II

(Acts whose publication is not obligatory)

COMMISSION

COMMISSION DECISION

of 17 January 1979

relating to proceedings under Article 85 of the EEC Treaty (IV/28.796 — Beecham/Parke, Davis)

(Only the English text is authentic)

(79/298/EEC)

THE COMMISSION OF THE EUROPEAN COMMUNITIES,

Having regard to the Treaty establishing the European Economic Community, and in particular Article 85 thereof,

Having regard to Council Regulation No 17 of 6 February 1962 [1], and in particular Articles 4, 6 and 8 thereof,

Having regard to the notification made on 28 January 1974 by Beecham Group Limited, Beecham House, Brentford, Middlesex, United Kingdom, pursuant to Article 4 of Regulation No 17, requesting that the Joint Research and Development Agreement entered into by it with Parke, Davis and Company, Joseph Campau at the River, Detroit, Michigan, United States, in May 1973 and amended on 23 February 1976 should, in so far as that agreement be found to come within the scope of Article 85 (1) of the EEC Treaty, be declared exempt from the application of that paragraph by virtue of paragraph 3 of the Article in question,

Having heard the undertakings concerned in accordance with Article 19 (1) of Regulation No 17 and with Regulation No 99/63/EEC [2],

Having regard to the summary of the notification published pursuant to Article 19 (3) of Regulation No 17 in Official Journal No C 248 of 19 October 1978,

Having regard to the opinion delivered on 22 November 1978 pursuant to Article 10 of Regulation No 17 by the Advisory Committee on Restrictive Practices and Dominant Positions,

I. THE FACTS

A. Object of the proceedings

1. These proceedings concern a research and development agreement between the Beecham Group Limited (hereinafter called 'Beecham'), a company registered in England and Parke, Davis and Company (hereinafter called 'Parke, Davis'), a company incorporated in the State of Michigan in the United States of America. Beecham and Parke, Davis have entered into the agreement with the aim of creating a pharmaceutical product (hereinafter called the 'Product') intended for the long-term prophylactic treatment of persons having a family medical history of hypertension or heart disease caused by the impairment of blood circulation.

B. The undertakings

2. (a) Beecham is a medium-sized manufacturer of pharmaceutical products in Europe. It has research, production and distribution facilities situated throughout the common market and

[1] OJ No 13, 21. 2. 1962, p. 204/62.
[2] OJ No 127, 20. 8. 1963, p. 2268/63.

worldwide and had a turnover in pharmaceutical products in 1976/77 of £ ... (1) million. Its total worldwide turnover during the same period was £ 720·8 million.

(b) Parke, Davis carries on business on a substantial scale in research, production and marketing of pharmaceutical products and has subsidiaries in the common market in France, Belgium and Italy. Parke, Davis had a turnover of $ ..... million in pharmaceutical products in 1976. Its total worldwide turnover during the same period was $ ..... million. Parke, Davis is a subsidiary of Warner Lambert, incorporated in the State of New Jersey in the United States of America and with a total worldwide turnover in a variety of fields of $ 2 500 million in 1977.

(c) Both undertakings market a wide range of human ethical pharmaceutical products within the common market and worldwide. A substantial proportion of each company's products falls within the same market category as those of the other, although in every instance the therapeutic application of the products in question may not be the same. Individually they have considerable experience in research and development and marketing of pharmaceutical products including products relating to the treatment of blood circulation irregularities.

However, neither party markets a product having the same therapeutic application as is intended for the Product.

(d) A number of other pharmaceutical companies of varying size conduct research in and market extensive ranges of drugs in the same therapeutic class as the Product, one of the most important in the industry as regards sales revenue, which is expected to exceed $ 300 million in the EEC during 1978. The companies with the largest share of this revenue include Sandoz, Boehringer Mannheim, Merck, CIBA Geigy and Boehringer Ingelheim.

C. **The research field**

3. Both Beecham and Parke, Davis have considerable research programmes. Their pharmaceutical research and development budgets were £ ... million in 1976/77 (£ ... million in 1977/78) for Beecham and $ ... million in 1976 for Parke, Davis. Parke, Davis' parent company, Warner Lambert, invests little in ethical drug research as its main activity in the pharmaceutical field is in proprietary drugs. Despite this research investment, neither of the parties has reached the level of certain other pharmaceutical producers, whose research budgets can represent 15 % or more of their turnover in pharmaceutical products. Furthermore, the fact that the largest part (about ... %) of such a research budget is generally spent on improvements on, or new applications of, existing products, shows the industry's experience of the financial risks involved in yielding a new product.

4. In the present case, the research and development is aimed at creating a new product which will differ in therapeutic application from all existing products. It is intended for the long-term prophylactic treatment of impairment of blood circulation and as no effective method of preventing the presently increasing occurrence of these problems exists, it would be of great medical benefit.

To achieve such results, detailed studies and tests requested by medical authorities must be made over a long period to ensure efficacy and safety in long-term use, thus increasing the risk of failure, especially at the later stages of what will have been a costly development programme. The result of these requirements is that the number of new drugs which reach the marketing stage compared to the thousands of compounds screened is extremely small.

Therefore, the research and development required for the Product will be particularly long and expensive. The parties estimate that the period involved will be in the region of 10 to 12 years, of which at least five to seven years will be devoted to development (clinical tests, etc.). The total cost over the 10 to 12 year period is likely to exceed $ 20 million. This figure is corroborated in a general way by publications such as Schwarzman's 'Innovation in the Pharmaceutical Industry', where the estimated average development cost in 1973 per new chemical entity was stated as $ 24·4 million.

5. Both parties had independently made preliminary investigations in the field in question and continue to research in related types of therapy. They had acquired expertise in the field complementary to one another. The individual research yielded few positive results and in view of the risk factors involved they both terminated their work in this field and

(1) In the published version of this Decision, some data have hereinafter been omitted, pursuant to the provisions of Article 21 of Regulation No 17/62 concerning non-disclosure of business secrets.

restarted only within the framework of the present cooperation which met the financial and technological criteria required to make the risk factors acceptable to both parties.

In this case each company had its own range of compounds for evaluation and the work took place separately at the laboratories of the two companies. The joint research thus took the form of joint planning of individual research and exchange of results (know-how and patent licences). This ensured that there was no unnecessary overlap of work.

These factors led to the parties entering the joint research and development agreement.

D. **The agreement**

(a) *General*

6. The joint research programme is divided into two stages : referred to respectively in the Agreement as the 'Project' and 'Development Programme'. The aim of the Project is to identify 'promising candidate substances' and complete tests for their study. These substances are then intended to be developed in a Development Programme with a view to their being marketed (Clause 1).

(b) *The Project*

7. The parties shall contribute an equal amount of research effort to the Project in terms of personnel and equipment, sharing the cost equitably between them and each establishing a separate research team to carry out the Project (Clause 2).

8. The planning of the details, scope and direction of the Project is from the outset to be conducted by the parties at regular meetings, which are to take place at least twice yearly. The planning covers the programme of work of each party, the nature and extent of the resources to be provided, estimating and control of costs, and provisions for balancing payments to equalize the contributions of the parties (Clauses 3 and 5).

9. The parties shall share all details of the work undertaken and hold regular meetings at not less than half-yearly intervals to appraise the work (Clauses 4 and 5).

10. The parties shall keep strictly confidential all information, know-how and data resulting from the Project or disclosed for its furtherance (Clause 6).

11. Either party shall have the right to apply for patents in its own name covering results deriving from its contribution to the Project. An application may be made for patents in the parties' joint names covering results derived from their joint contribution to the Project (Clause 7).

12. The Project continued initially until 4 May 1976. Under the Agreement, provided that a Development Programme was initiated in respect of at least one compound emerging from the Project or there was written agreement by the parties, the Project could continue thereafter for successive periods of two years.

13. If the Project were discontinued,

(a) by mutual consent ; or

(b) where a Development Programme was not initiated within the specified time limit ; or

(c) where agreement was not reached to continue the Project for a further period of two years,

neither party was under any further obligation to the other (Clause 10).

(c) *The Development Programme*

14. The Agreement provides for initial joint planning of any Development Programme and for the cost to be shared equally by the parties. Should one party consider that a substance justified further development and the other did not, the former could initiate a Development Programme individually. The results of such a Development Programme would be made available by the developing party to the other, as if the Development Programme had been undertaken jointly, unless the parties were at that time only undertaking one, or not undertaking any, Development Programme, in which case the non-developing party will pay up to 75 % of the other's development costs for such information. Clause 12 applies to Development Programmes, the provisions of the Agreement relating to the Project on disclosure of results and progress reports, appraisal meetings, confidentiality and patent rights (Clauses 4, 5, 6 and 7 respectively).

15. Either party may also withdraw from a Development Programme on six months' notice and, if it desires to market a substance developed thereafter by the continuing party, would be entitled to a licence as provided by Clauses 15 to 17 of the Agreement (referred to in 16 and 17 below), on payment of a sum not exceeding 75 % of the cost of development.

(d) *Commercial rights*

16. Each party shall have the right to receive from the other a non-exclusive royalty-free licence with full rights to grant sub-licences to manufacture, have manufactured, use and sell a Product without restriction under any know-how or letters patent other than Japanese patents (Clause 15 (a)). The exclusion arises from obligations Parke, Davis recognizes towards subsidiaries in Japan in which substantial holdings are held by third parties.

17. There shall be a full exchange of information on improvements to the production of the drug substance and pharmaceutical forms, including all changes in methods, for a period of 10 years from the first marketing of a Product (Clause 15 (b)).

The Agreement also provides that should either party make, develop, acquire, become entitled to or secure control over any improvement relating to any Product during a period of 10 years from the date of first marketing of such Product by either party, that party shall forthwith communicate in full such improvement to the other in confidence together with all available information concerning the mode of working and using the same (Clause 17 (a)). The Agreement also provides for the cross-licensing of such improvements (Clause 17 (b)).

E. **Agreement as amended on 23 February 1976**

18. In respect of commercial exploitation of the Product resulting from a Development Programme, the Agreement as originally notified provided that licences and sub-licences granted by either party were to bear royalties on all sales of any Product in any country by either party (hereinafter referred to as the 'Selling Party') or any licensees or sub-licensees of such party, and the Selling Party should pay to the other party royalties calculated as follows :

(i) on sales of any Product in consumer package form in any country where such product or its process of manufacture or formulation is protected by letters patent or by an application for letters patent, the royalty was at the rate of ... % of the Net Sales Value of such Product ;

(ii) on sales of any Product in consumer package form in any country where such Product or its process of manufacture or formulation is not protected by letters patent or by an application for letters patent as aforesaid, the royalty was at the rate of ... % of the Net Sales Value of such Product ;

(iii) on sales of any Product in bulk form (whether or not such Product or its process of manufacture is protected by letters patent or by an application for letters patent as aforesaid) the royalty was at the rate of ... % of the Net Sales Value of such Product ;

(iv) the Agreement provided a formula for determining the royalty payable on sales of Products in combination with other therapeutically active ingredients ;

(v) the obligation to pay royalties on sales in each country continued for a period of 10 years from the date when the Product was to be first marketed by the Selling Party in that country.

19. The obligation to communicate to the other party any improvement relating to any Product (see 17 above) was also for the period of 10 years from the date when the Product was to be first marketed by the Selling Party in each country.

20. The Agreement specifically excluded France (in addition to Japan) from the terms relating to the grant of licences. In view of this, special provision was made for sales in France and Japan. Each party was to use its best endeavours to ensure that the other enjoyed in France and Japan such rights as it would have had if France and Japan had not been excluded from the provisions of the Agreement. It then went on to state that :

'In the event that such endeavours shall not be successful, the parties in whose name such letters patent shall have been granted or enjoying such rights, shall make arrangements satisfactory to the other to ensure that each of them shall share equally in any profits or other benefits which that party shall derive from marketing ... in France and Japan'.

21. After the Commission had objected to the provisions detailed in points 18 to 20 above as being incompatible with Article 85 of the EEC Treaty, the parties agreed to remove the offending clauses, i.e. those relating to royalty payments, to the exclusion of France from the licensing provisions and to the profit-sharing clause relating to France and Japan. The parties also limited the obligatory exchange of information on improvements to 10 years from the date of first marketing the Product by either party. Each party undertook to grant royalty-free licences to the other with power to sub-license.

F. Termination of Project

22. The research work required by the Project and specified in the joint research programme was carried out individually by the parties using their own research facilities but with complete and regular exchange of information and results. Both parties therefore applied their research effort to a variety of compounds while avoiding duplication of work. The parties mutually agreed to terminate the Project from May 1978 and compounds, the result of the Project, are likely to be the subject of Development Programmes which are expected by the parties to require a further five to 10 years of close collaboration within the terms of the Agreement. The research costs for the five years of the Project were in the region of $ ..... million.

II. APPLICABILITY OF ARTICLE 85 (1) OF THE EEC TREATY

Article 85 (1) of the EEC Treaty prohibits as incompatible with the common market all agreements and concerted practices between undertakings which may affect trade between Member States and which have as their object or effect the prevention, restriction or distortion of competition within the common market.

A. Agreement between undertakings

23. The joint research and development Agreement is an agreement between undertakings within the provisions of Article 85 (1).

B. Relationship of parties

24. Both parties conduct research into, develop, produce and market a wide variety of pharmaceutical products. They are active in markets both within the Community and throughout the world. They are competitors in these markets in a large range of pharmaceutical products including substances in therapeutic classes related to that of the Product.

25. Both parties are, like other pharmaceutical producers, constantly searching for drugs to replace existing drugs or to produce drugs which offer better therapy. Even firms having a large share in certain fields are exposed to the market entry of competitors. Therefore they are actively engaged in research and development efforts. Obviously, they have to concentrate their efforts on certain therapeutic fields, but this does not mean that these efforts are restricted to these fields. They continue to strive to introduce new drugs. Competitive research and development is the 'driving wheel' of the pharmaceutical business and both companies' market success depends on the results of innovative competition.

Pharmaceutical companies generally spend considerably more than other companies on research (often 15 % of their turnover) and research and development up to the commercialization stage is especially costly due to the numerous and lengthy tests necessary to achieve the standards required by the national authorities. According to the parties, $ 20 million to $ 25 million per drug is required in the case of a new product. This underlines the importance of research and development in the pharmaceutical field.

26. Both Beecham and Parke, Davis, based on the experience they obtained in the therapeutical class to which the Product belongs, decided to undertake research in the area of the product which is aimed at a novel therapeutic application in the long-term control of the impairment of blood circulation. Both were in a position individually to make a full technological contribution to the joint research programme. Both were, in fact, capable of making their own tests and of bringing to the collaborative venture their own range of compounds for evaluation. Both intend to produce and market the Product individually. Both are therefore competitors.

C. Restriction on competition

27. During the period of the Project both parties continued to work with separate research teams in the field in question but subject to programmes of work agreed by them at the initial stage of the operation of the Agreement. Both parties also agreed to disclose to the other at regular intervals full details of all work undertaken in furtherance of the Project. The disclosure of results and regular interchange of progress reports is to be continued throughout any Development Programmes which may be undertaken following the successful screening of a likely compound which has been created by the collaborative research Project. In fact both teams tested and screened individually a number of compounds from which ... are likely to be the subject of Development Programmes.

28. Thus under their Agreement the parties have provided for and implemented a joint research programme of a closely collaborative nature. Each party must allow the other to participate in the results of knowledge acquired in the framework of the common research and development programme. This exchange of results will be in the form of oral or written communications or, if commercial property rights are acquired, in the form of a licence granted by the patent holder to the other party. In addition, the planning of the joint research programme is in itself coordinated between the parties. Together they decide the direction which the programme is to take, the substances to be investigated, and the resources in money and manpower to be assigned to the programme. This close collaboration continues throughout the period of any Development Programme in the same form as that put into effect during the Project. The collaboration between the parties at every stage of research and development means that neither can obtain a competitive advantage over the other at any point in the innovative cycle.

29. This collaboration covers the total research activity of the parties in the field of the Product and links the parties for a considerable time.

It is true that either party is contractually free to undertake independent research and development on a substance which the other party does not wish to retain in the joint programme. However, if the indications are that a substance may be worth further research, both parties will wish to continue with it and indeed could be inclined to favour the joint research to the detriment of their individual research in other fields. Consequently, it is unlikely to be removed from the joint programme. Conversely, the results of any such independent research must be made available to the other party, further reducing the incentive to undertake individual research.

30. There are also restrictions on individual research and development under the terms of the Agreement relating to discontinuation. Under the Agreement, should one of the parties wish to discontinue the Development Programme it may do so by giving written notice, in which case it will be entitled to a licence to manufacture, use or sell any Product of successful research undertaken by the other party when the results are wholly or substantially based on the results of the Project or Development Programme. Such licences are, however, only obtainable on payment to the continuing party of up to 75 % of its costs in furtherance of the Project or Development Programme. This clearly could discourage discontinuation and the commencement of individual research.

31. The collaboration is not limited to research and development but extends to the production stage. The parties are required to exchange information relating to improvements in the production of the drug substance and pharmaceutical forms for 10 years from first marketing the Product and, during the same period, any improvement of which either party may obtain knowledge either through its own scientific or commercial experiences or through a third party must be given to the other party with all relevant details relating to the mode of working or using the improvement. Both parties will, therefore, be able to combine their knowledge and expertise in order to improve the Product, with the result that it will have, during the period of the Agreement, the same composition, properties and application.

32. In all these respects the Agreement imposes an appreciable restriction upon competition between the parties during the research and development programme and during the first 10 years of production and marketing the Product. During this period both parties have available to them the same technical and pharmacological knowledge in the field of the Product. Even though they remain free to manufacture and market the Product in any country, in any quantity and under whatever trade marks they choose, each party is deprived, for a considerable period, of any possibility of achieving an advantage over the other in a pharmaceutical field which will have, in the case of successful research and development, important medical and commercial effects. Although the parties claim that competition between them and any other producers researching in the same or similar fields will be stimulated, this does not preclude the cooperation from restricting competition during the period of the Agreement between the parties who are competitors throughout the Community and worldwide. The Agreement, therefore, has the effect of restricting competition within the common market in the sense of Article 85 (1).

33. The present case, contrary to the opinion of the parties, can clearly be distinguished from those to which the Notice governing Agreements, Decisions and Concerted Practices in the field of Cooperation between Enterprises [1] applies. Agreements covered

[1] OJ No C 75, 29. 7. 1968, p. 3, corrected by OJ No C 84, 28. 8. 1968, p. 14.

by this Notice are those concerning merely exchange of experience and results and the joint execution of research work or the joint development of the results of research. The Notice makes clear that exchanges of this nature are only permissible, in terms of the effects on the competitive position of the parties to an agreement, up to the industrial application of the results of the cooperation and as long as the parties have a free hand with regard to their own research and development outside the joint project. In the present case, however, there are from the earliest stage continuing bilateral exchanges of specific information on applied research designed to lead to industrial application by both parties in production by the same process and of the same product.

The present cooperation therefore does not serve for information only, nor is it limited to research. It is a collaborative programme with the cooperation and bilateral exchanges affecting individual research and taking place throughout research and development and during the first 10 years of industrial application of the results of the joint programme.

The present case therefore goes beyond the abovementioned Notice and is to be considered under Article 85 (1). This conclusion is confirmed by Article 1 (1) (b) of Council Regulation (EEC) No 2821/71 [1] by which the Commission is entitled to grant a group exemption to agreements which have as their object :

'the research and development of products or processes up to the stage of industrial application, and exploitation of the results, including provisions regarding industrial property rights and confidential technical knowledge'.

Thus not only those Agreements going beyond the terms of this Regulation but also those within its limits are likely to raise the question of the applicability of Article 85 (1) and any exemption would have to be justified in terms of Article 85 (3).

D. Effect on trade between Member State

34. The common research and development is undertaken in the pharmaceutical sector, itself an area of intense activity, by two companies of importance and considerable size, which are active in every Member State and third countries. The cooperation prevents either party from obtaining a technological advantage over the other. The Product, which will only be marketed as a result of a successful outcome to the common research, will be made by the same process and under the same patents and at the same time will be commercialized throughout the Community by the parties or by their subsidiaries or associate companies as their own individual products and thus will be the subject of trade between Member States. The effect on such trade is likely to be substantial, taking into account the unique therapeutic application and effect of a successful Product on such common medical occurrence as impairment of blood circulation. Therefore the restrictions covered in II. C above are likely appreciably to affect trade between Member States.

III. APPLICABILITY OF ARTICLE 85 (3) OF THE EEC TREATY

Under Article 85 (3) the provisions of Article 85 (1) of the EEC Treaty may be declared inapplicable in the case of agreements between undertakings which contribute to improving the production or distribution of goods or to promoting technical or economic progress, while allowing consumers a fair share of the resulting benefit, and which do not :

(a) impose on the undertakings concerned restrictions which are not indispensable to the attainment of these objectives ;

(b) afford such undertakings the possibility of eliminating competition in respect of a substantial part of the products in question.

A. Technical and economic progress

35. The joint research programme for which the Agreement provides leads in the present case to technical and economic progress in terms of Article 85 (3).

36. The Product of the joint research and development is pharmacologically complex. It will not merely be an adaptation of, or have a similar therapeutic effect to, any existing marketed compound and its development would clearly contribute to technical progress. The creation of such a product would lead to the effective prevention or treatment of the impairment of blood circulation in certain sufferers for whom there is presently no known marketed compound having such effect.

[1] OJ No L 285, 29. 12. 1971, p. 46.

37. It is important for the Commission's assessment of this case that by reason of these specific properties of the Product, the necessary investigations and tests are unusually long and costly (see 4 above). The risks and costs involved to the parties individually are considerably reduced by their decision to recommence their former individual research in the form of collaboration in the use of their specialized facilities and complementary expertise in this and in related fields. The pooling of the research capacities and efforts of both parties is a major factor in providing, in pharmaceutical terms, a reasonable likelihood of success.

B. Consumer benefits

38. The relevant Product which is the subject of the joint research and development programme should result in more effective treatment of impairment in blood circulation and indeed should have beneficial properties (see 4 above) which do not as yet exist in any known compound. Because both parties may not have continued the research individually and since collaboration in research work avoids duplication in a highly sophisticated research field it is more likely that consumers will see quicker and better results in the form of a new product both as regards application and curative effects than in the case of independent research (see 5 above). The resulting benefit is therefore directed at, and will be readily available to, the consumer.

C. Indispensability of restrictions

39. Although the Commission is aware of the benefits of such joint research and development in terms of technical and economic progress and resulting consumer benefits, it must at the same time establish that the Agreement contains no restrictions on competition which are not indispensable to the attainment of its objectives and which would eliminate competition in respect of the products concerned.

Full exchange of information relating to the commonly-planned research efforts and their results during the Project and Development Programme with the effect of renouncing any individual or independent activity in that field is indispensable in the present case to the attainment of the advantages of the collaborative research which is based on close technical cooperation and mutual understanding. In the present case these advantages could be obtained only by means of the recommencement (see 5 above) of research by the parties within the joint programme.

All the results of their individual efforts, without exception, must be shared, even where there is disagreement over the justification for further development and one party initiates a Development Programme on its own. In such a case any results withheld might benefit one party, though only through the contribution of the other. It might also lead to duplication of work.

Either party is entitled to withdraw from the Development Programme and to restart independent research, in which case the other party is entitled to continue with the research and development while being obliged to grant, on receipt of up to 75 % of its research and development costs, a licence to the discontinuing party to use, manufacture and sell the product of any successful research. Such conditions were appropriate in order to ensure that both parties devoted maximum research effort to the joint programme and were dissuaded from discontinuing before positive results were obtained. On the other hand, the licensing conditions are necessary to allow both parties equal opportunity of obtaining the best return on their research efforts. Otherwise, one party could discontinue on the point of reaching positive results to which the other has essentially contributed.

40. The obligation on both parties to disclose experience gained from the results of the common research and development when it has led to an improved formulation or dosage form will ensure that at the initial stage of production both parties will be able to create the best possible therapeutic versions of the Product and at the lowest cost. It is at this stage that production of large quantities of a drug is most likely to create problems of pharmaceutical form and the exchange of information on these problems can, during an initial period, only be beneficial to both producer and consumer. However, the Commission could not accept different dates of commencement of the obligation varying with the start of marketing the Product in each country as had been provided in the notified Agreement. This would have had the effect of restricting competition for an unnecessarily long period as the obligation to exchange information would have been enforceable for a further 10 years each time marketing of the Product commenced in an additional country. The Commission took the view that the restrictions arising from these exchanges could not be extended beyond the specific and

limited period of the present exemption. As the timing for the date of first marketing of the Product cannot be specified, it is proposed to limit the period of exemption in order to give the Commission an opportunity of reassessing the effects of the commercial aspects of the Agreement and to ensure that the parties compete freely and without restriction as regards the Product after the expiry of the exemption.

41. Finally, the cooperation between the parties relates only to the Product and after the date of first marketing does not extend beyond technical information necessary for the most effective way of exploiting the results of the common research and does not extend to marketing cooperation or information which is likely to lead to additional restrictions on competition at the marketing stage.

42. An important consideration in justifying an exemption for the modified Agreement is that both parties remain completely free to manufacture and market the Product wherever, in whatever quantities and under whatever conditions, trademarks and prices they individually consider appropriate. To qualify for an exemption in these circumstances, joint research cooperation can only be admitted if the results of such joint research can be used by both parties freely and independently without any territorial or other restrictions on production or marketing within the common market.

The Agreement entitles each party to use the results of the common research as patent owner or licensee of the other party and to grant licences or sub-licences freely to third parties. In common research, if the grant of sub-licences is dependent on the agreement of the other party, either party would have the ability to prevent the other from using the results of the common research in pursuance of that other's individual interests and marketing policy. Additionally, third parties could be restricted in their ability to obtain licences for manufacturing the Product.

43. The grant of exemption was made subject to the following amendments to the Agreement (see 18 to 20 above):

(a) The Agreement in the notified form excluded the grant of licences in one Member State, France, where one of the parties had prior obligations to subsidiaries, albeit in a different business area from that covered by the Agreement. This led to a part of the common market being separated from the rest, so that free movement, throughout the common market, of the goods derived from the joint research was unjustifiably impeded. On the request of the Commission, the parties agreed to remove the exclusion of France from the licensing arrangements. In the present version, either party has the right to a licence for all territories (with the exception of Japan). However, even if either party is entitled, under the amended Agreement, to request a licence for all other countries, it must be clear that the Agreement does not lead, in fact, to market-sharing. Therefore, in order to avoid any possible market-sharing, the Commission intends to investigate the practical effects of the commercial terms to the Agreement. In particular, in order to establish the effects of the licensing provisions once a Product has been marketed, the parties may be required to furnish the Commission with details of all patent applications, and licences and sub-licences granted.

(b) As a parallel to the aforementioned exclusion of the grant of licences in France, the parties had agreed (see 20 above) that the excluding party should use its best endeavours to ensure that the other party enjoyed such rights as would have been available, had the exclusion not existed, to the extent that should its endeavours be unsatisfactory, it would share equally with the excluded party any profits or other benefits derived from marketing a Product in France. The Commission considered this clause as tantamount to a profit-sharing arrangement, and not indispensable to the attainment of the objectives of the Agreement. The parties have therefore deleted the offending clause.

(c) The grant of licences is no longer subject to royalties which were likely, before the amendment of the Agreement, to lead to restrictions which could not be considered indispensable. The Agreement provided for fixed royalties to be paid to the patent holder on sales of the licences and of any sub-licensee (see 18 above). The parties alleged that payment of royalties at these levels between them would be reasonable commercial terms and a necessary part of joint research. The Commission took the view, however, that equal contribution to joint research expenditure does not necessarily justify sharing the profit from mutual marketing exploitation.

Joint research gives access to improved technology which can be applied by either party corresponding to its own requirements, facilities and commercial interests. If the results of the common research can, particularly for technical reasons, only, or mainly, be used by one of the parties, the participation of the other by way of royalty payments in any benefit obtained from marketing a product of the joint research would seem reasonable. In the present case, however, the two companies both manufacture and sell pharmaceutical products throughout the world. There is no

indication that the results of the joint research can, for technical reasons, only be used by one of them.

In addition, the justification for the various levels of royalty payment cannot be seen as a reasonable participation in return on research investment, as they are not related to the total activity of either party in the Project. In view of the arrangement to balance all costs equally, it is clearly not the purpose of the royalty provisions to compensate the parties for excess or for disproportionate background or know-how contributions. The levels of royalty payments proposed, especially that relating to bulk sales, were likely to create a considerable disincentive for the parties to compete with one another, particularly where marketing raises difficulties, since substantial returns through royalties would have been obtained without production and marketing expenditure. The inference thus arising that the royalty provisions were intended to ensure that the parties share profits is supported by the terms relating to commercial exploitation in France and Japan (see 20 above), where profit-sharing was expressly provided for.

44. The amended Agreement does not therefore impose on the undertakings concerned restrictions which are not indispensable to the attainment of the objectives as set out in Article 85 (3).

D. Elimination of competition

45. The pharmaceutical industry generally is an area where competition is intensive both in research and development and in the market place. The pharmaceutical class to which the Product belongs is no exception, and some of the largest pharmaceutical companies active in the Community market a wide range of products in that category in every Member State. Although the Product would have a new therapeutic application, competition from the activities of the parties' competitors in the same therapeutic class could still be effective should, as is likely, the Product not be restricted in use to its new application.

46. As there is unlikely to be a marketable Product for a number of years, companies, particularly the largest, who are committed to extensive research and development programmes and have larger production capacities than the parties, must be considered capable of marketing a compound with a therapeutic application similar to the Product within the period of the Development Programme. In addition, after a successful Development Programme both parties will be competitors in the manufacture and marketing of the Product in every Member State.

47. For these reasons the Commission does not consider that the Agreement will give the parties the possibility of eliminating competition in respect of the Product in question.

All the requirements of Article 85 (3) are therefore satisfied.

IV. APPLICABILITY OF ARTICLE 8 OF REGULATION 17/62

48. In accordance with Article 8 (1) of Regulation No 17, a Decision in application of Article 85 (3) shall be issued for a specified period and conditions and obligations may be attached thereto. In addition, under Article 8 (2) of the said Regulation, the Commission has a duty to ensure that the requirements of Article 85 (3) continue to be satisfied.

49. The Agreement as notified and amended qualifies for exemption. Accordingly, under Article 6 (1) of Regulation No 17, the exemption will take effect from 23 February 1976, the date on which the two companies amended the Agreeement to satisfy the tests of Article 85 (3). In determining the duration of the exemption as provided by Article 8 of Regulation 17, account must be taken, having regard to the considerable investment by the two firms, of the need to allow them a sufficiently long period for the reasonable expectation of the realization of their objectives, particularly in view of the time required to complete a successful Development Programme reaching the marketing stage.

Since the Product is intended for the long-term prophylactic treatment of the impairment of blood circulation in humans the tests required to establish its efficiency and safety will have to be applied over a commensurately longer period than would be required for a compound which would be taken in smaller dosage and over a shorter period. However, the market position and overall size of the two companies and the

effects of progress in the therapeutic field in question require that the Agreement be reviewed within a reasonable term. It appears appropriate therefore to grant the exemption for a period of 10 years from the date of this Decision,

HAS ADOPTED THIS DECISION :

Article 1

The provisions of Article 85 (1) of the Treaty establishing the European Economic Community are, pursuant to Article 85 (3), declared inapplicable to the terms of the Agreement of 4 May 1973 as amended on 23 February 1976 between the Beecham Group Limited and Parke, Davis and Company relating to joint research and development, the exploitation of the results of joint or individual research and the exchange of manufacturing directions.

Article 2

Each of the two undertakings concerned shall forthwith inform the Commission of any amendment or addition to, or the discontinuation of, the Agreement specified in Article 1 and of any alteration in the nature or scope of the cooperation.

Article 3

This Decision shall take effect from 23 February 1976 and shall remain in force until 31 December 1988.

Article 4

This Decision is addressed to the Beecham Group Limited, Beecham House, Great West Road, Brentford, Middlesex, England, and Parke, Davis and Company, Joseph Campau at the River, Detroit, Michigan, USA.

Done at Brussels, 17 January 1979.

For the Commission

Raymond VOUEL

Member of the Commission