EN

Case No IV/M.954 - BAIN / HOECHST - DADE BEHRING

Only the English text is available and authentic.

REGULATION (EEC) No 4064/89
MERGER PROCEDURE

Article 6(1)(b) NON-OPPOSITION
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COMMISSION OF THE EUROPEAN COMMUNITIES

Brussels, 02.09.1997

PUBLIC VERSION

MERGER PROCEDURE
ARTICLE 6(1)(b) DECISION

To the notifying parties

Dear Sirs,

Subject: Case No IV/M.954 - Bain/Hoechst - Dade Behring
Notification of 31.07.1997 pursuant to Article 4 of Council Regulation № 4064/89

1. On 31.07.1997 Bain Capital, Inc. (Bain) and Hoechst AG (Hoechst) notified the creation of a joint venture, Dade Behring Holdings, Inc. (Dade Behring) to which both will contribute their existing in vitro diagnostics business and which will be jointly controlled by both parties.

2. After examination of the notification, the Commission has concluded that the notified operation falls within the scope of Council Regulation (EEC) No 4064/89 and does not raise serious doubts as to its compatibility with the Common market and with the functioning of the EEA Agreement.

I. The Parties

3. Bain is active in a number of areas, including recycled paper, software, drugstores, environmental data services, waste disposal, bicycles, home training equipment, vitamins, sporting goods, rain gear and contact lenses. In the area of diagnostics, Bain holds a 58.2% stake in Diagnostics Holding, Inc. (DH), which in turn holds all the stock of Dade International Inc. (Dade). Dade is a producer of in vitro diagnostics.

4. Hoechst produces and sells chemicals, plastics, dyestuffs, fibres, pharmaceuticals and crop protection products. Its in vitro diagnostics business is conducted through a wholly owned subsidiary, Behring Diagnostics GmbH (Behring).

II. The Operation

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5. The proposed operation consists in the creation of a joint venture to which Bain and Hoechst will contribute their entire in vitro diagnostic businesses. This operation will take place in two steps: DH will acquire Behring and be renamed Dade Behring Holdings, Inc. (DBH). As consideration Hoechst will receive 32.5% of the shares of DBH. After the operation, Bain will hold 39.6% of the shares in DBH, Hoechst will hold 32.5% and GS Capital Partners, L.P., a US limited partnership (GS), will hold 19.8%.

III. Concentration

6. After the transaction the joint venture will be jointly controlled by Bain and Hoechst. GS does not acquire control. DBH will be managed by a Board of Directors consisting of 11 directors, of which 7 will be appointed by Bain, 3 by Hoechst (including the Executive Chairman) and 1 by GS. The Board shall approve the business plan and budget of DBH annually by simple majority voting. This vote is however subject to the condition that no member of the board which has been appointed by Hoechst has voted against it. GS does not possess any veto rights.

7. The joint venture will perform on a lasting basis all the functions of an autonomous economic entity. Dade and Behring are already established full-function enterprises which have been active in the market with own production facilities and sales departments. The JV will not be dependent on its parents for either supply or sales.

8. The joint venture will not create a risk of co-ordination of the parents' competitive behaviour. Both Bain and Hoechst will cease to be active in the JV's market. Bain is not present in any upstream, downstream or neighbouring market. Hoechst is only present in the upstream production of peptides and human plasma. The JV's annual purchases of these two products amount to around ECU [...][1].

IV. Community Dimension

9. Bain, Hoechst and DBH have a combined aggregate worldwide turnover in excess of ECU 5,000 million (Bain [...][2] MECU, Hoechst 26,000 MECU, Dade Behring [...][2] MECU).[3] Hoechst and DBH each have a Community-wide turnover in excess of ECU 250 million (Hoechst 12,000 MECU, Dade Behring [...][2] 350 MECU). Neither Bain, nor Hoechst, nor DBH achieve more than two-thirds of their aggregate turnover within one and the same Member state. The notified operation therefore has a Community Dimension, but does not constitute a co-operation case under the EEA Agreement, pursuant to Article 57 of that Agreement.

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1 Confidential information, deleted from publication.

2 Confidential information, deleted from publication.

3 According to Par. 7 of the Commission notice on the notion of undertakings concerned, the undertakings concerned in this operation are Bain and Hoechst as the companies acquiring control, and Dade/Behring as preexisting business activities. The turnover figures for Bain and Hoechst exclude the respective turnover of Dade and Behring. The turnover for DBH combines the present turnover of Dade and Behring.

V. Competitive Assessment

1. Relevant Product Markets

a) Overview

10. The concentration concerns the area of diagnostic analysis. A diagnostic analysis is a procedure for monitoring the physiological condition of a subject. The analytical procedures differ, depending on whether they are designed for analysing the general health condition of a subject, a specific illness, a pre-birth pathology, or whether they concern the reaction of a subject to certain substances.

11. Diagnostic tests can be performed either in vitro or in vivo. In vitro (literally, "in glass") diagnostic (IVD) tests are conducted outside the body and are used to identify and measure substances in patients' tissue, blood or urine samples which enable physicians to diagnose, treat and monitor patients. The in vivo method concerns the use of diagnostic substances directly in or on the human body. The two methods are complementary for some applications.

12. Dade and Behring are only active in the field of in vitro diagnostics. A large part of the in vitro diagnostics is sold in the form of multi-use diagnostics systems to hospitals, commercial laboratories, university laboratories or other institutions. In addition, a significant quantity of in-vitro diagnostics is marketed as single-use products to general practitioners, public authorities, employers or others, and in some instances they are even sold as self-test kits over the counter (i.e. tests of pregnancy, sugar diabetes and cholesterol). Self-test kits probably are complementary to multi-use test kits for some applications.

13. The concentration between Dade and Behring concerns primarily multi-use in-vitro diagnostics, which are used on-site. These diagnostics products generally form a system, composed of a measuring instrument which is designed for the automated operation of several kinds of tests and reagents for that instrument. The reagents, i.e. the compounds and liquids used to perform tests, are supplied as part of a reagent kit which comprises among others a control substance and a test serum to verify the smooth functioning of the measuring instrument. A calibrator serves for regular - often weekly - adjustments of the measuring instruments.

14. The main part of the multi-use products business is characterised by a series of test kits which are adapted to a system. Most of the major suppliers offer a package consisting of a measuring instrument, a series of test kits and a comprehensive after-sale service including quality control. The development of a new system requires relatively large sums. The companies in the diagnostics industry spend about 10% of their total turnover on R&D. The average life span of a system gives the supplier a five year period within which to recoup the development costs. Only up to 20% of the turnover is achieved through the sale of instruments, while reagent kits account for most of the rest.

15. This explains that competition in the diagnostics market is mainly focused on sales of reagents and that the suppliers have a strong interest in obtaining long-term orders for a continuous supply of reagent kits. Diagnostics manufacturers are following different strategies in the pursuit of this aim. There is a trend among diagnostic companies to market their products as closed systems which are

designed for the exclusive use of their reagents. It is also a common feature of the industry that delivery contracts with customers are concluded for one or more years. Often, the instruments are only leased or otherwise put at the customers' disposal at a very low cost, or even for free, under the condition that the customer purchases a certain number of reagent kits over a certain time period.

16. From a technical viewpoint the reagents of a certain supplier can be used on the instrument of another producer, provided that the technologies correspond to each other. This may apply even for closed systems, depending on the means employed to achieve the closeness of the system (specific container shapes, bar-codes, etc.). It appears that the switch from one reagent supplier to the other requires a certain know-how on the side of the customer. Some large customers have indicated an unwillingness to become dependent on closed systems.

17. The field of in vitro diagnostics can be divided into four areas: clinical chemistry, immunochemistry, haematology, and microbiology. This corresponds to the first level of the so called "EDMA classification", a product classification produced by the European Diagnostics Manufacturers Association which seems to be generally accepted in the industry and which is used to compile sales data for individual reagents on a European scale. During the Commission's investigation most customers, on the other hand, stated that they were not familiar with this classification. They did however, for the areas affected by this operation, confirm that it was a sensible way to classify diagnostics also from a demand-side point of view.

18. In their notification, the parties have identified the four areas of the first level of the EDMA classification as product markets. In its previous decision in the area of in vitro diagnostics, the Commission has mainly looked at markets corresponding to the second level of the EDMA classification[4].

19. The concentration between Dade and Behring will lead to major overlaps in the field of immunochemistry diagnostics (more precisely in the areas of drug monitoring and of cardiac markers), and in the field of haematology (especially haemostasis).

b) Immunochemistry

20. Immunochemistry involves the use of targeted antibodies to identify and test enzymes, drugs, hormones and other substances found in relatively small concentrations in the body. Depending on the condition monitored, one can distinguish a number of applications. If these were to be regarded as product markets, according to the parties the only overlaps would exist in drug monitoring and cardiac markers.

21. Drug monitoring forms one application of immunochemical diagnostics. The term describes the analysis of blood and urine samples to determine the existence and the level of certain specified chemicals in the body of a person. One can further distinguish between therapeutic medicine monitoring (TDM) and drug abuse / toxicology tests (DAT). These groups would correspond to the second level of the

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[4] See Case IV/M.457 - Roche/Syntex

EDMA classification, i.e. the first subcategories of the category "immunochemistry". In addition to TDM and DAT, there are 13 other subcategories of immunochemistry.

22. In its previous decision the Commission has found that there are differences between TDM and DAT but left the product market definition open.

23. TDM concerns all those products which are provided for testing patients receiving ethical pharmaceuticals. The TDM reagents measure the medicine level in patients whose results are used by physicians to adjust the medicine dose. Therefore, TDM is generally carried out for use in a medical environment, whereas DAT is also applied for non-medical purposes, for instance in legal proceedings, for recruitment purposes, etc.

24. While it is true that depending on the make of the instrument, both TDM and DAT tests can be operated on the same systems, TDM and DAT are in some ways different for the user. TDM testing mostly requires quantification of analytes (one wants to know how many molecules are in the test fluid), whereas DAT testing is generally performed qualitatively or semi-qualitatively (one wants to know primarily whether somebody has consumed an illicit drug at all or not). DAT often is carried out in two steps. In a first step the analyte is "screened", by using either an antibody with a broad scope of application or by conducting a panel of several tests; in a second step the consumed drug is determined more specifically. Legal requirements can also oblige the laboratory to carry out additional DAT tests to confirm the result of a first test. TDM is in general carried out on sera, that is on blood samples, while tests on urine samples seem to be more common in the DAT area.

25. Cardiac markers measure cardiac enzymes present in the patient's blood. Abnormal measures can help predict heart attacks. Cardiac markers are not a category that corresponds directly to the EDMA classification. The parties have stated that it would be necessary to combine the EDMA groups "Classical Chemistry - Enzymes" and "Immunochemistry - Specific Proteins".

26. For the purpose of this case, it is not necessary to decide whether TDM and DAT, separately or together, or cardiac markers should be seen as relevant markets, or whether they should be seen as parts of an overall immunochemistry market because, in all alternative market definitions considered, effective competition would not be significantly impeded in the EEA or any substantial part of that area.

c) Haematology

27. Haematology encompasses in vitro diagnostics concerning the blood itself, especially cellular elements and certain functions of proteins such as coagulation and fibrinolysis. The EDMA classification divides this area in its second level into 8 different segments. If these were appropriate for market definition, the concentration would only lead to overlaps in the market for haemostasis (coagulation). Haemostasis diagnostics test blood coagulation (clotting) or platelet function. These tests are typically run before and during most surgeries or are performed to monitor patients on anti-coagulant therapy. They are an essential tool in preoperative, emergency and intensive care states to identify patients' risk of thrombosis or hemorrhaging. The answers to the Commission's investigation as

well as Behring's internal documents suggest that haemostasis should be considered a separate product market. For the purpose of this decision, this question may however remain open because, in all alternative market definitions considered, effective competition would not be significantly impeded in the EEA or any substantial part of that area.

2. Relevant Geographic Markets

28. In its previous decision, the Commission has found that the geographic reference markets for the in vitro diagnostics concerned (TDM and DAT) remain essentially national.[5]

29. In their notification, the parties have also indicated that the markets for in vitro diagnostics are national. They especially noted that there are significant price differences between Member states. These differences reflect the diversity among national medical cultures and in particular the divergences in national health policies, social security regulations and the technology used in laboratories.

30. Other elements that point at the existence of national markets are the fact that all major competitors have national distribution systems and the existence of appreciable differences of the parties' market share between neighbouring geographic areas. Almost all clients contacted by the Commission also indicated that they considered the markets as national as they had never bought diagnostics outside their Member state and did not consider it a viable possibility.

31. National regulation plays a certain role, but it is less stringent than in the case of pharmaceuticals. The Commission is preparing a directive for the harmonisation of national regulations on in vitro diagnostics. The directive is not likely to enter into force before 1998 and will not be effective immediately due to an implementation period of several years.

32. For the purpose of this decision, it is not necessary to further delineate the relevant geographic markets because, in all alternative geographic markets considered, effective competition would not be significantly impeded in the EEA or any substantial part of that area.

VI. Assessment

33. According to the parties, the markets affected by the operation are immunochemistry in France and haematology in Germany.

34. If one considered the second level of the EDMA classification to be appropriate for market definition, the number of affected markets increases. The parties would have combined market shares exceeding 25% for TDM in France and Sweden, for DAT in Austria, Belgium, France, Germany, the Netherlands, Portugal, Spain, Sweden, the UK and Norway, for cardicac markers in France, and for haemostasis in the EEA and on a national basis in Austria, Germany, Greece, Italy, and the Netherlands.

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5 See Case IV/M.457 - Roche/Syntex

1. Immunochemistry

a. Overall Market Share

35. In a market for all immunochemistry diagnostics, the parties would have a combined market share in the EEA of [...][5]. The only national market affected by the operation would be France where the parties would have a combined market share of (Dade [...][7], Behring [...][6]). The market leader in immunochemistry both in the EEA and France is the US company Abbott, one of the strongest player in the overall diagnostics business worldwide. Although Abbott is a high-price supplier, it is considered as an aggressive competitor. Abbott distinguishes itself by offering closed systems which are easy to use and therefore imply low handling costs. Other important competitors are Boehringer Mannheim (BM), the market leader in clinical chemistry, and Roche[8].

b. Drug Monitoring

36. In drug monitoring, Behring has acquired a strong position (in TDM and especially in DAT) through its acquisiton of the Syva (Syntex) diagnostics business from Roche in 1995.[9] Behring does not manufacture its own instruments for TDM and DAT, but markets analysers manufactured by third companies, including Roche and BM. Dade has acquired DuPont's in vitro diagnostics business in 1996 which had a lesser share in TDM and DAT.

37. If the market shares of Dade and Behring are aggregated, the two companies will have a market share in the EEA of [...][10] for TDM and [...][11] for DAT. In some Member states the combined market share will be considerably higher due to Behring's high market shares. In DAT significant overlaps occur in France where the JV will have a market share of [...][12] (Behring [...][13], Dade [...][14]), in Portugal (Behring [...][13], Dade [...][15]), in Austria (Behring [...][16], Dade [...][15]), and in Germany (Behring [...][16], Dade [...][15]). As for TDM, a significant overlap can only be found in France where Behring has a market share of [...][16] and Dade [...][15]. However, the largest of these markets has a value of 17 MECU.

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6 Confidential information, less than 20%.

7 Confidental information, less than 10%.

8 Roche has recently acquired Boehringer/Mannheim. This acquisition is still subject to EC and US regulatory approvals.

9 Syva, the diagnostics part of Syntex, was acquired by Roche in 1994 (Case IV/M.457). To fulfill a consent order with the FTC, Roche then had to sell Syva, but kept the pharmaceuticals part of Syntex.

10 Confidental information, less than 30%.

11 Confidental information, less than 40%.

12 Confidental information, less than 60%.

13 Confidental information, less than 50%.

14 Confidental information, less than 20%.

15 Confidental information, less than 10%.

16 Confidental information, less than 30%.

38. The major competitor of Dade/Behring in DAT and TDM is Abbott. As in the case of Dade and Behring, Abbott has important stakes in most of the Western European countries (e.g. in France 58% in TDM and 33% in DAT). Other important competitors are BM and Roche.

39. Behring's market shares are expected to decrease significantly in the future [...][17].

40. In addition, any potential market power of the parties is reduced by the fact that it becomes increasingly possible to perform drug monitoring tests on clinical chemistry instruments. This trend favours competitors with a strong position in classical clinical chemistry, such as BM. The parties themselves have very low market shares in this area.

c. Cardiac Markers

41. For cardiac markers, the concentration will lead to a significant overlap in France where the JV will have a combined market share of [...][18] (Dade [...][14], Behring [...][14]). The market has a value of 7 MECU. There are major competitors in BM (30%), Abbot (10%), Sanofi (10%) and Roche.

2. Haematology/Haemostasis

a. Overall Market Share

42. In a market for all haematology diagnostics, the parties would have a combined market share in the EEA of [...][14]. The only national market affected by the operation would be Germany where the parties would have a combined market share of [...][16] (Dade [...][14], Behring [...][14]). The overlap is almost entirely caused by Behrings' activities in haemostasis (see below). In haematology there are a number of strong competitors, both in the EEA and in Germany, such as Coulter (German market share around 20%), BM (18%), Ortho Diagnostic Systems (Johnson & Johnson), Biotest and Becton Dickinson.

b. Haemostasis

43. In haemostasis, the parties' combined market share in the EEA will be [...][17] (Dade [...][14], Behring [...][14]). On a national basis, the most significant market share addition occurs in Germany where the JV will have a combined market share of [...][12] (Dade [...][14], Behring [...][17], market volume 73 MECU). Less significant overlaps occur in Austria, Greece, Italy and in the Netherlands.

44. Although the JV will be in a strong position on the haemostasis market in Germany, this does not raise competitive concerns. As already stated, the main part of the JV's activities in this field is currently performed by Behring. It is noteworthy for Dade's activities that it does not produce a haemostasis instrument of its own, and, moreover, that in 1994 its previous supplier of instruments

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17 Confidental information, market share erosion due to technical and commercial reasons, relating to its lack of an own instrument.

18 Confidental information, less than 40%.

terminated the cooperation with Dade [...][19]. Dade's sale of haemostasis reagents may therefore be be expected to decrease [...][20].

45. In addition, on the German market BM is an important competitor with a market share of about 35%. Instrumentation Laboratory (IL) has a market share of 10%.

46. The customers contacted by the Commission all declared that they were not concerned by the parties' combined market position and that they would switch to competitors if the parties were to impose significant price increases. In coagulation this is possible, as Behring's and Dade's analyzers are open, i.e. customers may choose to use another company's reagents even if they bought their instruments from the parties.

47. Finally, as the market share distribution varies significantly between Member States, there are important competitors present also in all other countries. At least six competitors have 25% in one or more Member State. The concentration will thus not cause concerns for those other national markets.

VII. Conclusion

48. 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 functioning of the EEA Agreement. This decision is adopted in application of Article 6(1)(b) of Council Regulation (EEC) No 4064/89.

For the Commission,

19 Confidential information, deleted for publication.

20 Confidential information, deleted for publication.