. The parties endorse the Commission's approach.

V. COMPETITIVE ASSESSMENT

R6A (systemic antihistamines) – Germany and the United Kingdom

13. Antihistamines are drugs that reduce or eliminate effects (mostly allergic reactions) mediated by histamine, an endogenous chemical mediator that is released during

allergic reactions. In two prior Commission decisions that discuss antihistamines, the Commission considered that the relevant product market corresponded to the ATC 3 Class, R6A[6]. In the most recent case Novartis/Hexal it has been submitted that a potential distinction may exist between sedatives and non-sedative antihistamines. This potential distinction was not supported by the Commission investigation and the Commission left the exact product market definition open[7]. The market test in this case confirmed unequivocally the relevance of R6A market definition. The R6A ATC 3 Class includes drugs sold on prescription and OTC. The parties submit that there is significant competition between OTC and prescription pharmaceuticals in the antihistamines market. Patients continue to ask physicians to prescribe antihistamines even after they have become available OTC as the vast majority of OTC anti-histamines are semi-ethical drugs which can be reimbursed when purchased on prescription. Therefore, the parties submit that an assessment of the R6A market should take into account sales of both prescription and OTC antihistamines.

14. Based on IMS data for the ATC 3 Class R6A in Germany, the combined firm share is [20-30]% in value (with Schwarz adding [0-10]% to UCB's [20-30]%) and [20-30]% in volume (with Schwarz adding [0-10]% to UCB's [10-20]%). On a narrow segment limited to prescription R6A in Germany, the combined firm share is [30-40]% in value (with Schwarz adding [0-10]% to UCB's [30-40]%) and [40-50]% in volume (with Schwarz adding [0-10]% to UCB's [30-40]%).

15. Post-transaction the combined entity would still face significant competition from other companies such as Schering Plough ([20-30]%), Sanofi-Aventis ([10-20]%), Almirall Prodesfarma ([0-10]%), as well as from generic producers of prescription antihistamines. Moreover the transaction would not affect the number of prescription antihistamine compounds available in Germany as the molecule sold by Schwarz, mizolastine is marketed in parallel by Sanofi-Aventis.

16. Based on IMS data for the prescription R6A segment in the United Kingdom, the combined firm share would be [10-20]% (with Schwarz adding [0-10]% to UCB's [10-20]% share). The transaction would thus result in a relatively small increase of UCB's share. The market investigation confirmed that post-transaction the parties will be subject to a significant competitive pressure from other originator competitors and generics producers and did not identify any further competition problems in both Germany and the UK. Based on the foregoing the Commission considers that the transaction would not impede effective competition on the antihistamines market neither in Germany nor in the UK.

N3A (antiepileptics) – Belgium, Ireland, Spain, Netherlands, Greece, Austria, Germany, Italy, Luxembourg and the UK

17. In all three prior Commission decisions involving antiepileptic drugs ("AEDs"), the Commission has considered that the relevant product market corresponded to the ATC

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6 Case COMP/M. M.3354 – Sanofi-Synthelabo/Aventis, at §23; and Case COMP/M.1378 – Hoechst/Rhone Poulenc, at § 55

7 Case COMP/M.3751 – Novartis / Hexal § 86

3 Class N3A[8]. The market test in this case confirmed the appropriateness of N3A market definition for antiepileptics. In Sanofi/Synthelabo, the Commission also considered a potential distinction (i) between AEDs approved for the treatment of partial seizures and those approved for the treatment of generalised seizures; and (ii) between AEDs indicated for use as monotherapy and those approved for use as an adjunctive therapy only. However, the Commission left the exact product market definition open. In any case, in the present case the market definition can be left open as the transaction does not give rise to any competition concerns irrespective of market definition.

18. UCB is active in the N3A market through its levetiracetam molecule, which was launched in the EEA in 2000 and is sold under the brand name Keppra. In Europe, Keppra has obtained approvals for both adjunctive therapy and monotherapy for the treatment of partial seizures. and some generalised seizures[9]. Schwarz has an exclusive license to develop and market lacosamide ("LCM"), a compound currently in Phase III clinical trials for the treatment of neuropathic pain, as well as epileptic seizures. LCM is currently projected to be launched for the adjunctive therapy treatment of partial epileptic seizures in […]. […].

19. UCB's share of the value of total sales of AEDs, exceeds 15% in the following countries: (i) Belgium – [30-40]% ([0-10]% by volume); (ii) Ireland – [20-30]% ([0-10]% by volume); (iii) Spain – [20-30]% ([0-10]% by volume); (iv) the Netherlands – [20-30]% ([0-10]% by volume); (v) Greece – [20-30]% ([0-10]% by volume), (vi) Austria – [10-20]% ([0-10]% by volume); (vii) Germany – [10-20]% ([0-10]% by volume); (viii) Italy – [20-30]% ([0-10]% by volume); (ix) Luxembourg – [10-20] %[10] and (x) the UK – [10-20]% ([0-10]% by volume). The parties submit that market shares based on the number of prescriptions issued, i.e. by volume, are more indicative of market position than market shares based on value for the prescription N3A market given that the vast majority of AED prescriptions are for generic pharmaceuticals sold at a significantly lower price than the few remaining patented AEDs.

20. Even assuming that LCM will be successfully brought to the market in […] the parties submit that proposed transaction would not eliminate a unique competitive force, since: (i) LCM is only one of several new AEDs in development; (ii) […] (iii) the doctors are reluctant to unnecessarily switch patients from an existing treatment to a new AED; (iv) UCB faces a number of direct competitors in the provision of adjunctive therapy and monotherapy[11]; (v) Keppra goes off-patent in 2010 when it will start to face significant competition from generic levitacetam. The market investigation confirmed the parties' views outlined above, in particular most of the respondents confirmed that, to their knowledge, LCM is being developed for adjunctive therapy and will face competition from a number of oncoming pipeline products. Therefore, in view of the foregoing, the

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8 Case No COMP/M.1397 – *Sanofi/Synthelabo*, at § 63; Case No COMP/M.1846 – *Glaxo Wellcome/SmithKline Beecham*, at § 61; Case No COMP/M.3354 – *Sanofi-Synthelabo/Aventis*, at § 101

9 Although Keppra is awaiting approval for the treatment of primary generalized tonic clonic seizures (PGTCS),

10 Volume figures are not available

11 Including GSK (Lamictal), Pfizer (Neurontin and Lyrica), Novartis (Tegretol and Trileptal), Johnson & Johnson (Topamax), Sanofi-Aventis (Depakine), Eisai (Zonegran) and Cephalon (Gabitril).

Commission considers that the transaction would not impede effective competition on the antiepileptics market.

C1D (Coronary Therapy Excluding Calcium Antagonists and Nitrates) – prescription - Germany

21. In previous decisions, the Commission has defined the relevant product market for coronary therapy drugs as corresponding to the ATC 3 Class C1D[12]. The C1D market includes nitrates only when indicated for angina pectoris, as well as positive isotropic agents and all other cardiac preparations. The market test in this case largely confirmed this market definition.

22. Based on IMS data, the parties' combined firm share in prescription C1D in Germany is [20-30]% in value (with Schwarz adding [0-10]% to UCB's [20-30]%) and [10-20]% in volume (with Schwarz adding [0-10]% to UCB's [10-20]%).

23. Schwarz' activities in this market are limited to the production and marketing of a generic molecule, molsidomine, which is marketed by each competing supplier of coronary therapy drugs in Germany. Thus, the transaction would not affect the number of coronary therapy compounds available on the market in Germany. Moreover, barriers for new suppliers to start production of molsidomine are low given that the molecule is no longer patented. The market investigation did not identify any competition problems. Therefore, in view of the foregoing, the Commission considers that the transaction would not impede effective competition on this market.

B3A (haematinics, iron and all combinations) – Finland OTC

24. Haematinics, iron and all combinations encompass all substances/products used in the treatment/prevention of iron deficiencies, which can cause anaemia, a deficiency of red blood cells. In a previous decision, the Commission defined the relevant product market for haematinics, iron and all combinations as corresponding to the ATC3 class B3A[13]. Most of the respondents to the market test in this case agreed with this market definition. A small number of respondents pointed out that the market could be further broken down following ATC4 classification. The market definition can be left open in this case as the transaction even with the narrower product definition does not give rise to competition concerns.

25. Although the combined entity would hold a leading share in Finland [70-80]% (with UCB adding [0-10]% to Schwarz's [70-80]%), the transaction would not significantly impede effective competition on the haematinics, iron and all combinations market. Iron ferrous and folic acid are not patented - the parties commercialize the same off-patent substance under different brand name[14]. Thus the transaction would not provide UCB with control over key inputs or technologies that would impede the ability for competitors to expand or reposition.

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12 Case COMP/M.3354 – Sanofi-Synthelabo/Aventis, at § 23, Case COMP/M.1378 Hoechst/Rhone-Poulenc, at § 55. There is no ATC 4 class according to the EphMRA classification for C1D.

13 Case No IV/M2312 Abbott/BASF, 22/02/2001, at § 13

14 […]

26. Moreover the existing overlap will be completely removed as UCB, independently of the proposed transaction, has ceased production of its compound – Spartocine in the first quarter of 2006 and its Finnish sales are only of its remaining stock[15].

R1B or wider (systemic nasal preparations) – Spain OTC

27. Systemic nasal preparations include all preparations indicated primarily for rhinitis, allergic rhinitis, sinusitis, catarrh, nasal congestion and other similar conditions. In a recent decision[16], the Commission left the exact market definition open pointing that the relevant product market for systemic nasal preparations may be larger than ATC3 class R1B. The parties believe that systemic nasal preparations should be part of a wider cold and flu product markets comprising R4A (chest rubs and other inhalants), R1A7 (nasal decongestants), R1A9 (other topical nasal decongestants), and R5A (cold preparations without anti-infectives). A number of respondents to the market test did not agree with the larger market definition proposed by the parties. In any case it can be left open as the transaction even with the narrower product definition does not give rise to competition concerns.

28. On a market comprising OTC R4A, R1A7, R1A9 and R5A in addition to R1B, the parties' combined share is [0-10]% with Schwarz adding [0-10]% to UCB's [0-10]% in value and [0-10]% in volume with Schwarz adding [0-10]% to UCB's [0-10]%. Based on IMS data for OTC R1B, the parties' combined market share would be [10-20]% in value (with Schwarz adding [0-10]% to UCB's [10-20]%) and [10-20]% in volume (with Schwarz adding [0-10]% to UCB's [10-20]%).

29. The Commission considers that the transaction would not impede effective competition, even on a narrow market limited to the R1B class since: (i) post-merger the combined entity would face strong competition from at least twelve competitors including Almirall Prodesfarma, Aldo Union, Schering-Plough, each holding more than 15% market share, (ii) Schwarz provides a minor increment to UCB's market share. The market investigation did not identify any competition problems even on a narrower R1B market.

C4A (cerebral and peripheral vasotherapeutics) – Germany - prescription

30. Cerebral and peripheral vasotherapeutics are used primarily to improve arterial circulation, in particular for the treatment of cerebral vascular diseases or peripheral circulatory disorders excluding venous diseases. In previous decisions, the Commission defined the relevant product market for cerebral and peripheral vasotherapeutics as corresponding to the ATC3 class C4A[17]. The market test in this case unequivocally confirmed this market definition..

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16 Case COMP/M4007 Reckitt Benckiser/Boots Healthcare International

17 COMP/M3354 Sanofi-Synthelabo/Aventis, at § 75

31. Based on 2005 IMS data, the combined market share is [30-40]% in value (with UCB adding only [0-10]% to Schwarz [30-40]%) Per IMS, the combined share in volume is [0-10]% (each of Schwarz and UCB holding [0-10]%)[18].

32. The transaction would not give rise to any competition concerns as the overlap is minimal and will be removed completely as UCB ceased marketing its C4A compound in Germany in December 2005 and even before this decision was taken it held only a very small market share in this market.

R3F (Combinations of B2 stimulants and corticoidis) – Germany - prescription

33. Combinations of B2-Stimulants and Corticoids are indicated to simultaneously prevent asthma attack and chronic obstructive pulmonary disease (COPD) and also to relieve the symptoms of such conditions. In its previous decisions discussing the R3 market in detail, the Commission has left the market definition open, while undertaking its competitive assessment at the ATC 2, ATC 3 and ATC 4 levels[19]. Most of the respondents to the market test in this case confirmed that R3F is the appropriate market definition, while a small number of market players pointed out that R3 could be a more appropriate delimitation of the market.

34. The parties' combined market shares in the ATC 2 R3 market are very small and not conducive to any competition concerns. Schwarz, which sells Atmadisc, holds a limited market share in the prescription R3F market in Germany [10-20]% based on value ([10-20]% based on volume). Its market share is similar even at the narrowest ATC-4 level R3F1- Combinations of B2-Stimulants and Corticoids, inhalants), where it holds a limited share of [10-20]% based on value ([10-20]% based on volume).)[20]. UCB has not been present on this market, so far, however it is about to launch a new compound, Innovair. According to the parties, UCB's share based on Innovair is estimated to remain below 10% in Germany in the next five years. Based on this share estimate, UCB's postmerger share would remain below 25%. Moreover the compound sold by Schwarz (Atmadisc) is marketed in parallel by GSK under a different brand name (Viani). In addition, UCB will face competition from GlaxoSmithKline holding a share of [40-50]% ([40-50]% in volume) and AstraZeneca holding a share of [40-50]% ([40-50]% in volume). The market investigation confirmed the parties' view that the newly launched compound is not likely to gain quickly a significant market share and did not identify any further competition problems. Therefore, in view of the foregoing, the Commission considers that the transaction would not impede effective competition for combinations of B2 stimulants and corticoidis.

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18 There is a substantial difference between the volume (prescription) and value (retail sales) share data for C4A as reported by Intercontinental Medical Statistics (IMS) based on the fact that IMS does not report volume (prescription) data at the hospital level. Hospital sales account for the […] majority […] of sales made by Schwarz. Conversely, other suppliers may supply a proportionally larger amount to pharmacies, which are reflected in the IMS volume data, resulting in a larger volume share for those suppliers.

19 COMP/M.1846 – Glaxo Wellcome/ SmithKline Beecham; at § 150 and following; case M.3928 TEVA/IVAX, § 33.

20 IMS classifies all R3F pharmaceuticals within the same ATC 4 class in Germany, notably R3F1. IMS does not report sales or prescriptions for other ATC 4 classes in Germany. Therefore, the total volume/value of the R3F market in Germany is identical to the volume/value of a hypothetical market limited to R3F1 pharmaceuticals in Germany.

VI. CONCLUSION

35. 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 (EC) No 139/2004.

For the Commission
signed
Neelie KROES
Member of the Commission