Case No COMP/M.4418 - NYCOMED GROUP / ALTANA PHARMA

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REGULATION (EC) No 139/2004 MERGER PROCEDURE

Article 6(1)(b) NON-OPPOSITION
Date: 13/12/2006

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Office for Official Publications of the European Communities
L-2985 Luxembourg
To the notifying party

Dear Sir/Madam,

Subject: Case No COMP/M.4418 - NYCOMED GROUP / ALTANA PHARMA
Notification of 8.11.2006 pursuant to Article 4 of Council Regulation
No 139/2004¹
Publication in the Official Journal of the European Union No. C283, dated

1. On 08/11/2006, the Commission received a notification of a proposed concentration by
which Nycomed Group (“Nycomed”), a Danish pharmaceutical company acquires sole
control over Altana Pharma AG (“Altana Pharma”), a German pharmaceutical
company.

I. THE PARTIES AND THE CONCENTRATION

2. Nycomed and Altana AG concluded the SPA on 20 September 2006 by which
Nycomed will take over 100% of the issued and outstanding shares in Altana Pharma.
The acquisition of 100% of Altana Pharma’s shares, will confer to Nycomed sole
control over Altana Pharma. Therefore the transaction constitutes a concentration
under the Merger Regulation.

3. Nycomed manufactures and markets hospital products throughout Europe, and general practitioner and over-the-counter medicines in selected European countries. Nycomed is jointly controlled by Nordic Capital Fund V ("Nordic Capital", Jersey) and Credit Suisse Group ("CSG", Switzerland), which together hold [...] of the shares of Nycomed\(^2\).

4. Altana Pharma researches, develops, manufactures and sells pharmaceuticals with focus on innovative medicines for gastrointestinal and respiratory diseases, self-medication products and medical imaging. Altana Pharma is active in Europe and in South America;

5. Nordic Capital is a Jersey-based private equity fund which holds investments in companies in various industries. The parties submit that none of the companies controlled by Nordic Capital, with the exception of Nycomed, is active on any of the affected markets or otherwise overlaps with Altana Pharma’s activities\(^3\).

6. CSG is a global financial services group providing a range of banking and insurance products, including investment banking services. The parties submit that none of the companies controlled by CSG, with the exception of Nycomed, is active on any of the affected markets or otherwise overlaps with Altana Pharma’s activities.

II. COMMUNITY DIMENSION

7. The notified concentration meets the turnover thresholds of Article 1(2) of the Merger Regulation. The combined turnover of the undertakings concerned globally exceeds 5 billion euros (Nycomed\(^4\) [...] billion, Altana Pharma [...] billion), with the aggregated Community-wide turnover of each of the two parties being more than 250 million euros (Nycomed [...] million, Altana Pharma [...] million). None of the parties achieves more than two-thirds of its aggregated Community-wide turnover within one Member State. The Transaction thus has a Community dimension.

III. THE RELEVANT MARKETS

8. In previous decisions, the Commission has held that product markets in the pharmaceutical industry may be grouped into (a) existing pharmaceutical specialties, (b) active substances, and (c) future products. This transaction only concerns pharmaceutical specialties as there are no overlaps between the parties, whether horizontally or vertically, for the other possible subdivisions.

9. In previous decisions, the Commission has as a starting point used the Anatomical Therapeutic Classifications ("ATC") devised by the European Pharmaceutical Marketing Research Association ("EphMRA") and has stated that the third level of the

\(^2\) Nordic Capital holds [...] and CSG holds [...] of the shares of Nycomed. See case COMP/M.3755, Nordic Capital/Nycomed, 19/04/2005

\(^3\) On 1 September 2006 Nordic Capital, jointly with Apax Partners, launched a public bid for all the outstanding shares in Capio AB ("Capio"). Capio is active within private acute hospital services, private psychiatric hospital services and public/private healthcare outsourcing services. The parties submit that any links between Altana Pharma and Capio will be addressed in the merger notification to the Commission for the acquisition of joint control over Capio, and consequently these issues are not addressed in this note.

\(^4\) Including Nordic Capital and the CSG’s turnover figures.
ATC classification allows medicines to be grouped in terms of their therapeutic indications and can therefore be used as an operational starting point for market definition. However, the Commission has also recognized that in certain cases it may be necessary to analyze pharmaceutical products at a higher, lower or mixed level or to further subdivide the ATC classes on the basis of demand-related criteria.

10. The Commission has in the past, where it was possible and relevant, further subdivided pharmaceutical products into separate markets for OTC pharmaceuticals (pharmaceutical products which can be sold over the counter as opposed to prescription) due to differences in their accessibility for patients, medical indications, legal framework, marketing and distribution.

11. Also, in the previous Commission’s practice originator drugs and generics (off-patent drugs) were considered to be close substitutes for a given indication. Generics are often fully substitutable from the customer's or the prescribing doctor's point of view. Once the relevant patent protection has expired, the assessment of the competitive situation in any given market for pharmaceutical specialties has to take into account the fact that originator drugs are exposed to generic competition.

12. With regard to the geographic scope of the markets, the Commission has in previous decisions held that the relevant geographic market for pharmaceutical products including OTC products was national in scope. The argument has been that whilst the harmonization of technical legislation and marketing authorization proceedings at EU-level has contributed to the creation of an EU-wide market for pharmaceutical products, such an EU-wide market is still imperfect. Variations between Member States in relation to price setting, conditions of reimbursement and channels of distribution mean that, geographically, the market for pharmaceutical products is still national in many ways. The notifying party agrees with previous Commission practice.

13. The parties submit that Nycomed’s and Altana Pharma’s businesses are highly complementary and hence the overlap between their activities is limited. According to the parties, the transaction will lead to only one market where the combined market shares exceed 15%, namely proton pump inhibitors (“PPIs”). On the basis of a narrower product definition, which is contested by the parties, the tonics market would also be in excess of 15%.

14. Apart from the products listed above, the parties submit that their activities overlap to limited extent on six relevant product markets. These are: C1C (Cardiac stimulants excluding cardiac glycosides) in Germany, C4A (Cerebral and peripheral vasotherapeutics) in Germany, G4B (Other urological preparations) in Austria, M1A

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5 Case IV/M.1378, Hoechst/Rhône Poulenc, 09/08/1999; Case COMP/M.1835, Monsanto/Pharmacia & Upjohn, 30/03/2000; Case COMP/M.1846, Glaxo Wellcome/SmithKline Beecham, 8/05/2000; and Case COMP/M.1878, Pfizer/ Warner-Lambert, 22/05/2000.
8 According to the previous Commission’s decisions the relevant product market could be defined on the ATC 4 level (G4B3 – erectile dysfunctional products, G4B4 – urinary incontinence products). In such a case, no overlap exists. See: Case COMP/M.3544, Bayer Healthcare/Roche (OTC business), 19/11/2004.
9 Case IV/M.349, Yamanouchi/Fujisawa; Case IV/M.457, La Roche/Syntex; Case IV/M.950, Hoffmann La Roche/Boehringer Mannheim; and Case IV/M.1378, Hoechst/Rhône Poulenc.
(Antirheumatics, non-steroidal) in Belgium, M2A\(^{10}\) (Anti-rheumatics) in Austria, R3B (Xanthines)\(^{11}\) in Belgium. However on none of these markets both at ATC3 and ATC 4 levels the parties’ aggregated market shares exceed 10% (in most of these markets they are below 5%) and hence no competition concerns arise.

**A2B: Antiulcerants**

15. The anti-peptic ulcer category encompasses a variety of drugs used to treat a range of common disorders considered to be related to acid secretion by the stomach. These disorders notably include dyspepsia, peptic and duodenal ulcer diseases as well as gastroesophagel reflux disease. In the previous decisions, the Commission has analyzed this market on both ATC 3 (A2B - antiulcerants) and ATC 4 levels (A2B1 - H2 antagonists and A2B2 - acid pump inhibitors)\(^{12}\). In AstraZeneca\(^{13}\), the most recent pharmaceutical antitrust decision, after an overall in-depth investigation the Commission defined a separate relevant product market at the ATC 4 level for proton pump inhibitors ("PPIs") and separated from H2 blockers inter alia based on different modes of action, the different positions of PPIs and H2 blockers in the hierarchy of anti-peptic ulcerants, significant price differences, significant differences in sales, a one way substitution pattern in favour of PPIs. Based on its overall assessment the Commission concluded that H2 blockers were not able to exercise a significant competitive constraint on PPIs during the relevant years and in the geographic markets concerned.

16. In the present case, the parties submit that two of the potential sub-segments of the antiulcerant class: H2 antagonists and acid pump inhibitors are substitutable, at least to a certain extent. According to the parties, H2 blockers, which are the earlier generation of antiulcerants, can be substituted by the more recently launched PPIs. However, the same can not be said regarding substitution the other way around, mainly because the efficiency of the PPIs is superior when compared to the H2 antagonists.

17. In the current market investigation, most of the respondents to the market test considered that acid pump inhibitors (classified at A2B2 level) are not substitutable by H2 antagonists (classified at A2B1 level), since the former are more efficient by virtue of their more precise and potent mode of action, can be taken only once a day and have higher price reflecting their acknowledged therapeutic superiority. However, in this case, despite the fact that arguments in favour of a product market definition comprising only PPIs are prevailing, the market definition can be left open as the transaction does not give rise to serious competition problems irrespective of the product market definition.

**A13A and A11A: Tonics and vitamins with minerals**

10 Case IV/M.464, BMSC/UPSA and Case IV/M.500, American Home Products/American Cyanamid.
11 The Commission has previously considered the R3B market on an ATC-3 level in Case IV/M.632 Rhône-Poulenc Rorer/Fisons, 21/09/1995.
13 Case COMP/A.37.507/F3 – AstraZenca, 15/06/2005
18. Tonics and vitamins with minerals are largely OTC products for the general well-being, such as supplements of various kinds that have beneficial health-effects. Both parties are active in tonics’ market, which fall into A13A category according to the ATC level 3 classification. In previous Commission decisions, the competitive assessment was made at the A13A level.

19. However, according to the parties’ view, products in the A13A class are in closest competition with the multivitamins in the A11A class. Sales of tonics and multivitamins are mainly driven by marketing and tonics and multivitamins are perceived as substitutable by the end-users and they are sold through the same channels, namely pharmacies and retail stores. Most of the respondents to the market test supported the parties' view that the combination of A13A and A11A is more relevant product market definition. However, for the purpose of this case, the final market definition can be left open as the transaction does not give rise to serious competition problems irrespective of product market definition.

IV. ASSESSMENT

A2B: Antiulcerants/ A2B2 - proton pump inhibitors

20. In the area of acid-related gastrointestinal diseases, Altana Pharma is present with Pantoprazole, a proton pump inhibitor (PPI) which still enjoys substance patent protection. Pantoprazole, like most PPIs in the A2B2 category, are sold under prescription only.

21. The parties’ activities overlap in Austria and Belgium […]. The parties submit that the concentration will not lead to a reduction of quantity or quality of the compound.

22. In Austria, the parties’ products include Altana Pharma’s Pantoloc and Nycomed’s Zurcal. Altana Pharma manufactures Zurcal on behalf of Nycomed which then purchases the product from Altana Pharma and markets it independently from Altana Pharma. In 2005, on the A2B2 market (acid pump inhibitors) the combined entity would achieve market share of [50-60%] (Altana Pharma [40-50%] and Nycomed [10-15%]) measured in value. The parties' main competitors include: Astra Zeneca [15-20%], Takeda [10-15%], Johnson&Johnson [5-10%] and Novartis [5-10%]. If a wider market A2B is taken into account the combined entity would achieve market shares of [40-50%] (Altana Pharma [30-40%] and Nycomed [10-15%]) measured in value as a proportion of all sales within the A2B area. The parties' main competitors include: Astra Zeneca [15-20%], Takeda [5-10%], Johnson&Johnson [5-10%] and Novartis [5-10%].

23. In Belgium, Altana Pharma and Nycomed market Pantozol and Zurcal respectively. The arrangement between the parties is the same as in Austria. In 2005, on the A2B2 market the combined entity would achieve market share of [20-30%] (Altana Pharma [10-15%] and Nycomed [10-15%]) measured in value. On a wider A2B market, the combined entity would achieve market shares of [20-30%] (Altana Pharma [10-15%]

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14 Case IV/M.464, BMSC/UPSA, 06/09/1994 ; Case IV/M.457, La Roche/Syntex, 20/06/1994. Also, The Commission recently rejected in the Case COMP/M.3354 Sanofi-Synthelabo/Anetis, 26/04/2004, a proposed combined market for A11F (plain Vitamin B12), A11A, A11B, and A13A, on the basis that plain Vitamin B12 was indicated for a treatment of certain diseases, and not tonics or vitamin complexes including Vitamin B12.
and Nycomed [10-15%]) measured in value. The PPI market in Belgium is characterized by a large number of competitors, including generics manufacturers. The main competitors in Belgium are AstraZeneca [20-30%] with Losec (active substance Omeprazol, which went off patent in Belgium in 2001) and Nexium (based on an isomer of omeprazole, Esomeprazole), Sanofi-Aventis [5-10%] with its product Dakar, licensed from Takeda, Merck [15-20%], Stada [5-10%] as well as Johnson & Johnson [5-10%] with Pariet (active substance Rabeprazole).

24. Although the parties' combined market shares in the PPI markets especially in Austria are high, the transaction would not result in a significant impediment to effective competition. The combined entity would still face competition from other large pharmaceutical companies selling PPIs as well as generics producers selling PPIs whose substance patent protection has expired (such as omeprazole).

25. First, the parties' PPI compound approaches the expiry of patent protection […] and consequently the generic copies are bound to erode the parties' market position. The generic producers confirmed in the market test that they are interested in marketing generic pantoprazole after the patent expiry. Second, the parties expect entry of new versions of the PPIs, which are currently either in the latest stage of development or available in different geographic areas. The market test confirmed that there are new PPI products in the pipeline which include originators, which can be therapeutically more effective than pantoprazole and generic copies of other compounds which will exert downwards price pressure.

26. According to the parties' submission and partly confirmed by the market investigation, the fact that prices are negotiated with health authorities, which have a degree of buyer power in light of the array of therapeutically comparable products available, may have an impact on the ability of the merged entity to raise prices in Austria and Belgium. Moreover, in the two countries concerned the prices for original products must fall to the lower price levels of generics as soon as generic product enters the market. For the above reasons, the present transaction therefore does not give rise to any competition concerns on the market for PPIs.

**A13A and A11A: Tonics and vitamins with minerals**

27. On the combined market for tonics and vitamins (A13A and A11A) in Austria, the parties' combined market share is [5-10%] (Altana Pharma -[5-10%], Nycomed – [0-2%]) measured in value.” If only sales to pharmacies were taken into account, the parties’ combined market share would increase to [15-20%] (Altana Pharma – [15-20%], Nycomed – [0-2%]). On the narrower market for tonics (A13A), based on estimated sales through both pharmacies as well as other sales channels, the parties’ combined share is [20-30%], with the overlap of [0-2%] (Nycomed). However, if only pharmacies’ channel was considered, the parties' combined market share would be much higher ([40-50%] with [30-50%] - Altana Pharma, [0-5%] - Nycomed).

28. Irrespective of market definition the transaction would not raise any competition problems in the tonics market. Even in the narrowest market, the parties will continue to face competition from strong players, including Kwizda [20-30%], MedPharma

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15 This market share is based on adjusted figures that take into account sales made by pharmacies and sales through smaller pharmacies, supermarkets, drug stores that according to the parties’ estimates constitute half of the all sales.
[10-15%], Boehringer [5-10%]. If the sales to pharmacies where considered as a separate market the constraint from so called "mass-market" would be considerable. Tonics sales are mainly driven by marketing rather than by specific treatment indications or breakthrough formulations. Therefore the entry into this market is easy which is reflected by the wide penetration of private labels offered by supermarkets and drugstore chains. This was largely confirmed by the market investigation.

V. CONCLUSION

29. 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