II

(Acts whose publication is not obligatory)

COMMISSION

COMMISSION DECISION

of 6 October 1994

relating to a proceeding pursuant to Article 85 of the EC Treaty and Article 53 of the EEA Agreement
(IV/34.776 — Pasteur Mérieux-Merck)

(Only the English and French texts are authentic)

(Text with EEA relevance)

(94/770/EC)

THE COMMISSION OF THE EUROPEAN COMMUNITIES,

Having regard to the Treaty establishing the European Community,

Having regard to Council Regulation No 17 of 6 February 1962, first Regulation implementing Articles 85 and 86 of the Treaty [1], as last amended by the Act of Accession of Spain and Portugal, and in particular Articles 2, 4, 6 and 8 thereof,

Having regard to the notification on 4 June 1993 by Merck & Co. Inc. and Pasteur Mérieux Sérums et Vaccins pursuant to Article 4 of Council Regulation (EEC) No 4064/89 [2],

Having regard to the Commission's decision on 5 July 1993 that the notified operation does not fall within the scope of Regulation (EEC) No 4064/89 because it does not constitute a concentration within the meaning of Article 3 of the said Regulation [3],

Having regard to the parties' request pursuant to Article 5 (1) of Commission Regulation (EEC) No 2367/90 [4], as amended by Regulation (EC) No 3666/93 [5], to treat the notification pursuant to Regulation (EEC) No 4064/89 as an application within the meaning of Article 2 and/or a notification within the meaning of Article 4 of Regulation No 17,

Having regard to the Agreement on the European Economic Area (hereinafter referred to as 'the EEA Agreement'), and to the parties' request on 26 January 1994, pursuant to Articles 5 and 8 of Protocol 21 to the EEA Agreement, that their notification be extended to Article 53 of the EEA Agreement,

Having published a summary of the application and notification pursuant to Article 19 (3) of Regulation No 17 [6],

After consulting the Advisory Committee on Restrictive Practices and Dominant Positions,

Whereas:

I. THE FACTS

A. The procedure

(1) The notification concerns an operation under which Pasteur Mérieux Sérums et Vaccins (PMsv) and Merck & Co. Inc. (Merck) will organize their existing activities in the human vaccines and some related businesses within a territory being defined

(1) OJ No 13, 21. 2. 1962, p. 204/62.
(2) OJ No L 395, 30. 12. 1989, p. 1; amended version in OJ No L 257, 21. 9. 1990, p. 13.
(3) OJ No C 188, 10. 7. 1993, p. 10.
(4) OJ No L 219, 14. 8. 1990, p. 5.
(5) OJ No L 336, 31. 12. 1993, p. 1.
(6) OJ No C 94, 31. 3. 1994, p. 15.

as the EC and EFTA, through a jointly-controlled company, Pasteur Mérieux MSD SNC (the JV). The operation is organized by the way of a set of different agreements between the parties, most dated 25 May 1993 and includes a set of so-called 'ancillary agreements', in particular the Overview Agreement between the JV and Behringwerke AG (Behring).

(2) Since 5 July 1993, the operation has been examined pursuant to Articles 85 and 86 of the EC Treaty. Within two months, notably on 13 August 1993, the Commission informed the parties that it had serious doubts as to the compatibility of the notified operation with Community competition rules, and invited them to submit satisfactory proposals in order to prevent the case being closed by a negative decision.

(3) As a result the parties gave, with a viev to obtaining an exemption under Article 85 (3), an undertaking on 3 November 1993 to amend substantially the agreements with Behring and to grant specific rights to third parties in respect of some vaccines. This undertaking resulted in the following changes to the Behring agreements:

— conclusion of an exclusive manufacturing licence for Merck's monovalent Haemophilus Influenzae B (HIB) vaccine, used to prevent one of the forms of meningitis, in Germany (recital 27),

— conclusion of the Multivalent Technology Transfer Licence Agreement in the form described below (recital 44),

— amendments to the other agreements for the distribution of certain vaccines in Germany (recital 43).

The undertaking also resulted in the conclusion with Pierre Fabre Médicament SA (Pierre Fabre) of an exclusive manufacturing licence for Merck's monovalent Hib vaccine in France and distribution rights for France to Merck's measles/mumps/rubella (MMR) vaccine and its individual and bivalent components (recitals 32 and 33).

The parties also undertook that the JV would provide the Commission with annual reports on volumes, prices and/or market shares in connection with the German and French HIB markets, and the French Hepatitis B and measles/mumps/rubella markets.

(4) The entry into force of the EEA Agreement on 1 January 1994 and the parties' request on 26 January 1994 to extend their notification to Article 53 of the EEA Agreement, led to a further undertaking on 25 February 1994 pursuant to which on 16 May a letter of intent has been concluded with the Finnish company, Orion Pharmaceutical International (Orion), to enter into negotiations to grant Orion an exclusive manufacturing licence for Merck's monovalent Hib vaccine in the Nordic EFTA countries. However, on 13 June Orion turned down this offer (recitals 34 and 35).

(5) Lederle-Praxis Biologicals (LPB) is a subsidiary of the US pharmaceutical company American Cyanamid Company and active on the US vaccine markets and since 1991 in Europe with its HIB vaccine. On 15 June 1993 [1], this company lodged an application pursuant to Article 3 (2) of Regulation No 17 for the initiation of a proceeding under Articles 85 and 86 of the EC Treaty against Institut Mérieux, the parent company of PMsv; Merck and Smith Kline Beecham (SKB) (hereinafter referred to as 'the complaint'). The complaint consisted of two different parts. The first part related to LPB's allegation that the three firms are abusing their dominant positions in various Member States by not supplying Hepatitis B vaccine to LPB. LPB also requested the Commission to adopt interim measures to compel them to sell Hepatitis B vaccine to LPB on reasonable commercial terms and conditions including access to registration documents. The second part related to the formation of the JV between PMsv and Merck. The Commission has, by letter of 17 February 1994, pursuant to Article 6 of Commission Regulation No 99/63/EEC [2], informed LPB that it considers that there are not sufficient grounds for granting the first part of the application and that the second part will be dealt with in the context of the specific proceedings for notified agreements pursuant to Regulation No 17. LPB has, by letter of 22 April 1994, informed the Commission that it will not submit comments to the Commission's letter, but that it is intending to respond to the publication pursuant to Article 19 (3) of Regulation No 17 (see recitals 45 to 48).

B. The parties

(6) PMsv is a subsidiary of Institut Mérieux, itself a subsidiary of Rhône-Poulenc, a privatized French group of chemical and pharmaceutical companies active worldwide. PMsv is a specialist manufacturer of human vaccine products, blood proteins and other related biological products.

[1] At that time the Commission was assessing the notified operation under the Merger Regulation.

[2] Regulation No 99/63/EEC of 25 July 1963 on the hearings provided for in Article 19 (1) and (2) of Council Regulation No 17 (OJ No 127, 20. 8. 1963, p. 2268/63).

The turnover figures (million ecu for 1992) for Rhône-Poulenc and PMsv are: Rhône-Poulenc (worldwide: 11 962; EEA: 6 481) and PMsv (worldwide: 588, of which 414,6 from vaccine sales; EEA: 293, of which 226 from vaccine sales). PMsv's EEA turnover from immunoglobulins, *in vivo* diagnostics and sera was ECU 10,7 million in 1992.

(7) Merck is a major US company active worldwide in pharmaceuticals. Its total turnover (million ecu for 1992) was: (worldwide: 7 444, of which 374 from vaccine sales; EEA: 1 847, of which 43,9 from vaccine sales). In 1991 Merck formed a separate division for its vaccines business. Merck is not active in the fields of immunoglobulins, *in vivo* diagnostics and sera.

(8) In April 1992 the US Federal Trade Commission approved a joint venture between PMsv's indirect subsidiary, Connaught Laboratories Inc. and Merck for the research, development and marketing of new multivalent (i.e. a combination of several antigens in one vaccine) paediatric vaccines in the United States of America. The parent companies will distribute the vaccines for the JV by way of co-promotion: Merck distributes the vaccines to managed health care organizations and Connaught Laboratories Inc. to private paediatricians. The parties have also entered into similar co-promotion agreements for their existing paediatric vaccines.

C. The products

(9) The business of the JV will relate to human vaccines, specific immunoglobulins, *in vivo* diagnostics, sera and such additional products as the partners may from time to time determine. This Decision does not cover such additional products.

1. *The non-vaccine products*

(10) The specific immunoglobulins transferred by PMsv to the JV are rabies and tetanus immunoglobulins, which are life-saving products. These products are routinely administered with the vaccine after an animal bite or a wound. The diagnostics refer strictly to a tuberculin-test used in connection with PMsv's tuberculosis BCG vaccine. Sera are very minor products (ECU [. . .] [1] turnover in the EEA with 11 sera) which PMsv continues to provide for public health reasons. The most important product group within this operation, and the only one on which both PMsv and Merck are active, relates to human vaccines.

2. *Characteristics of the vaccines sector*

1. Vaccine R & D

(11) The importance of vaccination for public health is generally recognized [2]. However, vaccines are currently available for only a minority of the diseases for which they are required. R&D efforts for the development of new vaccines and vaccine technology are thus continuing and may be guided by reference to epidemiological studies. Just as for pharmaceuticals, however, R&D remains a complex, costly, long-term enterprise that requires large teams and multi-disciplinary approaches. The cost of development of a new product is very high [3] owing to enforced safety regulations and controls, risk of claims for damages and expensive clinical trials. Fundamental research, increasingly based on biotechnology and in particular recombinant DNA technology, is often conducted by specialized companies, scientific institutes or universities, which protect their research results through patents, the rights to which are then licensed to vaccine manufactures in return for royalty payments.

(12) Another objective is the combination of several existing vaccines into new multivalent vaccines. The R&D efforts involved here relate to the reformulation of each antigen, so that it can be effectively used in combination with the other antigens. With the exception of the combination of an inactivated vaccine with a live vaccine, all sorts of combinations are in theory possible [4].

(13) In the area of paediatric (obligatory or recommended) vaccinations, the development of a series of vaccine combinations, including any of DTP (diphtheria/tetanus/pertussis), HIB, polio and Hepatitis B — the so-called 'ideal children's vaccines' — is a generally recognized priority. The

[1] In the published version of the Decision, some information has hereinafter been omitted, pursuant to the provisions of Article 21 of Regulation No 17 concerning non-disclosure of business secrets.

[2] See, for example, the Commission communication of 2 March 1994 to the Council and the Parliament on the outlines of an industrial policy for the pharmaceutical sector in the European Community (COM(93) 718 final, Chapter 2, p 11).

[3] Estimated cost between US$ 100 to 200 million.

[4] Possible combinations include, e.g. a vaccine combining hepatitis A, B, C and E antigens, a meningitis combination, an MMR varicella combination or specifically targeted adult vaccine combinations on the basis of adjusted diphteria doses or a pneumococcus-flu combination.

benefits of such, ideally heat-stable, vaccines would include: fewer injections; fewer clinic visits; increased family acceptance, resulting in better coverage; cost savings with regard to necessary supplies (e.g. needles, syringes, vials), cold chain storage space and administration by medical personnel; greater ease of delivery; simplified record keeping and more efficient post-administration monitoring services.

(14) The vaccine manufacturers consider that the ideal antigens for these combinations should be based on an improved, so-called acellular, pertussis antigen; an injectable polio antigen and a recombinant Hepatitis B antigen. As regards pertussis, this is the result of perceived side effects with whole cell pertussis. These perceived effects are the reason why immunization against pertussis in the form of DTP, despite decades of experience to back it up, is currently not in general paediatric use in Italy and Denmark. As regards polio, the vaccine used for general immunization in almost all countries is in oral form and based on an attenuated virus. For a multivalent, an injectable polio vaccine is required. Currently, only PMsv and RIVM (the Dutch Public Health Institute) produce, based on their proprietary know-how, an injectable polio vaccine, based on a killed virus. If vaccinated with a killed virus, the possibility that a healthy child might develop the disease following vaccination is totally excluded. As regards Hepatitis B, a plasma-based vaccine (such as the one previously produced by PMsv), is no longer approved by health authorities in view of the blood-related risks.

2. Vaccine production

(15) Production of vaccines is a complex process involving growth of the cell culture, purification of the bulk vaccine, formulation, filling and packaging of the product. This process is often subject to proprietary know-how and may even be, as is the case with Hepatitis B production, patent-protected. The manufacturing facilities are controlled and qualified by the national regulatory authority according to the legal standards and provisions of the country where the production is located (including good manufacturing practice). As the regulatory qualification of the manufacturing facilities is part of the authorization of the vaccine product itself, a change of production facility or even change in production process will or may require the undergoing of new qualification and licensing procedure for the vaccine. Therefore even vaccine companies with worldwide activities manufacture all their products in one place where the national production qualification is recognized by the relevant authorities in all the countries in which the vaccine is to be distributed. Furthermore, in contrast to pharmaceutical products, in some countries vaccines need, in view of their biological nature and the inherent risks in such products of batch failures, a batch release from the relevant national control laboratory for each batch.

3. Vaccine distribution

(16) Vaccine companies distribute their products in the EEA on a country-by-country basis, because of national differences (in spite of technical harmonization achieved so far) relating to:

— epidemiology: e.g. HIB vaccine is in paediatric use mainly in northern Europe; Hepatitis B is in paediatric use mainly in southern Europe,

— immunization schemes: in particular, vaccination with certain vaccines may be compulsory in certain countries, but only recommended in other EEA countries; even the time schedules for identical vaccines vary from country to country for some paediatric vaccines (the tuberculosis vaccine BCG, DTP and polio vaccines),

— pharmacovigilance (i.e. the observation of unexpected effects of vaccination) and, in some countries, batch release requirements which need to be fulfilled on a national level,

— the widely varying price and reimbursement mechanisms: in some EEA countries vaccination is free of charge for some or all vaccines, whereas in other countries patients receive a partial or complete reimbursement,

— differences in the demand structure: in the Nordic countries, the Netherlands and Greece the supply of vaccines is virtually exclusively generated by public health institutes who either produce their own vaccines or purchase products in bulk or finished form through public tenders (in Iceland, Norway and Finland these institutes still have an import monopoly); in Ireland, Italy, Spain and the United Kingdom vaccines are purchased mainly through public tenders, but the doctors choose the vaccine they prescribe from a range of recommended available vaccines; in other EEA countries, chiefly France and Germany, vaccines are to a large extent supplied to the private market and distributed via wholesalers to pharmacies or directly to hospitals and (in the case of Germany), doctors; vaccine manufacturers therefore require a sales force to market successfully their products in these countries,

— differences in national preferences as to the presentation forms of vaccines, such as, e.g. vials, single-dose, multi-dose, multi-chamber syringes (1).

(17) These varying characteristics result in significant differences, from vaccine to vaccine, and from country to country.

This can be illustrated by reference to the three largest national markets in the EEA: France, Germany and Italy, each of which accounted for sales of about ECU 130 million in 1992. In Italy, the only country with a recommended general paediatric vaccination against Hepatitis B, sales of this vaccine alone totalled over 50 % of total sales, whereas there were virtually no sales of HIB vaccines. This last vaccine was in turn the most important vaccine in Germany with its sales amounting to about 25 % of total vaccine sales. Sales of flu vaccines in Germany were worth about ECU 15 million (12 % of total sales). In France, Hepatitis B and flu vaccines represented sales of over ECU 35 million each (giving each over 25 % of total sales).

3. *The position of the parties on the vaccine markets*

1. General overview

(18) Merck's European vaccine portfolio consists of MMR and its individual and bivalent components, HIB, Hepatitis B and pneumococcus (2). Despite entering the European vaccine markets as early as the beginning of the 70s, Merck only has staff dedicated to vaccines in the Netherlands and Spain (between one and three in each case) and a small group (less than 10) in Germany. Its Hepatitis B vaccine is promoted in Italy by its general hospital sales force. Merck thus works almost exclusively via independent distributors and public health institutes for the distribution of its vaccine portfolio in Europe. The distribution of this complete portfolio occurs in only one EEA country, Germany, where the vaccines are distributed by Behring. Sales in Germany represented in 1992 almost 50 % of Merck's vaccine sales in the EEA totalling ECU 43,9 million (i.e. only 2,3 % of Merck's total combined turnover of all products in the EEA). Another 30 % of total sales was accounted for by Hepatitis B vaccine sales in Italy. No vaccine was distributed in France.

(19) PMsv has a much larger vaccine operation in the EEA. In 1992 it offered some 40 vaccine combinations against some 20 diseases. The distribution of these vaccines occurs predominantly via its own subsidiaries or via the Nordic, Dutch and Greek public health institutes (see recital 16). Independent distributors play a role only in Germany (Roehm for the Connaught vaccines), Portugal, Greece and Ireland and, for its flu vaccine only, throughout the EEA. PMsv is thus present in all EEA countries. Nevertheless, PMsv's vaccine sales are concentrated in certain countries. France accounted for over 50 % of PMsv's total vaccine sales in the EEA. In 1992, PMsv was the only producer of all vaccines offered in France with the exception of flu (where its products — distributed by PMsv itself and other independent distributors — commanded over 90 % of the market) and Hepatitis B (where it accounted for over 50 % of the market, SKB accounting for the remaining part). In particular for paediatric vaccination (DTP, polio, BCG, HIB and MMR), where 3 000 French paediatricians (3 % of French doctors) prescribe almost half of these vaccines, PMsv was in a very strong position, partially owing to its ability to offer the complete paediatric range which relieved the prescribing doctors of the need to maintain distribution relationships (information exchange including medical representation visits, use of refrigerator, discounts) with more than one producer.

United Kingdom sales accounted for almost 20 % and German sales for almost 10 % of PMsv's total turnover. PMsv does not have (as will be explained below) a Hepatitis B vaccine for offer outside France, or a widely accepted MMR vaccine (rentals 22 to 24).

2. Product portfolio overlap

(a) Existing products

(20) The parties' existing products' portfolio shows an overlap for HIB, MMR (and its monovalent components), Hepatitis B, and pneumococcal vaccines.

(21) PMsv supplies two different HIB vaccines, its own product and the product originating from its Canadian subsidiary, Connaught Laboratories Inc., which was the first such vaccine launched in EEA markets in 1990. This is now marketed under two different brands. Merck's HIB vaccine entered the first EEA markets in 1991. The HIB vaccine is mainly used as a paediatric vaccine to prevent one of the forms of meningitis.

(22) As regards MMR, clinical studies have showed increased side-effects for the mumps strain used by

(1) This can be illustrated by reference to Merck's Hepatitis B vaccine, which is currently only available in vial. French doctors traditionally prefer the vaccine to be presented into a prefilled syringe, which would require a 75 000-dose stability study which might take one to two years.

(2) The use of pneumococcal vaccine is illustrated in recital 25.

SKB and PMsv. This has led SKB to withdraw its mumps and MMR products from all EEA markets, whilst PMsv currently offers them only in France [1], Italy and Greece. This leaves Merck as the only producer with widely accepted mumps and MMR vaccines (Berna, another Swiss-based competitor, is currently registering its MMR in Greece and Austria). The MMR market is an important one with sales in 1992 totalling over ECU 40 million in six Community countries (Germany, Italy, France, United Kingdom, Spain and Belgium), out of a total of almost ECU 45 million for the complete MMR family in these countries. It is estimated that an improvement of the mumps strain will take between three to five years.

(23) The Hepatitis B vaccine is no longer produced on a plasma basis, in view of the blood-related risks. All current formulations are produced by way of genetic engineering. This is, however, subject to different patent claims. There is, furthermore, considerable uncertainty as to the legal validity and precise scope of the different patent claims for Hepatitis B vaccine technology. Some patent applications have yet to be granted, and some of them may either be opposed or have already been partly or entirely revoked or are under appeal. For this reason, Merck and SKB decided to enter into cross-licensing arrangements in relation to rights which had been licensed by several research institutions to them. This cross-licence does not allow these parties to sub-license their acquired rights to other companies whereas a sub-licence to an affiliate such as a JV is allowed. Other producers which would like access to the patent rights involved, in order to avoid uncertainty and costs of litigation, therefore need at least a sub-licence of both Merck and SKB under their respective rights. Apart from Merck and SKB, Hepatitis B vaccines are also offered by Berna and the United Kingdom company, Medeva. Berna has received from Teijin, a Japanese producer, distribution rights for its Hepatitis B vaccine for Switzerland (where it is already on sale), Portugal, Spain, Italy and Greece. Medeva is at present appealing against a judgment of the United Kingdom High Court which found that its product infringed Biogen's patent (licensed to SKB).

(24) PMsv is licensed to sell its recombinant Hepatitis B vaccine as a monovalent in France, but not outside France. Moreover, it does not have the licences to include its Hepatitis B in a multivalent (even in France). Furthermore, PMsv believes that it would be unlikely to obtain a registration for its recombinant (monovalent) Hepatitis B vaccine outside France, [. . .].

(25) Currently, the pneumococcal vaccine is prescribed in order to prevent pneumococcal pneumonia in patients, in particular those who are immunocompromised (notably, patients whose spleens have been removed) or who have chronic conditions which make them particularly at risk for pneumococcal pneumonia, such as chronic obstructive pulmonary disease, heart disease, or liver disease. As a group, they are generally older adults.

Although the size of this target group is potentially large, the use of the vaccine has remained controversial. This is illustrated by the fact that, although the vaccines have been commercially available since the mid-70s in Europe and North America, the combined turnover in all EEA countries is estimated to total only about ECU 1,1 million, France being the largest single market with an estimated turnover of about ECU 500 000 (in some countries where the vaccine is sold it is even not registered, but provided on a 'named patient' basis). It should be noted that pneumococcal vaccine is different from the pneumococcal conjugate vaccine currently under development. This latter vaccine is expected to be used in infants and children to prevent a type of meningitis and inner ear infections. There is virtually no overlap of the target groups, or in the technology.

(b) Future vaccines

(26) Each of the parties is active in R&D work for a series of vaccines, but their R&D pipeline for vaccines in later stages of development currently overlaps only as regards a Hepatitis A and a varicella vaccine for use in normal children. Their pre-clinical trial research overlaps only as regards a pneumococcal conjugate vaccine. Furthermore, Merck has no acellular pertussis, or injectable polio vaccine research programme.

3. Geographical specifications

(a) Germany

(27) At present both PMsv and Merck have monovalent HIB, measles and rubella vaccines on sale in Germany. The most important, in terms of turnover, of these markets is the monovalent HIB market which totalled sales of over ECU 30 million in 1992, of which vaccines belonging to PMsv or its Canadian subsidiary Connaught Laboratories Inc. realized about 75 % and the Merck vaccine, introduced in 1992 and distributed by Behring, about 10 %. The only other competitor is LPB which also introduced its vaccine in 1992 and achieved a market share of about 15 %.

However, the parties have, by agreement of 26 May 1994 [2], granted Behring an exclusive

[1] [. . .].

[2] See recital 3.

licence under the HIB patents and know-how to manufacture (and distribute) Merck's monovalent HIB vaccine for sale in Germany. The licence enables Behring to establish its own manufacturing facility, or to arrange for the manufacture to be subcontracted to Merck or to a licensee in the Community of Merck or the JV.

(28) The monovalent rubella market has an estimated 1992 turnover of about ECU 2,5 million and totalled over 400 000 doses [1]. The bulk of the rubella vaccine is however sold as part of the MMR market which realized a turnover of more than ECU 20 million. The parties' monovalent rubella vaccines accounted for almost 95 % of the number of doses sold [. . .]. The remaining vaccines were sold by SKB and Wellcome, both internationally operating vaccine producers.

(29) The parties have a combined share of some 60 % [. . .] of the German monovalent measles market with a turnover in 1992 of less than ECU 300 000, the remaining market share realized with SKB's vaccines. The bulk of the measles vaccine is equally sold as part of the MMR vaccine.

(b) Greece

(30) At present, both parties still sell their MMR vaccines, each via an independent distributor, on the Greek market. Their vaccines are the only ones currently sold in Greece with a total turnover in 1992 of less than ECU 700 000 [. . .]. Berna, a Swiss-based vaccine producer, is however registering its MMR vaccine in Greece.

(c) Portugal

(31) On the Portuguese pneumococcal vaccine market, with a total turnover (ex factory prices) of less than ECU 3 000, the parties offered the only vaccines in 1992. However, none of the two vaccines is registered in Portugal, sales being made on a 'named patient'-basis as a service.

(d) France

(32) The parties have granted [2] to Pierre Fabre, by agreement of 30 June 1994, distribution rights for France to Merck's MMR and its individual and bivalent components. These rights are exclusive, except for the JV or its French affiliate in regard to MMR, monovalent mumps and bivalent measles/mumps. Pierre Fabre has the option of using Merck's trademarks in France for MMR, monovalent mumps and bivalent measles/mumps, or of using its own trademarks. Pierre Fabre agrees that, for the duration of the agreement, which is for 10 years with the option (at the sole discretion of Pierre Fabre) of further five-year prolongations, it will not engage in activities with regard to competing products.

(33) Also by agreement of 30 June 1994 Pierre Fabre received an exclusive licence under the HIB patents and know-how to manufacture Merck's monovalent HIB vaccine for sale in France. This licence enables Pierre Fabre to establish its own manufacturing facility, or to arrange for the manufacturing to be subcontracted to Merck or to a licensee in the Community of Merck or the JV. The rights granted to Pierre Fabre shall not affect the right of the JV or its French affiliate to sell Merck's monovalent HIB vaccine in France, should any regulatory or medical problems arise in connection with the monovalent HIB (PRP-T) vaccine presently marketed by PMsv in France. The duration of the licence is 10 years with further five-year prolongations at the sole discretion of Pierre Fabre.

(e) Nordic EFTA countries (Iceland, Norway, Sweden and Finland)

(34) PMsv's and Merck's HIB vaccines do not currently actively compete on the Nordic EFTA countries monovalent HIB markets. However, in 1991 and 1992 in Sweden and in 1992 in Norway, their vaccines were the only HIB vaccines sold, with 1992 sales totalling about ECU 4 million in Sweden and over ECU 1 million in Norway (PMsv's HIB vaccines accounting for some 90 % of these sales). However, the Swedish association of paediatricians recommended PMsv's PRP-T HIB vaccine for the general vaccination of infants in Sweden during 1993 and 1994. This recommendation, together with a clinical trial lasting from 1993 until May-June 1994 on 50 % of Swedish new born children involving PMsv's HIB vaccine, has led to Merck's vaccine almost disappearing from the market during 1993 and 1994. Statens Bakteriologiska Laboratorium, until June 1993 the holder of an import monopoly on vaccines, was the distributor of Merck's vaccine in Sweden and also offered it to the Norwegian State institute, but entered in June 1993 into a [. . .] supply agreement with PMsv.

[1] German merger law, under which the JV is also assessed, considers the monovalent rubella vaccine market as a *de-minimis* market as total turnover is less than DM 10 million for a product which is already at least five years on the market. This is also the case for the monovalent measles market.

[2] See recital 3.

(35) Nevertheless, in May 1994 the parties signed a letter of intent with Orion [1] whereby they agreed to enter into negotiations to grant Orion an exclusive licence to manufacture Merck's monovalent HIB vaccine for sale in the Nordic EFTA countries. Such a licence would have been along the same lines as the one entered into with Pierre Fabre for France. However, Orion informed the parties on 13 June 1994 that, after thoroughly investigating every possibility to introduce the vaccine in the Nordic countries, they had decided to turn down this offer. The parties indicated that the offer remains valid for other interested third parties.

D. The notified operation

(36) *Objectives and business scope of the JV*

The primary purposes and objectives of the JV are:

— the creation and development of new multivalent vaccines which would result in significant public health benefits as indicated in recital 13,

— the distribution of existing (and new) products in countries where they are not yet marketed (or would not be were it not for the creation of the JV),

— future research in (i) new vaccines, concentrated on specific European requirements (with respect to epidemiological and/or biological characteristics of the vaccines, adapted dosages, combinations or traditionally preferred delivery systems), from post-clinical phase II onwards; and (ii) related new technologies such as, e.g. the improvement or elimination of preservatives, improved vectors/new delivery systems (oral delivery), DNA/RNA-based research.

The business scope of the JV will be to facilitate the research of, oversee the development of, register, arrange for the manufacture (in principle by either PMsv or Merck) of, distribute, market and sell in the EC and EFTA vaccines, immunoglobulins, *in vivo* diagnostics, sera and such additional products as the partners may from time to time require.

(37) *Transfer of the existing business to the JV*

The JV will be set up in the form of a 'Société en nom collectif' (SNC) under French law, capitalized with FF 265 million by Merck's French subsidiary (Merck Sub), but on closing Merck Sub and PMsv will each hold a 50 % ownership. The SNC assembly of partners will be composed of two voting members representing the parent companies. Day-to-day activities will be managed by the gérant in the form of a French 'Société anonyme à directoire et conseil de surveillance' in which each parent will have an equal shareholding and equal representation.

Each party will transfer to the JV its existing product registration rights and will exclusively license to the JV the existing patents and the know-how owned by or licensed to it, except for any rights retained (i) to permit the continued manufacture of products solely for sale to the JV in the territory and (ii) for sale for use outside the territory [2], and except for rights of third parties existing prior to the JV. All other existing product rights such as copyrights, trade dress and tradenames will be licensed or transferred to the JV.

In addition PMsv will transfer or license certain tangible assets, its 'fonds de commerce' and the capital stock of certain of its subsidiaries. Each parent will also transfer to the JV its respective rights and obligations under distribution agreements with third parties, except for the agreements between Merck and Behring, its German distributor, with whom the JV concluded the Behring Agreements.

(38) *New vaccines*

Each parent agrees, subject to third party rights, to transfer or license to the JV the product rights (other than registrations) necessary to market the pipeline products (i.e. those vaccines which are at a late development stage) in any country of the territory as they arise, or, at the option of the JV, to render all reasonable assistance to enable the JV to obtain these rights in its own name. If the JV elects to commercialize such a product, the originating party will permit the JV to obtain product registrations for the product in the territory, subject to retention of such registrations as the originating party may require to continue to manufacture such product solely (i) for sale for use outside the territory, or (ii) for sale to the JV for

[1] See recital 4.

[2] The production facilities of the parties in Europe (this is only of relevance for PMsv) will not be transferred to the JV; see also recital 39 'Other arrangements — supply'.

use within the territory. If the JV elects not to bring such a product on the market, it may transfer or license the product rights (except for a product containing Merck's Hepatitis B) to a third party. If the JV pursues the development, it will fund and direct the post-phase II testing and post-launch development studies used to support the registration and marketing of the product in the territory. The patents and know-how resulting from development work funded by the JV shall belong to the JV for the territory, whereas the party engaged in the relevant development work outside the territory shall own the patents and know-how there.

As regards products at an early development stage (the future pipeline products), the originating party will at the commencement of post-phase II testing, offer the product to the JV. If the JV accepts the product, the JV will receive an exclusive licence, subject to third-party rights in the territory, for the product rights. The mechanism for product registration, sharing of development costs and intellectual ownership is identical to that for pipeline products. If the JV does not want to bring the product on the market, it is the originating party which may transfer or license all rights to a third party in the territory on terms no more favourable than those offered to the JV.

A development committee will be assembled in order to formulate, implement and direct the R&D strategy of the JV and the parents for the benefit of the JV in the territory.

The development committee shall:

— oversee communications regarding the R&D activities of the parents undertaken for the JV, including communications concerning discoveries,

— oversee the development of JV multivalent products,

— identify the most efficient utilization of the available resources of the parents for such development activities, and also identify the appropriate multivalent products for development,

— advise the management bodies of the JV.

All patents and know-how resulting from development work funded by the JV with respect to multivalent products shall belong to the JV, provided that the parents shall each be granted a non-exclusive, worldwide, royalty-bearing licence.

(39) *Other arrangements*

Administrative and support services (including accounting, treasury, management information, currency hedging and other financial services, legal, medical and regulatory services) may be provided by each of the parents on a cost basis.

Merck and PMsv will each supply, on a cost basis, the JV's requirements of existing products, the rights to which the parent transferred or licensed to the JV, and future products with respect to which the parent is the originator, and these the JV will either sell (as monovalent) or include in multivalent products. PMsv will, for so long as it has the capacity and can do so at a competitive cost, complete the finishing of the JV's multivalents unless all components come from Merck. The JV shall have the right to audit all these costs every two years. In the event that the JV determines that the costs are not reasonable, it may procure the relevant services (if permissible under the terms of patents/licences relating to such products) from the other or a third party, provided that this is on substantially more advantageous terms than the existing party is willing to offer.

Connaught Laboratories Inc. shall grant the JV an exclusive (subject to any third party rights) licence for the territory of product rights to its future products for a term of 30 years, which agreement shall terminate in the event that Connaught ceases to be a PMsv affiliate. The JV shall manage the existing distribution arrangements of Connaught in the territory and, at the option of the JV, shall serve as Connaught's distributor for its existing products, subject to any third-party rights.

(40) *Duration*

The agreement shall terminate automatically at the end of the year 2023 unless extended by mutual consent in writing.

However, Merck has the right to sell its interest at any time after 2001, with PMsv having the first option to purchase.

(41) *Non-competition*

The parents agree not to sell or supply, nor to license to a third party, prior to termination, a JV product or a competing product for use in the territory.

Merck will not, for a period of five years following the sale of its interest, sell, supply or license to a

third party a JV product sold by the JV prior to the sale of the Merck interest or a competing product.

None of the parents will solicit an employee of the JV to leave the JV for three years after the termination of the JV or the sale of its interest.

E. The Behring agreements

(42) *Behring*

Behring is a subsidiary of the German chemical concern Hoechst AG and a producer and distributor of pharmaceutical products (therapeutical and diagnostical). Behring realized in 1992 a worldwide turnover of ECU 632,6 million of which less than 20 % is accounted for by vaccine sales. These vaccine sales were concentrated in Germany. A very substantial part of its German sales was with products of other producers, mainly Merck (distributor for pneumococcal, MMR and HIB, agent for Hepatitis B). This makes Behring currently the most important vaccine manufacturer and distributor in Germany accounting in 1992 for almost half of the turnover realized on the German vaccine markets. Outside Germany, Behring is not active in the EEA with the exception of its flu vaccine which is distributed in France by Cassenne, another subsidiary of Hoechst AG.

(43) *Continuation of the distribution of Merck's existing vaccines (other than HIB — see recital 27) and co-promotion of some future JV vaccines*

Until 2004 Behring will be, in Germany, subject to any rights of third parties:

— the exclusive but for the JV (i.e. the sole) distributor of Merck's existing MMR (and its components) and pneumococcal vaccines; these vaccines each account for at least 40 % of the German markets,

— the sole agent for the distribution of Merck's existing Hepatitis B vaccine; Behring will sell in its own name, but for the account of the JV, this vaccine which commanded about half of the German Hepatitis B market in 1992,

— the exclusive co-promoter of the JV's future varicella, MMR varicella and Hepatitis A vaccines. A co-promotion agreement is an agreement whereby one party (the co-promoter) lends its marketing force to promote, as regards the medical profession a product of the originating party, which party retains the final responsibility as to price, quality standards, and quality and quantity of promotional efforts to be dedicated to its products.

Behring will have the right to make sales outside Germany in response to unsolicited requests. If Behring distributes a product of a third party competing to any of these vaccines, Behring's appointment will become non-exclusive for that vaccine.

(44) *Development by Behring of multivalents* [1]

The parties have entered into a set of agreements with Behring under which Behring has the option to procure from the JV its requirements for HIB, acellular pertussis and/or Hepatitis B antigens for inclusion in multivalents to be developed by Behring for sale in Germany (with the right to make sales outside Germany in response to unsolicited requests). This right lasts until 2004, but should Behring develop a multivalent at any time before that date, the right to procure the JV's antigens for that particular multivalent shall last for a minimum of five years from its first marketing and in any event until 2004. This development work will be on the basis of a Multivalent Technology Transfer Licence Agreement enabling Behring to use, sell, make or have made Behring multivalents under the licensed technology. The JV is obliged not to license other undertakings to exploit the licensed technology, defined as 'multivalent know-how' [2], in Germany.

In view of the Hepatitis B patent situation (see recital 23), Behring's rights with respect to multivalents developed by it containing Merck's Hepatitis B antigen are limited to the use and sale

[1] See recital 3.

[2] Meaning all information, discoveries, improvements, processes, formulas, data, engineering, technical and shop drawings, inventions, shoprights, know-how and trade secrets, in each case which during the term of the agreement are not generally known and which (a) relate to the development in Germany of (i) Behring multivalent products and/or (ii) the JV's HIB, Hepatitis B and/or acellular pertussis to be included in a Behring multivalent product and (b) are necessary to use or sell (and, in the case of Behring multivalent products (other than Hepatitis B multivalent products) make or have made) Behring multivalent products in Germany. Nothwithstanding the foregoing, multivalent know-how shall not include any such information or data which is proprietary to a third party and is available to the JV or any of its affiliates under a licence pursuant to which the JV or such affiliate does not have the right to grant sub-licences with respect to such matters.

of these products. The trademark and the product registrations of such vaccines will be owned by the JV; Behring will produce such vaccines as a subcontractor for the JV.

This agreement gives Behring the opportunity to develop a distinct set of multivalents for sale in Germany, based on its own antigens, JV antigens and/or third party antigens. Behring is also free to exploit outside Germany its own severable intellectual property rights created in developing a multivalent containing an antigen of the JV.

F. Third parties' observations

(45) The Commission has received comments on the notified operation, the essential content of which was published pursuant to Article 19 (3) of Regulation No 17, from LPB and SKB, two companies that are in competition on some of the markets involved with the notifying parties. LPB objected to the Commission's intention to exempt the JV [1] in view of the oligopolistic nature of the European vaccine markets where, according to LPB, three companies account for close to 90 % of sales of paediatric vaccines and the JV would immediately have an overall market share (paediatric and all human vaccines) of close to 70 % in the Community.

(46) LPB believes that the JV will have a detrimental effect on the future structure of competition as the combination of the resources of the parties will severely hinder the ability of other companies to enter the market for, especially, the new paediatric multivalent products. LPB considers that the development of a paediatric hexavalent containing DTP, HIB, Hepatitis B and polio vaccines, will have a dramatic effect on sales of the monovalents included so that companies, including LPB, which do not have access to Hepatitis B due to the, according to LPB, exceptionally broad patents, will face a severe threat to their ability to remain on the vaccines markets. LPB considers access to the Hepatitis B antigen as crucial in view of the already current paediatric vaccination against Hepatitis B in Italy, Spain and Portugal and the acknowledgment by all public health administrations in northern Europe that the spread of the Hepatitis B virus cannot be effectively controlled through the vaccination of so-called adult high-risk groups so that these administrations intend to recommend paediatric vaccination if the incremental cost is in relation to its benefits.

(47) The launch of the hexavalent vaccine will, according to LPB, be a spur to universal immunization against Hepatitis B (as the precedent of MMR shows), and LPB believes that there is no reason why the current schedule for the application of Hepatitis B should not be altered once the hexavalent product is available.

(48) LPB therefore argues that the Commission is under an obligation to take measures to ensure that the likelihood of effective competition from third parties in multivalent vaccines is maintained and argues that the agreements with Behring do not provide an adequate remedy for the negative effect of the JV on competition in the future markets for multivalent vaccines as, on the contrary, the agreements remove Behring as an important possible partner for other manufacturers who might be forced to seek alliances to survive once confronted with the market power of the JV. LPB thus concludes that the Commission, if it would exempt the JV, should require the JV to supply Hepatitis B to LPB, as one of only two global vaccines manufacturers in addition to the JV.

(49) The Commission obtained from the notifying parties, in reaction to LPB's comments, some factual clarification. The parties confirmed that Italy was the only country with a general paediatric recommendation for Hepatitis B vaccination; in Spain the vaccine is recommended for infants by six of the seventeen regional health authorities (of which only two put the recommendation into practice), and one other regional authority purchases the vaccine despite not officially recommending it; in Portugal the vaccine is to be made available free to 11- to 13-year old adolescents (rather than for infants).

(50) The Commission also received observations from SKB, like the parties to the JV, a global vaccines producer. SKB has summarized its observations as follows:

— the competitiveness of Community vaccine producers depends upon innovation, and access to new technologies and vaccine components,

— the activities of the JV appear to be limited to marketing and distribution, with some ancillary administrative functions: on this basis SKB does not believe that the JV will become a new competitive, innovative force in vaccine markets,

— the wide scope (extending to all of Merck's and PMsv's current and future vaccine technologies)

[1] See recital 5.

of the JV is such that the normal competitive processes in the vaccines markets in Europe, which ensure access to technology, are likely to be restricted,

— the duration of the arrangements is considerably longer than is usual or necessary for a distribution JV; SKB therefore believes that the Commission should retain an ability to review the effect of the JV on competition in vaccine markets at a later date,

— there are unlikely to be improvements to technology or production resulting from the formation of the JV; the improvements in distribution (despite the undertakings given by the parties in relation to Germany and France) are not likely to be substantial,

— cooperation arrangements could enable Merck and PMsv to collaborate productively for a limited period of time to bring needed combination products to the paediatric vaccine market. However, SKB believes that the terms of the JV go beyond what is reasonably necessary in this respect and may prevent competitors from bringing innovative new products to the market place, to the detriment of the public.

(51) In view of SKB's observation concerning access to vaccine technology, the parties amended their exclusive patent and know-how licences for the EEA to the JV by explicitly allowing the JV to sub- and or cross-license these intellectual property rights for the development and/or manufacture in the EEA of existing and future vaccines to other manufacturers.

II. LEGAL ASSESSMENT

A. Article 85 (1) of the EC Treaty and Article 53 (1) of the EEA agreement

1. *Agreement between undertakings*

(52) PMsv and Merck are undertakings within the meaning of the Articles 85 (1) of the EC Treaty and 53 (1) of the EEA Agreement. The set of agreements, most of them dated 25 May 1993, whereby the parties will organize their existing activities in the human vaccine business within a territory being defined as the EC and the EFTA, through a jointly-controlled company and the ancillary agreements which were also notified, are agreements within the meaning of Articles 85 (1) of the EC Treaty and 53 (1) of the EEA Agreement.

2. *Relevant market*

1. Relevant product market

(53) Each vaccine ensuring immunity against a specific disease forms a different product market. From the viewpoint of the consumer, no substitutability exists between vaccines protecting against different diseases. Furthermore each vaccine presents specific characteristics in respect to its development and production. Different technologies are used to develop and produce vaccines, the production itself is subject to specific regulatory requirements.

(54) For these same reasons multivalent vaccines are also considered as belonging to a different product market than the equivalent monovalent vaccines. Although the launch of a multivalent may have, when it is accepted by the health authorities/ medical community [1], the effect of replacing part of the equivalent monovalents, this is not sufficient to consider both products as belonging to the same product market. Indeed, the consumer/prescriber adopts relatively quickly a distinct usage whereby the multivalent is preferred for general immunization whereas the monovalents are mainly used for either brush-up immunization or as a booster for non-protected persons (and also retained by the producer in order to cope with possible adverse reactions to some antigens included in the multivalent). Examples of such processes are to be found in past experience with DTP and MMR multivalents.

2. *Relevant geographical market*

(55) At present, different conditions of competition prevail in the EEA countries in respect to the distribution of vaccines for the reasons laid down in recital 16. Another factor is the traditional preference for the national producer, which is often closely related to the State. For these reasons, and because it cannot be expected that the conditions of competition relating to, especially, epidemiology, the national legal frameworks and medical tradition, will change in the near future, the geographical markets are still national. Past experience with DTP and MMR has also shown this to be the case for multivalents.

[1] The acceptance by the health authorities/medical community of a particular multivalent depends on the relevant epidemiology and/or historical or traditional attitudes towards immunization against the monovalents it is composed of.

3. *Restrictions of competition*

1. Between the parties

(56) The parties transfer, by the different mechanismus described at Section D — The notified operation — to the JV their European distribution network, their existing European vaccine portfolio, their European-oriented R&D activities from post clinical phase II onwards and the resulting new vaccines and vaccine technology. This transfer has been strengthened by the non-competition obligations summarized in recital 41. In doing so, the parents eliminate competition on the European vaccine markets between themselves in so far as the parties are to be considered as actual or potential competitors.

a) Actual competition

(57) The parties are currently in competition with each other on five vaccine markets (see recitals 27 to 31). The creation of the JV will lead to an appreciable restriction of competition only on the German monovalent rubella and measles markets (see recitals 28 and 29). With regard to the Greek MMR market (recital 30), it has already been noted that, even though both parties are currently selling their vaccines in Greece, the side effects noted with the mumps strain used by PMsv (see recital 22), may lead PMsv, possibly upon insistence of the national health authorities, to withdraw its MMR vaccine. The elimination of this already weakened actual competition through the creation of the JV can therefore not be considered as an appreciable restriction of competition. However, the reasons why potential competition on this and other national MMR markets is restricted, are stated in recital 60.

(58) With regard to the German monovalent HIB market, the licence described in recital 27 will result in a competitive situation on the relevant market whereby Merck, via its distributor Behring, will be replaced by Behring which will now be able to act as an independent competitor on the market. The fifth market on which the parties' vaccines are currently both available is the Portuguese pneumococcal market (see recital 31). This market is characterized by an extremely limited total turnover (less than ECU 3 000). This is a consequence of the absence of an economically viable market potential for these vaccines, e.g. the lack of any registration of the products. All sales now occur, in the absence of distribution efforts taken by the manufacturers, upon specific request from the doctor, so-called 'named patient' sales. In view of both the possibility for doctors of buying this vaccine from any other competitor who offers it somewhere in the EEA, and the marginal importance of this market, the creation of the JV will have no appreciable effect.

b) Potential competition

(i) Existing products

(59) In view of the patent situation for Hepatitis B recombinant vaccines (see recitals 23 and 24), PMsv is not in a position to market, without the risk of litigation, this vaccine outside France. PMsv is therefore not considered as a potential competitor on the other EEA markets. This conclusion is strengthened by PMsv's belief that, in view of the characteristics of its product, it would be unlikely to obtain a registration outside France. Merck possesses all the necessary patent licences and its product could be registered in all EEA countries. In view of the Hepatitis B market potential in France, where 1992 sales totalled about ECU 40 million (i.e. almost as much as Merck's total turnover in the EEA), Merck has to be considered as a potential market entrant on the French market, even taking into account the French preference for a pre-filled syringe (see footnote 1 on page 5). The creation of the JV will thus lead to an appreciable restriction of competition on the French Hepatitis B market.

(60) With regard to the MMR market, it is considered that, in the absence of the JV, PMsv would have engaged in R&D to ameliorate its mumps strain so that it could have re-entered the MMR markets in three to five years, given the existing substantial demand for this multivalent vaccine. Merck's mumps strain is, as indicated in recital 22, currently the only one which is widely accepted. Therefore Merck can, in view of the limited distribution efforts currently needed, be considered as a realistic market entrant in all EEA MMR [1] markets where it is currently not established. The creation of the JV will thus lead to an appreciable restriction of competition on the MMR markets in all EEA countries since PMsv will not need to develop an improved MMR vaccine to compete with Merck's vaccine.

(61) The monovalent HIB vaccine has, in view of the epidemiology (see recital 16), only a limited market potential in Italy, Spain, Portugal and Greece where in 1992 no or almost no sales occurred. Merck's vaccine was sold in 1992 only in Germany [2], Sweden, Norway [3] (where sales were made by independent distributors) and in

[1] In 1992 MMR vaccination occured in all EEA countries.
[2] See recital 58.
[3] Recital 34 indicates why this is no longer the case in Sweden and Norway.

Spain [1]. Furthermore, the JV has granted a manufacturing licence for Merck's monovalent HIB vaccine to an independent third party in France (recital 33). This party (Pierre Fabre) can decide, even if it would appoint Merck or another licensee as its subcontractor for the production of the vaccine, the basic commercial terms such as quantity, price and promotion. In all other EEA countries, Merck has no own vaccines sales force (see recital 18) and its product is not yet registered in Denmark, Ireland and Austria. In view of the presence of other vaccines (notably from PMsv and LPB) on these markets, the current level of demand for this vaccine and in the absence of circumstances which would lead to a specific request for Merck's product, it cannot be expected that Merck would enter these markets (i.e. the monovalent HIB markets in all EEA countries except Italy, Spain, Portugal, Greece, Germany and France). This conclusion is corroborated by the impossibility of finding an independent third party to (re-)introduce, by way of a manufacturing licence, the vaccine in the Nordic EFTA countries (recitals 34 and 35). The creation of the JV will not, therefore, result in a restriction of competition on the monovalent HIB markets.

(62) The creation of the JV is not considered to lead to an appreciable elimination of competition on the pneumococcal markets. Both parties sell it in some EEA countries, but not in all. Potential entry in the other countries is not realistic, in view of the limited turnover and market potential for this vaccine on these markets (see recital 25).

ii) Future monovalents

(63) As regards future products in an advanced stage of clinical trials ('pipeline products'), it is realistic to assume that the parties, in view of their past performance, financial strength and existing vaccine knowledge, can be considered as potential competitors for these new monovalents for which their actual R&D portfolio shows an overlap: Hepatitis A and varicella. The creation of the JV will result in an appreciable restriction of competition on these European vaccine markets, as it is the JV which will take over the post phase II clinical trials and which will distribute the final products.

(64) An assessment of the restriction of competition between the parties for other new monovalent vaccines in earlier stages of R&D ('future pipeline products') is far more difficult, in view of the extremely broad range of such future research and the lack of precise indications as to the chances of bringing successful products to the markets. Furthermore, the parties remain autonomous in their basic R&D decisions and on the way in which they will allocate their respective budgets, particularly with respect to the early phases of clinical work, and especially fundamental basic research (or the buying in of such basic research undertaken by specialized institutes) which is far from market-oriented. However, within the Development Committee of the JV (see recital 38), the R&D activities of the parents, including communications concerning discoveries, will be discussed. It cannot be excluded, therefore, that these discussions will lead to the coordination of the basic R&D, which has already been triggered, with regard to paediatric multivalents, by the other JV between the parties in the United States of America (recital 8). In view of the parties' important position on the vaccine markets (worldwide presence, R&D budget), this coordination is likely to have an appreciable effect on R&D for future pipeline products in the EEA.

iii) Multivalents

(65) The multivalents which could be developed are specified in recitals 12, 13 and 14. The parties' own product portfolio (i.e. their existing vaccines/antigens and the antigens in an (advanced) stage of development) would allow them both to develop an MMR varicella multivalent. Merck already disposes of a MMR vaccine, and PMsv would have improved its vaccine (see recital 60). Furthermore, both have a varicella vaccine for use in normal children at a late stage of development (recital 26).

(66) However, their own product portfolio does not overlap for any of the other possible combinations so that both parties could not have formulated any of these multivalents alone. In particular with regard to the possible paediatric combinations, including DTP acellular, injectable polio, HIB and Hepatitis B (recitals 13 and 14), the only antigen to which both have access is HIB.

(67) It is accepted that, in the absence of the JV, Merck could have theoretically obtained bulk supplies of the only vaccine which can be considered as a commodity product: DTPwholecell. Despite the current success of e.g. PMsv's DTPwholecell-HIB combination in Germany, it appears that, if Merck were to start a development programme on the basis of such bulk supplies, the resulting vaccine would be likely to come to the market at a time when some other competitors would already

[1] Turnover in Spain was about ECU 10 000, less than 1 % of Merck's total sales in Spain, where it has one person dedicated to vaccine sales.

possess the more performant multivalents based on the acellular pertussis antigen. It can thus be concluded that this is not an economically viable course of action.

(68) It is, furthermore, not accepted that the parties could be considered as potential competitors for the development of these multivalents simply because of their ability to obtain access to the missing antigens via licences to proprietary know-how and/or patents, and possibly bulk supplies, from other manufacturers. Some of the potential antigens are not yet developed (Hepatitis C and E, most meningitis antigens). For the remaining antigens, and in particular DTPa, HIB and Hepatitis B, this is not a viable course of action.

It is not obvious that such licences would be granted, in view of their inherent complexity (the safety/stability problem for these relatively 'new' antigens when they are to be included in multivalents might give rise to serious liability risks). Furthermore, contractual relations with more than one manufacturer are required. And, in addition to the formal licence (and possibly bulk supply), there is a need for ongoing cooperation between the specialists of the originating parties when the antigens are 'blended' into multivalents involving a continuous, wide-ranging exchange of information on the basis of a trust relationship between different R&D teams.

Therefore, this course of action does not constitute a workable and flexible enough alternative to develop the wide range of different multivalents adapted to the needs of different European countries (e.g. in view of epidemiology, health policy approach and traditional preferences), which the JV intends to launch on the EEA markets.

(69) It can thus be concluded that the creation of the JV will result in an appreciable restriction only on the MMRvaricella multivalent markets.

2. Effects of the creation of the JV as regards third parties

(a) Existing and imminent vaccines and vaccine technology

(70) According to the notified agreements, the parent companies cannot supply or license their vaccines and vaccine technology to third parties for use in the EEA other than through the JV. Since the JV combines the individual parents' portfolios, the primary effect of the JV in relation to other producers results from the JV's increased sourcing autarky in relation to existing and imminent antigens ('pipeline products') and vaccine technology. Other producers will, in view of these arrangements, be limited in their possibilities to collaborate either with the parent companies or with the JV as a source for them to get access to their 'missing' antigens or vaccine technologies (delivery systems, vaccine combination technology, ...). This outside sourcing could become important for the development of multivalents, and in particular for some of the paediatric combinations. Given the position of the parties on the relevant markets, this will result, as regards existing and imminent vaccine technology, in an appreciable restriction of competition towards third parties.

(b) Future vaccines and vaccine technology

(71) In assessing the effects of the creation of the JV as regards other producers in relation to future antigens and vaccine technology, reference has to be made to the wide range of diseases against which vaccines could be developed and, if successful, lead to considerable sales opportunities, e.g. Hepatitis C, herpes or AIDS. Furthermore, no single firm can be considered, in view of the related costs (estimated cost of between US$ 100 to 200 million to bring a new vaccine to the market), to be capable of covering all these fields. Moreover, it is not only the limited number of vaccine producers with a European presence which at present spend, on a worldwide basis, more than ECU 25 million a year on vaccine related R&D (PMsv, SKB [1], Merck and LPB) that are able to engage in such research. Other producers, even those public and private 'national' companies, currently concentrating on the bulk paediatric markets (DTPwholecell, oral polio) recognize the importance of the costlier, more recent DNA-related research for the development of new vaccines. They can therefore, given the presence of numerous specialized companies, scientific institutes or universities engaged in basic biotechnology research, also be considered as potential competitors for some future vaccine markets.

There are, therefore, in view of the number of potential competitors for the wide range of future vaccines and vaccine technology, no indications that the creation of the JV will lead to appreciable

[1] SKB's vaccines turnover in 1992 was almost the treble of its 1990 vaccines turnover. The difference is due, predominantly, to sales of its Hepatitis vaccines.

restrictions of competition by reducing the sourcing-out possibilities of third producers for future vaccines and vaccine technology.

3. Restrictions of competition resulting from the Behring agreements

(72) The continuation of the sole distribution agreements for Merck's MMR (and its components) vaccines (see recital 43) restricts intra-brand competition for these products in Germany in so far as the JV is prevented from appointing further distributors. This is considered an appreciable restriction of competition in view of the important market position of the existing Merck-origin vaccines (market shares of at least 40 % in 1992). As Behring is currently the leading vaccine producer/distributor in Germany, the agreement may also have an appreciable effect on inter-brand competition on these markets as Behring could only take up distribution of a competing brand whilst losing its exclusive right. The same can, however, not be said for the pneumococcal vaccine in view of its limited market potential (Merck's transfer price-revenue is below ECU 15 000 per year).

(73) The continuation of the 'sole' agency agreement for Merck's Hepatitis B vaccine (see also recital 43) also restricts intra-brand competition for this product in so far as the JV is prevented from appointing further agents, and has an equally restrictive effect on inter-brand competition as indicated for MMR above. The agreement is therefore also considered to constitute an appreciable restriction of competition.

(74) The appointment of Behring as exclusive co-promoter, except for prior existing third party rights, along with the JV in Germany for the JV's future Hepatitis A, varicella and MMR varicella vaccines (see also recital 43) is not considered to constitute an appreciable restriction of competition. It does not limit the JV's ability to appoint other independent distributors for the products, nor would it prevent Behring distributing competing products. As Behring has no established loyalty towards the medical community for these (future) products, it cannot be said that this last possibility is unrealistic.

(75) The exclusive (but for the JV) licence by the JV to Behring under the Multivalent Technology Transfer Licence Agreement relating to the multivalent know-how with respect to the JV's monovalent HIB antigen of Merck origin, acellular pertussis and Hepatitis B antigens, allowing Behring to make (except for multivalents containing Hepatitis B — see rectital 44), use and sell Behring multivalents in Germany constitutes, in view of the marketing potential of such multivalents, an appreciable restriction on competition in Germany as other vaccine producers will not be able to receive from the JV such a licence to make, use and sell multivalents based on the JV's key antigens in Germany.

(76) The granting of the exclusive patent, know-how and trademark licence by the JV to Behring for the manufacture and distribution of Merck's monovalent HIB vaccine in Germany constitutes, in view of the market share of this vaccine in Germany, which was about 10 % in 1992, an appreciable restriction of competition, as Merck and the JV can neither grant licences or other vaccine producers nor manufacture or distribute the product for active sale in Germany themselves.

4. Restrictions of competition resulting from the agreements with Pierre Fabre

(77) The granting of the exclusive patent and know-how licence by the JV to Pierre Fabre for the manufacture and distribution of Merck's monovalent HIB vaccine in France constitutes, in view of the market potential of this vaccine in France, an appreciable restriction of competition, as Merck and the JV can neither grant licences to other vaccine producers nor manufacture or distribute (unless regulatory or medical problems arise in connection with the monovalent HIB vaccine presently marketed by PMsv in France) the product for active sale in France themselves.

(78) The exclusive (except for the JV or its French affiliate in regard to MMR, monovalent mumps and bivalent measles/mumps) distribution rights to Merck's MMR and its monovalent and bivalent components which are granted to Pierre Fabre for France constitute, especially in view of the market potential of Merck's MMR and monovalent mumps vaccine in France, an appreciable restriction of competition, as other vaccine distributors will not be able to distribute the products in France.

4. *Appreciable effect on trade between Member States and Contracting Parties*

(79) The creation of a JV in which two out of the three leading worldwide vaccine producers bring together their total European vaccine business as from post phase II R&D until distribution, has, in view of the parties' actual and potential strength in

vaccine R&D, production and distribution, an appreciable direct influence on the pattern of trade between Member States and Contracting Parties on those actual and/or future markets where the creation of the JV results in an appreciable restriction of competition.

(80) The Behring Agreements and the agreements with Pierre Fabre have an appreciable effect on trade between Member States and Contracting Parties as, by limiting the scope of the rights to the active marketing of the products in Germany and France respectively, the agreements render more difficult the unrestricted flow of trade which the Treaty and the EEA Agreement intend to create.

5. *Conclusion*

(81) The creation of the JV between PMsv and Merck falls foul of Article 85 (1) of the EC Treaty and Article 53 (1) of the EEA Agreement in respect of its effects on the German monovalent measles and rubella markets; the French Hepatitis B market; the MMR, MMR varicella, varicella, and Hepatitis A markets; and, as far as future pipeline products are concerned, in the field of R&D. In view of its effect on third parties, the JV and related agreements are restrictive on competition in so far as they limit to an appreciable extent the access of competitors to existing and imminent vaccines and vaccine technology, in particular for paediatric combinations.

The distribution agreements for the MMR (and its component) vaccines in Germany and France, the German Hepatitis B agency agreement, the Multivalent Technology Transfer Licence Agreement, and the HIB manufacturing licences with Behring and Pierre Fabre also fall foul of Articles 85 (1) of the EC Treaty and 53 (1) of the EEA Agreement.

B. Article 85 (3) of the Treaty and Article 53 (3) of the EEA agreement

1. *The JV*

1. Improvement of production or distribution, promotion of technical or economic progress

(a) Promotion of technical progress

(82) Through the JV the parties will discuss their experience regarding their R&D activities, cooperate with regard to the development activities from post phase II clinical trials for 'European'-oriented [1] vaccines, and put their existing antigen and vaccine technology portfolio at its disposal to allow the JV to develop new and more performant vaccines which can, in view of the information inflow from a distribution network [2] covering all EEA countries, be adapted to the specific needs of each individual country. By avoiding R&D overlaps and benefiting of the parties' respective strengths, this will lead to a qualitative promotion of technical progress. An indication of such improvements can be given by reference to the following expamples:

(83) The development of multivalent vaccines is, as indicated in recital 13, a generally recognized priority in view of the numerous advantages it would have for immunization (fewer injections, clinic visits and medical administration/costs, increased family acceptance, leading to a better coverage rate). All leading medical authorities have repeatedly argued for the development of paediatric multivalents combining DTP, polio, HIB and Hepatitis B. The JV will be able to start a development programme for such combinations as it will be the first vaccine producer to possess all the necessary antigens. Furthermore, it has the ability to adapt the combinations to specific national vaccine needs. This is important in view of the epidemiological differences between the EEA countries and the traditional preferences for the way in which the antigens are currently made available. Such specific combinations, which the JV is in a position to bring to the market sooner than would have been possible otherwise, will thus realize an important technical progress.

(84) Also in the field of monovalent vaccines the JV will, through the pooling of its experience and know-how, stimulate technical progress by bringing new and more performant vaccines to the market. This can by illustrated by reference to a varicella vaccine. PMsv possesses an existing vaccine for immunocompromised children only and its vaccine for normal children is in clinical phase II to III (registration expected for 1996); Merck already has in the United States of America

[1] With respect to epidemiological and/or biological characteristics of the vaccines, adapted dosages, combinations or delivery systems.

[2] Knowledge of the national distribution preferences as to presentation (vials, single-dose, multi-dose, multi-chamber syringes) and, more important, the support that can be given to make epidemiological studies, which are used to orientate R&D and clinical activities, and, in turn, are the most important vaccine 'marketing' element.

a varicella vaccine for use in normal children at a final stage of registration. However, Merck's vaccine needs storage in a freezer, a facility not common in the European vaccine distribution chain. However, it is estimated that due to a combination of Merck's vaccine and PMsv's stability factor allowing storage in a refrigerator (4 °C), a vaccine for normal children will be available sooner in the EEA than would have been the case in the absence of the JV.

This varicella vaccine will also be used for the development of a unique European MMR varicella vaccine involving PMsv's measles [1], Merck's mumps and the joint rubella strain.

(85) Another similar example is related to the future pneumococcal conjugate vaccine where the parties estimate that their vaccine will contain serotypes of both parents in order to optimize protection against the major strains of pneumococcus that causes meningitis, pneumonia and otitis media (inner ear infection) and whereby protein carriers (the medium) of both parties will be used for the conjugation. The JV's vaccine will thus have potentially fewer adverse effects (protein carrier technology), will be more directed to European epidemiology (serotypes-choice) and will be developed and made available sooner than without the JV.

(86) Advantages for technical progress are also expected in the development of new technologies to be used in overall vaccine production such as the improvement or elimination of preservatives, improved vectors/new delivery systems (oral delivery), DNA/RNA-based research, and so forth.

(b) Improvement in distribution

(87) As indicated in recital 18, Merck has, despite entering the EEA markets more than 20 years ago, a very limited presence, with the only notable exception being Germany. The JV will be based on PMsv's existing comprehensive distribution network, and will be able to assure a better coverage of Merck's existing (and future) vaccines throughout the whole EEA.

(88) As far as the specific French market is concerned, the manufacturing licence for Merck's monovalent HIB vaccine and the distribution rights for MMR (and its mono- and bivalents) granted to Pierre Fabre, establish another vaccine distributor in France. Pierre Fabre has, with the beginning of a paediatric vaccine product range, the possibility of taking up the distribution of other vaccines of other vaccine producers in France, a market with a paucity of (independent) distributors (see recital 19). As in this way a barrier to entry for, especially paediatric, vaccine distribution in France is removed, these agreements between the JV and Pierre Fabre may not only lead to an improvement in distribution for these vaccines but also for other, especially paediatric, vaccines.

2. Benefits to the consumer

(89) Achieving the above-indicated technical progress and improvements in distribution responds to a genuine public health concern. Numerous organizations, including the World Health Organization and the European Parliament, have underlined the benefits of accurate, stable and easy-to-administer vaccines for public health, and therefore also for consumers.

(90) The JV will, as stated above, be able to stimulate and speed-up the development of new vaccines, both mono- and multivalents, adapted to the needs of each EEA country. Furthermore, all the existing and future vaccines will be available throughout the EEA. By providing, sooner than otherwise might have been the case, an increased range of existing and future mono- and multivalents throughout the EEA, the consumer is allowed a fair share of the resulting benefits.

3. Indispensability

(91) In order to develop (paediatric) multivalents, a vaccine producer either has to have access to all the required antigens (as both PMsv and Merck for the MMR varicella), or he needs to develop possible synergies with other producers (as almost all other producers for the paediatric hexavalent). Any other partnership than that between

[1] Merck's measles vaccine does not meet the current European *Pharmacopeia* standards which adopted the World Health Organization criteria as to heat stability which require, given the needs of the developing world, the absence of the need for a cold chain. The Merck vaccine is nevertheless widely accepted in Europe as the distribution network disposes of a cold chain. Furthermore, PMsv has a measles development programme that could lead to administration and protection of the antigen at an earlier age.

themselves would have required PMsv and Merck to conclude agreements with more than one producer in view of the lack of similar synergy possibilities for, at least, a pediatric hexavalent. Even if a cooperation network, limited to an exchange of licences and bulk supplies, between multiple partners would have been possible, this is considered as too rigid to achieve the ambition of the JV, i.e. the development of the wide range of multivalents, adapted to the needs of different European countries. Therefore one requires more open-ended and far-reaching cooperation, able to adapt to unforeseen or new circumstances resulting from the continuous exchange of information between the parties. It is believed that only a JV provides a mechanism which is flexible enough to achieve this.

In addition, a JV is the only legal alternative which allows, as indicated in recital 23, to share the totality of its Hepatitis B patent rights with PMsv. The fact that the parties can share all their intellectual property rights facilitates the realization of (paediatric) multivalents on the basis of the Hepatitis B antigen.

As it is the ambition of the parties to develop a wide range of multivalents adapted to the needs of all EEA countries, the development of paediatric multivalents containing Hepatitis B is, in view of the epidemiology of Hepatitis B in southern Europe, crucial.

(92) Furthermore, it is indispensable that the scope of the JV should be extended beyond the development of (paediatric) multivalent vaccines. Only a JV structure is flexible enough to enable all future opportunities to be taken into account, thus promoting the development of new monovalents and vaccine technology. In addition, it is feared that even the development of multivalents would be hampered in view of (i) the impossibility of separating from multivalent development work the vaccine research needed to support other key programmes such as the involvement in new preservatives, the planning of research of new antigens to be included in new combinations and the collaboration in research for new delivery systems and vectors, and (ii) the inherent reluctance to brief a partner on the above points which contain proprietary know-how, as they have an importance outside the mulivalent range.

(93) Furthermore, it is indispensable for a proper functioning of the JV and for the achievement of all advantages that the scope of the JV is extended to the joint distribution of the existing and future vaccines by the JV. This conclusion is based upon the following considerations:

— the restrictions of competition resulting from joint distribution are, as indicated above, extremely limited. This is a consequence of the weak presence of Merck in Europe,

— it is not realistic to assume that Merck would have developed either (a) its own Europe-wide distribution network as:

  (i) Merck has, unlike a newcomer on the European vaccine markets such as LPB, no paediatric pharmaceutical sales force to build on;

  (ii) for Merck's subsidiaries the vaccines business is of a relatively minor importance (2,3 % of their total sales) with all the consequences this has on the group-
  internal investment priorities;

  (iii) physical distribution of vaccines requires considerable investment in a cold chain, or (b) extend distribution relationships with multiple independent third parties in view of the limited results achieved in the past 20 years (with the notable exception of Germany),

— there are only a limited number of vaccine distributors with a European-wide presence with whom Merck could have concluded an overall distribution agreement, notably PMsv and SKB,

— the alternative of a distribution agreement is not much less restrictive than a JV, and joint distribution facilitates the functioning of the JV by enabling Merck to divulge fully its R&D and production techniques to its partner as it, by the joint distribution, also fully benefits from the commercial advantage of its partner's strong own distribution network.

(94) Specific indications why joint distribution in the vaccine sector facilitates cooperation in R&D and production are:

— marketing plans for a vaccine are made at a very early stage, at the same time as one is engaged in R&D of the products, in particular by reference to epidemiological studies, which are used to orientate both R&D and clinical trials activities, and in turn for the subsequent marketing of the final products,

— pharmacovigilance (i. e. the observation of unexpected effects of vaccination) involves identification of significant health issues to enable any adverse health risks to be rectified;

in the absence of joint distribution, the R&D and production teams would have to rely on two sets of data for identical products, creating, apart form duplication of efforts, a further burden on required shifts in R&D and production,

— batch release: the biological nature of vaccines and the inherent risks in such products of batch failures, requires a constant interface between manufacturing and distribution teams. In some EEA countries, the distribution team needs a release from the relevant national control laboratory for each batch, whereas this requirement does not apply for pharmaceutical products; batch release thus creates a daily interdependence between both teams,

— national distribution preferences need to be taken into account for the presentation forms of vaccines (and thus their development), such as e. g. vials, single-dose, multi-dose, multi-chamber syringes.

4. Elimination of competition

(95) It is not considered that the creation of the JV will lead to an elimination of competition on the vaccine markets of the EEA. The reasons for this conclusion are the following:

a) Individual vaccine markets

(96) In view of SKB's current share of the French Hepatitis B market (which is over 30 % and increasing), the creation of the JV does not lead to an elimination of competition on that market. The same is true for the German monovalent measles market where SKB commanded about 40 % of the market in 1992. Competition on the German monovalent rubella market is not eliminated either in view of (i) the presence of two internationally operating vaccine producers (SKB und Wellcome), who despite a market share of less than 10 % remain a competitive force on the market able to develop further their position, and (ii) the increased intra-brand competition between the JV and Behring (the most important vaccine distributor in Germany [1].

(97) With regard to the MMR multivalent, Merck's vaccine is indeed currently the only widely accepted vaccine. However, just as PMsv would have, in the absence of the JV, improved its mumps strain (recital 60), the other vaccine producers and in particular SKB are also likely to update their mumps strain and re-enter these markets. Furthermore, another competitor, Berna, which is currently registering its MMR in Greece und Austria, uses another mumps strain and therefore has the potential to increase penetration in EEA countries other than those where it is currently available. Therefore, there remains effective potential competition.

(98) With regard to future markets, the following observations can be made: SKB currently has the only Hepatitis A vaccine registered and commercially available (since 1991) in Europe, Berna has a product on clinical trials in Germany and Biocine-Sclavo's product is awaiting registration; SKB already has a varicella vaccine on the market for immunocompromised children (e.g. PMsv's existing vaccine) and is active with R&D to adapt the product for healthy children. From the above considerations it can be concluded that SKB also has the potential to develop a MMRV aricella vaccine.

(b) Overall market structure

(99) The creation of the JV does not constitute an insurmountable barrier for other producers to enter future vaccine markets. The Commission has found no indication of a future vaccine market where competition would be eliminated as a result of this European JV. In particular with regard to the future paediatric hexavalent containing DTPa, polio, HIB and Hepatitis B, the creation of the JV will not bring about a change in the market structure. Only Merck and SKB were, in view of the Hepatitis B-patent situation (recital 23), in a legally secure position to bring such an hexavalent on the European markets. As a result of the creation of the JV, it is now the JV and SKB which are in a position to do so. Furthermore, it cannot be concluded, on the basis of the information at the disposal of the Commission, that SKB's possibility to develop such a hexavalent is purely theoretical.

(100) Furthermore, LPB's argument that the position on the vaccine markets of producers (such as itself) who currently market as a monovalent one of the antigens included in the hexavalent, is threatened, cannot be accepted. This alleged threat is based upon the presumption that the sales potential of the hexavalent (which the JV, contrary to LPB, is able to develop in view of its access to all the required antigens) will be such that sales of all other mono- or multivalents which do not combine all of the hexavalent antigens (e.g. DTPa, HIB, DTPa-HIB, DTP-polio, ...), will not remain possible on economical viable terms.

[1] Although Merck always retained the possibility to distribute its rubella vaccine in Germany itself, it never took up this right. The JV will, however, also distribute Merck's (and PMsv's) rubella vaccine itself in competition with Behring.

(101) First of all, for the reasons stated in recital 54, the mono- or limited multivalents, belong to a different market than the possible paediatric hexavalent. These other vaccines will thus continue to be sold in those countries which might use the paediatric hexavalent for general immunization, albeit in a more limited number of doses, for either brush-up immunization or as a booster for non-protected persons.

Furthermore, the Commission does not consider, on the basis of the actual information in its possession, that the paediatric hexavalent will be used in all EEA countries. Whilst the availability of such a hexavalent would realize a highly desirable objective for public health, the health authorities/medical community of a particular country or region will only accept the hexavalent for general immunization if (i) the hexavalent responds to the relevant epidemiology, which, as indicated in recital 16, is different in the EEA for at least two of the components, HIB and Hepatitis B; (ii) the hexavalent can be fitted into the vaccination schedules, which continue to differ to a large extent for the two other components, polio and DTP, and (iii) the traditional attitudes towards immunization against a particular antigen, e.g. the 'negative' attitude in Denmark and Italy toward pertussis; or the strong preference for oral polio vaccination in almost all countries are surmountable.

2. *The Behring agreements and the agreements with Pierre Fabre*

1. Distribution of MMR (and pneumococcal) vaccines

(102) The agreements whereby the JV agrees with Behring and Pierre Fabre to supply the MMR (and its mono- and bivalent components) vaccines for resale within Germany and France respectively only to Behring and Pierre Fabre respecitively fulfil the conditions laid down by Commission Regulation (EEC) No 1983/83 of 22 June 1983 on the application of Article 85 (3) [1] of the Treaty to categories of exclusive distribution agreements [2] so that these agreements are exempted pursuant to the Regulation. The Behring agreement in relation to the pneumococcal vaccine would, if it had been considered to fall foul of Articles 85 (1) of the EC Treaty and 53 (1) of the EEA Agreement, also be exempted pursuant to the Regulation.

2. The agency agreement for Hepatitis B vaccine

(103) The 'sole' agency agreement is considered to fulfil all the requirements laid down in Articles 85 (3) and 53 (3) for the granting of an individual exemption. The agreement will lead to an improvement in distribution because the JV is able to concentrate its sales activities, and it does not need to maintain numerous business relations with a larger number of dealers and is able, by dealing with only one dealer, to overcome more easily the distribution difficulties that exist in the German vaccine sector, resulting from linguistic, legal, and other differences relating, e.g. to medical tradition. The agreement facilitates the continued promotion of sales and is indispensable to intensive marketing and to continuity of supplies while at the same time rationalizing distribution. Consumers are allowed a fair share of the resulting benefit as German prescribers/doctors benefit via Behring's know-how and experience of an established information exchange network, which is concentrated on the specific German market. As there is another producer on the market and parallel imports and exports of the JV's product remain possible, competition is not eliminated.

3. The multivalent technology transfer licence

(104) The set of agreements regulating the cooperation between the JV and Behring as to the development of Behring multivalents and in particular the multivalent technology transfer licence agreement is a pure know-how licensing agreement, containing ancillary provisions relating to trademarks or other intellectual property rights, to which only two undertakings are party as laid down in Article 1 (1) of Commission Regulation (EEC) No 556/89 of 30 November 1988 on the application of Article 85 (3) [3] of the EC Treaty to certain categories of know-how licensing agreements [4].

(105) The agreement contains the following obligations as referred to by Article 1 (1) of the Regulation:

(1) an obligation on the JV not to license other undertakings to exploit the licensed technology in the licensed territory;

[1] And, pursuant to Articles 60 and 53 (3) of the EEA Agreement.
[2] OJ No L 173, 30. 6. 1983, p. 1.
[3] And, pursuant to Articles 60 and 53 (3) of the EEA Agreement.
[4] OJ No L 61, 4. 3. 1989, p. 1.

(3) an obligation on Behring not to exploit the licensed technology outside Germany, i.e. in territories within the common market which are reserved for the JV;

(5) an obligation on Behring not to pursue an active policy of putting the Behring multivalents on the market outside Germany, and in particular not to engage in advertising specifically aimed at those territories or to establish any branch or maintain any distribution depot there as Behring only has the right to make sales outside Germany in response to unsolicited requests;

(7) an obligation on Behring to use for Hepatitis B multivalent products (i.e a Behring multivalent containing the JV's Hepatitis B antigen) a trademark owned by the JV (the product registration for these products will also be owned by the JV).

(106) Despite the fact that the agreement does not contain any other obligations to which Article 3 of the Regulation would apply [1], the agreement cannot benefit from the block exemption solely because of the fact that the agreement lasts for a period which might be longer than the 10 years allowed under Article 1 (2) in those circumstances where Behring would benefit from the provision that the right to procure the JV's antigens and know-how for a particular Behring multivalent shall last, beyond 31 December 2003, for a minimum of five years from its first marketing.

(107) However, the possibility for Behring to start, due to the multivalent technology licence, development work for multivalents based on antigens of its own, the JV and/or a third party, will possibly lead to another series of multivalents which would constitute an important element of technical progress on the German vaccine markets. The fact that the agreement guarantees a minimal commercialization period of five years for each Behring multivalent so developed, and therefore does not benefit from the know-how block exemption, does not exclude the granting of an individual exemption in this case, as the agreement thus provides a further incentive for Behring to continue its R&D work for the creation of such multivalents, until the end of the year 2003.

(108) The Behring agreements are beneficial to the consumer as the multivalent technology licence agreement may lead to a second source of multivalents based on some of the JV's key antigens in Germany coming on the market, even at the end of 2003. In so far as the agreement allows Behring to exploit its own severable intellectual property rights, created in developing a multivalent containing an antigen of the JV, ouside Germany, this agreement might also lead to benefits to public health in the other EEA countries.

(109) The possible extension beyond the 10 year duration of the know-how block exemption in the case of some individual Behring multivalents is indispensable as without this possibility for Behring, it would not actively pursue new developments during the last couple of years before the normal end of the agreement, 31 December 2003.

(110) And, as at least both the JV and SKB are in a position to develop a competing range of multivalent, competition is not eliminated on the German markets.

4. The HIB manufacturing and distribution licensing agreements

(111) These agreements have been entered into by the parties to the JV with Behring and Pierre Fabre respectively, following intervention by the Commission, and contribute to the maintenance of effective competition on the German and French monovalent HIB markets.

(112) Without the agreement with Behring, competition on the German momovalent HIB market would be substantially reduced, as the parties to the JV would command control of three (PMsv's, Connaught Laboratories Inc's and Merck's) out of the four HIB vaccines offered in Germany, amounting to 85 % of the market. The granting of the exclusive manufacturing license to Behring, an independent vaccine producer and distributor, enables Behring to determine, in the short and long term, strategic decisions relating to price, quantities and distribution efforts devoted to the HIB vaccine of Merck origin. By permitting Behring to operate as an independent competitor on the German HIB market, the agreement contributes to an improvement in distribution while allowing consumers a fair share of the resulting benefit. As the exclusive nature of the licence is indispensable to allow Behring to operate as a viable source on the market and thus restores the competitive situation on the German monovalent HIB market, the agreement fulfils all the requirements laid down in Articles 85 (3) of the EC Treaty and 53 (3) of the EEA Agreement for the granting of an individual exemption.

(113) The agreement with Pierre Fabre for the French monovalent HIB market equally fulfils all the requirements for the granting of an individual exemption, for reasons similar to those indicated

[1] The other obligations relating to the non-severable intellectual property rights (right of first refusal granted to the JV or its parents), the supply of the JV's antigens by the JV and the field of use clause limiting Behring's rights to the development of multivalents, would in case they would be considered to fall within the scope of Article 85 (1), be exempted pursuant to Article 2 (2) of the Regulation.

above. Not only does it contribute to the entry of a competitor to the French monovalent HIB market where currently PMsv's HIB vaccine is the only one offered, but it may also contribute to the entry of other vaccines to the French markets, particularly paediatric ones, as indicated in recital 85.

D. Duration

(114) Pursuant to Article 8 (1) of Regulation No 17, an exemption shall be issued for a limited period.

In view of the fact that (i) the JV agreement will not terminate automatically before the end of the year 2023; (ii) that the Commission retains an ability to review the actual effect of the JV on competition in vaccine markets; (iii) that account has to be taken of the characteristics of the agreement and of the fact that the nature of the markets involved means that it takes a longer time before the advantages of the cooperation can be fully realized, e.g. the R&D work leading to the bringing of a new vaccine on the market usually takes in excess of 10 years, the Commission concludes that an exemption until 31 December 2006 is appropriate.

In the meantime, the Commission will follow closely the evolution of the different vaccine markets on which the JV will operate; in this context the Commission will take into account the information which the parties undertook to provide on an annual basis (see recital 3),

HAS ADOPTED THIS DECISION:

Article 1

1. The provisions of Article 85 (1) of the Treaty and Article 53 (1) of the EEA Agreement, pursuant to Article 85 (3) and Article 53 (3) respectively, are hereby declared inapplicable to the set of agreements whereby Pasteur Mérieux Sérums et Vaccins and Merck & Co. Inc. will organize their existing activities in the human vaccines, immunoglobulins, *in vivo* diagnostics and sera businesses within a territory being defined as the EC and EFTA, through a jointly-controlled company, Pasteur Mérieux MSD SNC (the JV).

2. The provisions of Article 85 (1) of the Treaty and Article 53 (1) of the EEA Agreement are, pursuant to Article 85 (3) and Article 53 (3) respectively, hereby also declared inapplicable to the agency agreement for Hepatitis B vaccine, the multivalent technology transfer licence, and the HIB manufacturing and distribution licence between the JV and Behringwerke AG.

3. The provisions of Article 85 (1) of the Treaty and Article 53 (1) of the EEA Agreement are, pursuant to Article 85 (3) and Article 53 (3) respectively, hereby also declared inapplicable to the HIB manufacturing and distribution licence agreement between the JV and Pierre Fabre Médicament SA.

4. The exemption shall apply until 31 December 2006.

Article 2

This Decision is addressed to the following undertakings:

1. Merck & Co. Inc.,
One Merck Drive,
Whitehouse Station,
USA — New Jersey 08889-0100;

2. Pasteur Mérieux Sérums et Vaccins,
Avenue Leclerc 58,
BP 7046,
F-69348 Lyon.

Done at Brussels, 6 October 1994.

For the Commission
Karel VAN MIERT
Member of the Commission