JUDGMENT OF THE COURT (Sixth Chamber)
1 April 2004 *

In Case C-112/02,

REFERENCE to the Court under Article 234 EC by the Oberverwaltungsgericht für das Land Nordrhein-Westfalen (Germany) for a preliminary ruling in the proceedings pending before that court between

Kohlpharma GmbH

and

Bundesrepublik Deutschland,

on the interpretation of Community law, in particular Articles 28 EC and 30 EC,

* Language of the case: German.

THE COURT (Sixth Chamber),

composed of: C. Gulmann (Rapporteur), acting for the President of the Sixth Chamber, J.N. Cunha Rodrigues, J.-P. Puissochet, R. Schintgen and F. Macken, Judges,

Advocate General: A. Tizzano,
Registrar: H.A. Rühl, Principal Administrator,

after considering the written observations submitted on behalf of:

— Kohlpharma GmbH, by W.A. Rehmann, Rechtsanwalt,

— the Commission of the European Communities, by H. Støvlbæk and S. Fries, acting as Agents,

having regard to the Report for the Hearing,

after hearing the oral observations of Kohlpharma GmbH, represented by W.A. Rehmann; of the Bundesinstitut für Arzneimittel und Medizinprodukte, repre-

sented by M. Wagner and A. von Hagen, acting as Agents; and of the Commission, represented by H. Støvlbæk and S. Fries, at the hearing on 13 March 2003,

after hearing the Opinion of the Advocate General at the sitting on 11 September 2003,

gives the following

Judgment

1 By order of 14 March 2002, received at the Court on 27 March 2002, the Oberverwaltungsgericht für das Land Nordrhein-Westfalen (Higher Administrative Court of North Rhine-Westphalia) referred to the Court for a preliminary ruling under Article 234 EC a question on the interpretation of Community law, in particular Articles 28 EC and 30 EC.

2 That question has arisen in proceedings between Kohlpharma GmbH ('Kohlpharma') and the Federal Republic of Germany concerning marketing authorisation for a medicinal product imported from Italy.

Main proceedings

3 The company Chiesi Farmaceutici SpA (hereinafter 'Chiesi') produces and markets the medicinal product Jumex in Italy under a marketing authorisation which it was granted in that country. That medicinal product is manufactured from the active ingredient selegiline hydrochloride. The company Orion Pharma GmbH (hereinafter 'Orion') produces and markets the medicinal product Movergan in Germany under a marketing authorisation issued to it in that country. Movergan is manufactured using the same active ingredient as that in Jumex.

4 TTheThe active ingredient used by Chiesi and Orion is supplied by the undertaking Chinoin Pharmaceutical and Chemical Works Co. Ltd (hereinafter 'Chinoin'), established in Hungary. While Chiesi has a licensing agreement with Chinoin, Orion receives its supplies, either directly or through Finland, under a supply agreement between Chinoin and Orion Corp. Finland.

5 Kohlpharma applied to the Bundesinstitut für Arzneimittel und Medizinprodukte (Federal Institute for Medicinal Products, hereinafter 'the Bundesinstitut') for marketing authorisation for the medicinal product Jumex, for the purpose of importing it into Germany. It referred to the medicinal product Movergan, which is already authorised in Germany, and requested that the marketing authorisation for that medicinal product be extended to Jumex.

6 ThThe Bundesinstitut rejected that application, citing the judgment in Case C-201/94 *Smith & Nephewand Primecrown* [1996] ECR I-5819. That judgment,

the Bundesinstitut argued, establishes that the extension to an imported medicinal product of a marketing authorisation already issued to another medicinal product in the State of importation is subject to the condition that the two medicinal products have a common origin, that is, that their manufacturers are part of the same group of undertakings or, at the very least, that they produce those medicinal products under agreements with the same licensor.

7 Kohlpharma appealed against that rejection decision to the Oberverwaltungsgericht, arguing that the medicinal product to be imported and that already authorised in the Member State of importation could not be required to have a common origin. In the case-law relating to parallel imports, it submitted, the Court did not establish the condition of identity of origin as a binding principle but merely took it into account, since the conditions of identity of products and of origin were in fact both satisfied in the cases which had been referred to it for a preliminary ruling.

8 In those circumstances, the Oberverwaltungsgericht für das Land Nordrhein-Westfalen decided, by order of 14 March 2002, to stay proceedings and to refer the following question to the Court for a preliminary ruling:

'Is it justified under Article 30 EC or other Community law for the competent German authority to obstruct the parallel import of a medicinal product by refusing marketing authorisation under the simplied procedure, contrary to Article 28 EC, although, on the one hand, it accepts that the medicinal product to be imported (Jumex), authorised for Chiesi Farmaceutici SpA in Italy, is as regards the medically active ingredient (selegiline hydrochloride) identical to the medicinal product (Movergan) produced by the German authorisation holder Orion Pharma GmbH, the medically active ingredient of which is delivered to the Italian firm by

the manufacturer, located in Hungary, on the basis of a licensing agreement, but is delivered to the German firm only on the basis of a supply agreement with Orion Corp. Finland, either directly or via Finland, if, on the other hand, that authority does not demonstrate in detail as regards either the medically active ingredient or the excipients, which it considers to differ in the present case both qualitatively and quantitatively, that the two medicinal products are not identical, and in particular are not manufacturered according to the same forumulation and using the same active ingredient or that they have different therapeutic effects?'

Question referred for a preliminary ruling

9 It must first be pointed out that:

— the main proceedings concern two medicinal products produced in Italy and Germany, respectively, by different manufacturers which obtained marketing authorisations in Italy and Germany, respectively, in accordance with the rules and procedures laid down in Community legisation, namely, at present, Directive 2001/83/EC of the European Parliament and of the Council of 6 November 2001 on the Community code relating to medicinal products for human use (OJ 2001 L 311, p. 67), which states that marketing authorisation will be granted only if, after verification of the particulars and documents relating to the efficacy and safety of the medicinal product at issue, it appears that the product is not harmful in normal conditions of use and that its therapeutic effect has been demonstrated (see Articles 8 to 11 of Directive 2001/83);

— the manufacturer of the medicinal product Jumex has not submitted an application for marketing authorisation in Germany;

— the two medicinal products at issue are manufactured using the same active ingredient supplied by the same undertaking.

10 Next, it must be recalled that:

— in those circumstances, Kohlpharma submitted an application for marketing authorisation for the medicinal product Jumex, which it wishes to market in Germany, and claimed that the marketing authorisation already granted to the medicinal product Movergan should be extended to the medicinal product Jumex, inasmuch as those two medicinal products are in its view essentially identical;

— the competent authorities refused to grant that application, since they took the view that it was not possible to extend the marketing authorisation for the medicinal product Movergan to the medicinal product Jumex, since the two medicinal products did not have a common origin.

11 In that context, in order to give a useful answer to the question referred for a preliminary ruling, the Court can take as a basis the premiss that, for the purposes of assessing their safety and efficacy, the two medicinal products do not differ significantly.

12 The question referred for a preliminary ruling must therefore be understood as asking essentially whether, if the assessment carried out on the safety and efficacy of the medicinal product which is already authorised can be applied to the second product without any risk to the protection of public health, Articles 28 EC and 30 EC preclude the competent authorities from refusing to grant marketing authorisation to the second medicinal product with reference to the first one solely on the ground that the two medicinal products do not have a common origin.

13 The refusal to issue a marketing authorisation for a medicinal product imported from another Member State, in which that product was issued a marketing authorisation, constitutes a restriction on the free movement of goods between Member States. Such a restriction is contrary to Article 28 EC unless it is warranted by imperative needs, in particular the protection of public health.

14 It is for the competent national authorities, before they issue a marketing authorisation, to ensure that the primary objective of the Community legislation, namely the safeguarding of public health, is fully complied with. Nevertheless, the principle of proportionality requires that, in order to protect the free movement of goods, the legislation in question be applied within the limit of what is necessary in order to achieve the aim of protecting health that is legitimately being pursued (see, to that effect, Case C-172/00 *Ferring* [2002] ECR I-6891, paragraph 34).

15 Once it has been established that the safety and efficacy assessment carried out for the medicinal product which is already authorised can, without any risk to the protection of public health, be used in respect of the medicinal product for which marketing authorisation is sought, the restriction on the free movement of goods

between Member States which results from the refusal to issue a marketing authorisation to the second medicinal product cannot be justified on grounds of protecting public health if that refusal is based solely on the fact that the two medicinal products do not have the same origin.

16 In a situation such as that in the main proceedings, the problem confronting the competent authorities as regards marketing authorisations for medicinal products is whether, as is claimed by the applicant for a marketing authorisation, the safety and efficacy assessment carried out for the medicinal product which has already been authorised can indeed be applied to the application for a marketing authorisation for the second medicinal product without any risk to the protection of public health.

17 In that regard, a common origin of the two medicinal products may constitute an important element in establishing that such is the case.

18 Nevertheless, the absence of a common origin for the two medicinal products does not in itself constitute a ground for refusing a marketing autorisation to the second medicinal product.

19 In circumstances such as those in the main proceedings, which are characterised by the fact that an active ingredient is sold to two different manufacturers established in two Member States, the applicant for marketing authorisation for

the second medicinal product may, for the purpose of assessing its safety and efficacy, demonstrate by means of available or accessible information that the medicinal product to be imported does not differ significantly from the medicinal product which is already authorised.

20 When, in particular in the case of an importer, the applicant does not have access to all the necessary information but provides data that make it at least plausible that the two medicinal products do not differ significantly for the purpose of assessing their safety and efficacy, the competent authorities must act in such a way that their decision as to whether to extend to the second medicinal product the marketing authorisation granted to the first one is taken on the basis of the fullest information possible, including information which is available to them or which they could have obtained through cooperation with the health authorities in other Member States.

21 The answer to the question must therefore be that, in the case where

— an application for a marketing authorisation for a medicinal product is submitted with reference to a medicinal product that has already been authorised,

— the medicinal product which is the subject of the application is imported from a Member State in which it has obtained a marketing authorisation,

— the thethe assessment of safety and efficacy carried out for the medicinal product which is already authorised can be used in the application for a marketing authorisation for the second medicinal product without any risk to public health,

Articles 28 EC et 30 EC preclude the applithe application being rejected solely on the ground that the two medicinal products do not have a common origin.

Costs

22 The costs incurred by the Commission, which has submitted observations to the Court, are not recoverable. Since these proceedings are, for the parties to the main proceedings, 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 (Sixth Chamber),

in answer to the question referred to it by the Oberverwaltungsgericht für das Land Nordrhein-Westfalen by order of 14 March 2002, hereby rules:

In the case where

— an application for a marketing authorisation for a medicinal product is submitted with reference to a medicinal product that has already been authorised,

— the medicinal product which is the subject of the application is imported from a Member State in which it has obtained a marketing authorisation,

— the assessment of safety and efficacy carried out for the medicinal product which is already authorised can be used in the application for a marketing

authorisation for the second medicinal product without any risk to public health,

Gulmann Cunha Rodrigues Puissochet

Schintgen Macken

Delivered in open court in Luxembourg on 1 April 2004.

R. Grass V. Skouris

Registrar President