EN

Case No COMP/M.4049 - NOVARTIS / CHIRON

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REGULATION (EC) No 139/2004
MERGER PROCEDURE

Article 6(1)(b) NON-OPPOSITION
Date: 06/02/2006

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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 Where possible the information omitted has been replaced by ranges of figures or a general description.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 Madam/Sir,

Subject: **Case No. COMP/M.4049 – Novartis / Chiron**

Notification of 23/12/2005 pursuant to Article 4 of Council Regulation No 139/2004[1] **("Merger Regulation")**

1. On 23/12/2005, the Commission received a notification of a proposed concentration pursuant to Article 4 of Council Regulation (EC) No 139/2004 by which the undertaking Novartis AG ("Novartis", Switzerland) acquires within the meaning of Article 3(1)(b) of the Council Regulation control of the whole of the undertaking Chiron Corporation ("Chiron", United States) by way of purchase of shares.

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

I. THE PARTIES AND THE OPERATION

3. Novartis is a Swiss-based pharmaceutical company that was created through the merger of Ciba-Geigy and Sandoz in 1996[2]. Novartis is the holding company of a multinational group of companies active in the development, production and distribution of medical products, including prescription drugs, over-the-counter ("OTC") drugs and animal health products.

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[1] OJ L 24, 29.1.2004 p. 1.

[2] See Case COMP/M.737 Ciba-Geigy / Sandoz

4. Chiron is a US-based biotechnology company active in blood testing products, biopharmaceuticals and human vaccines. Chiron´s blood testing business develops, manufactures and markets a range of blood screening products (equipments and reagents) whereas Chiron´s biopharmaceuticals business develops, manufactures and markets a range of therapeutic products, focussing on oncology products and treatment of infectious and pulmonary diseases. Chiron´s vaccines business develops, manufactures and markets vaccines, including influenza, meningococcal, paediatric and travel vaccines.

5. Prior to the proposed transaction, Novartis already holds a 42.2% interest in Chiron while the remaining shares are held by private investors. According to the parties, Chiron is independently governed, managed and operated so that Novartis does not exercise any decisive influence on Chiron's business decision and therefore does not control Chiron at present[3].

6. On 30/10/2005, Novartis and Chiron entered into an Agreement and Plan of Merger whereby Novartis shall acquire all of the outstanding shares of Chiron it does not already own.

II. CONCENTRATION

7. Under the proposed transaction, Novartis will acquire sole control over Chiron and the proposed transaction therefore constitutes a concentration within the meaning of Article 3(1)(b) of the Merger Regulation.

III. COMMUNITY DIMENSION

8. The combined aggregate worldwide turnover of the undertakings concerned exceeds EUR 5 billion (Novartis: EUR 24,4 billion, Chiron: EUR 1,4 billion, in 2004). The aggregate Community-wide turnover of the undertakings concerned exceeds EUR 250 million (Novartis: EUR […] billion, Chiron: EUR […] million, in 2004). The undertakings concerned do not achieve more than two-thirds of their aggregate Community-wide turnover in one and the same Member State. The concentration therefore has a Community dimension according to Article 1(2) of the Merger Regulation.

IV. RELEVANT MARKETS

9. The operation concerns the blood testing, human vaccines and biopharmaceuticals sectors.

A. Relevant product markets

In previous decisions, the Commission noted that medicines may be subdivided into therapeutic classes by reference to the "Anatomical Therapeutic Chemical" classification (ATC), devised by European Pharmaceutical Marketing Research Association (EphMRA) and maintained by EphMRA and Intercontinental Medical Statistics (IMS). The ATC is hierarchical and has 16 categories (A, B, C, D, etc.) each

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[3] See also Case COMP /M.3751 Novartis / Hexal

with up to four levels. The first level (ATC 1) is the most general and the fourth level (ATC 4) the most detailed. The third ATC level allows medicines to be grouped in terms of their therapeutic indications, i.e. their intended use. This level is generally used as the starting point for defining and enquiring about market definition in competition cases. However, it is appropriate to carry out analyses at other ATC levels, or a mixture thereof, if the circumstances of a case show that sufficiently strong competitive constraints faced by the undertakings involved are situated at another level, and that, therefore, there are indications that the third ATC level does not lead to a correct market definition.

Flu vaccines

10. Chiron manufactures and supplies influenza vaccines ("flu vaccines"), pediatric and travel vaccines. With regard to flu vaccines Chiron produces standard vaccines and vaccines designated for persons over the age of 65. Novartis does not produce any vaccines but, to a limited extent, supplies flu vaccines to wholesalers either under its own brand or for third parties, including Chiron.

11. In accordance with the Commission's general approach of using ATC level-3 classification as a starting point for market definition, the parties identified the manufacture and supply of human vaccines to wholesalers (J7A, "pure vaccines") as a possible product market relevant for the assessment of the proposed transaction. Alternatively, the parties suggested using the ATC level-4 classification J7A1 "influenza vaccines" which comprises only vaccines used for the same medical indication, namely vaccines against the human flu.

12. Respondents to the market investigation confirmed to a large extent that a product market comprising only flu vaccines would be more relevant as vaccines intended for other diseases are clearly not therapeutically substitutable to flu vaccines. In any event, the question of whether the relevant product market for the assessment of the proposed transaction is the ATC level-3 J7A class, the ATC level-4 J7A1 class or even narrower (i.e. according to the specific use) may be left open as it does not modify the competitive assessment.

13. Flu vaccines, as other human vaccines, are first manufactured, packaged and labelled and transported to a warehouse. The vaccines are then marketed and supplied to wholesalers but also to hospitals, governments and national or regional public health services or group buying organizations. These sales can be made either (i) directly by the manufacturer, (ii) through agency or distribution type of agreements (brand name of the manufacturer) or (iii) through co-marketing type of arrangements. The parties did not consider that different relevant product markets could be identified along the vaccines supply chain prior the wholesale level as vaccine producers may use different supply structure to market their vaccines. In particular, the parties have submitted that the distribution and marketing of flu vaccines (or vaccines in general) to wholesalers did not constitute a distinct relevant product market. The market investigation has revealed that the supply of flu vaccines to wholesalers is not being regarded as a distinct product market but as one level of distribution into the market for flu vaccines.

14. At any rate, the question of whether, besides the manufacture and supply of human vaccines (or flu vaccines) to wholesalers, the distribution and marketing of human vaccines (or flu vaccines) constitutes a distinct relevant product market may be left

open for the assessment of the proposed transaction as it does not modify the competitive assessment.

Biopharmaceuticals

15. In the biopharmaceuticals sector, the four product categories in which both Novartis and Chiron are active are: (i) multiple sclerosis treatments, (ii) immunosuppressive organ transplant therapy, (iii) aminoglycosides and (iv) cancer treatment. According to the parties, within each of these product categories, a wide range of biopharmaceuticals is used to treat different and unrelated aspects of the respective disease, leading to the definition of narrow product markets.

Multiple sclerosis (MS) treatments

16. MS is an autoimmune disease that affects the central nervous system, causing a wide variety of unpredictable neurological symptoms that result in increasing disability.

17. Within the pharmaceuticals products intended to treat MS, the parties differentiated between (i) disease modifying agents (immunostimulants and immunosupressants), which slow the course of MS disease progression by addressing the immunological causes of MS and (ii) products that relieve certain symptoms of MS patients, without actually slowing the course of the disease. Immunostimulants and immunosuppressants biopharmaceuticals do not share the same ATC level-3 class and a wide array of ATC level-3 classes apply to the range of products treating the various symptoms of MS. The Commission's market investigation has confirmed that immunostimulants, immunosuppressants and other symptomatic treatments belong to separate relevant product markets.

18. However, the relevant product markets in field of MS treatments for the purpose of this case may be left open as it does not modify the competitive assessment. Chiron is only active in the field of immunostimulants products with Betaferon (marketed by Schering) whereas Novartis in not active in the immunostimulants product market.

Immunosuppressive organ transplant therapy

19. Drugs used for immunosuppressive organ transplant therapy are designed to reduce the risk of organ rejection after transplant operations. All such drugs fall under ATC level-3 category L4A "immunosuppressive agents".

20. The parties however submitted that the L4A ATC level-3 could not serve as a basis to define the relevant product market for immunosuppressive agents as this would lead to the inclusion in the same market of products that have entirely different therapeutic purposes, uses and means of administration. The parties submitted that the L4A category should be further subdivided into:

- Primary immunosuppressants for general organ transplant therapy (ie. a primary treatment against organ rejection typically administered immediately following the transplant);

- Induction immunosuppressants for general organ transplant therapy (ie. a product that provides immediate redress in episodes of acute rejection);

- Accompanying immunosuppressants for general organ transplant therapy (ie. a product that is administered complementarily) and

- Accompanying immunosuppressants for specific transplant therapy.

21. In a previous decision[4], the Commission considered a similar approach but the relevant product market definition was finally left open. In the present case, the market investigation confirmed that the four categories identified by the parties corresponded to different types of immunosuppressive agents and could therefore constitute relevant product markets. However, a few respondents also underlined that many immunosuppressant products were used combined for the prevention of rejection after solid organ transplantation and could thus often be used as alternative treatment options for each other.

22. In any event, the question of whether immunosuppressive organ transplant therapy products is the relevant product market for the assessment of the proposed transaction or whether this category should be further subdivided may, however, be left open as it does not modify the competitive assessment.

Aminoglycosides

23. Aminoglycosides are antibiotics designed in particular to treat certain bacteria, so-called Gram-negative bacteria, which are the cause of illnesses such as Salmonella poisoning, meningitis and certain respiratory diseases. Their ATC level-3 classification is J1K, "aminoglycosides".

24. The parties, however, submitted that a product market definition based on the J1K class would lead to the inclusion in the same market of products which have different therapeutic purposes and uses. According to the parties, some aminoglycosides are only admitted for the treatment of specific illnesses. Chiron´s product, *TOBI,* is a medication approved only for the treatment of cystic fibriosis, a genetic disease that causes the body to produce an abnormally thick mucus which clogs the lungs and leads to life-threatening lung infections. *TOBI* is particularly well-suited to treat cystic fibriosis patients since, as an inhaled product, it targets directly the lungs and, as such, allows for more long term treatment without the systemic side effects of intravenous aminoglycosides such as Novartis´ *Gentamicin.* According to the parties, no doctor would therefore prescribe *Gentamicin* as an alternative to *TOBI,* and vice versa. The parties therefore submitted that a narrower product market definition, based on therapeutic purpose and use, must be applied.

25. The market investigation largely confirmed the parties' view that, although in the same ATC level-3 class, *TOBI* and Novartis' aminoglycosides products were not used for the same therapeutic purpose and did not belong to the same relevant product market. However, it is not necessary to further define the precise relevant product market in the field of aminoglycosides products for the purposes of the present case as it does not modify the competitive assessment.

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4 See Case COMP/ M.3751 Novartis / Hexal: distinction between primary immunosuppressants, accompanying immunosuppressants and induction immunosuppressants.

Cancer treatments

26. There is a broad variety of cancer treatment products, with various mechanisms and uses to fight against various and distinct forms of cancer. Chiron's cancer pharmaceutical, *Proleukin*, is used in the treatment of metastatic melamona (skin or renal cell cancer) and belongs to the ATC level-3 class L3A (immunostimulating agents excluding interferons). Neither Novartis nor Hexal– a company recently acquired by Novartis active in oncology products- manufacture or market any cancer treatment product used to treat metastatic melamona or belonging to the same ATC level-3 class.

27. As a consequence the relevant product market in the field of cancer treatment may be left open as it does not modify the competitive assessment.

Blood testing

28. Chiron and Roche, in which Novartis holds a 6.3 % minority stake (33% of voting rights), are both active in blood testing products. Novartis and Roche are however independently managed and Novartis' minority stake does not enable it to exert any decisive influence on Roche's business decisions.

29. As a consequence the relevant product market in the field of blood testing may be left open as it does not modify the competitive assessment.

B. Relevant geographic markets

30. In line with the Commission's previous decisions, the parties considered that all the relevant product markets mentioned above are national in scope.

31. With respect to the manufacture and supply of human vaccines to wholesalers the parties noted that vaccines manufacturers typically produce vaccines for the whole EU in only one or few member states. However, on the demand side, the supply of vaccines to wholesalers is affected by different national regulations and reimbursement systems in each member state, which confer to those markets a national dimension. The market investigation has confirmed that market characteristics, distribution channels and sales patterns for flu vaccines vary significantly among countries.

32. Therefore, all the relevant product markets mentioned above will be considered as national in scope for the purpose of the present case.

V. COMPETITIVE ASSESSMENT

33. The Commission came to the conclusion that the proposed transaction was not likely to impede effective competition in any of the product markets presented above in view of the absence or the very limited extent of competition or potential competition between Novartis' and Chiron's product offering before the transaction.

Flu vaccines

34. Chiron manufactures and supplies several influenza vaccines such as *Begrivac, Fluad, Aggripal, Addigrip* and *Flurivin* throughout the EU, but not in Austria. Novartis does not manufacture any influenza vaccines itself but supplies *HEXAL* under license from GlaxoSmithKIine in Germany, Chiron´s *Aggripal* under its own *Sandovac* brand in Austria, as well as Chiron´s *Begrivac* and *Fluad* in Austria.

35. As regards the German market, the license agreement between Novartis and GlaxoSmithKline regarding the supply of *HEXAL* in Germany will be terminated after the 2005/2006 flu season. As a consequence thereof, Novartis will entirely exit the market for flu vaccines in Germany and any overlap with Chiron products will cease to exist.

36. In Austria, there is no overlap between the parties as only Novartis (but not Chiron) is active. If a separate product market for the distribution and marketing of human or flu vaccines is considered, a vertical relationship would exist between Chiron and Novartis but the transaction would still not have any material impact on the Austrian market as Chiron's flu vaccines are already distributed and marketed by Novartis prior to the transaction.

37. In view of the above, the transaction does therefore not result in any competition concerns on this market.

Biopharmaceuticals

38. As indicated above, the transaction does not give raise to any overlap in the fields of (i) multiple sclerosis and (iv) cancer treatment.

Immunosuppressive organ transplant therapy

39. Novartis is active in various member states with a number of immunosuppressive agents, including *Sandimmun, Neoral*, *Simulect*, *Certican* and *Myfortic*. However, Chiron has currently no immunosuppressant agent on the market. It has one product, *Pulminiq,* which is currently in Phase III of clinical trials. In Phase III, drugs typically have only a 50% chance of making it to the market so that any overlap between the parties´ activities in immunosuppressants is at present only potential.

40. In addition, it should be noted that Chiron is developing *Pulminiq* under an exclusive licence from Novartis […]. The parties have therefore even before the notified operation not competed in this product. Finally, even if *Pulminiq* eventually makes it to the market, the parties submitted that Novartis´ products and *Pulminiq* would by no means be close substitutes. *Pulminiq* would be an accompanying immunosuppressant, specifically for lung transplant patients while Novartis´ *Sandimmun, Neoral* and *Sinulect* on the other hand are primary and induction immunosuppressants and *Certican* and *Myfortic,* both accompanying immunosuppressants, are intended for organ transplant patients generally and kidney transplant patients. As a result, the parties submitted that only a small number of patients of those who are currently prescribed *Certican* could be administered *Pulminiq* as an alternative.

41. The market investigation confirmed that *Pulminiq* and Novartis' immunossupressant products were not intended to have the same therapeutical effect. However, a few respondents underlined that both *Sandimmun / Neoral* and *Pulminiq* could be used in

the niche application of lung transplantation either as alternative treatment or combined. In view of the existence of alternative primary immunosupressants and of *Pulminiq* current stage of development (Phase III) and specific design as inhalant for lung transplant patients, the potential competition between *Sandimmun / Neoral* and *Pulminiq* would have been in any event very limited. The market investigation did not raise any concern that the proposed transaction would have a material impact on competition in the field of immunosupressants.

Aminoglycosides

42. Both Novartis (*Gentamicin,* marketed as *Servigenta* in Denmark) and Chiron (*TOBI*) are active in aminoglycosides biopharmaceuticals in various member states. Chiron has also an aminoglycoside (*TIP*) under development which is currently in Phase III of clinical trials. According to the parties, *TIP* has a 50-70% chance of final approval. Any overlap between *TIP* and *Gentamicin* is therefore only potential at present. Moreover, *TIP*, like *TOBI* is a drug specifically intended for cystic fibriosis patients.

43. As indicated above, the parties submitted that *TOBI* and *TIP* did / would not compete with Novartis' general aminoglycosides biopharmaceuticals, due to their different therapeutical indication as well as mode of application. The market investigation confirmed that *TOBI* and *TIP* on the one hand and *Gentamicin* on the other hand are not considered as alternative treatments for the same disease and that the transaction would thus not affect competition in the field of aminoglycoside products.

44. In view of the above, the transaction does therefore not result in any competition concerns on this market.

Blood testing

45. As indicated above, Novartis is not active in the field of blood testing products. The market investigation however revealed that Roche, in which Novartis has a 6.3% share, and Chiron were the only two suppliers for a number of blood testing products. Some respondents expressed their concerns about the effect that the proposed transaction could have on the current degree of competition between Chiron and Roche due to Novartis share holding.

46. The Commission carefully assessed these possibilities and came to the conclusion that, Novartis' minority shareholding in Roche was not sufficient (i) to provide Novartis with the ability to exercise a decisive influence on Roche's strategy and decisions in the field of blood testing and (ii) to provide Novartis with the economic incentive to distort competition between Chiron and Roche. The proposed transaction is therefore not likely to affect competition in the field of blood testing.

VI. CONCLUSION

47. 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