products exported to Austria and, conversely, Austrian products exported to the Community, but also extends to products originating in Community Member States which, after simply passing through Austrian territory, are reimported into the Community.

2. Articles 13 and 20 of the Agreement between the European Economic Community and the Republic of Austria, concerning the prohibition of quantitative restrictions on imports and measures having equivalent effect, must be interpreted as precluding the health authority of a Member State from making the grant of marketing authorization, sought by a parallel importer, for a medicine from Austria which is identical in all respects to a medicine already authorized by that health authority subject to the condition that the parallel importer produce documents which were already supplied to that authority by the manufacturer of the medicine at the time when marketing authorization was first applied for.

In circumstances where the health authority already possesses all the necessary information about the medicine and there is no dispute that the imported medicine and the authorized medicine are identical, to hold that Articles 13 and 20 of the Agreement do not preclude such requirements would be to deprive those articles of much of their effectiveness.

REPORT FOR THE HEARING
In Case C-207/91 *

I — Facts and procedure

A — *Facts*

Eurim-Pharm GmbH ('Eurim-Pharm') is a company whose registered office is in the Federal Republic of Germany and which markets pharmaceutical products.

In 1985 the company wished to sell in Germany, as part of its commercial activities, a medicine called 'Adalat R', which was manufactured in France by Bayer AG ('Bayer') and used against hypertension and pectoral angina.

Eurim-Pharm's commercial plan was to buy Adalat R on the Austrian market, where it was distributed by Bayer, affix a label with the name and address of Eurim-Pharm over

* Language of the case: German.

the Bayer packaging, and sell the product in Germany, in parallel with the distribution network established by Bayer, which already marketed Adalat R in that country.

In order to put that strategy into effect, and because the marketing of pharmaceutical products in Germany is subject to prior authorization, Eurim-Pharm applied for authorization to the competent German authority, the Bundesgesundheitsamt (Federal Health Authority), in a letter of 6 May 1985. In support of its application, it submitted documents establishing that the Adalat R was manufactured by Bayer and was identical with that lawfully sold by them in Germany.

On 11 July 1985 the Bundesgesundheitsamt rejected Eurim-Pharm's application on the ground that it did not contain the information which national legislation required to be communicated to the authority in question to enable it to determine whether, having regard to the therapeutic qualities of Adalat R and the dangers which might in certain cases result from its use, that product could be marketed in Germany.

Having unsuccessfully lodged an official complaint with the Bundesgesundheitsamt, Eurim-Pharm brought an action against its decision before the Verwaltungsgericht (Administrative Court) Berlin on 1 April 1988.

In the proceedings before that court, Eurim-Pharm argued that, under Articles 13 and 20 of the Agreement between the European Economic Community and the Republic of Austria (OJ, English Special Edition 1972 (31 December), p. 4), obstacles to the free movement of goods between the two Contracting Parties were to be removed. It would be contrary to such freedom of movement for the importer of a medicine from Austria to be required to supply information about it to the competent authority of the importing Member State when the medicine was already marketed in that State and the authority already had all the necessary documents.

In support of that argument, Eurim-Pharm cited the judgment of the Court of Justice in Case 104/75 *De Peijper* [1976] ECR 613, concerning the importation into one Member State of products from another. In Eurim-Pharm's opinion, that case-law should also apply to a product from Austria, since Articles 13 and 20 of the Agreement between the Community and Austria and Articles 30 and 36 of the Treaty are similarly worded and pursue the same objective, namely the elimination of obstacles to trade.

Articles 13 and 20 of the Agreement provide as follows:

'Article 13

1. No new quantitative restriction on imports or measures having equivalent effect shall be introduced in trade between the Community and Austria.

2. Quantitative restrictions on imports shall be abolished on 1 January 1973 and any measures having an effect equivalent to quantitative restrictions on imports shall be abolished not later than 1 January 1975.'

'Article 20

The Agreement shall not preclude prohibitions or restrictions on imports, exports or goods in transit justified on grounds of public morality, law and order or public security, the protection of life and health of humans, animals or plants, the protection of national treasures of artistic, historic or archaeological value, the protection of industrial and commercial property, or rules relating to gold or silver. Such prohibitions or restrictions must not, however, constitute a means of arbitrary discrimination or a disguised restriction on trade between the Contracting Parties.'

The Bundesgesundheitsamt disputed Eurim-Pharm's reasoning, arguing that the provisions of the Agreement did not have direct effect and could not, therefore, be invoked directly by Eurim-Pharm before a national court. It maintained, moreover, that the similarity in drafting between those provisions and Articles 30 and 36 of the Treaty was not a sufficient reason for interpreting them in the same way.

In response to the arguments of Eurim-Pharm and the Bundesgesundheitsamt, the Verwaltungsgericht noted that the Court of Justice had adopted differing approaches with regard to the interpretation of agreements concluded by the Community with non-member countries. In some instances it had interpreted provisions of such agreements by analogy with the corresponding articles in the Treaty (judgments in Case 65/79 *Procureur de la République* v *Chatain* [1980] ECR 1345 and in Case 253/83 *Kupferberg II* [1985] ECR 157), whilst in other cases it had, on the contrary, taken the view that a different interpretation was necessary, having regard to the different aims pursued by the Treaty and by those agreements (judgments in Case 270/80 *Polydor* v *Harlequin Record Shops* [1982] ECR 329 and in Case 104/81 *Kupferberg I* [1982] ECR 3641).

B — *Question referred for a preliminary ruling*

In those circumstances, the Verwaltungsgericht decided to stay the proceedings and, by an order of 14 June 1991, referred the following question to the Court for a preliminary ruling:

'As far as parallel imports of pharmaceutical products are concerned, are Articles 13 and 20 of the Agreement between the European Economic Community and the Republic of Austria (OJ, English Special Edition 1972 (31 December), p. 4) to be interpreted in accordance with the same principles as Articles 30 and 36 of the EEC Treaty, so that authorization to place into circulation a pharmaceutical product to be imported into Germany from Austria which is in all respects identical to a pharmaceutical product already authorized in Germany cannot be made to depend on whether the importer submits to the competent health authority documents or information already in its possession?'

C — *Procedure before the Court of Justice*

The order of the Verwaltungsgericht was lodged at the Court Registry on 1 August 1991.

In accordance with Article 20 of the Protocol on the Statute of the Court of Justice, written observations were submitted:

— on 12 December 1991 by the Commission of the European Communities, represented by J. Sack, Legal Adviser, acting as Agent,

— on 13 December 1991 by Eurim-Pharm, represented by W. A. Rehmann, of the Munich Bar,

— on 20 December 1991 by the Italian Government, represented by I. M. Braguglia, Avvocato dello Stato,

— on 24 December 1991 by the United Kingdom, represented by S. L. Hudson, acting as Agent.

Upon hearing the Report of the Judge-Rapporteur and the views of the Advocate General, the Court decided to open the oral procedure without any preparatory inquiry.

II — Written observations submitted to the Court

Eurim-Pharm considers that Articles 13 and 20 of the Agreement between the Community and Austria prevent an economic operator wishing to import a medicine from Austria into the Community from being obliged to communicate information required by national legislation to the competent authority of the importing State if the medicine is already marketed in that State and the authority in question already holds the information requested.

In support of its position, Eurim-Pharm argues, first, that Articles 13 and 20 have direct effect since they are clear, precise and unconditional. The company submits that no other condition needs to be satisfied for the direct effect of those provisions to be recognized in the Community. In particular, it is not necessary for such an effect to be similarly recognized on Austrian territory by the Austrian courts. If, however, reciprocity were required, Eurim-Pharm points out that no Austrian court has so far denied that those provisions have direct effect.

Secondly, Eurim-Pharm argues that Articles 13 and 20 provide for the elimination of barriers to the free movement of goods between the Community and Austria, save where those barriers are justified by legitimate interests (in particular, the protection of public health).

In that respect, Eurim-Pharm makes two points.

First, it maintains that to require an economic operator to supply in support of an import application documents which the competent authority already has constitutes a barrier to trade. That barrier cannot be justified by the need to protect public health, since the authority holds all the information it needs in order to determine whether, having regard to public health requirements, marketing authorization for the product may be granted.

The information required by the German legislation, essentially concerning the technical characteristics of the medicine, is in principle known only to the manufacturer, which in the present case is Bayer. Eurim-Pharm does not specify whether it asked Bayer to supply the information, but in any event it did not have that information and was therefore unable to supply it to the Bundesgesundheitsamt.

Next, Eurim-Pharm argues that, in a similar case, the Court of Justice held that rules obliging an economic operator to supply documents which the authority already had in support of an import application for a medicine constituted an unjustified barrier to trade (judgment in *De Peijper*, cited above). In the company's submission, that decision, which concerned the importation of a medicine into one Member State from another, must be extended to cover the importation into the Community of a medicine from Austria. That extension is justified by the fact that Articles 13 and 20 of the Agreement, which contain rules on the free movement of goods between the Community and Austria, are drafted in the same manner as Articles 30 and 36 of the Treaty and pursue the same objective, namely the elimination of unjustified trade barriers between the States concerned.

The *Italian Government* maintains that the Agreement between the Community and Austria does not apply in this case. So far as importation into the Community is concerned, the Agreement covers only products originating in Austria. Since the Adelat R was manufactured in France, it cannot be regarded as originating in Austria.

In any event, the Government considers that the provisions referred to in the question, namely Articles 13 and 20 of the Agreement, do not apply. In health matters, the Government submits, it is not Articles 13 and 20 of the Agreement but Article 15(2) which contains the rules applicable to the movement of goods between the Community and Austria. That article reads as follows:

'The Contracting Parties shall apply their agricultural rules in veterinary, health and plant health matters in a non-discriminatory fashion and shall not introduce any new measures that have the effect of unduly obstructing trade.'

The Italian Government also argues that Articles 13 and 20 cannot be interpreted in the same way as the corresponding articles in the Treaty.

On that point, the crux of its argument is concerned not with the obligation of the health authority of a Member State to refer to documents it already holds in order to deal with a request for authorization, but with the obligation assumed by Member States to admit to their markets products which are lawfully manufactured or marketed in another Member State.

That obligation, arising from Articles 30 and 36 of the Treaty, assumes that the States concerned impose the same requirements concerning the production and sale of medicines. Such similarity exists between Member States following the harmonization directives adopted by the Council on the matter, but does not exist between the Community and Austria, since there has been no approximation of their respective legislative provisions. Articles 13 and 20 cannot therefore be interpreted in the same way as the corresponding articles of the Treaty, and the possibility for an importer to refer to information already supplied to the health authority cannot be extended to persons wishing to import a medicine from Austria into the Community.

The *United Kingdom* also contends, as its principal argument, that the Agreement does not apply in this case. In its opinion, the main aim of the Agreement is to facilitate the access of products originating in Austria to the Community market. Since the Adalat R was manufactured in France, it must be regarded as originating not in Austria but in the Community.

In the alternative, should the Court find that the Agreement does apply, the United Kingdom maintains that Articles 13 and 20 cannot be interpreted in the same way as Articles 30 and 36 of the Treaty.

In support of its position, it begins by describing the method used when interpreting provisions in agreements between the Community and non-member countries. In its view, such provisions must be interpreted in the light of the aims of the agreements of which they form part. Therefore, when such agreements pursue aims that differ from those of the Treaty, such provisions cannot be interpreted in the same way as the corresponding articles of the Treaty. Thus, in its judgment in the *Polydor* case, the Court took the view that a national measure which constituted an unjustified obstacle to intra-Community trade might be legitimate in the context of a free-trade agreement with a non-member country, having regard to the difference in aims between the Treaty and the agreement. The Court's position in that case was subsequently confirmed in three judgments, namely in *Chatain*, *Kupferberg I* and *Kupferberg II*, cited above. The same approach was taken by Advocate General Van Gerven in his Opinion in Case 70/87 *Fediol* v *Commission* [1989] ECR 1781.

Having described the method to be used in interpreting Community agreements with non-member countries, the United Kingdom goes on to examine the consequences for the

meaning of Articles 13 and 20 of a comparison between the respective aims of the Agreement and the Treaty.

It begins by observing that the aim of the Treaty in relation to the free movement of goods is not only to remove obstacles to trade between Member States but also to create a single market within the Community. Such a market presupposes that Member States exchange information on products whose manufacture and marketing are authorized on their territory, and that as part of such cooperation an exporting Member State forwards to an importing Member State the information it needs in order to determine whether the marketing of a particular product should be authorized.

It goes on to maintain that no such obligation of administrative cooperation arises from the free-trade Agreement between the Community and Austria.

It advances three arguments in support of that proposition.

First, neither when the Agreement was concluded nor during its implementation did the Community and Austria intend to assume an obligation to cooperate for administrative purposes.

Secondly, if an obligation to cooperate were to be inferred from the Agreement between the Community and Austria, it would also have to be inferred from all the agreements whereby the Community gave undertakings to certain countries to eliminate obstacles to the entry of their products onto Community territory. In the present case, that would mean the member states of the European Free Trade Association ('EFTA') with whom the Community had concluded reciprocal free-trade agreements, but it would also apply to the African, Caribbean and Pacific ('ACP') countries in relation to whom the Community had undertaken to remove obstacles on a non-reciprocal basis. In the United Kingdom's submission, the Community obviously did not intend, when concluding all those agreements, to impose an obligation on Member States to cooperate for administrative purposes with all the signatory States.

Thirdly, whilst the agreements concluded by the EFTA countries amongst themselves envisage the elimination of obstacles to trade, they do not impose an obligation to cooperate for administrative purposes. It would be paradoxical if the obligations arising under those agreements were less extensive than those under the Agreement between the Community and Austria.

Finally, the United Kingdom notes that if Eurim-Pharm bought the Adalat R in Austria rather than in France, where it was manufactured, that is because it was less expensive there.

It makes two points in that respect.

First, Eurim-Pharm should not be allowed to obtain its supplies in a non-member country in order to benefit from lower prices there, while at the same time taking advantage of derogations granted to certain economic operators in trade between Member States.

Secondly, to allow the importer of a medicine to refer to information already supplied by another economic operator might be against the interests of non-member countries like Austria, where those products are purchased for subsequent re-importation into the Community. In the view of the United Kingdom, the manufacturer or distributor would probably attempt to put an end to those parallel imports by raising the price of the product in those countries, thereby risking a rise in pharmaceutical prices there.

The *Commission* considers that the scope of the *De Peijper* judgment, cited by Eurim-Pharm, should be restricted to trade between Member States, and that reference to documents which the authority of the importing State already has at its disposal should not be permitted if the imported medicine originates in a non-member country.

It puts forward two arguments in support of that view.

First, such a facility can be granted only if the State of origin is obliged to communicate the information it has about the medicine to the importing State and, furthermore, those two States have similar legislation on the manufacture and marketing of medicines.

The Commission points out that, in its *Polydor* judgment, the Court considered that provisions in free-trade agreements on the free movement of goods could not be interpreted in the same way as the corresponding articles of the Treaty since, unlike the Treaty, such agreements did not imply the progressive harmonization of legislation between the signatory States.

Secondly, the Commission argues that no dispensation should be granted from supplying documents on the importation into the Community of a medicine originating in Austria without a guarantee that similar dispensation would be granted in Austria to importers of Community products. In that regard, the Commission lays emphasis on the equality of conditions of competition which the free-trade Agreement seeks to establish in commercial relations between Austria and the Community.

III — Answers to the question put by the Court

The Court asked Eurim-Pharm, the United Kingdom and the Commission whether Adalat R, which was manufactured in the Community, could be regarded as a product originating in Austria, which is a condition for the Agreement to be applicable in the present case.

In reply to the question, Eurim-Pharm stated that the Adalat R was manufactured in Germany, but did not give its opinion as to the applicability of the Agreement to the present case.

Amplifying its written observations, the United Kingdom took the view that the Agreement could not apply, since the Adalat R was manufactured in the Community, then exported to Austria in order to be reimported into the Community. It justified its position by referring to the aim of the Agreement, namely to facilitate exports from the signatory parties and thereby develop their economies. That aim implied that, in order to benefit from the free-trade regime provided for by the Agreement, the product had to undergo some processing in the exporting country. That requirement was not satisfied in the present case, since the Adalat R had not undergone any processing in Austria.

The Commission, for its part, states that under Article 2 of Protocol No 3 to the Agreement, the latter applies to goods originating in the Community which are exported to Austria, do not undergo any working or processing there, and are then reimported into the Community.

R. Joliet
Judge-Rapporteur