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Case No IV/M.495 - Behringwerke AG / Armour Pharmaceutical Co.

Only the English text is available and authentic.

REGULATION (EEC)No 4064/89
MERGER PROCEDURE

Article 6(1)(b) NON-OPPOSITION
Date: 03/04/1995

Also available in the CELEX database
Document No 395M0495

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

COMMISSION OF THE EUROPEAN COMMUNITIES

Brussels, 03.04.1995

PUBLIC VERSION

MERGER PROCEDURE
ARTICLE 6(1)(b) DECISION

To the notifying parties

Dear Sirs,

Subject: **Case No. IV/M.495 - Behringwerke AG/Armour Pharmaceutical Co.**
Your notification of 28.02.1995 pursuant to Article 4 of Council Regulation No. 4064/89

1. On 28 February 1995 Behringwerke AG (Behring) and the Armour Pharmaceutical Co (Armour) notified to the Commission an operation whereby they create a concentrative joint venture and transfer to it their worldwide plasma derivative businesses.

2. After examination of the notification, the Commission has concluded that the operation falls within the scope of Council Regulation No 4064/89 and does not raise serious doubts as to its compatibility with the common market and the EEA agreement.

I THE PARTIES

3. Armour manufactures and distributes human pharmaceutical products. It is incorporated in the United States of America. Its ultimate parent is Rhône-Poulenc SA (France), the companies in whose group are engaged in organic intermediates and minerals, specialty chemicals, fibres and polymers, health care and agrochemicals.

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4. Behring, incorporated in Germany, is a manufacturer and distributor of pharmaceutical products. Its ultimate parent is Hoechst AG (Germany). The activities of the Hoechst group are the manufacture and sale of chemicals, plastics, dyestuffs, fibres, pharmaceuticals and crop protection products.

II THE OPERATION

Joint control

5. The joint venture will operate through subsidiaries, each of which will be under the ultimate control of the directors of the holding company of the joint venture. Three of these directors will be appointed by Behring and three by Armour. One of them will be the chairman of the board; he may in different circumstances be a nominee of Behring or Armour. The chairman has a casting vote but not in relation to matters beyond operational decisions in the ordinary course of business; these expressly include the approval of the business plan (including the annual budget and the investment plan) and the annual financial statement, the acquisition or divestiture of shares in any company, accumulated investments in excess of USD [...][1], the appointment or removal of the senior executives, the disposal of accumulated assets in excess of USD [...][1] and all other matters of extraordinary importance (defined generally as any matter which involves more than [...][1] of the consolidated revenues of the joint venture). In relation to matters reserved to the shareholders each party is obliged (unless required otherwise by law) to vote in accordance with any resolution adopted by the board. The joint venture is accordingly subject to the joint control of the parties.

Full function joint venture

6. The parties will transfer to the joint venture their worldwide plasma derivative businesses, including plasma collection. Its activities will be - blood- and plasma-derived products, recombinant or synthetically produced substitutes for plasma-derived products, gene therapy (another substitute for plasma-derived products), collection of blood and blood plasma, and research and development in blood plasma. Each party will assign to the joint venture or grant to it long licences of the necessary assets - all its plasma collection centres, all manufacturing facilities which undertake fractionation of plasma, all research and development activity in blood and plasma derivatives and their substitutes, all marketing and sales organisations and sales organisations and know-how and the required management skills and intellectual property. The operation thus creates a full-function joint venture.

7. The only exception is that, at least in the short term, the joint venture will use the existing distribution systems used by Behring and Hoechst in those countries where its sales do not justify the creation of its own distribution system. The distributors might in certain countries be Hoechst or Behring themselves; in such cases the agreement between them and the joint venture will be at arm's length and will give the distributor no exclusivity and no authority to vary the conditions of sale. The countries in the European Union where the joint venture will have its own distribution system from the beginning are Germany, the United Kingdom, France, Italy, Spain and Austria.

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Absence of coordination

8. Neither Behring nor any other company in the Hoechst group will be active on the market of the joint venture or on any neighbouring market. Although Behring and Armour have other human pharmaceutical interests, the supply of blood- and plasma-derived products is entirely distinct from any of those activities.

9. Another Rhône-Poulenc company, Pasteur Mérieux Sérums et Vaccins (Mérieux), participates with Merck & Co Inc (USA) in a cooperative joint venture (Merck-Mérieux JV) which has been exempted under the EEC Treaty art 85(3) and the EEA Agreement.[1] The Merck-Mérieux JV supplies immunoglobulins as part of its vaccines business. But the two products (Immunoglobulin Antibacterial and Immunoglobulin Antiviral) which are common to both the Merck-Mérieux JV and the present joint venture represent no more than [...][1] of the turnover of the present joint venture in the EEA. They represent only a subsidiary part of the Merck-Mérieux JV's vaccine business which is also reflected by its low market share in these products. In addition the distribution systems used by the two joint ventures are largely distinct.

10. There is thus no possibility of coordination between the parties among themselves or between them and the joint venture.

Conclusion

11. The operation thus creates a concentration within articles 3(1)(b) and 3(2) of the Regulation.

III COMMUNITY DIMENSION

12. Hoechst and Rhône-Poulenc have a combined aggregate worldwide turnover in excess of 5000 million ECU (Hoechst - 25,860 million ECU, Rhône-Poulenc - 13,278 million ECU). Each of them has a Community-wide turnover in excess of 250 million ECU (Hoechst - 11,973 million ECU, Rhône-Poulenc - 6,514 million ECU), but they do not achieve more than two-thirds of their aggregate Community-wide turnover within one and the same Member State. The notified operation therefore has a Community dimension.

IV COMPATIBILITY WITH THE COMMON MARKET

A. Relevant Product Markets

13. Medicines can be broken down into therapeutic classes according to the Anatomical Therateupic Classification ("ATC") which is recognised and used by the World Health Organisation. This classification, previously used by the Commission[1], enables medicines to be grouped according to their composition and therapeutic properties.

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(2) O.J. L309/1 of 02.12.1994.
(3) Deleted; business secret: less than 5%.
(4) See inter alia decisions IV/M.072 - Sanofi/Sterling Drug (10.6.1991); IV/M.457 - La Roche/Syntex (20.6.1994); IV/M.500 - AHP/American Cynamid (19.9.1994); IV/M.555 - Glaxo/Wellcome (28.2.1995).

14. The third level classes of the ATC classification provide a grouping of medicines according to their therapeutic properties, that is, their intended use and therefore may be accepted as an operational market definition. It may be necessary, however, to carry out analyses at another level of ATC classification where it is appropriate to group particular 3rd level categories together, for example. This will be the case where products from different ATC classes compete as possible treatments for a specific diagnosed medical condition.

15. According to the above approach, the current operation involves 13 (3rd and 4th level) pharmaceutical plasma products which the joint venture will manufacture and market. Plasma products are derived from human plasma, which is one of the components of whole blood, by means of a series of technical processes called fractionation, and must be licensed by government authority. Products derived from plasma are in a special domain in the pharmaceutical world because they come from a natural body fluid for the collection of which manufacturers depend on the willingness of donors. When the plasma has been collected, it can be frozen for later use in blood transfusions or it can be separated in many of its components which are used to treat clinical conditions.

The Affected Markets

16. The concentration will only lead to combined markets shares in the case of four of the above-mentioned 13 plasma products. These product markets are the following:

    a) Human Albumin
    b) Intravenous Immunoglobulin (IVIG)
    c) Factor VIII
    d) Factor IX.

    a) **Human albumin** is a plasma fraction which restores the volume of the blood following severe shock, trauma, surgery and burns. It is, along with Factor VIII, the most important product to be derived from plasma as it is a necessity in the emergency rooms and operating theatres of hospital. It is also used for protein-consuming and circulatory disorders. This plasma product has been in the market for the past 50 years and there are no significant worldwide patents in force today.

    b) **Intravenous immunoglobulin** is currently used to substitute for primary and secondary antibody deficiencies and for the treatment of autoimmune disorders. This plasma product was first introduced in Europe in the late 1960's by Behring and the market was opened up to competition in the 1980's. Since then its use has accelerated at a tremendous rate due to the development of liquid preparations which have made administration easier and increased its acceptance.

    c) **Factor VIII** is, together with Factor IX, the human coagulation factor in which most common deficiencies occur. There are at least 14 clotting factors which work interactively. If any one of these factors is missing, or defective, or present in insufficient amount, the remaining factors cannot together achieve clotting. Factor VIII is the coagulation factor which is lacking from the plasma of patients with haemophilia A, which is the best known of clotting deficiencies and an inherited blood disorder. Factor VIII plasma-derived concentrates have been used for over two decades to treat patients with this deficiency, improving considerably the quality and longevity of their lives. Intravenous infusions of these plasma product, at the earliest symptom of bleeding, are the mainstay of treatment for this disease.

Product Innovation

17. The Factor VIII market is characterized by continuous product innovation, mainly in an effort to achieve virus safety through inactivating, as effectively as possible, the viruses naturally occurring in human plasma. These viruses are primarily the hepatitis A, B and C viruses and the HIV (AIDS) virus. The second reason for continuous product innovation is the manufacturers' effort to achieve the highest possible degree of product purity through the elimination of substances which could impair the effectiveness of the products. In relation to this last concern, according to the parties, Monoclonal Purification, a method which was developed in 1987, has proved to achieve a high degree of Factor VIII purity.

18. With regard to virus inactivation, several different methods are used for processing the different plasma-derived concentrates which are in the market today. These are, namely, Solvent Detergent (SD) in combination with Dry Heat, SD with Pasteurization, SD with Monoclonal Purification, Pasteurization, Pateurization with Monoclonal Purification, and Vapour Steam. In general, different manufacturers use different procedures, or combinations of procedures, for processing their own factor VIII concentrates, but, as no method has so far proved to be clearly the best, in that it guarantees at the same time both maximum safety and the greatest degree of purity, all of these products compete with each other.

19. Moreover, in 1993/1994, two recombinant products were introduced in the market in competition with the plasma-derived concentrates. In these recombinant technology products Factor VIII is produced in hamster cells by way of genetic engineering. While, according to the parties, these recombinant products are widely perceived as offering more guarantees of safety and purity because of not being derived from human plasma, this last advantage is for the moment offset by the need to use human albumin as a stabilizer in these products. They are also dependent on the Monoclonal Purification method for their optimal quality. Consequently, for both the plasma-derived products and the more "state of the art" recombinant products, the relative degree of virus safety and product purity are the basis for the arguments used by manufacturers in competing for market shares with their particular products which, though manufactured through different methods, are nonetheless interchangeable with those of their competitors.

d) **Factor IX** is used to treat patients with haemophilia B, a condition caused by a deficiency in this coagulation factor. Similar to Factor VIII products, Factor IX products are differentiated based on viral inactivation and purification procedures of manufacturers.

B. Geographic markets

20. The harmonisation of technical legislation within the Community and the entry into force on 1.1.1995 of new marketing authorisation procedures for medicines represent the completion of the Single Market Programme from the point of view of the scientific and technical requirements for medicines. Since the beginning of 1995, pharmaceutical companies have the option (and indeed the obligation as far as biotechnical products are concerned) to submit an application for authorisation of new medicines to the European Medicines Evaluation Agency (EMEA), which makes a recommendation to the Commission whose decision is binding on all Member States.

21. However, the geographic reference markets for the sale of medicines remain for the purpose of a competition assessment essentially national, for reasons stated in the Commission´s previous decisions (see footnote 1). In the notification form Behring and Armour refer to the same source without contesting this approach.

22. In addition, the parties refer to the traditionally different national registration, safety standards, social security and pricing systems for plasma derivatives. As a result of these conditions, market entry of major suppliers like Behring, Immuno (A), Bayer (D) or Sandoz (CH) in different Member States occurred over a period of 40 years and rather inconsistently. There are substantial differences in the undertakingś market shares as well as significant price differences for similar or identical products between different Member States.

23. For the above reasons, the impact of the concentration has to be assessed in relation to national markets. The notified operation involves the markets in different Member States, in particular Germany and Austria.

V. ASSESSMENT

24. The total sales of the joint venture achieve a combined volume of 836 million Ecu of which 330 Mio Ecu fall to the EU. More than 60% are outside the EU, i.e. in the U.S., Japan and other parts of the world due to Armour's strong presence in these markets. Armour only achieved 59 Mio Ecu in plasma-derived products in the EU. While the sales of the JV will fall to 13 different plasma derivatives, the parties have, on the basis of the ATC classification, identified only 4 affected markets with a combined market share of more than 10%. These are the markets for Human Albumin, Intravenous Immunoglobulin (IVIG), Factor VIII and Factor IX, described under Relevant Product Markets above.

Human Albumin

25. With regard to Human Albumin, Armour is rather insignificant on European markets; it achieves an EEA-wide market share of [...][1)(1)]. In 1994, the only overlap between the parties occurred on the German market, where Behring and the German Red Cross are the largest supplier of Human Albumin, each with a market share of [...][1)]. The increment by Armour is only [...][(6)] (1993: [...][(6)]). Another significant competitor is the large Austrian pharmaceutical manufacturer Immuno who achieves [...][1)] of the market. The rest falls to smaller suppliers. The concentration will thus undoubtedly not lead to the creation or strengthening of a dominant position.

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(5) Market shares figures for Human Albumin, Immunoglobulins and Factor IX in 1993 represent actual sales of Behringwerke and Armour and, for competitors, they are derived from publications from Marketing Research Bureau Inc./California (MRB), a recognised market research institute which provides worldwide and country surveys of the plasma market. For 1994, figures rely on estimation by the parties. As to market shares for factor VIII in Germany, see para 29.

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Intravenous Immunoglobulin (IVIG)

26. IVIG has been a particularly rapid-growing market since 1980 due to new indications and increased efficiencies in production. The only overlap of the parties' activities within the EEA is again in the German market. Behring here achieved [...][1] in 1993 and [...][9] in 1994. Armour's share also declined slightly from [...][1] in 1993 to [...][10] in 1994. The parties, with a combined market share of [...][1], are exposed to competition from large, research based pharmaceutical firms like Sandoz and Bayer as well as from specialised medium-sized pharmaceutical companies like Immuno and Biotest who all have market shares between [...][9] and [...][9] respectively, and from some other smaller manufacturers. Although the new entity will become the leading supplier of IVIG, it will, due to this market structure, not have an unlimited scope of action.

Factor VIII

27. Factor VIII is in terms of sales the most important plasma-derived product apart from Human Albumin. Total sales of factor VIII in the EEA amounted in 1993 to 443 Mio Ecu (Human Albumin: 403 Mio; IVIG: 196 Mio; Factor IX: 107 Mio). Factor VIII will also represent the core business of the plasma derivatives of the JV in the EEA of which it represents about [...][1]. Since Behring as a traditionally strong supplier in this field and Armour as a relatively new entrant in Europe are both active in this market, it is also the product which shows several overlaps of market shares, two of which exceed 40% (Germany and Austria). These countries will be dealt with in detail below. At EEA level, the parties have, according to the figures given in the notification, achieved a combined share of [...][11], followed by Baxter ([...][10]) and Immuno ([...][10]) in 1994.

28. In Denmark, the Netherlands, Italy and Sweden, Behring and Armour have a combined market share of [...][1] or less in 1994; in the UK, Armour's share of [...][13] will be increased by [...][1] of Behring. (Source: MRB figures provided by the parties). The new entity will be faced with strong domestic and partly state-owned suppliers in those markets. This is equally true for Spain, where Behring achieved [...][11], Armour [...][10] in 1994. Baxter and Grifols who achieve [...][11] and [...][13] respectively in Spain, can be considered to limit the scope of action of the new JV in Spain.

Germany

29. The enquiry made by the Commission revealed that data onmarket shares from different sources differ. According to sales figures which the Commission obtained from the parties and from the other suppliers to the German market, the market volume amounted to about 206 Mio Ecu in 1994 (1993: 184 Mio Ecu). Germany, thus, represents more than 40% of the total EEA market. The parties achieved a combined market share of [...][12] (Behring about [...][1], Armour [...][10]). This share, lower than in 1993 ([...][12]), is due to a decrease

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of Behring's share in 1994. The rest of the market falls to 7 suppliers two of which are comparatively insignificant, at least in the area of factor VIII, whereas the other five competitors have shares of between 8 and 19%[1]. These suppliers are either large pharmaceutical manufacturers (Bayer, Baxter, Alpha) or medium-sized but specialised and research-based companies like Immuno, Octopharma and Biotest. Immuno is said to have a broader product portfolio than suppliers like Baxter and Bayer.

30. The German market for factor VIII has in the past been characterised by the leading role of Behring over several years. By means of its plasma-derivatives manufactured on the basis of the pasteurisation method, Behring increased its market share to [...][1] in 1991 or even more according to some competitors. Since then, Behring saw a decline of its position in factor VIII to the current share of about [...][1]. This decline, in particular since 1994, is due to a significant change in the product range of Factor VIII resulting from the gradual introduction of recombinant products (see para 19 above). These new products are perceived by clinics and patients as better in terms of virus safety and purity. Their long-term health risks have not yet been fully explored but are not considered as an issue which will delay the gradual penetration of recombinant products.

31. Behring will, through the JV, get access to products with this new technology since Armour has, through supply arrangements, been granted a fixed annual quantity of recombinant products by Bayer and Baxter, [...][1]. Baxter and Bayer who are currently the only worldwide manufacturers, were granted the exclusive license for recombinant products by Genetics Institute (USA) and Genentech (USA) respectively, who developed the products. They are supplying them to the German market since early 1994 (Baxter) and mid 1994 (Bayer). Due to their recombinant products, both companies have been able to increase their shares in the German market significantly. Armour is expected to launch its recombinant products in mid-1995, after completing registration procedures.

32. The parties furthermore claim that the access of the JV to the new recombinant products is limited by the quantities to be supplied under their agreements with Bayer and Baxter. Thus, in 1995, supplies could not exceed [...][19] units which represent [...][1] of the total world factor VIII market. It can be questioned if these limitations, [...][19], substantially hinder the JV from supplying the gradually increasing demand in Germany and other EEA countries and in the US, which is the other major market for factor VIII products. The attractive price level for recombinant products in Germany as compared to the US might rather make it plausible to supply the German market with the amount which is actually demanded. However, the entity will be exposed to actual competition in Germany by two strong manufacturers, Baxter and Bayer, who are already present with their recombinant products and who appear to be able to constrain the scope of action of the JV.

33. Further evidence of the decisive influence of recombinant products is given by what market participants expect to be the future development of the factor VIII market Competitors consulted by the Commission had either already switched to selling only recombinant factor VIII products or expected an increase of the share of recombinant products up to 50% in 2 to 3 years in Germany (1994: 15%). This view is shared by the

(16) For reasons of confidentiality, exact sales figures or percentages cannot be provided.
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demand side, represented mainly by the German university clinics (see para 34 below). The clinic of Bonn, for example, even expects up to 80% of its own consumption to be of recombinant products within 2 years; for 1995 it indicated a share of probably 50% of its total factor VIII purchases. The parties estimated the share of recombinant products in Germany at 25% in 1995 and 60 to 80% by the year 2000. Competition in the field of factor VIII products will finally result from potential competitors like Pharmacia (S) and Novo Nordisk (DK). Pharmacia (previously Kabi), in particular, is expected to enter the German market in 2 to 3 years after having completed clinical tests and the registration of its own product.

34. While such a delay in launching a new product might limit the chance of gaining a significant market share, the structure of the demand side in plasma-derived products, in particular in factor VIII, in Germany, nonetheless allows smaller or new entrants to achieve a position in the market. German pharmaceutical legislation allows direct marketing of factor VIII products to the haemophilia centres of clinics; since autumn 1994, this equally includes recombinant products. Thus, almost all sales are made to the university clinics where haemophilia patients are treated. The remaining sales are made to pharmacies who supply those patients who treat themselves at home, following the instructions given by the university clinics. Most of the sales fall to 10 major clinics. Among these, the University Clinic of Bonn is by far the largest customer with 30-40% of total purchase volume. The investigation made by the Commission showed that clinics purchase from at least 3 suppliers; the clinic of Bonn has 7 different suppliers. The volume falling to each supplier per clinic varies, and supply agreements are, if not continuously revised, concluded for a maximum of 12 months. While in the past, long-standing relationships between clinics and supplies characterised the market, clinics now appear to switch more easily to other suppliers.

35. Innovation in the sensitive field of virus safety and purity is a more important element of competition than prices (see para 19 above). This is supported by the example of the clinic of Bonn which reduced its purchases from Behring from [...][1] in 1993 to [...][21] in 1994 and has announced a purchase commitment of [...][21] in 1995. This partly explains the decrease of Behring's market share and is attributed by the parties to the arrival of recombinant products and to their relatively old pasteurisation method.

36. It can, for the above reasons, be expected that the demand side in factor VIII will exercise purchase power which would equally constrain the behaviour of the JV in the market.

37. As to research and development, it has already been set out that innovation is a decisive element of competition in the factor VIII market (see para 17 above). The JV between Behring and Armour will have an enhanced capacity to invest in research and development. However, research and development on Factor VIII will, likewise, be carried out by the other main manufacturers, in response to the continued demand of patients, doctors and hospitals for greater product safety, purity and efficiency, and innovation can be expected to continue on the market as a whole. The basic research in new technologies, such as recombinant technology and gene therapy, is carried out by university departments or private industry bio-technnology companies, through licensing, co-operation, sponsorship or joint-ventures with pharmaceutical companies. These university departments and bio-technology companies usually rely on the superior strength of the

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pharmaceutical manufacturers in financial and other capital resources for the ensuing phases of expensive clinical trials, completion of the product development, the obtention of regulatory approvals, and finally the marketing of the finished product. In this respect, not only Behring and Armour, but also Baxter, Bayer, Alpha and Immuno are able to carry out R&D with universities and bio-technology companies.

38. With regard to research and development in recombinant technology, at present clinical trials are being carried out on a second generation recombinant product, without human albumin, which is expected to be in the market in the next 2 to 3 years. However, the research and development in gene therapy, in which several of the main pharmaceutical manufactuers in the Factor VIII market are involved, is not expected to result in the launch of a new product in the market before the beginning or middle of the next decade (2002 - 2005).

39. In conclusion, Behring and Armour will through the JV maintain the position of market leader in the German factor VIII market which is at present held by Behring alone. For the time being, there is also a considerable gap in market shares between the new entity and the following competitor. However, as the market for factor VIII is undergoing a significant structural change due to the recombinant products, the position of the JV will be exposed to competition from at least two large suppliers in this field. In addition, its scope of action will be constrained by a highly concentrated demand side (clinic haemophilia centres). Thus, it is not expected that the proposed concentration will create or strengthen a dominant position in the German market for factor VIII.

Austria

40. The Austrian market for factor VIII had a total volume of 13,3 Mio Ecu in 1994 and aounted to less than 3% of the total EEA market. Although similar to Germany in regulatory framework, structure of demand side, access by foreign suppliers and imports of plasma, the Austrian market is currently characterised by a significantly higher degree of concentration than the German market. The combined share of the parties in factor VIII amounted to [...][(1)] in 1994 (1993: [...][(22)]) on the basis of their own sales figures and MRB data provided by the parties. Immuno, the national producer, achieved [...][(1)] in 1994.

41. This market structure, however, is the result of a substantial change of traditional purchase behaviour of Austrian customers, i.e. haemophilia centres of clinics, in recent years. Due to [...][(1)], Austrian clinics significantly reduced their purchases from Immuno and switched to Behring and, more recently, also to Armour. Immunós share decreased from [...][(22)] in 1990 to [...][(23)] in 1993, whereas Behring saw an increase from[...][(1)] to [...][(1)]. Armour who only entered the Austrian market in 1993, achieved [...][(1)] last year. This strong fluctuation of market shares, which distinguishes the Austrian market from the German market, is due to the small Austrian market volume which falls to a few large clinic customers. The reaction by clinics as reflected in their purchasing policy, following

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particular developments such as infection problems, may lead to rapid changes in the market structure. This feature of the Austrian market is supported by the fact that most recently it was Behring who saw a substantial decline (from [...][1] in 1993 to [...][1] in 1994, and with the expectation of a further decrease since it lost [...][1] in Jan./Febr. 1995) as it has indicated during the investigation made by the Commission. The recent losses of Behring apparently were to the benefit of Armour whose monoclonally purified plasma-derived products have been perceived as superior to Behring's pasteurised products. Immuno, however, started to recover slightly ([...][1] in 1994) [...][32]. Furthermore, Immuno has applied for registration for a high purity plasma-derived product (Immunate STIM+), which can be expected to challenge, in particular, the position of Armour's plasma derivatives. In the field of plasma derivatives, the German producer, Octopharma, is also expected to launch a new plasma-derived factor VIII product in Austria.

42. The most important element of competition in the Austrian market is, however, the imminent introduction of recombinant factor VIII products. As opposed to the situation in the German market, neither Bayer nor Baxter have yet entered the Austrian market. However, both have applied for registration. The registration process for Bayer's recombinant product is already well advanced and registration is expected in the very near future. Baxter expects to obtain registration within 1 or 2 years. Likewise, Pharmacia (Kabi) is currently testing its recombinant factor VIII product in clinics in Austria. It is expected to be in the market in about three years at the latest. The new JV will, as for Germany, be supplied with a limited quantity of Bayer and Baxter's recombinant products. Nonetheless, the supply arrangement combined with the requirements of registration for Armour's future recombinant products will lead to a considerable delay in Armour's entry into the Austrian market.[...][1] This registration by Armour will, as experience has shown, take another 6 to 12 months. The delay for Armour in entering the Austrian market gives Baxter and Bayer a significant competitive advantage. Clinics in Austria, which have been contacted by the Commission, stated that they are waiting for the registration of the recombinant products and would be willing to switch to these products.

43. Once Baxter and Bayer have entered into supply agreements with major Austrian clinics, any other supplier, including Armour, will have more difficulty in entering the market. Armour will have to make patients and clinics switch to their products and will therefore be forced to compete fiercely, e.g. on prices. This is equally true for Pharmacia (Kabi) who will probably enter the Austrian market still later than Armour. Both Armour and Pharmacia (Kabi) may have a reasonable chance of gaining a market position in recombinant products due to the purchasing policies of clinics which aim at splitting purchases among several suppliers. However, the market structure with 3 or 4 suppliers, which is to be expected in the future, will ensure competition in the total factor VIII market in Austria and, thus, constrain the scope of action of the new JV.

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Factor IX

44. As to Factor IX, the only member state where the combined market shares of the parties exceed 25% is Germany. In 1993 the market share of Behring in Germany was [...][(1)] and of Armour [...][(1)]. Here the chief competitor of Behring is Immuno, whose market share increased from [...][(1)] in 1992 to [...][(1)] in 1993, contributing substantially to a corresponding decline ([...][(33)] to [...][(33)]) in Behring's market share for the same period. Concern about the safety of another Factor IX product of Behring during 1994 caused at least a temporary reduction in Behring's market share in 1994 to [...][(1)]; Immuno increased its share to [...][(1)], but the main beneficiary was Armour, which increased its share from [...][(34)] to [...][(1)]. A further decrease arising from the same cause is anticipated for 1995. Thus even though a small increase in market share results from the operation no dominant position is created through the proposed concentration in this market.

Market for the collection of blood plasma

45. Behring and Armour have up to now been both active in the upstream market for the collection of blood or plasma through collection centres in the US. Behring, in addition, has six blood collection centres in Germany. These activities will be transfered to the JV. The need for plasma is determined by the demand for plasma-derived end products such as Human Albumin, Factor VIII, etc. Up to now, several markets in Europe have had a constant need for imports of plasma since they were not self-sufficient in this respect. The European Directive 89/381 adopted in 1989 aims at encouraging self-sufficiency of Member States in blood and plasma "coming from voluntary unpaid donations". This, however, is still far from being achieved. For example, in Germany and Austria all the suppliers import plasma for part of their needs. Whereas Armour is nearly completely integrated upstream, Behring purchases a significant volume from third party plasma centres in the U.S., as do Bayer, Baxter and Alpha, besides obtaining plasma from their own centres. Pharmacia's supply is entirely from donations in Scandinavia. Therefore, the proposed concentration does not appear to have a restrictive impact on the access of other suppliers to the collection of blood plasma.

VI. CONCLUSION

46. Based on the above information, the concentration will not create or strengthen a dominant position as a result of which effective competition will be significantly impeded in the common market or in a substantial part of it.

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(37) Deleted; business secret: below 45%.
(38) Deleted; business secret: below40%.
(39) Deleted; business secret: below 10%.

47. For the reasons outlined above, the Commission has decided not to oppose the concentration 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 4064/89.

For the Commission