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(Acts whose publication is not obligatory)

# **COMMISSION**

#### **COMMISSION DECISION**

of 15 December 1975

relating to a proceeding under Article 85 of the Treaty

(IV/27.073 — Bayer / Gist-Brocades)

(Only the German and Dutch texts are authentic)

(76/172/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 proceeding which the Commission opened on its own initiative on 18 December 1974, pursuant to Article 3 of Regulation No 17, in respect of the agreements on the manufacture and supply of raw penicillin and 6-aminopenicillanic acid concluded in 1969 and 1971 between Bayer AG, Leverkusen, Germany and Gist-Brocades NV, Delft, the Netherlands,

Having regard to the notification of the agreements by the two undertakings on 5 May 1975,

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

Having regard to the summary of the agreements published pursuant to Article 19 (3) of Regulation No 17 in *Official Journal of the European Communities* No C 198 of 29 August 1975,

Having regard to the opinion of the Advisory Committee on Restrictive Practices and Dominant Positions delivered pursuant to Article 10 of Regulation No 17 on 21 October 1975,

Whereas:

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## The facts

1. Subject matter of the proceeding

This proceeding concerns a series of agreements between Bayer AG (hereinafter referred to as 'Bayer') and Gist-Brocades NV (hereinafter referred to as 'Gist-Brocades'), concluded in 1969 and 1971 and amended in 1973 and 1975, for the man facture of raw penicillin in plants belonging to Gist-Brocades and the supply of this raw penicillin to Bayer, and for the manufacture of 6-aminopenicillanic acid (6-APA) in plants belonging to Bayer, part of which is produced under contract for Gist-Brocades

- 2. The products
- (a) Raw penicillin is that natural metabolic product of the penicillium mould. It is the primary source for the manufacture of the sterile salts penicillin G and penicillin V and is increasingly being used for the manufacture of the intermediate product

<sup>(1)</sup> OJ No 13, 21. 2. 1962, p. 204/62.

<sup>(2)</sup> OJ No 127, 20. 8. 1973, p. 2268/63.\*

6-APA, which, in its turn, is chemically processed into semisynthetic penicillins such as ampicillin. Raw penicillin is also used to obtain 7-aminodesacetoxycephalosporanic acid (7-ADCA), an intermediate product for the manufacture of cephalosporin specialities.

Since the end of the 1960s, raw penicillin production has no longer been patented. Special knowledge of fermentation techniques is, however, required for the cultivation and propagation of productive moulds. The setting up of new plants requires considerable investment. The production costs of raw penicillin accounts for between 50 and 70 per cent of the cost of the semisynthetic penicillin specialities manufactured from it.

(b) 6-APA was discovered by Beecham in 1957. Beecham holds both the product and process patents. Those product patents still valid in some Member States will terminate in July 1978.

In 1960 Bayer discovered a biological process, which was different from Beecham's process. Beecham, among others, received a licence for this new process from Bayer and the right to grant sublicences. Beechman in turn gave Bayer a licence under its product patent and at the same time issued other licences or sublicences to a whole series of firms, including some located in the common market.

In 1966 Gist-Brocades developed a new chemical process for the manufacture of 6-APA, which was different from Bayer's process, and issued licences to Bayer in the common market and to a large number of non-Community manufacturers, primarily to those in the USA. In those countries where pharmaceutical products are not patentable (Italy and Eastern Europe) the Gist-Brocades process is the most widely used, since, as it is a chemical process, it is the one where the patent specification is easiest to follow.

Further processes have been developed more recently: the most important, which are already capable of industrial application, are Bayer's new enzyme process, Beecham's new enzyme process, which is different from Bayer's process, and processes developed by Astra (Sweden), SNAM-Progetti (Italy) and Ishimaru (Japan).

The manufacture of 6-APA is not so costly as that of raw penicillin. Wherever a chemical process can be used, it can be manufactured without difficulty in plants hitherto used for other chemical processes, since little special adaptation is needed.

6-APA is an intermediate product; the manufacturers process a part into semisynthetic penicillins and sell the rest to other firms for processing. This processing can be done by several methods, which have been patented by a number of manufacturers. These semisynthetics are either processed by the manufacturer itself into proprietary medicinal products or sold in bulk for processing by other firms in the pharmaceutical industry which do not manufacture their own 6-APA.

Various market stages can thus be distinguished: raw penicillin, 6-APA as an intermediate product, semisynthetic penicillins in bulk form, the end products penicillin G and penicillin V as sterile salts and the various brands of semisynthetic penicillin specialities which the individual final manufacturers sell to hospitals and pharmacies.

(c) Cephalosporins are not covered by the agreements but are closely related to them. These are either manufactured from raw penicillin with 7-ADCA as an intermediate product, or from cephalosporin C (patented by the UK National Research Development Corporation) with 7-amino-cephalosporanic acid (7-ACA) as an intermediate product. Gist-Brocades has process patents both for 7-ADCA and for 7-ACA. Other processes have been patented by Glaxo, Ciba and Lilly.

Antibacterial substances in their broader sense include penicillin and cephalosporin preparations and the broad- and medium-spectrum antibiotics such as the sulfonamides, chloramphenicol and the tetracyclines. However, there are substantial differences in the medicinal properties of the various individual products and in the tolerance levels, side-effects, price and circumstances of prescription.

- 3. The undertakings concerned
- (a) Bayer is one of Europe's largest pharmaceutical manufacturers. It has production, processing and distribution establishments throughout the common market. Its sales of pharmaceutical products in 1974 ran to some DM 1 600 million worldwide, of which domestic sales amounted to DM 550 million. The greater proportion of exports were to non-Community countries.

Penicillin products account for roughly 14 % of Bayer's total sales. In 1974 domestic sales of penicillin amounted to DM 133 million and exports to DM 100 million, of which 80 % were exported outside Europe. Bayer's main business is in finished semisynthetic penicillin preparations, especially ampicillin and its compounds. Bayer

sells 6-APA only to Farmitalia and to Recherches et Industrie Thérapeutiques (RIT) and bulk ampicillin and phenepicillin only to Pfizer, Merck and Hoechst. Belgium and Italy are the only common market countries to which it supplies semisynthetic penicillin specialities. It is not involved in the related cephalosporin market.

- (b) Gist-Brocades is primarily an undertaking which uses fermentation techniques, using products such as enzymes, yeast and alcohol. Its main business is in intermediate products and it sells 6-APA and ampicillin in bulk. It also manufactures 7-ADCA, which it processes into cephalosporin preparations. However, finished preparations account for a smaller proportion of Gist-Brocades' turnover than of Bayer's. Gist-Brocades has a production plant in Portugal (Mycofabril), marketing companies in the United Kingdom, Italy, Belgium and France and cooperation agreements with Grünenthal in Germany. In 1974 its sales of pharmaceutical products totalled Fl 400 million, and penicillin sales accounted for Fl 135 million of that amount.
- (c) Before concluding the agreements in question, both Gist-Brocades and Bayer were manufacturing raw penicillin. Gist-Brocades was working on a much larger scale, producing 560 mega against Bayer's 100 mega in 1970. Gist-Brocades' earnings were also higher, because it had better moulds and more advanced fermentation techniques. Bayer was at that time obtaining its additional requirements of raw penicillin from Rhône-Poulenc and, to an increasing extent, from Gist-Brocades.

Both Bayer and Gist-Brocades were producing 6-APA in their own plants. In 1969 Bayer produced 65 metric tons by its own biological process while Gist-Brocades produced 70 metric tons by its chemical process in a plant which had earlier been used for the manufacture of chloramphenicol.

The expansion of the penicillin business meant that production had to be increased. Bayer had to decide whether to cover its increased requirements of raw penicillin by a heavy investment in new plant or by entering into long-term supply contracts. In any event its 6-APA capacities had to be extended. Gist-Brocades had to expand its raw penicillin production and had to decide whether to extend its existing 6-APA capacity or convert it to 7-ADCA manufacture, in which event it would cover its 6-APA requirements through long-term supply contracts.

### 4. The agreements

The Commission was informally advised of the agreements in 1971; they were formally notified on 5 May 1975. Amendments were made on 14 March 1973 and 5 June 1975. The agreements can be summarized as follows.

The two supply contracts are dated 7 May 1969 and were concluded on the basis that Bayer did not intend to expand its raw penicillin plant and that Gist-Brocades did not intend to expand its 6-APA plant. Gist-Brocades was prepared to expand its own raw penicillin plant if Bayer would give it financial assistance and enter into a long-term purchase agreement. The same applied to Bayer with regard to the plant in which it was manufacturing 6-APA partly by its own process and partly by the Gist-Brocades process under a licensing agreement which was also concluded on 7 May 1969. By an agreement dated 14 March 1973, Bayer's commitment to supply Gist-Brocades with 6-APA was transformed into an arrangement for production under contract.

Bayer and Gist-Brocades have each granted the other a series of loans to enlarge their plants (Bayer DM 25.6 million and Gist-Brocades DM 14.9 million). These loans are for 10-year terms and repayable in equal instalments with interest, the first payment being due two years from the date of the loan.

The agreements provide for five-year quantity programming. In the short-term programmes, Bayer and Gist-Brocades have to inform each other no later than three months before the start of a given supply year of the quantities they will actually require. In each case the parties are obliged to supply this required quantity to the extent that the requirement can be met from that part of its plant which is financed by the other. The quantities ordered may be increased or reduced by up to 5 % or 10 % in the course of the year.

Should the quantities required by one party exceed the capacity of that part of the other party's plant which the former has financed, and should the latter thereby be induced to extend its plant, the first party is obliged to give financial assistance. However, there is no obligation to carry out such extensions. If the supplier partner refuses to extend its plant, then the customer-partner may, as is also the case as and when the agreement is terminated, require the former to grant it a licence in respect of all existing industrial property rights and to supply it with the latest technical know-how and, in the case of raw penicillium mould and techniques for its propagation.

The quality of the products to be supplied is fixed by agreement and the following are taken into account in determining prices:

- manufacturing costs, which are calculated on a jointly approved scale based on the relevant firm's total production of raw penicillin or 6-APA, as the case may be;
- interest on the capital involved;
- interest and repayments on the loan given by the other firm;
- research costs (where specifically agreed);
- a 'co-producer surcharge', that is an amount fixed per unit at a rate which varies according to the quantity supplied;
- where appropriate, adjustment for exchange-rate fluctuations;
- in the event that world market prices fall below the prices calculated as above, the co-producer surcharge is reduced.

Each firm is entitled to have the other's business books and records examined by experts in order to verify these cost components.

Both firms retain complete autonomy in the area of research and development. Both parties are to carry out comprehensive research programmes, Gist-Brocades into raw penicillin and Bayer into 6-APA; research results will be exchanged. Where research costs rise in one firm, the other must contribute financially in proportion to the quantities purchased by it. Gist-Brocades is obliged to keep Bayer as precisely up to date on new developments in fermentation techniques as Bayer would have been had it done its research itself. Bayer undertakes to keep secret all confidential information and papers it receives.

Through the licensing agreement concluded at the same time, Gist-Brocades granted Bayer a non-exclusive, non-transferable licence for its chemical process and provided Bayer with the necessary know-how for the manufacture of 6-APA in Germany. Bayer further received a non-exclusive, non-transferable licence for the worldwide utilization and marketing of the 6-APA manufactured under the licence. Both firms undertook to inform each other of any improvements in the manufacturing process and to grant each other licences in respect of such improvements. The same conditions apply should a new process for the manufacture of 6-APA be discovered. As long as Bayer continues to supply Gist-Brocades with 6-APA, the licence is free of charge. If the supply agreement terminates an 'appropriate' royalty is to be charged. On 5 June 1975 the two firms agreed to release each other from the obligation not to contest the validity of existing or future industrial property rights.

These supply contracts and contract-production and licensing agreements were supplemented by a basic agreement concluded on 19 May 1971. This covered the financing of new production plants or extensions to existing plants, for raw penicillin in the case of Gist-Brocades and for 6-APA in the case of Bayer; the transfer of these plants to two joint subsidiaries; the creation of a joint cooperation coordination committee; and the exchange of information and research results. Accordingly, Bayer and Gist-Brocades formed Penicillin-Chemie GmbH, Elberfeld, and Penicilline-Chemie Delft, BV, each taking a 50 % shareholding and appointing an equal number of directors. The land on which the plants for production of raw penicillin and 6-APA were to be built was leased to the joint subsidiaries, which were to lease back each plant to whichever firm was producing there.

After the Commission had objected to the formation of these joint subsidiaries as incompatible with Article 85 because they were a means of joint control of production and investment, the two firms agreed on 5 June 1975 to terminate the basic agreement; specially by ceasing to include the joint subsidiaries in their collaboration, either by winding them up or by each selling its shares to the other, and to disband the coordinating committee, but at the same time to extend the duration of the supply contracts and contract-production agreements from 10 to 30 years.

These contracts and agreements will continue in force until the year 2001 or until the last loan has been repaid, whichever is the later. Penicillin Chemie GmbH Elberfeld has been liquidated and Bayer's shares in Penicilline Delft BV have been transferred to Gist-Brocades.

### 5. Subsequent developments

Under these agreements, Gist-Brocades had expanded its raw penicillin and Bayer its 6-APA capacity. Gist-Brocades now concentrates on raw penicillin and Bayer on 6-APA.

Gist-Brocades supplies Bayer with the raw penicillin it requires, and the rest of its production is either sold to others or processed by Gist-Brocades itself into derivatives, a small proportion of which is made into penicillin V. Approximately half the raw penicillin is processed under contract by Bayer into 6-APA Gist-Brocades, using the chemical process licensed to it by the latter. Bayer processes the rest into 6-APA using its own recently developed enzyme process, most of which is further processed into semisynthetic penicillins. Bayer does not sell large quantities of 6-APA to third parties, whereas Gist-Brocades' sales are considerable, having nearly tripled during the years 1971-74

Both raw penicillin and 6-APA are marketed worldwide. Transport costs are not significant.

Through its plant expansion Gist-Brocades has become one of the world's largest raw penicillin manufacturers (about 16 % of world production), but Pfizer and Beecham each also manufacture on a similar scale. Pfizer has a world market share of about 13 %, while Beecham's share will reach about 12 % upon completion of the projected expansion of its raw penicillin plant. Other major producers manufacturing both for their own use and for sale, are Glaxo, Bristol, Wyeth, Rhône-Poulenc and Hoechst.

Following the extension of Bayer's 6-APA capacity, Bayer and Gist-Brocades have joined Beecham and Bristol (USA) as the world's leading manufacturers. The quantities which Bayer processes for Gist-Brocades and manufactures for its own use account for an estimated 15% of the market. The most important competitors are Beecham with 20% and Bristol with 12.5%. Italian firms account for about 15%. The recent commencement of 6-APA manufacture by the new Beecham, Astra and Ishimaru processes is not taken into account here.

For both raw penicillin and 6-APA the highest concentration of production is clearly located within the common market countries: about 60 % of the worldwide output is manufactured there, whereas the quantity of processed end-products actually consumed in these countries is considerably smaller, amounting to about 25 to 30 % of worldwide consumption. However, production and consumption levels in the Eastern bloc countries have not been taken into account, due to the lack of reliable statistics.

On the market for penicillins and the related substance cephalosporin, which is also partly based on raw penicillin, semisynthetic penicillin specialities account for 48 %, cephalosporin for 32 % and the traditional penicillins G and V for some 20 %.

Bayer has a leading position on the German market for semisynthetic penicillin specialities but is less important elsewhere in the Community. The main suppliers in the other Member States are Rhône-Poulenc in France, Farmitalia in Italy, Beecham and Glaxo in the United Kingdom and Ireland, Astra in Denmark, and Bristol, Beecham, RIT and Mycofarm (Gist-Brocades) in the Benelux countries.

Gist-Brocades' patents for intermediate products give it a position of great importance in the cephalosporin market. Its chief competitors are Glaxo, Lilly and Ciba-Geigy; Bayer is not involved in this market.

The main penicillin V suppliers are Bristol, Lilly, the Danish firm Novo and the Austrian firm Biochemie of the Sandoz Group.

- 6. The average prices for raw penicillin and 6-APA appear to be falling, as can be seen from a comparison of the 1970 and 1974 figures. The wholesale prices for ampicillin preparations, the most widely sold semisynthetic penicillin speciality, were cut by 15 % in 1971 and by 10 % in 1974. As for the prices of other semisynthetic penicillins, some rose slightly and others fell. The prices of penicillin G and V have remained more or less constant over the last ten years.
- 7. The essential contents of the notification have been published pursuant to Article 19 (3) of Regulation No 17, but the Commission has received no comments from third parties.

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### Applicability of Article 85 (1)

Article 85 (1) prohibits as incompatible with the common market any agreement between undertakings which may affect trade between Member States and which has as its object or effect the prevention, restriction or distortion of competition within the common market.

- 1. Bayer and Gist-Brocades are undertakings within the meaning of Article 85.
- 2. The agreements between them are agreements within the meaning of Article 85.
- 3. The object and effect of the agreements is to restrict competition within the common market.
- (a) Competition between the two firms in research is restricted by the obligation imposed by the licensing agreement to issue licences to each other not only for improvements to existing processes for the manufacture of 6-APA but also for new, independently developed processes. The effect is that for the duration of the agreement neither of the two firms can obtain a competitive advantage over the other in research nor can either gain individually by keeping research results to itself.

(b) Competition between the two firms is further restricted in the manufacture of raw penicillin and 6-APA.

Bayer and Gist-Brocades have been and still are competitors in the manufacture and sale of raw penicillin, 6-APA and special penicillin derivatives. Before the agreements were concluded both firms were in business independently of each other at all marketing stages. At the time the agreement was made, both were sufficiently large and experienced to be able independently to expand their production plants or set up new plants in order to meet rising demand. The larger of the two, Bayer could, as its internal planning documents confirm, have itself, without any outside assistance, made the heavy investment required in order to set up a new penicillin plant.

Gist-Brocades could have continued producing 6-APA in its own plant, using the process which it had itself developed and patented, and if necessary could have expanded its production without Bayer's help.

In each giving up part of its business in favour of the other, Bayer and Gist-Brocades are operating a specialization arrangement supported by longterm supply contracts and joint investment arrangements. For the duration of the reciprocal longterm supply contracts, they have in effect agreed not to compete with each other in the manufacture of the intermediate product which each has left to the other, although both could have continued to produce. In the case of 6-APA the two firms themselves have stated that even processing firms which had never been in business as manufacturers before could enter the market on the manufacturing side and that they have to consider this factor when selling 6-APA to such firms. This applies all the more to Gist-Brocades, because it is a patent holder with experience of manufacture.

The agreements in fact contain no express provision for the parties to cease competing in this way. However, in the Commissions' view it is clear from all the circumstances of the case that they must have agreed to do so. Bayer gave up manufacturing raw penicillin and Gist-Brocades gave up manufacturing 6-APA simultaneously, between the two actions the causal link is evident. Neither of the two firms wished by giving up its production to become unilaterally dependent on the other, since both feared that 'the eventual outcome of such a one-sided relationship would be a battle for market shares'. Each has been financially involved in the other's new or expanded plants and each has agreed to provide additional finance when necessary. It is in the interests of both to see that these plants are operated as economically as possible, in other words to obtain their requirements as far as possible from these plants. On the termination of the agreements each has undertaken to transfer to the other the mould (raw penicillin) or know-how (6-APA) required for renewed independent production. Gist-Brocades has undertaken to give Bayer licences not only for improvements to its existing 6-APA manufacturing process but also for entirely new processes. This procedure is logical only if the firms are to specialize and to continue doing so even if the other party discovers a new process. Given these circumstances, it would serve neither the spirit nor the purpose of the agreement if, during its course, one party was able to become an independent competitor in the manufacturing preserve of the other.

- (c) The specialization agreement is supported by reciprocal long-term supply contracts. Although the two firms are not expressly required to obtain all their requirements under these contracts, the mutual long-term commitment and mutual dependence created by the specialization and the joint investments inevitably mean that each firm will generally try to cover its requirements by buying from the other. The prices calculated by the jointly-established formula are so favourable that purchases from third parties would be pointless unless, for unforeseeable reasons, one of the firms could not produce enough or could not produce at all.
- 4. The agreements involve undertakings from more than one Member State. They concern goods which, whether processed or not, can be and are dealt with in trade between Member States.

The agreements give each firm the opportunity to strengthen its position on its respective domestic markets, to shield itself from the influence of the other and to coordinate its policy with the other on those markets, which they both supply. They may therefore affect trade between Member States and consequently fall within the scope of Article 85 (1).

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### Applicability of Article 85 (3)

Under Article 85 (3), the provisions of Article 85 (1) of the Treaty may be declared inapplicable in the case of any agreement which contributes to the improvement of the production or distribution of goods or to the promotion of technical or economic progress, while allowing consumers a fair share of the resulting benefit, and which does 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.
- 1. For the agreements to contribute to the improvement of production or distribution, or to promote technical or economic progress, they must objectively constitute an improvement on the situation that would otherwise exist. The fundamental principle in this respect, established at the time the common market was formed, lays down that fair and undistorted competition is the best guarantee of regular supply on the best terms. Thus the question of a contribution to economic progress within the meaning of Article 85 (3) can only arise in those exceptional cases where the free play of competition is unable to produce the best result economically speaking.

In the present case, a specialization agreement for production has been made between two firms which are financially strong and of importance and experience on the market concerned. In such circumstances it cannot be assumed, on those facts alone, that neither firm would, without the assistance of the other, hitherto a major competitor, be able to bear the costs and economic risks involved in expanding the capacity needed for the rationalization of production.

Account must however be taken of the limitations on Bayer's ability to expand its raw penicillin plants to cover rising supply requirements. The quality and yield of Bayer's raw-penicillin strain were very low, and an increase in yield could not be expected. In order to improve production of raw penicillin, Bayer had to obtain the aid of a firm experienced in fermentation techniques. The improvement and expansion of Bayer's own existing raw penicillin plant with the help of Gist-Brocades was not as economical for technical reasons, as a jointly financed expansion of Gist-Brocades' raw penicillin capacities. At the same time this arrangement with Gist made it possible for Bayer to change from raw penicillin to the manufacture of 6-APA in larger quantities and under modernized conditions. The agreements therefore contribute to the improvement of production.

- As a result of the agreements both firms have been able to expand their production to an extent which should allow the consumer to enjoy the resulting benefit. These benefits will stem from the improved production which the combined technical knowledge of the firms makes possible. Firms which do not have raw penicillin or 6-APA production facilities at their disposal will now be able to obtain these products in larger quantities from the parties to the agreement, particularly from Gist-Brocades, whose sales to other firms of raw penicillin and of 6-APA have nearly tripled during the years 1971-74, while prices have shown a downward trend. As a result those other firms have been able to produce larger quantities of penicillin specialities and to market them in competition with Bayer and Gist-Brocades. The greater number of end-products available on the market and the general trend to lower prices show that the consumer is receiving a fair share of the benefits of the agreement. However, in order that the Commission may follow developments on the market, certain obligations should be imposed upon the parties.
- 3. All the clauses of the agreements as amended are indispensable to the attainment of the stated objectives.
- (a) The decision by each firm that for the duration of the agreement it will not manufacture the specialized product on which the other will concentrate is essential, as are the long-term mutual supply contracts. There are, however, no exclusive supply conditions. If additional supplies are required, each firm is free to obtain its needs on the open market. Thus each firm is provided with a basis sufficient to permit it to develop its production and marketing plans while remaining free to make its own decisions as to the utilization or expansion of that part of its production capacity in the field covered by the specialization agreements which is not required to fulfil its supply commitments. Bayer is able to expand its 6-APA production as it thinks fit with a view to processing greater quantities of semisynthetic penicillin specialities. Gist-Brocades is free to determine itself the amount of raw penicillin to be produced and therefore the quantity to be processed into either of the sterile salts penicillin G, or V or into 7-ADCA, the intermediary product for the manufacture of cephalosporin. Each firm is required to make a proportionate financial contribution only when it seeks from the other quantities in excess of the capacities of the jointly financed plant.

(b) In the earlier versions of the agreement there was no such provision for separate action on the market independently of the specialization arrangements. The plants were originally to be transferred to joint subsidiaries in which both firms were to hold shares and appoint directors. The formation of these joint subsidiaries would have had the effect of bringing the production of raw penicillin and 6-APA and investment under joint control. Since each firm was to be equally represented, both in the management of the subsidiary and on the coordinating committee, either would have been able to veto any management decision with which it did not agree. The result would inevitably have been that ouput would have been determined by joint agreement; neither firm would have been able, without the other's approval, to increase the quantities available to it for resale to other firms or for processing, and hence to increase, to the detriment of the other, the quantities supplied to the market by it.

It was not possible to regard such an extensive competitive restriction on investment and production as indispensable to the specialization agreement.

- (c) The no-challenge clause in the licensing agreement has also been removed as an unnecessary restriction. If Gist-Brocades and Bayer, two of the world's largest 6-APA manufacturers, had continued to agree not to contest the validity of each other's patents, the result might have been that third parties would have been prevented from exploiting freely for the benefit of the consumer processes which did not in fact merit the protection of a patent.
- (d) On the other hand, the requirement on the parties to issue licences both in respect of improvements to the existing processes and of new 6-APA manufacturing processes is an indispensable part of the specialization scheme, since it permits the optimum use of plant for the latest and most economic processes. Since the licences are not to be exclusive, they can be issued to other firms. An obligation should be imposed which will enable the Commission to supervise the operation of this clause.
- (e) Thus agreements, as amended, no longer contain any restrictions which are not economically indispensable. The decisive factor is that neither on paper nor in practice is either firm in a position to prevent or hinder free trade within the Commu-

nity in 6-APA, whether it be manufactured by Gist-Brocades', Bayer's, or any other process.

- 4. The agreements do not afford the undertakings concerned the possibility of eliminating competition in respect of a substantial part of the products in question
- (a) In considering the question of exemption the market situation within the common market cannot be taken in isolation, because it is so closely associated with the situation on the world market. Both raw penicillin and 6-APA are marketed worldwide without regard to origin. Transport costs are not significant. Manufacturers from third countries offer their products for sale within the common market and manufacturers from within the Community are active as suppliers in third countries.
- (b) Taking as the relevant market that for raw penicillin and 6-APA, it is clear from the available data, albeit estimated in some cases, that Bayer and Gist-Brocades both have substantial shares of that market, with the expansion of its raw penicillin capacity, Gist-Brocades will become one of the most important manufacturers in the world, with about 16 % of world production. However, its lead over the next largest independent supplier is not so great as to give it a decisive role on the market. Pfizer, which also supplies the Community market, accounts for 13 % of world production, and is followed by such important firms as Glaxo, Beecham, Rhône-Poulenc, Squibb and Hoechst; indeed Beecham will, as a result of recent investments, virtually double its raw penicillin output by 1977, and will rank more or less equally with Gist-Brocades.

As a result of the agreement, the market position of the two firms with regard to 6-APA is also significant. The amount of 6-APA at Gist-Brocades' disposal, taking into account that produced under contract by Bayer, is about 15 % of world production, and Bayer's production for its own use also accounts for about 15 %. The world's largest producer is Beecham, with an estimated world market share of 20 %, while Bristol is another manufacturer of comparable importance. This analysis of the market does not take into account the increase in the number of major 6-APA manufacturers which may be expected shortly as a result of the recent development on an industrial scale of the new Astra, Snam-Progetti and Ishimaru processes.

- (c) In considering the market positions of the firms concerned the Commission has also taken into account the fact that raw penicillin is not only the essential raw material for the manufacture of 6-APA but that it can also be used in the production of both the sterile penicillin salts G and V and the intermediary products 7-ADCA and 7-ACA on which Gist's cephalosporin production is based. However, other manufacturers, who do not themselves produce penicillin, make cephalosporin specialities on the basis of the primary element, cephalosporin C. The importance of these products in relation to the penicillin specialities is increasing. It is clear, therefore, that these producers influence the market in primary and intermediary penicillin products. In their marketing of raw penicillin and 6-APA, Gist and Bayer have to take these manufacturers into account.
- (d) Finally the Commission takes the view that production specialization does not in this case have the result that the firms concerned, by extending the range of their respective products, sell the same products at the same or similar prices, or that they restrict their activities to separate markets. In the case of 6-APA derivatives, the two firms, Bayer and particularly Gist-Brocades, sell different products, both in bulk and in packaged form for retail sale, while both firms have different sales policies in relation to 6-APA. Bayer processes most of its 6-APA production into specialities, whereas Gist-Brocades supplies the greater part of its 6-APA to entirely independent processing firms.

The parties in this case are accordingly not in a position to eliminate competition in respect of a substantial part of the products in question.

5. In accordance with Article 8 (2) of Regulation No 17, the Commission has a duty to ensure that the requirements of Article 85 (3) continue to be satisfied.

To enable the Commission to observe the practial effects of this specialized collaboration, in particular as regards the market position of third parties, each party will be required to provide the Commission each year with details of all investments, production and supplies to the other party and to third parties, together with details of the average prices charged.

The Commission must, furthermore, ensure that competition between the two firms and between either of them and other competitors is not affected

by any factor extraneous to the present Decision. Such restrictions could in particular arise from interlocking shareholdings or directorates or joint or reciprocal participation, irrespective of whether all the firms concerned belonged to the Bayer and Gist-Brocades groups or whether some of them belonged to one of those groups while the others were actual or potential competitors. This not only applies particularly to those products which are the immediate concern of these proceedings, nanemly raw penicillin and 6-APA, but also generally to products which are comparable with the intermediate product 6-APA in that they are or can be manufactured from raw penicillin (7-ADCA and 7-ACA).

In order to enable the Commission to achieve this objective the two firms should be required to provide advance information of any such potential restrictions.

IV

#### Duration of the exemption

Accordingly, the agreements as notified and amended can, subject to certain obligations, qualify for exemption. In accordance with Article 6 (1) of Regulation No 17, the exemption will take effect from 5 June 1975, the date on which the two firms adapted their agreements to satisfy the tests of Article 85 (3). In determining the duration of the exemption as provided by Article 8 of Regulation No 17, account must be taken, having regard to the considerable investment by the two firms with a view to their specialization, of the need to allow them a sufficiently long period for the realization of their objectives. Nevertheless, the market position of the two firms, the structure of the market itself and technical progress require that the agreements be reviewed within a reasonable time. It appears appropriate therefore to grant the exemption for a period of eight years,

HAS ADOPTED THIS DECISION:

#### Article 1

Pursuant to Article 85 (3) of the Treaty establishing the European Economic Community, Article 85 (1) thereof is declared inapplicable to the agreements relating to the manufacture and distribution of raw penicillin and 6-aminopenicillanic acid, made on 7 May 1969 and amended on 14 March 1973 and 5 June 1975, between Bayer AG, Leverkusen, and Gist-Brocades NV, Delft.

### Article 2

The following obligations are attached to this Decision:

- 1. Each of the two undertakings concerned shall forthwith inform the Commission of any change or addition to the agreements specified in Article 1, even where such changes or additions are the result of arbitration proceedings.
- 2. With regard to raw penicillin and 6-APA, the two undertakings shall each year, by 30 June at the latest, inform the Commission of:
  - (a) all licenses issued to each other pursuant to the agreements, and of the terms of such licenses;
  - (b) all investments, existing capacities and actual production figures;
  - (c) the quantities processed by themselves, those supplied to each other and the quantities sold to any other undertaking;
  - (d) the yearly average prices charged on supplies to each other and to other undertakings;
  - (e) the wholesale prices charged to pharmacies on sales of semisynthetic penicillin specialities, including list prices and any rebates.
- 3. Each of the two undertakings concerned shall forthwith inform the Commission of any of the

following forms of link between itself and the other undertaking or between itself and any other undertaking:

- (a) acquisition of a holding of 25 % or more in the capital of an undertaking;
- (b) common directors or managers,
- (c) formation or acquisition of joint subsidiaries.

This obligation applies to all undertakings which directly or indirectly manufacture, process or sell penicillin or cephalosporins.

#### Article 3

Article 1 of this Decision shall take effect from 5 June 1975 and shall remain in force until 31 December 1983.

This Decision is addressed to Bayer AG, Bayerwerk, D 509 Leverkusen, Germany, and to Gist-Brocades NV, Wateringseweg, Delft, Netherlands.

Done at Brussels, 15 December 1975.

For the Commission

A. BORSCHETTE

Member of the Commission