JUDGMENT OF THE COURT (Fifth Chamber)
1 July 1993 *

In Case C-207/91,

REFERENCE to the Court under Article 177 of the EEC Treaty by the Verwaltungsgericht (Administrative Court), Berlin, for a preliminary ruling in the proceedings pending before that court between

Eurim-Pharm GmbH

and

Bundesgesundheitsamt

on the interpretation of Articles 13 and 20 of the Agreement between the European Economic Community and the Republic of Austria, concluded and approved on behalf of the Community by Council Regulation (EEC) No 2836/72 of 19 December 1972 (OJ, English Special Edition 1972 (31 December), p. 4),

THE COURT (Fifth Chamber),

composed of: G. C. Rodríguez Iglesias, President of the Chamber, M. Zuleeg, R. Joliet, J. C. Moitinho de Almeida and F. Grévisse, Judges,

Advocate General: G. Tesauro,
Registrar: L. Hewlett, Administrator,

after considering the written observations submitted on behalf of:

— Eurim-Pharm GmbH, by W. A. Rehmann, of the Munich Bar,

* Language of the case: German.

— the Italian Government, represented by L. Ferrari Bravo, Head of the Legal Affairs Department at the Ministry of Foreign Affairs, acting as Agent, assisted by I. Braguglia, Avvocato dello Stato,

— the United Kingdom, by S. L. Hudson, of the Treasury Solicitor's Department, acting as Agent, and by N. Paines, Barrister,

— the Commission, by J. Sack, Legal Adviser, acting as Agent,

having regard to the Report for the Hearing,

after hearing the oral observations of Eurim-Pharm, the United Kingdom and Italian Governments, and of the Commission at the hearing on 11 November 1992,

after hearing the Opinion of the Advocate General at the sitting on 18 February 1993,

gives the following

Judgment

1 By order of 14 June 1991, lodged at the Court on 1 August 1991, the Verwaltungsgericht Berlin referred for a preliminary ruling, pursuant to Article 177 of the EEC Treaty, a question on the interpretation of Articles 13 and 20 of the Agreement between the European Economic Community and the Republic of Austria, concluded and approved on behalf of the Community by Council Regulation (EEC) No 2836/72 of 19 December 1972 (OJ, English Special Edition 1972 (31 December), p. 4; 'the Agreement').

2 The question had arisen in proceedings between Eurim-Pharm, a company registered in the Federal Republic of Germany, and the Bundesgesundheitsamt (Federal Health Authority), concerning the authority's refusal to authorize the placing into circulation on the domestic market of 'Adalat R', a medicine which is used against hypertension and pectoral angina.

3 Under Paragraphs 21 and 73(1) of the Gesetz über den Verkehr mit Arzneimitteln ('Law on Medicines') of 24 August 1976, medicines may be marketed in Germany only with the authorization of the Bundesgesundheitsamt. Under Article 22 of that Law, the granting of authorization is subject to the production of documents establishing the qualitative and quantitative composition of the product, the manufacturing process used, the means and duration of storage, the quality control methods, its therapeutic qualities and, finally, the results of analytical, pharmacotoxicological and clinical examination. Under Paragraph 24a, where a medicine has already been the subject of a decision granting authorization, the applicant may refer, as regards the information concerning the manufacturing process, means of storage and quality control methods, to documents lodged by a previous applicant. However, Paragraph 73(1) provides that that simplified authorization procedure does not apply to imports of medicines.

4 Adalat R is manufactured in Germany by Bayer AG Leverkusen ('Bayer AG'), which obtained authorization from the Bundesgesundheitsamt to market it in that country. Bayer AG also exports the medicine to Austria, where it is distributed by Bayer Pharma-Wien.

5 In 1985 Eurim-Pharm sought to buy Adalat R on the Austrian market in order to resell it in Germany. In accordance with the Law on Medicines, it requested the necessary authorization from the Bundesgesundheitsamt. It did not intend to repackage the medicine, but merely to affix on the packaging a label referring to itself in its capacity as importer and reseller. In support of its application, Eurim-Pharm supplied an analysis establishing that the Adalat R imported from Austria was identical with the Adalat R authorized by the Bundesgesundheitsamt. As regards the information on manufacture, length of storage and quality control methods, Eurim-Pharm referred to the documents supplied by Bayer AG at the time when that company had applied for marketing authorization.

6 The Bundesgesundheitsamt rejected the application on the grounds that the documents submitted by Eurim-Pharm did not establish the method of the product's manufacture, its length of storage and the quality control methods used, and that, since neither the simplified authorization procedure nor the case-law of the Court

concerning parallel imports between Member States was applicable, a 'reference' to the documents submitted by the manufacturer was not sufficient.

7 Eurim-Pharm then lodged an official complaint with the Bundesgesundheitsamt, submitting an expert's report establishing that the qualitative and quantitative composition of the Adalat R marketed in Austria was identical to that of the product marketed in Germany. The company argued that the documents required could be supplied only by the manufacturer, Bayer AG, and that, by virtue of the Agreement between the EEC and Austria, the refusal of the Bundesgesundheitsamt was unjustified, since the missing documents were in the file lodged by Bayer AG in support of its application for authorization. Finally, it argued that the case-law of the Court of Justice on the parallel importation of medicines between Member States was applicable, and referred in particular to the judgment in Case 104/75 *De Peijper* [1976] ECR 613, in which rules which made the grant of marketing authorization to a parallel importer of a medicine subject to the production of documents which had already been supplied to the relevant health authority by the manufacturer were held to constitute a measure having effect equivalent to a quantitative restriction on imports.

8 Following the rejection of its official complaint, Eurim-Pharm brought an action before the Verwaltungsgericht Berlin. That court found first, on the basis of information which it had requested from Bayer AG, that the composition of the Adalat R marketed in Austria was identical with the Adalat R authorized by the Bundesgesundheitsamt. It then found that, for reasons of medicinal safety, the national rules require each economic operator to apply for individual authorization to market a medicine, and that Eurim-Pharm could not obtain such authorization because it had not submitted all the documents required by that legislation. The national court raised the question whether the identical wording of, on the one hand, Articles 13 and 20 of the Agreement and, on the other, Articles 30 and 36 of the EEC Treaty, allowed the interpretation of the Treaty given in *Peijper*, cited above, to be applied to the relevant articles of the Agreement.

9 The Verwaltungsgericht Berlin therefore stayed the proceedings in order to refer 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?'

10 Reference is made to the Report for the Hearing for a fuller account of the facts of the case, the legislation at issue and the written observations submitted to the Court, which are mentioned or discussed hereinafter only in so far as is necessary for the reasoning of the Court.

The applicability of the Agreement

11 The United Kingdom and the Italian Republic argue that the Agreement is inapplicable to products originating in one of the Member States of the Community which, after simply passing through Austrian territory, are reimported into the Community.

12 That argument cannot be accepted.

13 First of all, by virtue of Article 2, the Agreement applies to products 'originating in the Community or Austria'. It cannot be deduced from that provision, or from Article 1 of Protocol No 3 concerning the definition of the concept of 'originating products' and methods of administrative cooperation (OJ, English Special Edition 1972 (31 December), p. 38) that the scope of the Agreement is limited to Community products exported to Austria and, conversely, Austrian products exported to the Community.

14 The applicability of the Agreement to products which are reimported into the Community is confirmed by the second subparagraph of Article 9(3) of Protocol No 3, as amended by Council Regulation (EEC) No 3386/84 of 3 October 1984 (OJ 1984 L 323, p. 1), which provides that EUR.1 certificates are to be issued by the customs authorities of each of the countries concerned where the goods have either been held before their re-exportation in the same state or undergone the working or processing referred to in Article 2 of the Protocol.

15 Finally, that interpretation is consistent with the aim of the Agreement, which, according to Article 1, is to promote the harmonious development of economic relations between the European Economic Community and the Republic of Austria and thus to foster the advance of economic activity between them.

The applicability of Article 15 of the Agreement

16 The Italian Government maintains that, if the Agreement were applicable, it is Article 15(2) thereof that would be relevant. It comprises a provision specific to health matters, which is worded 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.'

17 It follows, in the Italian Government's submission, that, provided they are not discriminatory, national rules apply to parallel imports of medicines.

18 That interpretation cannot be accepted.

19 The above provision must be read in the light of Article 15 as a whole, which provides in paragraph (1):

'The Contracting Parties declare their readiness to foster, so far as their agricultural policies allow, the harmonious development of trade in agricultural products to which the Agreement does not apply.'

20 Article 15 is therefore a provision which specifically and exclusively concerns trade in agricultural products. By contrast, industrial products such as medicines are covered by Articles 13 and 20 of the Agreement; the protection of health is ensured by Article 20, which, like Article 36 of the Treaty, allows derogations from the principle of the prohibition of quantitative restrictions on imports laid down by Article 13 on grounds relating to the protection of life and health of humans.

The interpretation of Articles 13 and 20 of the Agreement

21 The question referred to the Court essentially asks whether, so far as concerns the importation of medicines, Articles 13 and 20 of the Agreement between the European Economic Community and the Republic of Austria, concluded and approved on behalf of the Community by Council Regulation (EEC) No 2836/72 of 19 December 1972, must be interpreted as precluding the health authority of a Member State from making the grant of marketing authorization 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.

22 The United Kingdom and Italian Governments and the Commission recall that, in its judgment in the *Peijper* case, the Court admittedly held that national rules which make the grant of marketing authorization to a parallel importer of a medicine subject to the production of documents which have already been supplied to the competent health authority by the manufacturer of that medicine constitute a measure having equivalent effect to a quantitative restriction on imports which is not justified on grounds relating to protection of the life and health of humans.

They consider, however, that that interpretation cannot be applied in the context of a free-trade agreement, since the latter makes no provision either for harmonization of legislation or for administrative cooperation in the pharmaceutical sector.

23 That argument cannot be accepted.

24 Even on the assumption that the Court's case-law on Articles 30 and 36 of the Treaty cannot be applied to the interpretation of Articles 13 and 20 of the Agreement, it is sufficient to note that, since the German health authority already possessed all the necessary information about the medicine and there was no dispute that the imported medicine and the authorized medicine were identical, the authority had no need to secure cooperation of any kind from the Austrian authorities.

25 In those circumstances, to hold that Articles 13 and 20 of the Agreement do not preclude rules of the kind at issue here would be to deprive those articles of much of their effectiveness.

26 For all those reasons, the answer to the national court's question must be that Articles 13 and 20 of the Agreement between the European Economic Community and the Republic of Austria, concluded and approved on behalf of the Community by Council Regulation (EEC) No 2836/72 of 19 December 1972, are to be interpreted as precluding the health authority of a Member State from making the grant of marketing authorization 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.

Costs

27 The costs incurred by the United Kingdom and Italian Governments and by the Commission of the European Communities, which have submitted observations to the Court, are not recoverable. Since these proceedings are, for the parties to the main action, a step in the proceedings pending before the national court, the decision on costs is a matter for that court.

On those grounds,

THE COURT (Fifth Chamber),

in answer to the question referred to it by the Verwaltungsgericht Berlin by order of 14 June 1991, hereby rules:

Articles 13 and 20 of the Agreement between the European Economic Community and the Republic of Austria, concluded and approved on behalf of the Community by Council Regulation (EEC) No 2836/72 of 19 December 1972, are to be interpreted as precluding the health authority of a Member State from making the grant of marketing authorization 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.

Rodríguez Iglesias Zuleeg

Joliet Moitinho de Almeida Grévisse

Delivered in open court in Luxembourg on 1 July 1993.

J.-G. Giraud G. C. Rodríguez Iglesias

Registrar President of the Fifth Chamber