EN

Case No IV/M.821 - Baxter / Immuno

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REGULATION (EEC) No 4064/89 MERGER PROCEDURE

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

Brussels, 09.10.1996

PUBLIC VERSION

MERGER PROCEDURE
ARTICLE 6(1)(b) DECISION

To the notifying parties

Dear Sirs,

Subject: Case N° IV/M. 821 - Baxter / Immuno
Notification of 09.09.1996 pursuant to Article 4 of Council Regulation No. 4064/89

1. On 9 September 1996 Baxter International Inc. notified to the Commission an operation whereby it will acquire the whole of Immuno International AG.

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 with the functioning of the EEA agreement.

THE PARTIES AND THE OPERATION

3. The case was notified on 9 September 1996. The proposed operation consists in the acquisition, by way of purchase of shares, of the whole of the Switzerland-based company Immuno International AG ("Immuno") by the US undertaking Baxter International Inc. ("Baxter"). Both of them are manufacturers of plasma derivatives and other pharmaceutical products. The acquisition of the entire share capital of Immuno will take place in three consecutive steps; however, Baxter will have sole control over Immuno from the first step, with the acquisition of 54,32 % of the voting rights.

Rue de la Loi 200 - B-1049 Brussels - Belgium
Telephone: exchange (+32-2)299.11.11
Telex: COMEU B 21877 - Telegraphic address: COMEUR Brussels

CONCENTRATION

4. As stated above, Baxter will have sole control over the whole of Immuno from the moment of the closing of the first step of the operation. Furthermore, it will take over full responsibility for and control over Immuno's management and operation from this moment. It will also have a majority on the Board, where there is not any qualified majority requirement. The acquisition of Immuno by Baxter constitutes thus a concentration within the meaning of article 3(1)b of the Council Regulation 4064/89, of 21 December 1989 (the "merger regulation").

COMMUNITY DIMENSION

5. The combined Worldwide turnover of the parties exceeds 5 000 million ECU (Baxter 7 439 mECU; Immuno 405 mECU). The aggregate Community-wide turnover of each of those undertakings is more than 250 mECU (Baxter 960 mECU; Immuno 334 mECU). They do not achieve more than two-thirds of their Community turnover in one and the same Member State. The proposed concentration has therefore a Community dimension.

COMPATIBILITY WITH THE COMMON MARKET

Relevant Product Markets

6. The notifying party's approach to market definition is in line with previous Commission decisions in the pharmaceutical sector[(1)], that is, a product market definition based on internationally agreed therapeutic categories of drugs (mainly the Anatomical Therapeutic Classification, "ATC", used by the World Health Organization) adapted to the specific products particularities and uses. The Commission stated in the above said decisions that products derived from plasma are in a special domain in the pharmaceutical world. This is so mainly by reason of their particular characteristics in terms of collection, production and use.

7. The main area affected by the operation is the one for the manufacture and sale of plasma derivatives. Within this area five affected markets have been identified by the parties:

   a) Albumin products (Concentrated Albumin and Plasma Protein Fractions) are the oldest known plasma fraction products, which are mainly used in major surgery cases where patients lose large quantities of blood in the treatment of shock and burns. On the basis of quantity, these are the most important products in the plasma derivatives market. They have been in the market for the past 50 years and there are no significant worldwide patents in force today.

   b) Intravenous Immunoglobulins (IVIG) are currently used to protect patients against infectious diseases and to treat patients with auto-immune diseases.

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(1) Case IV/M.555 Glaxo / Welcome; Case IV/M.495 Behringwerke AG / Armour Pharma Co, et al.

They were first introduced in Europe in the late 1960's. IVIG are sold lyophilized and in liquid form; the development of liquid preparations have made administration easier and increased their acceptance.

c) Factor VIII is a specific plasma protein, which is missing in patients suffering from haemophilia A. Factor VIII enables the treatment of those patients by substituting the missing factor. These concentrates have been used for over two decades to treat patients with this deficiency, and during this period significant new technologies concerning purification and virus activation have been developed. Another significant innovation are recombinant products (produced from non human mammalian by way of genetic engineering), which appeared on the market in 1993-94.

d) Factor IX, including Prothrombin Complex Concentrate (P.C.C., a concentrate of which the active ingredients are Factors II, VII, IX and X), is used to treat patients with haemophilia B, a condition caused by a deficiency in the coagulation factor, as well a number of other coagulation disorders occurring occasionally.

e) Products for the treatment of bleeds in haemophilia patients with inhibitors. Those are the products used to treat Haemophilia A and B patients who develop inhibitors that neutralize the infused Factor VIII and Factor IX. These patients face, in case of severe bleeds, a life threatening situation. Current options for the treatment of these patients include Plasma derived Activated Prothrombin Complex Concentrate (APCC), P.C.C., Porcine Factor VIII and Activated Factor VII. In the opinion of the notifying party, all these treatments form one product market.

8. The two companies' research programs do not overlap except for general viral inactivation research which is generalised within this industry. Conglomerate aspects are not significant either. If Baxter has a wide range of activities including kidney failure products, cardiovascular products, supply of medical equipment to hospitals and others, Immuno's activity is primarily dedicated to plasma derivatives the reminder being vaccine development.

Relevant Geographical Markets

9. For the geographic market definition, the notifying party also adopts the Commission's line, albeit asking it to give full weight in its assessment to the trend towards a European-wide market for plasma. According to the notifying party, this trend is greatly due to the fact that plasma derived products have benefitted from the European harmonization process. Since the beginning of 1995 pharmaceutical companies have the possibility (and the obligation in the case of biotechnological products, such as recombinant medicines) to submit an application for authorization of new medicines by the European Commission to the European Medicines Evaluation Agency (EMEA).

10. However, the geographical reference markets for the sale of medicines, including plasma derivates, remain essentially national for the purposes of a competition assessment. The sale of medicines is influenced by the administrative or purchase policies adopted in Member States by national

health services. In addition to that, there exist significant differences in prices for similar products, market shares, branding, distribution and other previously stated elements (cfr. footnote 1) which clearly show the national character of these markets.

11. For the above reasons, the impact of this concentration has to be assessed in relation to national markets.

ASSESSMENT

12. Annex 1 provides the share of sales at EU level for the product markets identified above. The industry of plasma derivatives in the EU is relatively concentrated, the main players being Centeon (the result of the merger between Armour and Bheringwerke), the merged entity Immuno+Baxter, Alpha and Bayer.

13. There are in addition, a number of smaller players (such as Biotest, Octapharm, etc...) which very often play a significant role at national level. The not for profit organizations also have an important position in their respective domestic markets. At this national level, the parties appear to have important market shares (above 25%) in the following relevant markets (see also annex 2 for details about the overlap and the market share of the main competitors):

-Factor VIII. In Germany [...][(2)], Italy [...][(3)], Spain [...][(2)]and Sweden [...][(2)].
-IVIG: Sweden [...][(4)]

-Treatment of bleeds in haemophilia patients with inhibitors.: The parties have an estimated share of overall sales in the EU of [...][(5)]; the notifying party has not been able to provide market shares at national level, due to absence of data. During its enquiry, the Commission has had confirmation of the unreliability of data for this product market.

Factor VIII

14. With respect to **Factor VIII,** the parties will become the EU leaders in sales, with an overall estimated share of [...][(6)]. Only Centeon will approach the size of the merged entity at EU level. All other competitors are smaller in size, although significant in individual relevant markets (which remain national).

15. In its decision in the Case 495 (Behringwerke / Armour Pharmaceutical), the Commission stated that the market for factor VIII is undergoing a significant change due to the introduction of recombinant products (i.e. those produced from non-human sources by way of genetic engineering). Baxter, Bayer, and more recently Centeon, seem to remain the only worldwide manufacturers of

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(2) Deleted business secrets - between 35-45%
(3) Deleted business secrets - between 45-55%
(4) Deleted business secrets - between 55-65%
(5) Deleted business secrets - between 75-85%
(6) Deleted business secrets - between 25-35%

recombinant Factor VIII. The share of the recombinant product is estimated at 60% to 70% for the year 2000 by market operators. Immuno, however, is not involved in recombinant Factor VIII, so there will be no addition of shares or reinforcement of Baxter's position in this area. The proposed concentration will not have any significant impact in the development of this technology.

16. Furthermore, in its clearance of the merger between Armour and Behring, the Commission took into account the competition induced among Factor VIII suppliers by the continuous innovation to improve product purity and achieve virus safety. Finally, the Commission also took into account that demand is composed of a small number of clinics, each accounting for a large proportion of the sales of individual suppliers. Clinics often use yearly tender procedures to procure their supplies of Factor VIII products, and therefore should in principle be able to constrain the merged entity's behaviour as long as there are alternative suppliers.

17. The above considerations still apply not only to Germany, but also to Italy, where significant competitors will remain; to Spain, where Immuno has traditionally had a very weak position [...][(7)]; and Sweden, where, as in Germany, most of the sales fall to a reduced number of clinics which use typically annual tender procedures or long term contracts. Thus, dominance is not likely to arise for Factor VIII in any of the affected national markets.

IV IG

18. In **Intravenous Immunoglobulins (IVIG)**, the parties attain a high market share in Sweden only. In other Member States, their share is [...][(7)]. The Swedish IVIG market value amounts to around 7 million ecus.

19. IVIG market shares have dramatically changed in the last years. If Pharmacia/Upjohn accounted for nearly all sales in Sweden in 1984, it had been replaced by Sandoz three years later. Sandoz's share was dramatically reduced by the entry of Baxter, Immuno and the re-entry of Pharmacia/Upjohn in the period from 1990 to 1995. Sandoz's monopoly position has been thus reduced to a market share of less than 10%. Besides, Centeon and Bayer have registered products in Sweden, which combined with tendering procedures by a small amount of large hospitals would allow for effective entry in a short period of time. Furthermore, the parties argue that the expected switch from lyophilised IVIG to liquid IVIG in Sweden will further erode their market share, since they do not have liquid IVIG. Certain practical advantages of liquid IVIG vs. lyophilised IVIG in terms of safety, stability or convenience of use (the product does not have to be reconstituted) have been described by almost all of the Hospitals contacted by the Commission during its enquiry. None of these hospitals have expressed any concerns about the proposed concentration.

20. Given the above reasons, and particularly the highly concentrated structure of the demand side in IVIG combined with the remarkable fluctuation of market

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(7) Deleted business secrets

shares in this area, the proposed operation is not likely to result in any creation or reinforcement of a dominant position in the IVIG market in Sweden.

Treatment of bleeds in haemophilia patients with inhibitors (TBHPI)

21. The parties will enjoy very high market shares in this limited market. After the operation there will remain only three other actual competitors in the EEA as a whole, i.e. Speywood (UK), LFB (France) and Novo Nordisk (Denmark).

22. Given the above considerations, the Commission focused a large part of its enquiry in the investigation of the characteristics of this market and the assessment of the impact of the operation on it. During the course of this enquiry, the main customers of TBHPI products as well as the actual and potential competitors were contacted.

23. The estimated value of this market is ECU 52 million for the whole EEA; the number of patients which are treated with these products is about 1.000 in this geographical area. The parties are active in the segment of the APCC, with Baxter's Autoplex and Immuno's FEIBA. This last product has historically been the most widely used option. Among the competitors' products in this area ACSET (LFB), Hyate:C (Speywood) and NovoSeven (Novo Nordisk) can be mentioned.

24. However, Baxter's Autoplex EU market share is reduced and has decreased to some extent in the last years [...][(7)]. The notifying party argues that this position is deemed to erode further because, according to them, this product is not as readily available as competing products; nor does it exist in high potency formulation. Moreover it is not indicated for Haemophilia B patients (while most competing products are). Differences in the process of virus inactivation, [...][(7)], were also noted by some customers as the reasons for a possible reduction of its use in the future.

25. More important are the market changes produced by the recent introduction of NovoSeven by Novo Nordisk. NovoSeven is a recombinant activated Factor VII concentrate, which competes with the other treatment options in most of the EEA. This concentrate is widely perceived in this market as having significant therapeutical qualities in terms of safety and efficacy, which potentially make it a very promising product, which could even become the "product of choice" in the medium term.

26. Although the specific nature of this market makes any evolution forecast highly speculative, the Commission has had confirmation that NovoSeven has already gained a large market share at EU level in a significatively short period of time. Thus, since its marketing approval in the EU on 23 February 1996 until August 1996, it gained a significant market share at EU level. This fact, together with the highly flexible market evolution patterns that it evidences, are extremely likely to neutralise any potential dominance situation in this market.

27. Furthermore, the role of Immune Tolerance Induction protocols, designed to eradicate the formation of inhibitors, also has to be taken into account. These protocols could have the effect of further reducing the number of patients who have to be treated with these specialized TBHPI products. This is so because

patients which are successfully treated with these protocols get permanently free of the inhibitors and can subsequently be treated with standard plasma products. Such programmes, pioneered in Germany (about twenty years ago) and in Sweden, have become increasingly used throughout the EU over the last three years.

28. The concentration of the demand, the purchasing patterns and the volatility of the market are additional facts that militate against any dominance situation. All those reasons ensure that, despite the high market shares that the new entity will enjoy in this market, competition will be maintained and no dominant position will be created or reinforced with the proposed operation.

Other considerations

29. In its enquiry, the Commission has contacted the main hospitals in the EU in the area of plasma derivatives, as well as the main competitors. None have expressed any concerns about the concentration, except two competitors that have expressed reservations about the extent of the range of plasma derivatives combined by the merged entity, which in theory could raise the possibility of bundling. However, this potential danger has not been substantiated by these competitors. There are several competitors active in the plasma derivatives markets such as Alpha, Bayer, Upjohn/Pharmacia and Centeon, and possibly a number of the smaller competitors. The only area where the parties are present on their own is the specialised market of the treatment of bleeds in haemophiliac patients with inhibitors, which represents less than 4% of the plasma derivatives markets. Furthermore, no evidence of bundling has been found after the concentration between Behringwerke and Armour in 1995

Possible oligopolistic dominance

30. With this second concentration, the plasma derivatives markets become relatively concentrated. Nevertheless, given the highly specialised needs of patients and their great product awareness and given the basic characteristics of demand, with a limited number of hospitals, and the importance of product innovation, in particular the development of recombinant technologies, it seems unlikely that the proposed concentration will create or reinforce a collective dominant position in the affected markets. Furthermore, firms in these markets are very heterogeneous, in terms of size, market shares in each Member State and degree of specialisation.

CONCLUSION

31. Based on the above information, 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 No 4064/89.

For the Commission

ANNEXE I

Albumine		**Factor IX**		**IVIG**	
Total EEA market (mecus)	359,2		60,9		225,8
NFP	[...](8)	Centeon	[...](9)	NFP	[...](10)
Marcucci	[...](10)	*Immuno+Baxter*	[...](10)	Sandoz	[...](10)
Centeon	[...](10)	LFB	[...](11)	*Immuno+Baxter*	[...](10)
Immnuno+Baxter	*[...](12)*	Alpha	[...](11)	Centeon	[...](11)
Alpha	[...](13)	BPL	[...](11)	Biotest	...](11)
Biotest	[...](14)	Marcucci	[...](14)	Bayer	[...](11)
		Others	[...](11)	Marcucci	[...](11)
	100%		100%	Others	[...](14)
					100%
[...](7)		[...](7)			[...](7)

Factor VIII		**Haemophilia**	
Total EEA market (mecus)	493,9		
Immuno+Baxter	[...](6)	*Immuno+Baxter*	[...](5)
Centeon	[...](6)		
BPL	[...](11)	Speywood	[...](11)
Alpha	[...](11)	LFB	[...](11)
Bayer	[...](11)		100 %
Marcucci	[...](11)		
LFB	[...](11)		
Others	[...](11)		
	100%		
[...](7)			

(8) Deleted business secret - between 30-40%
(9) Deleted business secret - between 40-50%
(10) Deleted business secret - between 15-25%
(11) Deleted business secret - between 5-15%
(12) Deleted business secret - between 10-15%
(13) Deleted business secret - between 5-10%
(14) Deleted business secret - below 5%

1995 mkt shares (by value)

(figures were deleted for reasons of business secrets and replaced by ranges)

1. Albumin

Italy	
Mkt value (mECU):	126.1
Mkt shares:	
B+I:	[25-35]
Marcucci:	[55-65]
Others:	[15-25]

2. Factor IX

Spain	
Mkt value (mECU):	2.1
Mkt shares:	
B+I:	[15-25]
Centeon:	[55-65]
Grifols:	[15-25]
Others:	[5-15]

3. IVIG

Germany	
Mkt value	44.2
Mkt shares	
B+I:	[15-25]
Centeon:	[25-35]
Bayer:	[15-25]
Sandoz:	[15-25]
Others:	[15-25]
Spain	
Mkt value	16.5
Mkt shares	
B+I:	[15-25]
Bayer:	[45-55]
Grifols:	[25-35]
Others:	[below 5%]
Sweden	
Mkt value	6.9
Mkt shares	
B+I:	[55-65]
Pharma:	[25-35]
Sandoz:	[5-15]
Others:	[below 5%]

4. Factor VIII

Germany	
Mkt value	230.4
Mkt shares	
B+I:	[35-45]
Centeon:	[35-45]
Bayer:	[5-15]
Others:	[15-25]
Italy	
Mkt value	32.7
Mkt shares	

B+I:	[45-55]
Marcucci	[35-45]
Centeon:	[5-15]
Others:	[below 5%]

Spain	
Mkt value	27.9
Mkt shares	
B+I:	[35-45]
Bayer:	[35-45]
Others:	[15-25]

Sweden	
Mkt value	21.9
Mkt shares	
B+I:	[35-45]
Centeon:	[15-25]
Others:	[35-45]

5. Inhibitors for the treatment of bleeds in haemophilia patients
(Data n.a.)