JUDGMENT OF THE COURT OF FIRST INSTANCE
(Fifth Chamber, Extended Composition)

26 October 2000 *

In Case T-41/96,

Bayer AG, established in Leverkusen (Germany), represented by J. Sedemund, Rechtsanwalt, Cologne, with an address for service in Luxembourg at the Chambers of A. May, 398 Route d'Esch,

applicant,

supported by

European Federation of Pharmaceutical Industries' Associations, established in Geneva (Switzerland), represented initially by C. Walker, Solicitor, and subsequently by T. Woodgate, Solicitor, with an address for service in Luxembourg at the Chambers of A. May, 398 Route d'Esch,

intervener,

* Language of the case: German.

Commission of the European Communities, represented by W. Wils and K. Wiedner, of its Legal Service, acting as Agents, with an address for service in Luxembourg at the offices of C. Gómez de la Cruz, of the Legal Service, Wagner Centre, Kirchberg,

defendant,

supported by

Bundesverband der Arzneimittel-Importeure eV, established in Mülheim an der Ruhr (Germany), represented by W.A. Rehmann and U. Zinsmeister, of the Brussels Bar, with an address for service in Luxembourg at the Chambers of Bonn and Schmitt, 7 Val Ste Croix,

intervener,

APPLICATION for the annulment of Commission Decision 96/478/EC of 10 January 1996 relating to a proceeding under Article 85 of the EC Treaty (Case IV/34.279/F3 — Adalat) (OJ 1996 L 201, p. 1),

THE COURT OF FIRST INSTANCE
OF THE EUROPEAN COMMUNITIES
(Fifth Chamber, Extended Composition),

composed of: J.D. Cooke, President, R. García-Valdecasas, P. Lindh, J. Pirrung and M. Vilaras, Judges,

Registrar: J. Palacio González, Administrator,

having regard to the written procedure and further to the hearing on 28 October 1999,

gives the following

Judgment

Background

1 The applicant, Bayer AG (hereinafter 'Bayer' or 'the Bayer Group'), is the parent company of one of the main European chemical and pharmaceutical groups and has a presence through its national subsidiaries in all the Member States of the Community. For many years, it has manufactured and marketed under the trade name 'Adalat' or 'Adalate' a range of medicinal preparations whose active ingredient is nifedipine, designed to treat cardio-vascular disease.

2 In most Member States, the price of Adalat is directly or indirectly fixed by the national health authorities. Between 1989 and 1993, the prices fixed by the

Spanish and French health services were, on average, 40% lower than prices in the United Kingdom.

3 Because of those price differences, wholesalers in Spain exported Adalat to the United Kingdom from 1989 onwards. French wholesalers followed suit as from 1991. According to Bayer, sales of Adalat by its British subsidiary, Bayer UK, fell by almost half between 1989 and 1993 on account of the parallel imports, entailing a loss in turnover of DEM 230 million for the British subsidiary, representing a loss of revenue to Bayer of DEM 100 million.

4 Faced with that situation, the Bayer Group changed its delivery policy, and began to cease fulfilling all of the increasingly large orders placed by wholesalers in Spain and France with its Spanish and French subsidiaries. That change took place in 1989 for orders received by Bayer Spain and in the fourth quarter of 1991 for those received by Bayer France.

5 Following complaints by some of the wholesalers concerned, the Commission started an administrative investigation procedure concerning alleged infringements of Article 85(1) of the EC Treaty (now Article 81(1) EC) by the Bayer Group in France and Spain.

6 On 10 January 1996, the Commission adopted Decision 96/478/EC, which forms the subject-matter of this action, relating to a proceeding under Article 85 of the EC Treaty (Case IV/34.279/F3 — Adalat) (OJ 1996 L 201, p. 1; 'the Decision').

7 In the words of Article 1 of the Decision, 'the prohibition on the exportation to other Member States of the products Adalate and Adalate 20 mg LP from France and on that of the products Adalat and Adalat-Retard from Spain, as has been agreed as part of their ongoing business relations, between Bayer France and its wholesalers since 1991, and between Bayer Spain and its wholesalers since at least 1989, constitutes an infringement of Article 85(1) of the Treaty on the part of Bayer AG'.

8 Under Article 2 of the Decision:

'Bayer AG shall bring the infringement to an end and shall in particular:

— send, within two months of notification of this Decision, a circular to the wholesalers in France and in Spain stating that exports are allowed within the Community and are not penalised,

— include this clarification, within two months of notification of this Decision, in the general terms and conditions of sale for France and Spain.'

9 Article 3 of the Decision imposes a fine of ECU 3 million on Bayer.

10 Article 4 fixes a periodic penalty of ECU 1 000 for each day's delay in performing the specific obligations set out in Article 2.

Procedure and forms of order sought by the parties

11 By application lodged at the Registry of the Court of First Instance on 22 March 1996, Bayer brought an action for the annulment of the Decision.

12 By separate document lodged at the Court Registry on the same day, the applicant also applied for suspension of the operation of Article 2 of the Decision. By order of the President of the Court of First Instance of 3 June 1996, suspension of the operation of Article 2 of the Decision was granted and costs were reserved.

13 On 1 August 1996, a German association of importers of medicinal products, the Bundesverband der Arzneimittel-Importeure eV ('the BAI') applied for leave to intervene in support of the form of order sought by the Commission.

14 On 26 August 1996, the European Federation of Pharmaceutical Industries' Associations ('the EFPIA'), a professional association representing the interests of 16 national professional associations in relation to the medicinal products industry, applied for leave to intervene in support of the form of order sought by the applicant.

15 By orders of 8 November 1996, the President of the Fifth Chamber (Extended Composition) of the Court of First Instance granted the two associations leave to intervene. The interveners lodged their statements in intervention on 12 February 1997. The main parties lodged their observations on the statements in intervention on 11 April 1997.

16 On hearing the report of the Judge-Rapporteur, the Court of First Instance decided to open the oral proceedings and, by way of measures of organisation of

procedure pursuant to Article 64 of the Rules of Procedure, to put a series of questions in writing to the applicant and the Commission, requesting them to reply to those questions at the hearing.

17 The parties presented oral argument and replied to the written and oral questions of the Court of First Instance at the hearing on 28 October 1999. At the hearing, in support of some of its replies to questions by the Court, the Commission requested leave to place on the Court's file some of the annexes to the statement of objections sent to the applicant during the administrative procedure. Since the applicant made no objection, and stated that the documents in question did not contain any confidential information concerning it, all the parties, including the interveners, received copies of those annexes and had the opportunity to express an opinion on them during the hearing.

18 The applicant claims that the Court of First Instance should:

— annul the Decision;

— in the alternative, annul the fine of ECU 3 000 000 imposed upon it;

— further in the alternative, reduce the fine;

— order the Commission to pay the costs.

19 EFPIA, the intervener in support of the applicant, claims that the Court of First Instance should:

— annul the Decision;

— order the Commission to pay the costs of its intervention.

20 The Commission contends that the Court of First Instance should:

— dismiss the application;

— order the applicant to pay the costs.

21 BAI, the intervener in support of the Commission, contends that the Court of First Instance should dismiss the application.

The Decision

22 The Decision concerns Adalat, a product belonging to a category of medicinal products known as 'calcium antagonists', suitable for treating certain cardiovascular diseases (coronary heart disease, arterial hypertension and congestive heart

failure) (eighth recital). However, the scope of the Decision is limited to two products in the Adalat range, namely the 10 mg capsule (marketed in the United Kingdom and Spain under the name 'Adalat' and in France under the name 'Adalate') and the 20 mg modified-release tablet (marketed in the United Kingdom and Spain under the name Adalat-Retard and in France under the name 'Adalate 20 mg LP') (fourth recital).

23 As regards the geographical market, the Decision held that the relevant markets in this case were the national markets (recitals 150 to 152), taking account of the fact that, at the time of the activities penalised, the business of the pharmaceutical industry took place in an essentially national context, marketing authorisation for a medicinal product falling exclusively within the competence of the Member States. Moreover, the sale of medicines was influenced by the administrative, and particularly purchasing, policies adopted in Member States, especially in France and Spain, where prices were directly set by the competent national authority. Finally, the Decision states that differences in price-fixing methods and refund arrangements meant that there were wide disparities in the prices of medicinal products in Member States.

24 As regards the product market, the Decision states (recital 153) that it is defined by reference to the criterion of identical therapeutic uses for the various competing products.

25 As regards, finally, the relevant market in relation to the conduct examined in the Decision, it may be seen from recital 154 that the United Kingdom was taken to be the major relevant market 'since the agreements directly affect this market by protecting it from parallel imports', and that, 'secondarily,..., the markets from which the parallel imports originate, France and Spain' were deemed to be relevant markets 'since they are artificially closed through the hindering of parallel exports'.

26 With regard to the market shares held by Bayer with the marketing of Adalat, the Decision (recital 23) states that they are indicated by reference to the major therapeutic uses of the product. The Commission considered that, in France, Adalate represented a market share of 5.1% on the coronary heart disease market and 4.1% on the hypertension market. In Spain, Adalat represented 7.4% on the coronary heart disease market and 8.7% on the hypertension market. In the United Kingdom, the market shares were 19.6% on the coronary heart disease market and 16.6% on the hypertension market. Finally, in the Community (of 12), Adalat represented 7.6% of the coronary heart disease market and 5.8% of the hypertension market (recitals 24 to 27).

27 The Decision describes the conduct of the Bayer Group when faced with the phenomenon of parallel exports of Adalat from Spain and France to the United Kingdom, and the reactions of the wholesalers and customers of Bayer Spain and Bayer France in that respect.

28 As to the legal assessment of that conduct, the Decision states (recitals 155 to 159) that Bayer France and Bayer Spain committed an infringement of Article 85(1) of the Treaty by imposing an export ban as part of their commercial relations with their respective wholesalers, that the latter knew the real reasons of Bayer France and Bayer Spain, and that they aligned their conduct in accordance with the requirements of Bayer France and Bayer Spain. The Decision considers that this constitutes an appreciable restriction of competition and has an appreciable effect on trade between Member States.

Substance

29 The applicant pleads, primarily, infringement of Article 85(1) of the Treaty inasmuch as its conduct, as referred to in the Decision, was unilaterally planned

and adopted by itself, and does not fall within the scope of that provision in the absence of any agreement between itself and its wholesalers concerning exports of products delivered to the United Kingdom. In the alternative, the applicant claims that the Commission made an obvious error of assessment by applying that provision to conduct that was lawful by virtue of Article 47 of the Act of Accession of Spain to the European Communities concerning the protection of patents. In the further alternative, it puts forward a plea in law alleging breach of the principles of legal certainty and proportionality through the imposition of a fine pursuant to a novel application of Article 85 of the Treaty, and infringement of Article 15(2) of Council Regulation No 17 of 6 February 1962 (First Regulation implementing Articles 85 and 86 of the Treaty (OJ, English Special Edition 1959-1962, p. 87).

The main plea in law, alleging infringement of Article 85(1) of the Treaty, in that the Commission considers that provision to be applicable to the facts of the case

I — *Arguments of the parties*

30 According to the applicant, the relevant facts in this case may be summarised as follows: in a Member State in which prices have been fixed by the national health authorities well below the prices charged in other Member States, a manufacturer who does not dominate the market accepts orders from wholesalers only in respect of a volume corresponding to the quantities normally sold in their traditional delivery areas. The reason for which the orders for products are partially refused lies in the fact that the wholesalers disproportionately raise the quantities normally ordered for the purpose of exporting the surplus in order to profit from price differences. For the applicant such a practice is unwelcome because it causes major turnover losses for its own subsidiaries established in the other States, threatening their economic existence. So as not to commit an infringement of Article 85 of the Treaty, it gives its sales personnel strict instructions to solve the problem solely by unilaterally placing quotas on the

quantities ordered and citing to the wholesalers as the reason only 'stock shortages'. In time, the wholesalers nevertheless discover the true motives of the manufacturer. Given that the latter accepts orders only if they are at the level of the quantities ordered previously, the wholesalers pretend to adjust their orders accordingly while at the same time obtaining larger supplies for export by asking other wholesalers to buy the products for them. In fact, the parallel exports continue and even increase.

31 The applicant points out that, in most Member States, the price of Adalat is directly or indirectly fixed by the health services of the State, which, on account of the use of very different criteria, causes enormous price differences between one Member State and another. In particular, during the period at issue — from 1989 to 1993 — in Spain and France the State health services fixed the prices on average 40% lower than in the United Kingdom, where the prices of pharmaceutical products are subject to a different form of control by the State, based on the profits of the pharmaceutical companies.

32 It was on account of such price differences that Spanish wholesalers, who traditionally undertake the supply of pharmacies in their Spanish sales area and buy Adalat from the applicant's Spanish subsidiary, began in 1989 to export that product in large quantities to the United Kingdom, thereby achieving far larger profits than those achieved by supplying their traditional customers in Spain (the applicant states, for example, that a single wholesaler suddenly ordered a quantity representing nearly half the total consumption of Spain; see recital 114 of the Decision). The applicant adds that, because of the immense profits to be made with those exports, some of the Spanish wholesalers even completely gave up supplying the Spanish pharmacies to which they normally delivered in order to resell nearly all their Adalat in the United Kingdom. That situation caused major supply shortages for pharmacies in certain regions of Spain, and forced Bayer, in order to protect patients, to deliver directly to the pharmacies neglected by the Spanish wholesalers.

33 As for French wholesalers, the applicant states that similar events took place in France as from September-October 1991, when those wholesalers began, in turn, to export large quantities of Adalat to the United Kingdom.

34 The applicant maintains that it was in the face of that situation, and having regard to the long-term problems for Bayer UK, that it wished to react against that phenomenon of parallel imports, which was examined at the highest level of decision-making and responsibility. After thorough discussions and a meticulous legal examination of the various possible measures, taking account of the Commission's decision-making practice and the Community case-law on the matter, it was decided that, rather than ceasing to supply the wholesalers altogether and itself assuming the task of distribution, a 'softer' measure should be chosen — merely a reduction in the quantities delivered. The applicant therefore decided to accept orders from wholesalers only on the basis of their orders in the previous year, while nevertheless allowing them to be raised by about 10% per year, in line with the rise in consumption.

35 The applicant acknowledges that it has an internal information system in order to try to establish the existence and level of parallel imports, but denies both the scope of that system, as alleged in the Decision, and the statements as to its actual application in relation to French and Spanish wholesalers, which are circumstances from which the Commission erroneously deduces the existence of an 'export ban'. It explains that the system consisted only of noting the quantities delivered to each wholesaler in previous years and, on the basis of those 'reference quantities', increased, reasonably, by about 10% per annum to take account of both inflation and the rise in general price indices, of fixing in advance the quantities to be delivered annually and monthly.

36 The applicant denies having put into practice a policy of supply contingent upon compliance with an alleged export ban, as argued by the Commission, and explains that the system established does not involve the carrying out of subsequent checks to determine whether the quantities delivered had been exported.

37 Finally, the applicant emphasises the freedom of wholesalers to export the products delivered, arising from the fact that, knowing that Bayer did not in any way monitor the final destination of those products, they could not fear 'sanctions' if the ultimate destination of the products was the United Kingdom. The wholesalers took '*de facto*' advantage of that freedom, to a large extent exporting the products which had been delivered to them and those delivered to other wholesalers or local agents.

38 The applicant maintains that the Commission has not established the existence of an agreement between Bayer and its wholesalers, and claims that there was no intention to establish an agreement either on its part, because it considered it lawful to implement a unilateral policy of limited delivery in order to make parallel exports more difficult, or on the part of the wholesalers, who demonstrated by their conduct their total opposition to such a policy being applied. In the applicant's submission, the Commission's argument amounts to saying that the requirement of the existence of an agreement between undertakings within the meaning of Article 85 of the Treaty is fulfilled even if the party placing the order merely pretends to alter his conduct, and his actual conduct proves quite clearly that he specifically does not wish to conclude the alleged agreement. Such an approach is, the applicant submits, contrary to the wording and the purpose of Article 85, since concurrence of wills, that is to say the central element in the concept of agreement, would no longer be necessary in such a concept of agreement.

39 Moreover, the applicant maintains that, in order to justify the adoption of that new approach, the Commission could not rely on decision-making and case-law precedents, given the differences between the facts in this case and those in point in previous decisions concerning hindrances to parallel exports.

40 The applicant claims that, hitherto, it has been undisputed that the partial or complete refusal of deliveries constitutes a unilateral act that cannot fall within Article 85 of the Treaty. In the absence of an agreement within the meaning of Article 85(1) of the Treaty, that provision cannot be applied in this case. In its submission, the Commission's argument extends the scope of Article 85 of the Treaty to a unilateral refusal of delivery which could fall only under Article 86 of

the Treaty, is such a way as to eliminate the systematic delimitation between the scope of Article 85 and that of Article 86.

41 According to the applicant, by adopting the Decision, the Commission embarked upon a new experiment in order to test the viability of a policy approach based upon a new and special legal regime for parallel imports and the problems raised by them in competition matters. That policy went beyond the scope of the current Treaty, which, although it aims to establish an internal market, does not go so far as to prohibit, by means of provisions relating to competition, a unilateral line of conduct in the absence of a dominant position, solely on the ground that that conduct is aimed at preventing parallel exports.

42 Furthermore, the decision of principle contained in the Decision has a scope going far beyond this case and would entail a very wide obligation to contract on undertakings which do not dominate the market, given that a manufacturer could not refuse to fulfil orders on the grounds referred to above without infringing Article 85 of the Treaty. That result would diametrically contradict the wording and scheme of Articles 85 and 86 of the Treaty.

43 Next, the applicant criticises the Commission for ignoring the fact that competition for pharmaceutical products is greatly distorted by price regulations, which are different in each Member State. The applicant contends that those regulations are difficult to reconcile with Article 30 of the EC Treaty (now Article 28 EC). It also argues that the national systems for directly and indirectly fixing the prices of pharmaceutical products, which are very different from each other, greatly distort competition and therefore infringe Article 3(g) of the EC Treaty.

44 It also notes that, in the pharmaceutical area, the Community is still far from achieving an internal market, and criticises the fact that undertakings are treated

as if it had already been achieved, whereas the Community has not taken any effective measures to harmonise national systems for fixing prices so that the conditions of competition are not distorted.

45 It also challenges the Commission's argument that Community rules are not necessary because, in the long term, parallel imports will bring about harmonisation of the prices of medicinal products.

46 The applicant proposes that certain witnesses be heard in order to prove, first, that the conduct of certain Spanish wholesalers, who had exported all their boxes of Adalat, had endangered the supply of many Spanish pharmacies; second, that the decision no longer to fulfil all orders had been preceded by a meticulous legal examination of the compatibility of that decision with Community law; and, third, that the Commission had declined to pursue an investigation prior to the one which gave rise to this action, in which the conduct of Bayer towards parallel importers would already have been examined.

47 The EFPIA, which has intervened in support of the applicant, endorses the applicant's arguments.

48 The Commission contends that the infringement is constituted by the agreement between the applicant and Spanish and French wholesalers concerning the ban on exporting the product Adalat to other Member States.

49 It maintains that Bayer France and Bayer Spain planned and imposed an export ban, and that, in order to establish it, the Bayer Group set up a system for monitoring parallel imports consisting in identifying exporting wholesalers, drastically reducing deliveries, monitoring the final destination of the quantities

delivered, and penalising wholesalers who exported deliveries by reducing deliveries in the future. The Commission considers it established that Bayer put that system into operation, that the wholesalers knew the applicant's motives, and that they consented to the export ban because they knew that, otherwise, they had to expect that their orders would be fulfilled only at the level of the needs of the national market, or at a lower level fixed by the applicant.

50 The Commission submits that it is incorrect to maintain that Bayer decided, in a generalised manner, to deliver to all the wholesalers quantities at least equivalent to the reference quantity, namely the quantity of the previous year increased by 10%. Thus, the reductions in deliveries in relation to orders were not applied to all the wholesalers in accordance with the alleged single reference level (see recital 96 of the Decision). For certain wholesalers, the orders were reduced to the level of the previous year without applying the 10% increase (case of CERP Lorraine, referred to in recitals 87 and 165 of the Decision, and the case of Hefame, referred to in recitals 122 to 124 and 168 of the Decision), while in other cases the size of the reduction could even have harmed the capacity of the wholesalers concerned to supply their traditional market in sufficient quantity (case of Hufasa, referred to in recitals 114, 127 and 166 of the Decision, and the case of Cofares, referred to in recitals 121 and 169 of the Decision).

51 The wholesalers therefore considered that the restrictions imposed were linked to exports and that, in view of the possible retaliatory measures, they had every interest in formally complying with the export ban, which they did. The wholesalers agreed with the applicant not to export Adalat so as to obtain sufficient supplies in return.

52 The Commission claims that, in order to put that export ban into place, the applicant counted on the acquiescence of the wholesalers, and maintains that the concurrence of wills is not contradicted by the fact that the two parties did not have the same interest in concluding the agreement. An agreement within the meaning of Article 85(1) of the Treaty requires only that the two parties have an interest in its being concluded, without there being any need for that interest to be identical. Since the wholesalers had an interest in avoiding restrictions on

deliveries and the applicant had an interest in preventing, or at least limiting, parallel exports, a concurrence of wills to prevent, or at least limit, parallel exports existed.

53 The Commission maintains that the fact that the wholesalers did not completely renounce exports cannot call into doubt the existence in this case of an agreement or an acquiescence on their part in relation to the export ban. Whilst it recognises that the Spanish and French wholesalers would have preferred to continue their export operations to the United Kingdom, it claims that they had reduced the quantities ordered to a level such that Bayer must have had the impression that they were responding to its declared wish to see them limit themselves to the needs of their traditional markets only.

54 The Commission contends that the Decision is entirely consistent with its decision-making practice and the case-law of the Court of Justice, the concept of an agreement having formed the subject of a similar interpretation, in particular, in Case C-277/87 (Summary publication) *Sandoz* v *Commission* [1990] ECR I-45 and Case C-279/87 (Summary publication) *Tipp-Ex* v *Commission* [1990] ECR I-261.

55 The Commission denies having called into question the delimitation between the scope of Article 85 and that of Article 86 of the Treaty. It maintains that in this case the facts fall within Article 85 concerning agreements because the wholesalers decided themselves to bend to the will of the applicant and ensure sufficient supplies by agreeing to limit exports. Therefore, the Commission argues, the considerations of legal policy put forward by the applicant are based on premisses that are themselves erroneous, for which reason it is not necessary to examine them further.

56 The Commission does not agree with the applicant's statement that the pharmaceutical sector constitutes a special market to which the competition

rules should apply only in a limited way. It acknowledges that many Member States continue to intervene in the pharmaceutical products market and that, given the existing differences in approach, average prices and consumption habits differ. The Commission points out, however, that it has been held that it cannot challenge price control systems as such by recourse to the rules on the free movement of goods, but can only combat possible discriminatory repercussions in the light of Article 30 of the Treaty. It was for that reason that the Commission attacked only State measures which clearly discriminated in favour of national pharmaceutical industry or research.

57 It maintains that the fact that the Member States have different systems for regulating prices does not mean that the objective of establishing an internal market does not apply to the pharmaceutical area. It contends that since, in any event, the price regulation systems leave undertakings sufficient margin for manœuvre, parallel imports must not be hindered either by State measures or by conduct in restraint of competition by the undertakings. Moreover, if State measures hindering parallel exports are prohibited, measures taken by undertakings pursuing the same goal, as in this case, should also be prohibited. Consequently, the Commission argues, the very fact of hindering parallel imports of medicinal products infringes Article 85 of the Treaty, as is shown in particular by the *Sandoz* judgment.

58 The Commission adds that, in its judgments in Case 15/74 *Centrafarm* v *Sterling Drug* [1974] ECR 1147 and Joined Cases 55/80 and 57/80 *Musik-Vertrieb Membran* v *GEMA* [1981] ECR 147, the Court of Justice has already stated that the rules on the implementation of the free movement of goods apply to an industry whether or not the national provisions concerned have been subject to harmonisation. The Commission therefore concludes that steps may also be taken to combat export bans even in the pharmaceutical sector, as is clear from the case-law of the Court of Justice. It refers in particular, as regards Article 30 of the Treaty, to Case 104/75 *De Peijper* [1976] ECR 613, Case 102/77 *Hoffman-La Roche* v *Centrafarm* [1978] ECR 1139, and Case 187/80 *Merck* v *Stephar and*

Exler [1981] ECR 2063, and, concerning Article 85(1) of the Treaty, to the judgment in *Sandoz*, cited above.

59 The Commission then affirms that it sets out from the principle that, in the long term, parallel imports will bring about the harmonisation of the price of medicinal products and it does not consider it acceptable for parallel imports to be hindered so as to enable pharmaceutical companies to impose excessive tariffs in countries not applying any price control in order to compensate for lower profits in Member States which intervene more on prices.

60 The BAI states, on the one hand, that, in the medicinal-products market, pharmacies are unable both economically and logistically to keep a full assortment of current medicines in stock in sufficient quantities, and, on the other hand, that, by reason of their position and function on that market, wholesalers are obliged to have such an assortment in stock, so as to be able to deliver rapidly to a pharmacy all the medicinal products ordered by it, lest it turn to a wholesaler having the necessary stocks. In those circumstances, and bearing in mind the structure of the pharmaceutical market and of the system for monitoring distribution established by Bayer, the BAI contends that wholesalers had no option but to yield to that control, significantly reduce orders and hence significantly reduce exports, without the manufacturer needing to threaten them expressly.

61 As regards the export ban, the existence of sanctions against exporting wholesalers is, for the BAI, indisputable, because Bayer constantly monitored the distribution of its products and always adapted itself to market developments. In support of that contention, it maintains that the table of orders for 'Adalate 20 mg LP' contained in recital 87 of the Decision clearly proves that any wholesaler who carried out exports had to expect a subsequent reduction in the volumes delivered, and that Bayer reacted each time to the volume of the wholesalers' orders and penalised exporting wholesalers by making very large reductions in deliveries.

II — *Findings of the Court of First Instance*

A. *Preliminary observations*

62 It is settled case-law that, where it hears an action for the annulment of a decision applying Article 85(1) of the Treaty, the Court of First Instance must undertake a comprehensive review of the question whether or not the conditions for applying Article 85(1) are met (Case 42/84 *Remia* v *Commission* [1985] ECR 2545, paragraph 34; Joined Cases 142/84 and 156/84 *BAT and Reynolds* v *Commission* [1987] ECR 4487, paragraph 62).

63 Under the first paragraph of Article 85(1) of the Treaty:

'[T]he following shall be prohibited as incompatible with the common market: all agreements between undertakings, decisions by associations of undertakings and concerted practices 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...'

64 It is clear from the wording of that article that the prohibition thus proclaimed concerns exclusively conduct that is coordinated bilaterally or multilaterally, in the form of agreements between undertakings, decisions by associations of undertakings and concerted practices.

65 In this case, it is found in the Decision that there is an 'agreement between undertakings' within the meaning of that article. The applicant maintains,

however, that the Decision penalises unilateral conduct on its part that falls outside the scope of the article. It claims that the Commission has given the concept of an agreement within the meaning of Article 85(1) of the Treaty an interpretation which goes beyond the precedents in the case-law and that its application to the present case infringes that provision of the Treaty. The Commission contends that it has fully followed the case-law in its evaluation of that concept and has applied it in a wholly appropriate manner to the facts of this case. It therefore needs to be determined whether, having regard to the definition of that concept in the case-law, the Commission was entitled to perceive in the conduct established in the Decision the factors constituting an agreement between undertakings within the meaning of Article 85(1) of the Treaty.

B. *The concept of an agreement within the meaning of Article 85(1) of the Treaty*

66 The case-law shows that, where a decision on the part of a manufacturer constitutes unilateral conduct of the undertaking, that decision escapes the prohibition in Article 85(1) of the Treaty (Case 107/82 *AEG* v *Commission* [1983] ECR 3151, paragraph 38; Joined Cases 25/84 and 26/84 *Ford and Ford Europe* v *Commission* [1985] ECR 2725, paragraph 21; Case T-43/92 *Dunlop Slazenger* v *Commission* [1994] ECR II-441, paragraph 56).

67 It is also clear from the case-law in that in order for there to be an agreement within the meaning of Article 85(1) of the Treaty it is sufficient that the undertakings in question should have expressed their joint intention to conduct themselves on the market in a specific way (Case 41/69 *ACF Chemiefarma* v *Commission* [1970] ECR 661, paragraph 112; Joined Cases 209/78 to 215/78 and 218/78 *Van Landewyck and Others* v *Commission* [1980] ECR 3125, paragraph 86; Case T-7/89 *Hercules Chemicals* v *Commission* [1991] ECR II-1711, paragraph 256).

68 As regards the form in which that common intention is expressed, it is sufficient for a stipulation to be the expression of the parties' intention to behave on the market in accordance with its terms (see, in particular, *ACF Chemiefarma*, paragraph 112, and *Van Landewyck*, paragraph 86), without its having to constitute a valid and binding contract under national law (*Sandoz*, paragraph 13).

69 It follows that the concept of an agreement within the meaning of Article 85(1) of the Treaty, as interpreted by the case-law, centres around the existence of a concurrence of wills between at least two parties, the form in which it is manifested being unimportant so long as it constitutes the faithful expression of the parties' intention.

70 In certain circumstances, measures adopted or imposed in an apparently unilateral manner by a manufacturer in the context of his continuing relations with his distributors have been regarded as constituting an agreement within the meaning of Article 85(1) of the Treaty (Joined Cases 32/78, 36/78 to 82/78 *BMW Belgium and Others* v *Commission* [1979] ECR 2435, paragraphs 28 to 30; *AEG*, paragraph 38; *Ford and Ford Europe*, paragraph 21; Case 75/84 *Metro* v *Commission* ('*Metro II*' [1986] ECR 3021, paragraphs 72 and 73; *Sandoz*, paragraphs 7 to 12; Case C-70/93 *BMW* v *ALD* [1995] ECR I-3439, paragraphs 16 and 17).

71 That case-law shows that a distinction should be drawn between cases in which an undertaking has adopted a genuinely unilateral measure, and thus without the express or implied participation of another undertaking, and those in which the unilateral character of the measure is merely apparent. Whilst the former do not fall within Article 85(1) of the Treaty, the latter must be regarded as revealing an agreement between undertakings and may therefore fall within the scope of that article. That is the case, in particular, with practices and measures in restraint of competition which, though apparently adopted unilaterally by the manufacturer in the context of its contractual relations with its dealers, nevertheless receive at least the tacit acquiescence of those dealers.

72 It is also clear from that case-law that the Commission cannot hold that apparently unilateral conduct on the part of a manufacturer, adopted in the context of the contractual relations which he maintains with his dealers, in reality forms the basis of an agreement between undertakings within the meaning of Article 85(1) of the Treaty if it does not establish the existence of an acquiescence by the other partners, express or implied, in the attitude adopted by the manufacturer (*BMW Belgium*, paragraphs 28 to 30; *AEG*, paragraph 38; *Ford and Ford Europe*, paragraph 21; *Metro II*, paragraphs 72 and 73; *Sandoz*, paragraphs 7 to 12; *BMW* v *ALD*, paragraphs 16 and 17).

C. *The application of the concept of an agreement in this case*

73 In this case, in the absence of direct documentary evidence of the conclusion of an agreement between the parties concerning the limitation or reduction of exports, the Commission has held that the concurrence of wills underlying that agreement is clear from the conduct of the applicant and the wholesalers referred to in the Decision respectively.

74 Thus, in the Decision, the Commission states (recital 155) that 'Bayer France and Bayer Spain have committed an infringement of Article 85(1)' of the Treaty and that the conditions for applying that article were met because those subsidiaries imposed 'an export ban as part of their continuous commercial relations with their customers'. It then states (recital 156) that 'analysis of the conduct engaged in by Bayer France and Bayer Spain vis-à-vis their wholesalers shows that Bayer France and Bayer Spain have imposed an export ban in their commercial relations with their wholesalers' and presents it as an established fact (recital 176) that the wholesalers adopted 'an implicit acquiescence in the export ban'.

75 Where, therefore, the Commission refers in the Decision to the 'export ban', it views it as a unilateral demand which has formed the subject-matter of an agreement between the applicant and the wholesalers. If the Commission concluded that an agreement existed contrary to Article 85(1) of the Treaty, it did so because it considered it established that the applicant sought and obtained an agreement with its wholesalers in Spain and France, the purpose of which was to prevent or limit parallel imports.

76 The applicant acknowledges having introduced a unilateral policy designed to reduce parallel imports. However, it denies having planned and imposed an export ban. In that regard, it denies ever having had discussions with the wholesalers, let alone making an agreement with them, in order to prevent them from exporting or to limit them in the export of the quantities delivered. Moreover, it states that the wholesalers did not adhere in any way to its unilateral policy and had no wish to do so.

77 In those circumstances, in order to determine whether the Commission has established to the requisite legal standard the existence of a concurrence of wills between the parties concerning the limitation of parallel exports, it is necessary to consider whether, as the applicant maintains, the Commission wrongly assessed the respective intentions of Bayer and the wholesalers.

1. The alleged intention of the applicant to impose an export ban

(a) Preliminary observations

78 The Decision presents it as an established fact that the French and Spanish subsidiaries of the applicant imposed on the French and Spanish wholesalers

respectively an export ban which was put in place by identifying the exporting wholesalers and applying successive reductions in the volumes delivered to them if it became apparent that they were exporting all or part of the products in question. In the words of the second paragraph of recital 156 of the Decision, the export ban 'may be deduced from the following additional factors: (a) a system for detecting exporting wholesalers, and (b) successive reductions in the amounts supplied by Bayer France and Bayer Spain where wholesalers export all or some of the products'.

79 In the Decision, the Commission sets out (recitals 160 to 170) the reasons for which it considered it to have been established that the applicant carried out 'successive reductions in the amounts supplied by Bayer France and Bayer Spain where wholesalers export[ed] all or some of the products' and that, therefore, 'supply [was] subject to compliance with an export ban'. In particular, the Commission states in the first paragraph of recital 160: 'Whenever wholesalers export some of the products supplied, they run the risk of having their subsequent orders cut by Bayer France and Bayer Spain.' It adds in recital 163:

'The evidence in the Commission's possession shows that supply of the quantities allowed by Bayer France and Bayer Spain is subject to compliance with an export ban. Bayer France and Bayer Spain make the extent of the reduction in the amounts they supply dependent on the wholesalers' conduct in response to the export ban. If the wholesalers infringe the export ban, this entails a further automatic reduction in the supplies they receive.'

80 The Commission concludes (recital 170):

'All these aspects of the conduct of Bayer France and Bayer Spain show that the two companies have subjected their wholesalers to a permanent threat of

reducing the quantities supplied, a threat which was repeatedly carried out if they did not comply with the export ban.'

(b) The scope of the system for monitoring the distribution of Adalat established by the applicant

81 The applicant admits that, in order to apply its policy of fulfilling orders only in so far as they met the traditional needs of the wholesalers, it used a general monitoring system for the distribution of Adalat. It also admits that it had an interest in knowing which wholesalers were export-oriented in order to be able to apply that policy correctly. But it argues that that information system did not enable it to carry out checks subsequent to delivery in order to discover whether or not the products delivered had been actually exported or not. The system consisted solely in determining the quantities delivered to the wholesalers during previous years and, on that basis, fixing in advance the quantities which it wished to deliver to each wholesaler. Therefore, the applicant maintains, the Commission's argument that Bayer made deliveries to each wholesaler subject to verification that the quantities delivered in accordance with the new policy had not finally been exported to the United Kingdom, and had established a system for penalising wholesalers continuing to export after the implementation of that policy, is factually inaccurate.

82 In order to describe the system for monitoring the distribution of Adalat established by the applicant, the Commission relies upon the document reproduced in recital 109 of the Decision, emanating from Bayer Spain, which Commission officers found at the premises of Bayer France. That document consists of a series of conference slides used by a manager of the Spanish subsidiary to explain at a meeting held at the premises of Bayer France the system for controlling the distribution of Adalat established in Spain. According to the Commission, that document gives a complete description of the system used by the applicant for identifying which of its customers were exporting.

83 The applicant admitted at the hearing that those slides correctly describe the system which it applied. Since this is a document which, by its nature, was supposed to be used exclusively inside the Bayer Group, it should be regarded as illustrative of the way in which Bayer decided to face up to parallel imports.

84 The Court notes that those slides begin with a summary of the problem, indicating that the volume of orders for Adalat grew up to 300% in a few weeks, that that increase caused stock shortages, that it put uniform delivery throughout the country at risk, that it caused general discontent amongst wholesalers, the 'internal and external sales organisation' and pharmacists, and, finally, that it disturbed the rhythm of production due to urgent needs for Adalat.

85 Next, they show that the applicant considered that the most appropriate solution to the problem raised by the sudden and exorbitant increase in orders for Adalat was to define a delivery limit in advance for each wholesaler, taking into account a series of considerations, including 'identification of possible exporters'. The document also shows that, in order to implement that monitoring system in Spain, the Bayer Group had prepared itself to have to discuss limits to the volume of supplies assigned to each wholesaler. For that purpose, the Group had planned, first, a single argument to be presented by the lower echelons of its distribution department, namely an 'interruption in stocks' and, second, the designation of a person responsible for direct contacts with wholesalers who, predictably, would insist on obtaining a reappraisal of the limits fixed.

86 The slides show that, for the purpose of applying the limit fixed for each customer, the system established enabled an order from a customer exceeding the quantity attributed to be blocked automatically, so as to allow a 'manual' monitoring of that order. It is further stated that that system has, amongst other advantages, that of enabling 'suspect wholesalers' to be identified. Finally, as regards the action to be taken over orders controlled manually, those slides show

that the system leads to 'the quantity being reduced rather than the cancellation of the order'.

87 The practical application of that monitoring system is precisely illustrated by the table, headed 'Result', contained in those slides and reproduced at the end of recital 109 of the Decision. That table shows that Bayer Spain fixed monthly and annual limits in advance for the orders of each wholesaler and that it verified on the occasion of each delivery note whether the wholesaler had exceeded those limits.

88 However, those slides do not contain any indication of an intention by Bayer to prohibit exports or to monitor the quantities actually exported by each of the wholesalers under examination and to react in consequence.

89 Therefore, and contrary to the interpretation put forward by the Commission, the contents of that internal document cannot be regarded as demonstrating that the applicant had based its strategy on the monitoring of the final destinations of the products delivered and the penalisation of the exporting wholesalers.

90 It is necessary next to examine the various examples of French and Spanish wholesalers to whom the Commission refers in support of its contention that the reductions in supplies were not pre-established unilaterally but constituted the reaction to the wholesalers' conduct in the matter of orders, thus proving the existence of the policy of systematically monitoring exports and penalising wholesalers who exported the products supplied.

91 In relation to the case of CERP Lorraine, the Commission refers to the table of orders placed by that French wholesaler, set out in recital 87 of the Decision. The

Commission states that, according to that table, whereas CERP Lorraine placed average monthly orders of between 50 000 and 70 000 packets of Adalat between June 1991 and February 1992, and had received 69 000 packets from Bayer France in July 1991, it received only 35 000 in September 1991, then 15 000 per month during the following three months, and only 7 500 in February 1992. The Commission maintains that those reductions in supplies proves that Bayer did not always apply the same criterion, namely the reference quantities fixed by reference to orders in the previous year.

92 The wording of recital 87 of the Decision shows that, from September 1991, Bayer significantly reduced its supplies to that wholesaler in relation to previous months and that it gave as the reason problems with stock shortages on the French market. However, no reference is made to possible exports of the quantities supplied. The Commission cannot therefore rely on that order table in support of its argument that supply was conditional. On the contrary, that recital in the Decision also reproduces a letter from Bayer France to CERP Lorraine in which, the Commission says, Bayer France points out that 'CERP Lorraine's monthly requirements (on average) were 9 000 packets a month' and that, for that reason, Bayer France was unable to keep pace with increased demand the following year. That statement must be interpreted as a confirmation that, as the applicant claims, its new delivery policy was based on the traditional needs of each wholesaler, which, in the case of CERP Lorraine, were between seven and nine times less than the quantities ordered in the months preceding the establishment of the new policy. The applicant's argument is confirmed by recital 165 of the Decision, which states that Bayer France closely monitored the orders of CERP Lorraine and agreed to deliver to it only at the strict level of the previous year.

93 The case of the French wholesaler OCP calls for a like finding. Recital 91 of the Decision sets out the situation of that wholesaler, which had announced to Bayer France a planned order of 50 000 packets of Adalat for March, April and May 1992. Mention is made of a telex from OCP to Bayer France, complaining that it delivered only 15 000 packets in February and 5 000 in March. However, in the

absence of any reference to an export ban of any kind, the Commission cannot use that telex to support its argument that supply was conditional.

94 As regards the Spanish wholesaler Hefame, the Commission claims that it had also been identified as a parallel exporter. In recital 120 of the Decision, which reproduces the explanations which Hefame is said to have given to dissatisfied customers in the United Kingdom, the Commission argues in particular that the comment 'the parallel-export is to[o] big and the multinational-control' (which, in the Commission's submission is a reference to Bayer) proves that the applicant was indeed monitoring the situation, knew exactly which wholesalers carried out parallel exports and penalised them in consequence. However, even if that document does, it is true, show that Bayer applied supply restrictions to Hefame which caused problems for the latter's customers, it is not capable of sustaining the Commission's argument that supplies were conditional upon the final destination of the products delivered, since none of those factors can be interpreted as proof of an attempt on Bayer's part to ban exports of the products supplied and to penalise such a practice. On the contrary, the fact that Bayer limited itself to establishing a policy of limited supply in accordance with national needs appears to be corroborated by the following sentences, contained in the document reproduced in recital 120 of the Decision:

'I understand you are not happy about this news but in one year all are change [*sic*] and the parallel-export is to[o] big and the multinational-control.... For quite some time now we have been experiencing serious difficulties in obtaining sufficient quantities of [Adalat], (...) and (...) from Spain.... It would appear that, once more, Bayer and (...) are doing their utmost to keep availability of their products strictly in line with their presumed needs for Spain, thereby impeding free trade within the EC. Is there any way in which you can take any action against these companies?'

95 Again in relation to Hefame, recitals 122 to 124 of the Decision set out the agreements made by that wholesaler with a number of small wholesalers. In the words of one of those agreements, which forms part of the Commission's file, a

small wholesaler undertook 'to support, by supplying products or quantities of the products that it may have available, in addition to those provided by Hefame, to facilitate the normal supply of Hefame's foreign customers with the necessary quantities'. The Commission maintains that, if Hefame concluded those agreements, that was because it knew that, as a parallel exporter identified by the applicant, it would not obtain fresh supplies of Adalat. That proves, the Commission submits, that supplies did not take place in accordance with pre-set values or thresholds, as certain wholesalers who were not suspected had received larger quantities without difficulty, and that the applicant applied a very clear distinction between wholesalers who were suspected of carrying out parallel exports and those who were not known as being parallel exporters. Finally, the Decision states (recital 124) that the applicant rapidly hindered such distribution amongst wholesalers, since it identified the small wholesalers as also being parallel exporters and likewise reduced the supplied intended for them in consequence.

96 The Court notes that those extracts from documents do reveal the existence of agreements set up by that wholesaler with other local wholesalers in an attempt to obtain packets of Adalat in addition to those supplied directly by the applicant. However, they do not provide any evidence in support of the assertion that the applicant made its supply policy for each wholesaler conditional upon the actual conduct of the latter in relation to the final destination of the products supplied. Contrary to what the Commission claims, the documents referred to in recital 122 of the Decision do not demonstrate that supplies under the new policy did not take place in accordance with pre-set values or thresholds on the basis of historic needs. Moreover, the Commission itself states, in recitals 124 and 168 of the Decision, that Bayer, putting into practice its new policy of confining itself to historic needs, where it found that small wholesalers were procuring deliveries of unusually high quantities in relation to their 'normal' needs on the local market, decided to supply them only up to the level of their traditional needs.

97 As regards the case of Cofares, the Commission cites in recital 121 of the Decision a statement which that wholesaler is alleged to have made at the time of the Commission's investigation on its premises.

98 That statement refers, first, in a general way, to the difficulties raised by certain laboratories in respect of the delivery of products intended for export and also, more particularly, to discussions between Cofares and Bayer Spain concerning the extent of the needs of its national market. However, even though that statement refers to supply difficulties, it makes no mention of any export ban imposed by Bayer or of an attempt by Bayer to monitor the actual destination of products supplied in Spain so as to react in consequence if they were exported. Therefore, the Commission cannot rely on that statement either in support of its argument that supplies were conditional.

99 As regards Hufasa, recital 127 of the Decision reproduces the minutes taken by that wholesaler of a meeting held with the managers of Bayer Spain with the object of obtaining larger supplies, a document to which the Commission attributes particular significance (see recitals 166 and 167 of the Decision) for the purposes of establishing the existence of an export ban.

100 However, that document of Hufasa does not contain any reference to an export ban imposed by the applicant or to the alleged implementation by the latter of a policy of systematic monitoring *a posteriori* of the actual destinations of the products supplied. Contrary to what the Commission claims, nothing in that document proves the alleged need for Hufasa to make Bayer understand that it would not engage in exports.

101 It should also be noted that the Decision itself sets out factual considerations (recitals 96 and 159) which confirm the applicant's case concerning the supply policy that was established. Thus, where in recital 96 it states that 'Bayer France accepts as normal an increase or decrease of 10% in domestic requirements', the Decision itself contradicts the Commission's argument that Bayer did not have

recourse to the approach referred to. The same observation may be made with regard to recital 159, which, referring to recitals 78 and 79, states that 'the Commission has in its possession documents setting out monthly lists of the quantities ordered and the highlighted increase in their amount as compared with the statistics for the previous year'.

102 Finally, in this case, the Commission cannot counter the applicant's statement, to the effect that the quantities of products to be supplied were fixed in advance according to the historic needs of the party concerned, increased by 10% and taking no account of any possible exportation of the products, by arguing that that policy may not always have been applied in an exact or automatic way. As the applicant explained at the hearing, since there was a delay of some months in implementing its new supply policy, it is possible that wholesalers who received very large quantities of the products after the adoption of that policy subsequently had their supplies reduced to the level corresponding to their traditional needs determined by the internal statistics of the Bayer Group. That was in particular the case with CERP Lorraine (described in recital 87 of the Decision) which, at the beginning of 1991, received all its orders of more that 60 000 packets of Adalat a month and subsequently received only 9 000, the quantity corresponding to its orders prior to the development of the problem of parallel imports. Moreover, the fact that wholesalers whom the applicant did not perceive as exporters were able to obtain extra quantities more easily than wholesalers who were identified as exporters, which the applicant does not appear to contest as such, cannot invalidate the findings made above concerning the lack of evidence of the alleged policy of monitoring exports actually carried out and penalising the exporters in question.

103 As regards the allegedly probative documents set out in detail in recitals 83 to 85 and 96 to 103 of the Decision, concerning France, and, as regards Spain, in recitals 110 to 131, to which recital 160 of the Decision refers in support of the Commission's argument, it need merely be observed that, like the documents contained in the recitals which have just been examined, they do not in any way

demonstrate the establishment by Bayer of a supply policy conditional upon actual compliance with an alleged export ban.

104 At the hearing and in reply to a question put by the Court, the Commission referred to recitals 80, 110, 140 and 147 of the Decision in support of its argument that supply was conditional upon compliance with the export ban.

105 Those recitals of the Decision reproduce letters exchanged between managers of the British and French subsidiaries, between the Spanish subsidiary and the parent company of the Bayer Group, between the British subsidiary and the parent company, and an internal board memorandum of Bayer France. All those documents concern the implementation by the Bayer Group of its new supply policy and the system for monitoring the distribution of Adalat in order to deal with the problem of parallel imports. Those documents prove that the Bayer Group had an interest in identifying wholesalers intending to export. However, in the absence of any reference in those documents to any intention to monitor the conduct of each wholesaler and to penalise him if he were found to have exported the products supplied, the Commission cannot rely on them in support of its argument.

106 Finally, the Commission's arguments based on the subjective perception of the situation by the wholesalers are not capable of altering the foregoing conclusions as to the applicant's alleged intention to impose an export ban and penalties for failure to comply with it.

10- The Commission claims that the wholesalers were aware of the applicant's motives and that, therefore, they regarded the restrictions imposed by Bayer as

being linked to exports. It adds that the wholesalers had every interest in formally complying with the export ban and that they therefore accepted that ban in order to ensure a sufficient supply of Adalat. Finally, it claims that wholesalers who did not follow the export ban left themselves open to threats and sanctions on the part of Bayer.

108 However, as has just been held, the Commission has not established that the applicant put in place a policy for monitoring the final destination of the products delivered under the new policy and making supply conditional on that destination. Therefore, the argument that the wholesalers had every interest in formally complying with the export ban in order to ensure a sufficient supply of Adalat is factually inaccurate. Moreover, the Commission has not proved to the requisite legal standard the existence of sanctions against wholesalers who had decided to export the packets of Adalat and threats by Bayer in that regard. Nor has the Commission put forward anything that would even indicate that Bayer 'demanded' of wholesalers that they should not export the products supplied or that a wholesaler gave 'assurances' to Bayer concerning exports. On the contrary, as the applicant maintains, in the absence of any monitoring of the final destination of the products supplied, the wholesalers did not have to fear sanctions and did not fear them, as is apparent from the statement of the wholesaler quoted in recital 185 of the Decision: 'The important thing was actual receipts rather than the order.' In those circumstances, the wholesalers' knowledge of the applicant's intention to prevent parallel imports is not capable of establishing the alleged link between the restriction of supplies and the conduct of the wholesalers in the matter of exporting.

109 Having regard to the above, it must be concluded that the Commission has not proved to the requisite legal standard either that Bayer France and Bayer Spain imposed an export ban on their respective wholesalers, or that Bayer established a systematic monitoring of the actual final destination of the packets of Adalat supplied after the adoption of its new supply policy, or that the applicant applied a policy of threats and sanctions against exporting wholesalers, or that it made supplies of this product conditional on compliance with the alleged export ban.

110 Nor, finally, do the documents reproduced in the Decision show that the applicant sought to obtain any form of agreement from the wholesalers concerning the implementation of its policy designed to reduce parallel imports.

2. The alleged intention of the wholesalers to adhere to the applicant's policy designed to reduce parallel imports

(a) Preliminary observations

111 The applicant acknowledges in this case that it adopted and unilaterally implemented a new supply policy designed to make it more difficult for wholesalers to carry out parallel exports. According to case-law, as has already been noted, apparently unilateral conduct on the part of a manufacturer, adopted in the context of the contractual relations which it maintains with his dealers, may in reality form the basis of an agreement between undertakings within the meaning of Article 85(1) of the Treaty, if express or implied acquiescence by the other contracting parties in the attitude adopted by the manufacturer is established.

112 The Commission claims that, in order to establish its policy of restricting supplies, the applicant counted on the acquiescence of the wholesalers.

113 Therefore, in the circumstances of this case, it is necessary to consider whether the Commission has proved to the requisite legal standard the express or implied adherence of the wholesalers to the unilateral policy of preventing parallel imports adopted by Bayer.

(b) Proof of the wholesalers' 'implicit acquiescence'

114 The Commission maintains in recital 176 of the Decision that the wholesalers' conduct reflected an 'implicit acquiescence in the export ban', and describes that conduct in more detail in recitals 181 to 185. It arrives at that conclusion in the light of a series of facts which it considers to be established.

115 First, the Commission notes (recital 180), on the one hand, that the wholesalers were aware of the existence of the export ban, a factor, it claims, which had been decisive in the *Sandoz* case and in the light of which the mere 'fact that they did not react to the export ban suggested that they accepted it and that the necessary evidence substantiating the existence of an agreement' was present, and, on the other hand, that, as in *Sandoz*, the export ban formed part of continuous commercial relations between Bayer France or Bayer Spain and their respective wholesalers.

116 Secondly, the Commission states (recital 180) that, in this case, as a further element in addition to those held to be relevant in *Sandoz*, 'the conduct of the wholesalers shows that they have not only understood that an export ban applies to the goods supplied, but also that they have aligned their conduct on this ban'.

117 The Commission contends that that 'alignment of the wholesalers' conduct on the requirements imposed by Bayer France and Bayer Spain' is established by the finding that, once they had understood the real intentions of Bayer France and Bayer Spain, the wholesalers demonstrated, 'at least in appearance, their acceptance... of their supplier's export ban in their commercial relations with

the supplier' (recital 181). They adapted themselves to the requirement of Bayer France and Bayer Spain, as is proved by the various systems they put in place in order to obtain supplies, particularly the system of spreading orders intended for export among the various agencies and the orders with small wholesalers (recital 182).

118 According to the Decision (recitals 183 and 184), the wholesalers 'compl[ied] with the national "quotas" imposed by their supplier, negotiating as far as they could to increase them to the maximum, thus bowing to the strict application of and compliance with the figures regarded by Bayer France and Bayer Spain as normal for the supplying of the domestic market'. That attitude shows, the Commission claims, that the wholesalers 'were aware of the real motives of Bayer France and Bayer Spain and of the tactics deployed by the two companies to thwart parallel exports: they adapted to the system established by their supplier so as to comply with its requirements'.

119 It should, however, be borne in mind, first, that, as has been held, the Commission has not sufficiently established in law that Bayer adopted a systematic policy of monitoring the final destination of the packets of Adalat supplied, that it applied a policy of threats and penalties against wholesalers who had exported them, that, therefore, Bayer France and Bayer Spain imposed an export ban on their respective wholesalers, or, finally, that supplies were made conditional on compliance with the alleged export ban.

120 Second, there is nothing in the documents before the Court to show that Bayer France or Bayer Spain required any particular form of conduct on the part of the wholesalers concerning the final destination of the packets of Adalat supplied or compliance with a certain manner of placing orders, its policy having consisted

simply in limiting supplies unilaterally by determining in advance the quantities to be supplied, using traditional needs as the basis.

121 Finally, the Commission has not established that the applicant made any attempt to obtain the agreement or acquiescence of the wholesalers to the implementation of its policy. It has not even claimed that Bayer sought to get the wholesalers to change their way of formulating orders.

122 It follows that the statements contained in recitals 181 to 185 of the Decision, on the basis of which the Commission considers that the wholesalers aligned their conduct in accordance with the alleged export ban, fail on factual grounds, because they are based on factual circumstances that have not been established.

123 Since, in this case, the Commission does not have any document referring expressly to an agreement between Bayer and its wholesalers concerning exports for the purpose of establishing a concurrence of wills, it claims to have followed the case-law approach consisting of examining the actual conduct of the wholesalers in order to determine the existence of their acquiescence. Thus, the Commission states in recital 180 of the Decision: 'In the present case,... the conduct of the wholesalers shows that they have not only understood that an export ban applies to the goods supplied, but also that they have aligned their conduct on this ban.' By contrast, the applicant maintains that it is precisely their conduct which is the best proof that there was no concurrence of wills.

124 In the circumstances of this case, it therefore needs to be determined whether, having regard to the actual conduct of the wholesalers following the adoption by the applicant of its new policy of restricting supplies, the Commission could legitimately conclude that they acquiesced in that policy.

(i) The conduct of the French wholesalers

125 As a preliminary point, it should be borne in mind that recital 96 of the Decision, in which the Commission gives a general description of the way in which the three French wholesalers organised themselves in order to try to obtain supplies, states:

'The three wholesalers adopted the same method: they stopped placing orders for export and made arrangements to increase the orders which were officially intended for the French market.

Bayer France accepts as normal an increase or decrease of 10% in domestic requirements. The wholesalers have a number of local agencies situated throughout France which normally provide supplies at local level.

The domestic orders placed by each of the agencies increased, with no indication being given to Bayer France of their destination. The aim was to induce Bayer France to believe that domestic demand had increased, by spreading it over the different agencies. The amounts which were in fact intended for export were then rechannelled within each wholesaler's organisation so that they could be exported.'

126 Recitals 97 to 101 of the Decision, which are devoted to setting out the strategy put in place by the wholesaler CERP Rouen in order to circumvent Bayer's policy of restricting supplies, reproduce several letters exchanged between October 1991 and January 1992 between CERP Rouen's central purchasing department and the directors of the group's local agencies in order to obtain the extra packets of

Adalat needed by the Boulogne agency, which had responsibility within the group for exporting to the United Kingdom. However, contrary to what the Commission claims, the passages of those documents are not capable of proving that that wholesaler agreed to cease exporting, reduce its orders or limit its exports, or that it tried to give Bayer the impression that it was going to do so. The only illustration they provide is that of the reaction of an undertaking in trying to continue its export activities as far as possible. There is no direct mention or evidence of an intention to support Bayer's policy of preventing exports, of which the wholesaler was perfectly aware, as is indicated in recital 94 of the Decision.

127 Examination of the documents referred to in recitals 102 and 103 of the Decision, concerning the cases of CERP Lorraine and OCP, merely confirms that finding. Moreover, recital 102 shows that, despite the difficulties raised by Bayer's attitude, CERP Lorraine succeeded in obtaining significant quantities for export. That recital contains an extract from an internal CERP Lorraine report, in which the author states:

'Although I do not see a favourable solution in the short term concerning supplies from Bayer (we have managed to obtain minimal quantities of product through the agencies), I think that the budget should be attainable at the end of the financial year.'

128 The documents reproduced in recitals 105, 106 and 107 go in the opposite direction to the Commission's argument, because they show that the CERP Lorraine and CERP Rouen wholesalers did not genuinely adapt their orders to the new policy of restricting supplies put in place by Bayer. They show that Bayer are 'blocking supplies of Adalat' ordered by CERP Lorraine (recital 105), that CERP Rouen's demand at the beginning of 1992 amounted to 'up to 50 000 packets a month' but that it was able to supply 'only 7 000 packets' to meet that

demand, and that OCP had sent Bayer an initial order projection of 50 000 packets per month for February and March 1992, but that it was supplied with only 15 000 packets in February and 5 000 packets in March (recitals 91 and 107).

129 It follows that the passages reproduced in recitals 96 to 107 of the Decision are not capable of supporting the argument that the French wholesalers expressly or impliedly agreed to the policy put in place by Bayer. Those passages do not refer to any predisposition to adhere in any way to Bayer's policy of preventing parallel exports. On the contrary, they bear witness to the fact that those wholesalers adopted a line of conduct demonstrating a firm and persistent intention to react against a policy that was fundamentally contrary to their interests.

(ii) The conduct of the Spanish wholesalers

130 Nor, in relation to the Spanish wholesalers, do recitals 113 to 130 of the Decision contain anything capable of supporting the argument of tacit acquiescence put forward by the Commission.

131 On the contrary, recitals 115, 118, 119 and 120 contradict such an argument. Those recitals show, first, that Bayer Spain constantly maintained its policy of restricting supplies to the level of traditional needs and, second, that the wholesalers were very annoyed by the losses caused by the impossibility of obtaining the quantities necessary to respond to orders from their British customers. Particular note should be taken of recital 115, which reproduces passages from documents exchanged between CERP Rouen and its Spanish subsidiary Commercial Genové: 'Every week I want a copy of the order forms for Adalat and (...) sent to the laboratories and the delivery notes corresponding to those orders. I am trying to present a watertight case against the labs (...). With

regard to your fax today concerning (...) and Bayer laboratories, I give you my word that I am doing my utmost to obtain supplies greater than our requirements. The laboratories are refusing to listen to any arguments. They know that the quantities they supply to us are easily enough to cover the needs of the Spanish market.' Similarly, the quotations contained in recital 118 — 'they do not supply as much as we need. We have only stock for our market' — and in recital 119 — 'Bayer does not deliver to us the quantities we order' — demonstrate that, contrary to what the Commission alleges, the wholesalers did not adapt their ordering policy to the new situation and continued to order quantities greater than their traditional needs.

132 It is necessary to examine the case of each of the Spanish wholesalers concerned by the Decision.

133 As regards Cofares, the main wholesaler in Spain, the Decision states in recital 121 that the proof of its acquiescence is to be found in the statement made by the managers of that undertaking during an investigation by the Commission at its premises. The managing director of Cofares is said to have stated that 'Cofares' export activity account[ed] for a very small proportion of its total invoicing because of the difficulties posed by certain laboratories (including Bayer) to orders for export', and that, in his capacity as director with responsibility for purchasing, 'when Bayer set an Adalat quota for Cofares that was initially clearly insufficient to cover the requirements of its domestic market... [he] warned them of a possible complaint because of such restrictions. Since then, Bayer ha[d] supplied Cofares with sufficient quantities to meet national consumption of the product in question'.

134 Contrary to what the Commission claims, it cannot be deduced from that document that 'Cofares complied with Bayer Spain's requirement that it confine itself to its domestic market'.

135 The first sentence, to the effect that the negligible extent of exports in relation to turnover was due to the difficulties caused by certain laboratories in supplying products for export, does not in itself constitute direct evidence of an agreement between that wholesaler and Bayer Spain that the packets of Adalat received should not be exported. The fact that the exports were negligible cannot lead to the conclusion that they did not exist or that they had ceased. On the contrary, that statement may demonstrate that, at least in part, Cofares continued to export. The fact that, unlike the situation as regards the other wholesalers, the Decision does not show that Cofares set up a strategy for circumventing Bayer's policy does not reverse the burden of proving its acquiescence in Bayer's new policy, which still rests with the Commission. Since this was the largest wholesaler in Spain, with 20.6% of the market (according to recital 112 of the Decision), the Commission could not legitimately consider that the statement reproduced in recital 121 proves that Cofares complied with Bayer Spain's requirement that it confine itself to its domestic market without verifying whether Cofares had a strong export tradition and without considering the possibility that, quite simply, Cofares had decided to view exports only as a very subsidiary possibility; such a decision might have been the most reasonable one to take given the difficulty of obtaining additional quantities of products in relation to habitual needs. That is so *a fortiori* in view of the lack of any reference in the Decision to the relative importance of Adalat in the overall sales of Cofares.

136 Moreover, that statement by the managing director of Cofares, rather than being evidence of alleged adherence to an alleged export ban, calls for the finding that Bayer's policy of restricting supplies, together with the difficulties raised by other laboratories, had led that wholesaler to consider exporting only once appropriate supply of the domestic market was assured. That interpretation seems more plausible than that of the Commission, bearing in mind, in particular, the fact that wholesalers are required to ensure the distribution of products on the national market in an appropriate and stable manner, and that this case concerns the premier national wholesaler.

137 According to recital 137 of the Decision, the figures for export sales between 1989 and 1993, supplied by Cofares at the Commission's request, show that export sales 'remained at a minimum level' and that proves that 'Cofares accepted the regime imposed by Bayer Spain and confined itself strictly to the Spanish domestic market'.

138 However, examination of those figures reveals rather the contrary, because, even if it constitutes a minimal percentage of Cofares's sales as a whole, the percentage corresponding to exports of Adalat only rises in the course of the years, in an irregular but constant fashion, as is demonstrated by the fact that the smallest percentage of the five years under consideration is precisely that of the first year, namely 1989. Finally, it should be added that it was hard for the Commission to come to the above conclusion without knowing the figures for the years before 1989, that is to say the period immediately prior to the establishment by Bayer Spain of its policy of restricting supplies. Without that information, it is impossible to determine whether Cofares modified its tendency to export that product following the introduction of that policy by Bayer.

139 As regards the passage, contained in the statement, concerning the discussions between the managing director of Cofares and Bayer Spain, it needs to be considered whether, in the absence of any direct or indirect reference to the freedom to export the quantities received, the fact that the parties agreed to increase the supply quantities initially assigned by Bayer to that wholesaler in order to ensure that its national needs were met demonstrates acquiescence by the wholesaler in the applicant's policy designed to make parallel exports difficult. Recital 143 of the Decision contains a passage of a document which, although it was not directly relied on by the Commission in the context of this question, must be referred to because it is an internal memorandum of Bayer Spain which also refers to the quota which Bayer initially conceded to Cofares to cover its needs on the national market.

140 That internal memorandum shows that Bayer Spain and Cofares discussed minimum supply quantities to enable that wholesaler to meet its growth and penetration needs on the national market and that they reached an agreement on the figures corresponding to those needs. It appears to be undisputed that Bayer Spain assured Cofares that the supplies would, at least, correspond to those quantities. It is also clear that Bayer Spain was ready to envisage revision of the reduced supply levels initially adopted if problems in supplying the national market appeared, bearing in mind its legal and moral obligation to ensure appropriate distribution of its products on the Spanish market.

141 However, nothing in that internal memorandum refers to the slightest restriction on the freedom of Cofares to assign products received after the conversations on the level of national needs to exports. The Commission therefore has no basis for arguing that Cofares was supplied only after assuring Bayer that the supplies were intended solely for the internal market. Finally, it should be noted that, during the bargaining, Bayer Spain claimed that Spanish pharmacies not supplied by the wholesalers were supplied directly by the manufacturer. That fact, instead of indicating that the wholesalers were prevented or penalised by Bayer when they decided to export those products even at the cost of abandoning parts of the national market, seems rather to demonstrate that they were covered in that respect by the manufacturer.

142 In those circumstances, the conclusion must be that neither the document referred to by recital 143 of the Decision nor the statement by the managing director of Cofares reproduced in recital 121 of the Decision may be construed as proving either the alleged 'requirement' by Bayer Spain that the wholesaler should stay in the domestic market or any acceptance of that requirement on the part of Cofares.

143 The Decision then goes on to describe (recital 122) how the Spanish wholesaler Hefame established a system for obtaining packets of Adalat for export. It sets out in detail a standard agreement headed 'Cooperation Agreement for External Markets' which Hefame concluded with several small wholesalers in order to obtain larger quantities of medicinal products that it was profitable to export, including Adalat. However, there is nothing in that document to show that Hefame's conduct had been favourable to any idea of acquiescing in Bayer's new policy.

144 As regards the Spanish subsidiaries of CERP Rouen, the description of the conduct of Commercial Genové, Hufasa and Disdasa, contained in recitals 125 to 129 of the Decision, confirms the lack of proof of any concurrence of wills or acquiescence in the policy of preventing parallel exports.

145 The Commission itself says in recital 126 of the Decision:

'Documents were found on the premises of Commercial Genové showing that CERP Rouen used its Spanish subsidiaries, Commercial Genové, Hufasa and Disdasa, to meet British demand. CERP Rouen thus acted as an international group and made use of all its scope both in France and in Spain for obtaining supplies of the necessary quantities for its British customers. Under this system, the Spanish subsidiaries were used in the same way as the French regional agencies: they were asked to make a plausible increase in their orders for the Spanish market, and the amounts thus obtained were supplied to British customers on behalf of CERP Rouen.'

146 The Decision then refers to the wholesaler Hufasa (recital 127), citing a record of a meeting between Hufasa and Bayer Spain which is alleged to demonstrate that Hufasa fully accepted Bayer Spain's arguments, namely that it had to concentrate on domestic sales. In that regard, the Commission relies on the following quotation in particular: '... we had reached an agreement with Bayer to maintain higher supplies of Adalat, it was better not to submit figures that would not be accepted as possible for Hufasa and which revealed our interest in exporting significant amounts.'

147 That record shows that a conversation took place between a representative of Hufasa and managers of Bayer Spain, during which the Bayer managers refused to supply the quantities requested because they accounted for 50% of the domestic market and were much higher than those of other firms in the same area; that the Hufasa representative reacted by arguing that his company needed larger quantities of Adalat on the ground, in particular, that the estimate of needs for the domestic market had been made on the basis of needs recorded in an untypical year in which Hufasa had suffered a crisis that was reflected in the abnormally low level of Adalat purchases; and that, following those conversa-

tions, Bayer undertook to revise the supply limit figures and increase them to the level of those of another, unidentified, wholesaler.

148 That record clearly shows that the true intentions and the actual conduct of the Spanish subsidiaries of the CERP Rouen group could not be further removed from any intention to comply with, or align themselves upon, Bayer's policy of preventing parallel imports. It is sufficient in that regard to cite the part of that document which follows the passage cited above and to read it in the context of the group strategy adopted by CERP Rouen: 'I took the view that it was more important to obtain a quantity of Adalat for export with very plausible figures rather than to maintain a very high level of orders which would not be supplied. The important thing was actual receipts rather than the order. That is no doubt why (...) orders less than forecast.' Moreover, whilst it is true that the record reproduced shows that that company bargained hard with Bayer Spain to secure its acknowledgement that its traditional domestic needs were higher and that they should be satisfied, that fact cannot serve to support the Commission's statement that 'Hufasa completely accepted Bayer Spain's arguments, namely that it had to concentrate on domestic sales.'

149 Finally, although the Hufasa manager refers in that record to 'an agreement with Bayer to maintain higher supplies of Adalat', which Hufasa is said to have concluded with Bayer Spain, it is clear from the literal content of that statement and its context that the parties limited themselves to negotiating the exact determination of the quantities which the wholesaler traditionally requested, that being the criterion in accordance with which the applicant had decided to adjust its new supply policy, and the upward revision of the figures for national needs and, therefore, the quantities to which Hufasa was to be entitled pursuant to that criterion. Since the sentence '[T]his led them to believe that a substantial proportion of the product was intended for export' was only a subjective assessment on the part of the Hufasa manager, it cannot be regarded as demonstrating an intention on the part of Bayer to deal with the question of exports or the actual destinations of the products supplied. Moreover, it is not in any event capable of contradicting the general sense of the record, which merely reflects the difficulties which Bayer was encountering in implementing its new policy of reducing supplies and in which, what is more, there is nothing capable

of establishing that Bayer Spain and Hufasa concluded an agreement to limit or to prevent in any way parallel exports of the packets of Adalat supplied. The absence of any concurrence of wills in relation to exports is corroborated, moreover, by the text of this recital in the Decision itself, where the Commission states:

'However, the record is explicit; the pressure put on Bayer Spain on the basis of domestic-market arguments was merely a means used by Hufasa to obtain the amounts intended for export.'

150 Recitals 128 and 129 of the Decision set out the content of a letter from CERP Rouen to its subsidiaries and of a letter sent to CERP Rouen by its subsidiary Commercial Genové, also concerning the mechanism put in place by that group to try to obtain more products of the applicant in Spain and underlining the difficulty in obtaining extra packets of Adalat. The Commission cannot rely on these documents either in order to establish that the subsidiaries of CERP Rouen in Spain wished to adhere in any way whatsoever to Bayer Spain's new policy designed to limit parallel exports of the products supplied.

151 Examination of the attitude and actual conduct of the wholesalers shows that the Commission has no foundation for claiming that they aligned themselves on the applicant's policy designed to reduce parallel imports.

152 The argument based on the fact that the wholesalers concerned had reduced their orders to a given level in order to give Bayer the impression that they were complying with its declared intention thereby to cover only the needs of their traditional market, and that they acted in that way in order to avoid penalties, must be rejected, because the Commission has failed to prove that the applicant demanded or negotiated the adoption of any particular line of conduct on the

part of the wholesalers concerning the destination for export of the packets of Adalat which it had supplied, and that it penalised the exporting wholesalers or threatened to do so.

153 For the same reasons, the Commission cannot claim that the reduction in orders could be understood by Bayer only as a sign that the wholesalers had accepted its requirements, or maintain that it is because they satisfied Bayer's requirements that they had to procure extra quantities destined for export from wholesalers who were not 'suspect' in Bayer's eyes and whose higher orders were therefore fulfilled without difficulty.

154 Moreover, it is obvious from the recitals of the Decision examined above that the wholesalers continued to try to obtain packets of Adalat for export and persisted in that line of activity, even if, for that purpose, they considered it more productive to use different systems to obtain supplies, namely the system of distributing orders intended for export among the various agencies on the one hand, and that of placing orders indirectly through small wholesalers on the other. In those circumstances, the fact that the wholesalers changed their policy on orders and established various systems for breaking them down or diversifying them, by placing them through indirect means, cannot be construed as evidence of their intention to satisfy Bayer or as a response to any request from Bayer. On the contrary, that fact could be regarded as demonstrating the firm intention on the part of the wholesalers to continue carrying on parallel exports of Adalat.

155 In the absence of evidence of any requirement on the part of the applicant as to the conduct of the wholesalers concerning exports of the packets of Adalat supplied, the fact that they adopted measures to obtain extra quantities can be construed only as a negation of their alleged acquiescence. For the same reasons, the Court must also reject the Commission's argument that, in the circumstances

of the case, it is normal that certain wholesalers should have tried to obtain extra supplies by circuitous means since they had to undertake to Bayer not to export and thus to order reduced quantities, not capable of being exported.

156 Nor, finally, has the Commission proved that the wholesalers wished to pursue Bayer's objectives or wished to make Bayer believe that they did. On the contrary, the documents examined above demonstrate that the wholesalers adopted a line of conduct designed to circumvent Bayer's new policy of restricting supplies to the level of traditional orders.

157 The Commission was therefore wrong in holding that the actual conduct of the wholesalers constitutes sufficient proof in law of their acquiescence in the applicant's policy designed to prevent parallel imports.

3. The case-law precedents cited by the Commission

158 The Commission contends that the Decision entirely corresponds to its decision-making practice and to the case-law of the Court of Justice on the concept of an agreement, and maintains that in this case, as in a number of previous cases, there was an export ban inserted into a series of continuous commercial relations between the supplier and its customers, as witnessed by the fact that the wholesalers placed orders, were regularly supplied and received corresponding invoices, and that there was tacit consent on the part of the wholesalers, which the Commission maintains is established by the reduction in orders.

159 However, it cannot effectively rely on the case-law precedents referred to in order to call into question the analysis, which has led the Court to conclude that in this case acquiescence of the wholesalers in Bayer's new policy has not been

established and that the Commission has therefore failed to prove the existence of an agreement.

160 The Commission relies first on *Sandoz*, in which it maintains that, as in this case, the distributors on the one hand tacitly consented to the export ban in order to maintain their commercial relations (paragraph 11 of the judgment) and, on the other hand, although they had no interest in abandoning exports, accepted the manufacturer's export ban because they wished to continue obtaining the goods.

161 That case concerned the penalty imposed by the Commission on a subsidiary of a multinational pharmaceutical company, Sandoz, which was guilty of inserting into invoices which it sent to customers (wholesalers, pharmacies and hospitals) the express words 'export prohibited'. Sandoz had not denied the presence of those words in its invoices, but had disputed that there was an agreement within the meaning of Article 85(1) of the Treaty. The Court of Justice dismissed the action after replying to each of the applicant's arguments. It considered that the sending of invoices with those words did not constitute unilateral conduct, but, on the contrary, formed part of the general framework of commercial relations which the undertaking maintained with its customers. It reached that conclusion after examining the way in which the undertaking proceeded before authorising a new customer to market its products and taking into account the practices repeated and applied uniformly and systematically at each sales operation (paragraph 10 of the judgment). It was at that stage in its reasoning that the Court of Justice dealt with the question of the acquiescence of the commercial partners in the export ban, mentioned in the invoice, in the following terms:

'It should also be noted that the customers of Sandoz PF were sent the same standard invoice after each individual order or, as the case may be, after the delivery of the products. The repeated orders of the products and the successive payments without protest by the customer of the prices indicated on the invoices, bearing the words "export prohibited", constituted a tacit acquiescence on the part of the latter in the clauses stipulated in the invoice and the type of commercial relations underlying the business relations between Sandoz PF and its

clientele. The approval initially given by Sandoz PF was thus based on the tacit acceptance on the part of the customers of the line of conduct adopted by Sandoz PF towards them.'

162 It was only after those findings that the Court of Justice concluded that the Commission was entitled to take the view that 'the whole of the continuous commercial relations, of which the "export prohibited" clause formed an integral part, established between Sandoz PF and its customers, were governed by a pre-established general agreement applicable to the innumerable individual orders for Sandoz products. Such an agreement is covered by the provisions of Article 85(1) of the Treaty'.

163 Although the two cases resemble each other in that they concern attitudes of pharmaceutical groups designed to prevent parallel imports of medicinal products, the concrete circumstances characterising them are very different. In the first place, unlike the situation in the present case, the manufacturer in *Sandoz* had expressly introduced into all its invoices a clause restraining competition, which, by appearing repeatedly in documents concerning all transactions, formed an integral part of the contractual relations between Sandoz and its wholesalers. Second, the actual conduct of the wholesalers in relation to the clause, which they complied with *de facto* and without discussion, demonstrated their tacit acquiescence in that clause and the type of commercial relations underlying it. On the facts of the present case, however, neither of the two principal features of *Sandoz* is to be found; there is no formal clause prohibiting export and no conduct of non-contention or acquiescence, either in form or in reality.

164 Second, the Commission relies on the judgment in *Tipp-Ex* v *Commission*, cited above, in which the Court of Justice confirmed its decision penalising an agreement designed to prevent exports and in which, unlike the situation in *Sandoz*, there had not been a written stipulation concerning the export ban. It claims that Tipp-Ex, like the applicant in this case, had also argued before the Court of Justice that this was a unilateral measure that did not fall within the scope of Article 85(1) of the Treaty, and that, since the supplies from the

distributor to the parallel exporter had actually taken place, there was no common interest in parallel exports being terminated.

165 That case concerned an exclusive distribution agreement between Tipp-Ex and its French distributor, DMI, which had complied with the manufacturer's demand that the prices charged to a customer should be raised so far as was necessary to eliminate any economic interest on his part in parallel imports. Moreover, it had been established that the manufacturer carried out subsequent checks so as to give the exclusive distributor an incentive actually to adopt that conduct (recital 58 of Commission Decision 87/406/EEC of 10 July 1987 relating to a proceeding under Article 85 of the EEC Treaty (OJ 1987 L 222, p. 1). Paragraphs 18 to 21 of the judgment show the reasoning followed by the Court of Justice, which, after finding the existence of a verbal exclusive distribution agreement for France between Tipp-Ex and DMI and recalling the principal facts, wished to examine the reaction of and, therefore, the conduct adopted by the distributor following the penalising conduct adopted by the manufacturer. The Court of Justice then found that the distributor 'reacted by raising by between 10 and 20% the prices charged only to the undertaking ISA France. After the interruption of ISA France's purchases from DMI during the whole of 1980, DMI refused at the beginning of 1981 itself to supply Tipp-Ex products to ISA France'. It was only after those findings with regard to the conduct of the manufacturer and the distributor that the Court of Justice arrived at its conclusion as to the existence of an agreement within the meaning of Article 85(1) of the Treaty:

'it is therefore established that DMI acted upon the request of Tipp-Ex not to sell to customers who resell Tipp-Ex products in other Member States' (paragraph 21 of the judgment).

166 In *Tipp-Ex*, therefore, unlike the situation in the present case, there was no doubt as to the fact that the policy of preventing parallel exports was established by the manufacturer with the cooperation of the distributors. As indicated in that judgment, that intention was already manifest in the oral and written contracts existing between the two parties (see paragraphs 19 and 20 concerning the distributor DMI and 22 and 23 concerning the distributor Beiersdorf) and, if there were any remaining doubt, analysis of the behaviour of the distributors,

pressed by the manufacturer, showed very clearly their acquiescence in the intentions of Tipp-Ex in restriction of competition. The Commission had proved not only that the distributors had reacted to threats and pressure on the part of the manufacturer, but also the fact that at least one of them had sent the manufacturer proof of its cooperation. Finally, the Commission itself observes in this case that, in *Tipp-Ex*, in order to determine whether an agreement existed, the Court of Justice took the approach of analysing the reaction of the distributors to the conduct of the manufacturer running counter to parallel exports and that it was in assessing that reaction of the distributor that it concluded that there must be an agreement in existence between it and Tipp-Ex designed to prevent parallel exports.

167 It follows that that judgment, like *Sandoz*, merely confirms the case-law to the effect that, although apparently unilateral conduct by a manufacturer may lie at the root of an agreement between undertakings within the meaning of Article 85(1) of the Treaty, this is on condition that the subsequent conduct of the wholesalers or customers may be interpreted as *de facto* acquiescence. As that condition is not fulfilled in this case, the Commission cannot rely on the alleged similarity between these two cases in support of its argument that acquiescence existed in this case.

168 For the same reasons, neither the Commission nor BAI may validly rely on the assessments carried out by the Court of Justice in *BMW Belgium*, *AEG* and *Ford and Ford Europe* in support of their argument that acquiescence by the wholesalers exists in this case.

169 In *BMW Belgium*, in order to determine whether there was an agreement within the meaning of Article 85(1) of the Treaty between BMW and its Belgian dealers, the Court of Justice examined the measures capable of demonstrating the existence of an agreement, in that case circulars sent to BMW dealers, 'according to their tenor and in relation to the legal and factual context in which they [were]

set', and concluded that the circulars in question 'indicate[d] an intention to put an end to all exports of new BMW vehicles from Belgium' (paragraph 28). It added that 'in sending those circulars to all the Belgian dealers, BMW Belgium played the leading role in the conclusion with those dealers of an agreement designed to halt such exports completely' (paragraph 29). Paragraph 30 of that judgment shows that the Court of Justice intended to confirm the existence of acquiescence by the dealers.

170 In *AEG*, in which the respective intentions of the manufacturer and the distributors do not appear clearly and in which the applicant expressly relied on the unilateral nature of its conduct, the Court of Justice considered that, in the context of a selective distribution system, a practice whereby the manufacturer, with a view to maintaining a high level of prices or to excluding certain modern channels of distribution, refused to approve distributors who satisfied the qualitative criteria of the system did 'not constitute, on the part of the undertaking, unilateral conduct which, as AEG claims, would be exempt from the prohibition contained in Article 85(1) of the Treaty. On the contrary, it forms part of the contractual relations between the undertaking and resellers' (paragraph 38). The Court of Justice then sought to determine the existence of acquiescence by the distributors by stating: 'Indeed, in the case of the admission of a distributor, approval is based on the acceptance, tacit or express, by the contracting parties of the policy pursued by AEG which requires inter alia the exclusion from the network of all distributors who are qualified for admission but are not prepared to adhere to that policy' (paragraph 38). That approach has been confirmed in the other selective-distribution cases decided by the Court of Justice (*Ford and Ford Europe*, paragraph 21; *Metro II*, paragraphs 72 and 73; *BMW* v *ALD*, paragraphs 16 and 17).

171 It follows that the Commission cannot rely on the case-law precedents which it has cited in order to establish the existence of an agreement in this case.

4. The Commission's argument that, in order to prove the existence of an agreement, it is sufficient to find that the parties maintain their commercial relations

172 The Commission's reasoning shows that it maintains, albeit ambiguously (see the structure of the Decision summarised in recitals 155 and 156 and developed in recitals 171 to 188), that the mere finding of fact that the wholesalers did not interrupt their commercial relations with Bayer after the latter established its new policy designed to restrain exports is a sufficient ground for it to hold that the existence of an agreement between undertakings within the meaning of Article 85(1) of the Treaty is established.

173 Such an argument cannot be accepted. The proof of an agreement between undertakings within the meaning of Article 85(1) of the Treaty must be founded upon the direct or indirect finding of the existence of the subjective element that characterises the very concept of an agreement, that is to say a concurrence of wills between economic operators on the implementation of a policy, the pursuit of an objective, or the adoption of a given line of conduct on the market, irrespective of the manner in which the parties' intention to behave on the market in accordance with the terms of that agreement is expressed (see, in particular, *ACF Chemiefarma*, paragraph 112; *Van Landewyck and Others*, paragraph 86). The Commission misjudges that concept of the concurrence of wills in holding that the continuation of commercial relations with the manufacturer when it adopts a new policy, which it implements unilaterally, amounts to acquiescence by the wholesalers in that policy, although their *de facto* conduct is clearly contrary to that policy.

174 Moreover, in accordance with the general scheme of the Treaty, an undertaking may be penalised under Community competition law only if it has infringed prohibitions contained in Article 85(1) or Article 86 of the Treaty. In that respect, it should be noted that the applicability of Article 85(1) is based on a number of conditions, namely that, (a) there must be an agreement between at least two undertakings or a similar arrangement such as a decision of an association of

undertakings or a concerted practice between undertakings, (b) that arrangement must be capable of affecting trade within the Community, and (c) that it must have as its object or effect the restriction of competition to an appreciable extent. It follows that, in the context of that article, the effects of the conduct of an undertaking on competition within the common market may be examined only if the existence of an agreement, a decision of an association of undertakings or a concerted practice within the meaning of Article 85(1) of the Treaty has already been established (Case *56/65 Société Technique Minière* v *Maschinenbau Ulm* [1966] ECR 235, at p. 248 et seq.). It follows that the aim of that provision is not to 'eliminate' obstacles to intra-Community trade altogether; it is more limited, since only obstacles to competition set up as a result of a concurrence of wills between at least two parties are prohibited by that provision.

175 That interpretation of Article 85(1) of the Treaty was followed by the Court of Justice in Case C-73/95 P *Viho* v *Commission* [1996] ECR I-5457, paragraphs 15 to 17, in which, upholding a judgment of the Court of First Instance, it held that the fact that the policy implemented by a parent company consisting essentially in dividing various national markets between its subsidiaries might produce effects outside the ambit of the group which were capable of affecting the competitive position of third parties could not render Article 85(1) of the Treaty applicable, even when read in conjunction with Article 2 and Article 3(c) and (g) of the EC Treaty. On the other hand, such unilateral conduct could fall under Article 86 of the Treaty if the conditions for its application, as laid down in that article, were fulfilled.

176 Having regard to the foregoing considerations, and contrary to what the Commission and the BAI appear to maintain, the right of a manufacturer faced, as in this case, with an event harmful to his interests, to adopt the solution which seems to him to be the best is qualified by the Treaty provisions on competition only to the extent that he must comply with the prohibitions referred to in Articles 85 and 86. Accordingly, provided he does so without abusing a dominant position, and there is no concurrence of wills between him and his wholesalers, a manufacturer may adopt the supply policy which he considers necessary, even if, by the very nature of its aim, for example, to hinder parallel imports, the

implementation of that policy may entail restrictions on competition and affect trade between Member States.

177 The Commission relies in this respect on the judgment of the Court of Justice in Joined Cases C-267/95 and C-268/95 *Merck and Beecham* [1996] ECR I-6285, as a basis for arguing that in all circumstances parallel imports must be protected. It maintains that, in that judgment, the Court of Justice put an end to speculation concerning the scope of the solution adopted in the judgment in Case 187/80 *Merck* v *Stephar and Exler* [1981] ECR 2063 by stating that the control of prices in certain Member States did not justify any derogation from the principle of the free movement of goods and that the possibility of preventing parallel imports entailed an undesirable partitioning of national markets. Therefore, the Commission maintains, even in the pharmaceutical sector, parallel imports may not be hindered either by national measures or by agreements between undertakings.

178 It should, however, be noted that, in that judgment, the Court of Justice limits itself to answering the question concerning, first, the expiry date of certain transitional provisions contained in the Act of Accession of the Kingdom of Spain and the Portuguese Republic (Articles 47 and 209 of the Act of Accession) which permitted the prevention of parallel exports of pharmaceutical products from those countries into other parts of the Community, and, second, the legal regime applicable to parallel imports after the expiry of the relevant transitional periods and to the question whether the scope of the solution adopted in *Merck* v *Stephar and Exler* should be reconsidered. The reasoning of the Court of Justice in *Merck and Beecham* does not concern the issue in this case, which does not fall within the law on the free movement of goods under Articles 30, 34 and 36 of the EC Treaty (now, after amendment, Articles 28 EC, 29 EC and 30 EC), and, contrary to what the Commission claims, does not in any way presume a general prohibition on preventing parallel exports applying not only to Member States but also, and in all cases, to undertakings.

179 In reality, rather than supporting the Commission's argument, that judgment merely confirms that, under the system of the Treaty, it is not open to the Commission to attempt to achieve a result, such as the harmonisation of prices in the medicinal products market, by enlarging or straining the scope of Section 1 (Rules applying to undertakings) of Chapter 1 of Title VI of the Treaty, especially since that Treaty gives the Commission specific means of seeking such harmonisation where it is undisputed that large disparities in the prices of medicinal products in the Member States are engendered by the differences existing between the state mechanisms for fixing prices and the rules for reimbursement, as is the case here (see recitals 151 and 152 of the Decision). As the Court of Justice pointed out in paragraph 47 of the judgment in *Merck and Beecham*, it is settled case-law that distortions caused by different price legislation in a Member State must be remedied by measures taken by the Community authorities (see Case 16/74 *Centrafarm* v *Winthrop* [1974] ECR 1183, paragraph 17; *Musik-Vertrieb Membran and K-tel International* v *GEMA*, paragraph 24; Joined Cases C-427/93, C-429/93 and C-436/93 *Bristol-Myers Squibb and Others* [1996] ECR I-3457, paragraph 46; *Merck and Beecham*, paragraph 47).

180 An extension of the scope of Article 85(1) of the Treaty, such as that proposed by the Commission, would lead to a paradoxical situation in which refusal to sell would be penalised more heavily in the context of Article 85(1) than in that of Article 86, since the prohibition in Article 85(1) would hit a manufacturer deciding to refuse or restrict future supplies but without terminating his commercial relations with his customers altogether, whereas, under Article 86, refusal to supply, even where it is total, is prohibited only if it constitutes an abuse. The case-law of the Court of Justice indirectly recognises the importance of safeguarding free enterprise when applying the competition rules of the Treaty where it expressly acknowledges that even an undertaking in a dominant position may, in certain cases, refuse to sell or change its supply or delivery policy without falling under the prohibition laid down in Article 86 (see Case 27/76 *United Brands* v *Commission* [1978] ECR I-207, paragraphs 182 to 191).

181 Nor, finally, can the Commission rely in support of its argument upon its conviction, which is, moreover, devoid of all foundation, that parallel imports will in the long term bring about the harmonisation of the price of medicinal products. The same applies to its claim that 'it is not acceptable for parallel imports to be hindered so that pharmaceutical undertakings may impose excessive rates in countries not applying any price control in order to compensate for lower profits in Member States which intervene more on prices'.

182 It follows that the Commission could not legitimately regard an agreement between the wholesalers and the manufacturer as being established on the basis of the mere finding that pre-existing commercial relations continued.

D. *Conclusion*

183 It follows from the whole of the foregoing considerations that the Commission incorrectly assessed the facts of the case and made an error in the legal assessment of those facts by holding it to be established that there was a common intention between Bayer and the wholesalers referred to in the Decision, which justified the conclusion that there was an agreement within the meaning of 85(1) of the Treaty, designed to prevent or limit exports of Adalat from France and Spain to the United Kingdom.

184 As a result, the principal plea in law raised in this action must be declared to be well founded. The Decision must therefore be annulled, without there being any need to hear witnesses, as proposed by the applicant, or to examine the pleas in law raised in the alternative, alleging erroneous application of Article 85(1) of the Treaty to conduct that was legitimate under Article 47 of the Act of Accession of Spain to the European Communities, and misapplication of Article 15 of Regulation No 17 in imposing a fine on the applicant.

Costs

185 Under Article 87(2) of the Rules of Procedure, the unsuccessful party is to be ordered to pay the costs if they have been applied for in the successful party's pleadings. As the Commission has been unsuccessful and the applicant has applied for costs, the Commission must be ordered to bear its own costs and pay those incurred by the applicant, including those incurred by it in the proceedings for interim relief.

186 Under the third subparagraph of Article 87(4) of the Rules of Procedure, the Court of First Instance may order an intervener other than those mentioned in the preceding subparagraph to bear its own costs. In this case, the EFPIA, which has intervened in support of the applicant, and the BAI, which has intervened in support of the Commission, must be ordered to bear their own costs.

On those grounds,

THE COURT OF FIRST INSTANCE
(Fifth Chamber, Extended Composition),

hereby:

1. **Annuls Commission Decision 96/478/EC of 10 January 1996 relating to a proceeding under Article 85 of the EC Treaty (Case IV/34.279/F3 — Adalat);**

2. **Orders the Commission to bear its own costs and to pay the costs incurred by the applicant, including those incurred by the latter in the proceedings for interim relief;**

3. **Orders the European Federation of Pharmaceutical Industries' Associations and the Bundesverband der Arzneimittel-Importeure eV to bear their own costs.**

Cooke García-Valdecasas Lindh

Pirrung Vilaras

Delivered in open court in Luxembourg on 26 October 2000.

H. Jung J.D. Cooke

Registrar President

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