JUDGMENT OF THE COURT (Fifth Chamber)
10 November 1994 *

In Case C-320/93,

REFERENCE to the Court under Article 177 of the EEC Treaty by the Landgericht Saarbrücken, Germany, for a preliminary ruling in the proceedings pending before that court between

Lucien Ortscheit GmbH

and

Eurim-Pharm Arzneimittel GmbH

on the interpretation of Articles 30 and 36 of the EEC Treaty,

THE COURT (Fifth Chamber),

composed of: G. C. Rodríguez Iglesias, President of the Court acting as President of the Chamber, R. Joliet (Rapporteur), President of the Chamber, and J. C. Moitinho de Almeida, Judge,

* Language of the case: German.

Advocate General: C. Gulmann,
Registrar: H. A. Rühl, Principal Administrator,

after considering the written observations submitted on behalf of:

— Lucien Ortscheit GmbH, by Adalbert Kunschert, Rechtsanwalt, Saarbrücken,

— Eurim-Pharm Arzneimittel GmbH, by Wolfgang A. Rehmann, Rechtsanwalt, Munich,

— the Belgian Government, by Patrick Duray, Assistant Adviser in the Ministry of Foreign Affairs, Foreign Trade and Development Cooperation, acting as Agent,

— the French Government, by Hélène Duchêne, Secretary for Foreign Affairs in the Directorate of Legal Affairs of the Ministry of Foreign Affairs, and Catherine de Salins, Foreign Affairs Adviser in the Directorate of Legal Affairs in that Ministry, acting as Agents,

— the Greek Government, by Ioannis Konstantinos Chalkias, Assistant Legal Adviser in the State Legal Service, and Christina Sitara, Legal Representative in the State Legal Service, acting as Agents,

— the Commission of the European Communities, by Richard Wainwright, Legal Adviser, and Angela Bardenhewer, of its Legal Service, acting as Agents,

having regard to the Report for the Hearing,

after hearing the oral observations of Lucien Ortscheit GmbH, Eurim-Pharm Arzneimittel GmbH, the Greek Government, represented by C. Sitara and Panagiotis Kamarineas, State Legal Adviser, and the Commission at the hearing on 28 April 1994,

after hearing the Opinion of the Advocate General at the sitting on 16 June 1994,

gives the following

Judgment

1 By order of 24 March 1993, received at the Court on 21 June 1993, the Landgericht Saarbrücken (Saarbrücken Regional Court) referred to the Court for a preliminary ruling under Article 177 of the EEC Treaty two questions on the compatibility with Articles 30 and 36 of the EEC Treaty of a rule of national law prohibiting advertising for foreign medicinal products which are not authorized in Germany but which can be imported into that country under certain conditions.

2 Those questions arose in proceedings between two companies importing medicinal products, Lucien Ortscheit GmbH and Eurim-Pharm Arzneimittel GmbH. Lucien Ortscheit seeks an order that Eurim-Pharm cease all advertising for foreign medicinal products not authorized by the German authorities.

3 Under Paragraph 21(1) of the Arzneimittelgesetz (Law on medicinal products, 'the AMG'), medicinal products may not be marketed in the Federal Republic of Ger-

many unless they have been authorized by the competent federal authorities. That rule also applies in principle to imported medicinal products (Paragraph 73(1) of the AMG).

4 However, under Paragraph 73(3) of the AMG, foreign medicinal products which have not been authorized in Germany may be imported if they have been authorized in their country of origin, provided they have been ordered by pharmacies in limited quantities on the basis of a prescription from a doctor, dentist or veterinary surgeon.

5 Article 8(2) of the Heilmittelwerbegesetz (Law on advertising in the health sector, 'the HWG') provides, however, with reference to those medicinal products:

'Advertisements containing an offer to obtain specified medicinal products by individual importation under ... Paragraph 73(3) shall ... be prohibited.'

6 Making use of the opportunity afforded by Paragraph 73(3) of the AMG, Eurim-Pharm imports into Germany medicinal products which have not been authorized by the German authorities. Since April 1992 it has published advertisements in German publications aimed at professionals in the health sector, indicating which non-authorized products it imports and the address from which they can be obtained.

7 On 14 October 1992 Lucien Ortscheit, a competitor of Eurim-Pharm, applied to the Landgericht Saarbrücken for an order that Eurim-Pharm desist from those acts, on the ground that they were prohibited by Paragraph 8(2) of the HWG.

8 The Landgericht Saarbrücken considered that the advertisements published by Eurim-Pharm were advertisements within the meaning of Paragraph 8(2) of the HWG and that the question arose whether that provision was compatible with Community law; it therefore referred to the Court for a preliminary ruling two questions on the interpretation of Articles 30 and 36 of the Treaty:

'1. Is the national prohibition of advertising for medicinal products which despite the requirement of authorization are not authorized in Germany, but may lawfully be imported from another Member State of the European Communities in response to an individual order if they have already been lawfully put into circulation in that Member State, a measure having equivalent effect to a quantitative restriction within the meaning of Article 30 of the EEC Treaty?

2. If the prohibition of advertising described above is a measure having equivalent effect within the meaning of Article 30 of the EEC Treaty, in what circumstances can it be permitted by way of exception under Article 36 of the EEC Treaty for the protection of health and life of humans?'

The first question (Article 30 of the Treaty)

9 It must be observed first that the prohibition of advertising under Paragraph 8(2) of the HWG applies solely to foreign medicinal products. Since it thus does not have the same effect on the marketing of medicinal products from other Member

States as on the marketing of national medicinal products, it must fall within the scope of Article 30 of the Treaty (see the judgment in Joined Cases C-267/91 and C-268/91 *Keck and Mithouard* [1993] ECR I-6097, paragraph 16).

10 Secondly, the prohibition of advertising at issue may restrict the volume of imports of medicinal products not authorized in Germany, since it deprives pharmacists and doctors, whose participation is essential for the import of those medicinal products under Paragraph 73(3) of the AMG, of a source of information on the existence and availability of such products.

11 A provision such as that in Paragraph 8(2) of the HWG is therefore a measure having equivalent effect to a quantitative restriction within the meaning of Article 30 of the Treaty.

12 The answer to the first question must therefore be that the national prohibition of advertising for medicinal products which despite the general requirement of authorization are not authorized in a country, but may be imported from another Member State of the European Communities in response to an individual order if they have already been lawfully put into circulation in that Member State, is a measure having equivalent effect to a quantitative restriction within the meaning of Article 30 of the Treaty.

The second question (Article 36 of the Treaty)

13 By its second question the national court asks essentially whether the prohibition of advertising at issue is justified under Article 36 of the Treaty on grounds relating to the protection of health and life of humans.

14 It must be observed that Article 36 of the Treaty remains applicable as regards the manufacture and marketing of proprietary medicinal products as long as harmonization of national rules has not been fully achieved in that field (see the judgments in Case 215/87 *Schumacher* [1989] ECR 617, paragraph 15; Case C-369/88 *Delattre* [1991] ECR I-1487, paragraph 48; Case C-347/89 *Eurim-Pharm* [1991] ECR I-1747, paragraph 26; Case C-62/90 *Commission* v *Germany* [1992] ECR I-2575, paragraph 10; and Case C-317/92 *Commission* v *Germany* [1994] ECR I-2039, paragraph 14).

15 It must be emphasized that Council Directive 92/28/EEC of 31 March 1992 on the advertising of medicinal products for human use (OJ 1992 L 113, p. 13), which *inter alia* imposes on the Member States an obligation to subject the advertising of medicinal products to health professionals to strict conditions and effective monitoring (see the sixth recital in the preamble and Articles 6 to 14), does not apply to the main proceedings. The events giving rise to those proceedings occurred in the period from April to October 1992, whereas in accordance with Article 15(1) the directive was to be transposed by the Member States by 1 January 1993 at the latest.

16 That being so, it should be noted that it is also settled law that the health and life of humans rank foremost among the property or interests protected by Article 36 of the Treaty and that it is for the Member States, within the limits imposed by the Treaty, to decide what degree of protection they intend to ensure.

17 However, national rules or practices having, or likely to have, a restrictive effect on the importation of pharmaceutical products are compatible with the Treaty only to the extent that they are necessary for the effective protection of health and life of humans. A national rule or practice cannot benefit from the derogation provided for in Article 36 if the health and life of humans may be protected just as effectively by measures which are less restrictive of intra-Community trade (see the judgments, cited above, in Case C-62/90 *Commission* v *Germany*, paragraphs 10 and 11; *Schumacher*, paragraphs 17 and 18; *Delattre*, paragraph 53; and *Eurim-Pharm*, paragraph 27).

18 In this case it must be noted that Member States are entitled, at the present stage of harmonization and in the absence of a procedure for Community authorization or mutual recognition of national authorizations, to prohibit entirely the marketing in their territory of medicinal products which have not been authorized by the competent national authorities. Under Article 3 of Council Directive 65/65/EEC of 26 January 1965 on the approximation of provisions laid down by law, regulation or administrative action relating to proprietary medicinal products (OJ, English Special Edition 1965-1966, p. 20), as amended by Council Directive 89/341/EEC of 3 May 1989 (OJ 1989 L 142, p. 11), 'no proprietary medicinal product may be placed on the market in a Member State unless an authorization has been issued by the competent authority of that Member State'.

19 As the Advocate General has rightly stated in paragraph 23 of his Opinion, the prohibition of advertising in Paragraph 8(2) of the HWG has the purpose of ensuring that the individual importation of medicinal products which have not been authorized remains an exception, in order to prevent the general requirement of national authorization under German law from being systematically circumvented. If medicinal products which were not authorized in Germany could be advertised there, there would be a danger that manufacturers would obtain authorization for their medicinal products in a Member State imposing fewer requirements and then import them into Germany on the basis of individual orders which they would have encouraged by advertising campaigns.

20 The prohibition of advertising imposed by Paragraph 8(2) of the HWG is therefore necessary for the effectiveness of the national authorization scheme. Consequently, it is justified on public health grounds under Article 36 of the Treaty.

21 The answer to the second question must therefore be that the prohibition of advertising at issue is justified under Article 36 of the Treaty on grounds pertaining to the protection of the health and life of humans.

Costs

22 The costs incurred by the Belgian, French and Greek 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 proceedings, a step in the action 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 questions referred to it by the Landgericht Saarbrücken by order of 24 March 1993, hereby rules:

1. **The national prohibition of advertising for medicinal products which despite the general requirement of authorization are not authorized in a country, but may be imported from another Member State of the European Communities in response to an individual order if they have been lawfully put into circulation in that Member State, is a measure having equivalent effect to a quantitative restriction within the meaning of Article 30 of the EEC Treaty.**

2. **That prohibition of advertising is justified however under Article 36 of the EEC Treaty on grounds pertaining to the protection of the health and life of humans.**

Rodríguez Iglesias Joliet Moitinho de Almeida

Delivered in open court in Luxembourg on 10 November 1994.

R. Grass
Registrar

G. C. Rodríguez Iglesias
President, acting as
President of the Fifth Chamber