JUDGMENT OF THE COURT (Sixth Chamber)
10 September 2002 *

In Case C-172/00,

REFERENCE to the Court under Article 234 EC by the Landgericht Köln (Germany) for a preliminary ruling in the proceedings pending before that court between

Ferring Arzneimittel GmbH

and

Eurim-Pharm Arzneimittel GmbH,

on the interpretation of Article 28 EC and Article 30 EC,

* Language of the case: German.

THE COURT (Sixth Chamber),

composed of: F. Macken, President of the Chamber, C. Gulmann (Rapporteur), J.-P. Puissochet, V. Skouris and J.N. Cunha Rodrigues, Judges,

Advocate General: L.A. Geelhoed,
Registrar: L. Hewlett, Administrator,

after considering the written observations submitted on behalf of:

— Ferring Arzneimittel GmbH, by G. Hess, Rechtsanwältin,

— Eurim-Pharm Arzneimittel GmbH, by M. Epping, Rechtsanwältin,

— the Commission of the European Communities, by J.C. Schieferer, acting as Agent,

having regard to the Report for the Hearing,

after hearing the oral observations of Ferring Arzneimittel GmbH, represented by G. Hess, Eurim-Pharm Arzneimittel GmbH, represented by W.A. Rehmann,

Rechtsanwalt, the Swedish Government, represented by A. Kruse, acting as Agent, and the Commission, represented by J.C. Schieferer, at the hearing on 22 November 2001,

after hearing the Opinion of the Advocate General at the sitting on 7 February 2002,

gives the following

Judgment

1 By order of 14 April 2000, received at the Court on 10 May 2000, the Landgericht Köln (Regional Court, Cologne) referred to the Court for a preliminary ruling under Article 234 EC four questions on the interpretation of Article 28 EC and Article 30 EC.

2 Those questions were raised in proceedings between Ferring Arzneimittel GmbH ('Ferring') and Eurim-Pharm Arzneimittel GmbH ('Eurim-Pharm') concerning the parallel import into Germany by Eurim-Pharm of a medicinal product manufactured by Ferring.

Legal framework

Community law

3 Under Article 28 EC quantitative restrictions on imports and all measures having equivalent effect are prohibited between Member States. However, according to Article 30 EC prohibitions or restrictions on import which are justified on the ground, *inter alia*, of the protection of health of humans are authorised so long as they do not constitute a means of arbitrary discrimination or a disguised restriction on trade between Member States.

4 According to the first paragraph of Article 3 of Directive 65/65/EEC of the Council 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 (I), p. 17), as amended by Council Directive 93/39/EEC of 14 June 1993 (OJ 1993 L 214, p. 22, 'Directive 65/65'), no medicinal product may be placed on the market in a Member State unless a marketing authorisation has been issued by the competent authority of that Member State.

5 Article 4 of Directive 65/65 defines in detail the procedure, documents and information necessary for the issue of a marketing authorisation.

6 Article 5 of Directive 65/65 states that the marketing authorisation is to be refused if after verification of the particulars and documents listed in Article 4 it appears that the medicinal product is harmful in the normal conditions of use, or that its therapeutic efficacy is lacking or is insufficiently substantiated by the applicant, or that its qualitative and quantitative composition is not as declared.

7 According to Article 29a of the Second Council Directive 75/319/EEC of 20 May 1975 on the approximation of provisions laid down by law, regulation or administrative action relating to proprietary medicinal products (OJ 1975 L 147, p. 13), as amended by Directive 93/39, the Member States are to set up a pharmacovigilance system which, amongst other things, imposes obligations on the holder of a marketing authorisation relating to the registration and notification of all adverse reactions to those medicinal products on humans. To that end reports must be submitted to the competent authorities at regular intervals and must be accompanied by a scientific evaluation.

National law

8 Under Paragraph 105 of the Arzneimittelgesetz (Law on Medicinal Products of 1976, 'AMG'), the medicinal products which were already on the German market when that law entered into force on 1 January 1978 could be marketed in Germany without an express authorisation, on the basis of an 'implied' authorisation, obtained by means of a declaration made to the competent authority. However, those old medicinal products could remain on the German market only if an appropriate application for an extension of the implied authorisation (hereinafter 'application for renewal') had been submitted at the latest by 30 April 1990.

9 Under Paragraph 31(1)(2) of the AMG a marketing authorisation lapses on written notice of waiver. Under subparagraph 4 of that provision, in its original

version, the medicinal product concerned could still, notwithstanding such waiver, be sold for a period of two years to allow stocks to be cleared. That rule also applied to medicinal products benefiting from an implied authorisation. The eighth law amending the AMG removed, with effect from 11 September 1998, the possibility of benefiting from a two-year clearance period in the case of waiver of an implied authorisation. On the other hand, under Paragraph 105(5)(c) of the AMG it was possible to postpone the lapse of the implied authorisation until 31 December 2004 by withdrawing the application for its renewal.

10 According to a communication from the Bundesinstitut für Arzneimittel und Medizinprodukte (Federal Institute of Medicines and Medicinal Products) of 17 April 1996, on the authorisation of medicinal products which are the subject of parallel imports, parallel importers are entitled, merely by giving notice to the competent authority, to place on the market medicinal products which were already on the market under an implied authorisation, by indicating the relevant reference number ('parallel import licence'). When the importer holds such a licence, there is no formal identity check between imported medicinal products and those on the German market.

11 According to that communication, in the case of an application for renewal submitted by the holder of an implied authorisation the administrative practice is to continue to allow parallel imports, as long as they are consistent with the medicinal product of reference, until the renewal procedure is completed.

The main proceedings and the questions referred for a preliminary ruling

12 Ferring marketed in Germany, under reference number 10545, a medicinal product known as 'Minirin Spray' ('the old version') which is an antidiuretic

consisting of an active substance known as 'Desmopressin' on the basis of an implied authorisation issued under Paragraph 105 of the AMG.

13 Since June 1996, Eurim-Pharm has imported that medicinal product from another Member State and marketed it in Germany under the same reference number, 10545.

14 By letter of 14 July 1999, Ferring waived the implied authorisation, by notification to the Bundesinstitut für Arzneimittel und Medizinprodukte, on the ground that it was now marketing a medicinal product known as 'Minirin Nasenspray 5 ml' ('the new version') under a marketing authorisation obtained in accordance with the new provisions of the AMG on such authorisations. The new version contains different excipients which improve its thermostability at room temperature while the old version had to be kept in a cool place.

15 Subsequently, Ferring brought proceedings against Eurim-Pharm before the Landergericht Köln for an order restraining it from importing and marketing the old version, basing its application on the fact that, since it had waived its marketing authorisation, Eurim-Pharm was marketing that product without authorisation.

16 On 25 October 1999 the Landgericht made an interim order restraining Eurim-Pharm from importing the old version and placing it on the German market under reference number 10545.

17 As regards the merits of the case, the Landgericht held first of all that the two-year clearance period provided by Paragraph 31(4) of the AMG in its original version did not apply to implied authorisations. Next, it pointed out that Community law considerations did not call for the lifting of the prohibition on importation ordered in the interlocutory proceedings, as the possibility of relying on existing marketing authorisations, which arises from the relationship of dependency between product and authorisation, only applies to authorisations which are in force. In the absence of a marketing authorisation the parallel importer has no basis on which to operate. Finally, even a possibility of continuing to market the product on a transitional basis only cannot exist without an authorisation of reference, as the question whether the old and new versions are sufficiently similar from a therapeutic point of view must be examined as a preliminary issue in the proceedings brought by Eurim-Pharm for the grant of a parallel import licence. However, the Landgericht takes the view that it is possible that the Court will reject such an analysis.

18 In those circumstances, the Landgericht Köln stayed proceedings and referred to the Court the following questions for a preliminary ruling:

'1. Do Articles 28 EC and 30 EC preclude national law which prohibits the marketing of medicinal product X,

— for which there existed hitherto in Member State A an implied authorisation which has now lapsed because the licence holder has waived it,

— which hitherto, and for several years, has been brought by way of parallel importation from Member State B into Member State A and has been placed on the market there by reference to the abovementioned implied authorisation,

— which the manufacturer and authorisation holder is replacing with a new preparation Y [which it] is placing on the market in Member State A on the basis of a separate authorisation, and,

— where preparation Y differs from preparation x only in respect of modified excipients, leading to improved temperature stability and thus making storage in the refrigerator unnecessary?

2. Is it of relevance to the judgment if there was available to the holder of the authorisation which has now lapsed a lawful possibility of waiving that authorisation in such a way that the marketability of the medicinal product was preserved for a certain (transitional) period?

   If so, on the basis of what criteria is such a holder required, in his choice of conduct, to take account of the free movement of goods within the Community?

3. Is it of relevance to the judgment if medicinal product Y in the new formulation is placed on the market only in Member State A or if it is also found on the market in other Member States?

4. Is it of relevance to the judgment if, when the two formulations exist side by side simultaneously in Member State A, there is a danger of incorrect storage of medicinal product X?'

The questions referred for a preliminary ruling

Preliminary observations

19 According to the principles laid down in Directive 65/65, no medicinal product may be placed on the market for the first time in a Member State unless a marketing authorisation has been issued in accordance with the directive by the competent authority of that State. Applications for marketing authorisations for a medicinal product submitted by the person responsible for placing it on the market must contain the information and be accompanied by the documents listed in Article 4 of the directive, even where the medicinal product concerned is already the subject of an authorisation issued by the competent authority of another Member State (Case C-94/98 *Rhône-Poulenc Rorer and May & Baker* [1999] ECR I-8789, paragraph 23).

20 However, those principles are subject to exceptions resulting, on the one hand, from the directive itself and, on the other, from the rules of the EC Treaty relating to the free movement of goods.

21 Those rules, as interpreted by the Court, mean in particular that an operator who has bought a medicinal product lawfully marketed in one Member State under a marketing authorisation issued in that State can import that medicinal product into another Member State where he already has a marketing authorisation without having to obtain such an authorisation in accordance with Directive 65/65, and without having to provide information about the verification, prescribed by the directive, of efficacity and non-toxicity of the medicinal product. It is not necessary for the protection of public health to subject parallel importers to such requirements, as the competent authorities of the Member State

of importation already have all the information necessary to carry out that verification (see in particular Case 104/75 *De Peijper* [1976] ECR 613, paragraphs 21 and 36 and Case C-201/94 *Smith & Nephew and Primecrown* [1996] ECR I-5819, paragraph 22).

22 In such a case the parallel import is authorised in the State of importation by reference to the marketing authorisation issued in accordance with Directive 65/65 ('marketing authorisation of reference').

23 It follows from the foregoing that, where the marketing authorisation of reference is withdrawn at the request of its holder and, more particularly, in a situation such as that in point in the main proceedings, the parallel import licence raises a particular problem where:

— the reason for the withdrawal is that the holder of the authorisation has replaced the old version of the medicinal product with a new version, for which he obtained a new marketing authorisation, which differs from the old version only in the excipients it contains and,

— the old version is still lawfully marketed in another Member State under a marketing authorisation which has not been waived by its holder.

24 A similar situation has already been the subject of questions referred to the Court for a preliminary ruling in *Rhône-Poulenc Rorer and May & Baker*, cited above.

However, in that case the point in issue was whether, taking account of the fact that the United Kingdom authorities had accepted that the parallel import licences of an old version of a medicinal product may be annexed to the marketing authorisation issued for the new version, the imports of the old version could be regarded as parallel imports, so that the ordinary authorisation procedure laid down by Directive 65/65 did not apply.

25 By contrast, in the case in the main proceedings the withdrawal of the marketing authorisation of reference means, in accordance with German law as stated by the national court, that it is no longer possible for the parallel importer to continue to import the old version of the medicinal product as the mere fact that the marketing authorisation of reference has been withdrawn entails the automatic withdrawal of the parallel import licence.

26 In order to answer the questions referred for a preliminary ruling, which it is appropriate to examine together, it is important to ascertain whether Articles 28 EC and 30 EC preclude national legislation which provides that the withdrawal of a marketing authorisation for a medicinal product on application by the holder of that authorisation means that the parallel import licence for that product automatically ceases to be valid and whether the matters mentioned in the second, third and fourth questions are relevant in that respect.

Observations submitted to the Court

27 Ferring argues that in consequence of the cancellation of the marketing authorisation which it held for the old version, the legal basis for placing that

product on the market ceased to exist. Eurim-Pharm must therefore apply for a new parallel import licence by reference to the new marketing authorisation. In the course of that procedure the competent authority in the Member State must ascertain whether the old and new versions have different therapeutic effects. Until that authority reaches a decision, the old version cannot be marketed.

28 Next, Ferring argues that it is not legitimate to oblige it to retain, for the benefit of parallel importers, an implied authorisation or to exercise the option that was available to it to withdraw the application for renewal of that authorisation, which would have the result that the old version could be marketed until 31 December 2004. It claims that it makes good sense to place medicinal products on the market as soon as possible on the basis of new marketing authorisations that are in conformity with Community law.

29 Finally, it emphasises that if the two versions of the medicinal product in question in the main proceedings coexist on the market, the risk of confusion cannot be excluded since the old version may be kept at room temperature notwithstanding that there may be a warning on the product's packaging, aimed at prompting the consumer to keep that product in a cool place.

30 While stressing that justification for cessation of parallel imports on the ground of public health is excluded in the case in the main proceedings, Eurim-Pharm argues that the old version must at the very least be permitted to be marketed for a transitional period. As regards the pharmacovigilance system, it points out that the German authorities have all the information obtained in the course of the various authorisation procedures. In addition, they can contact the authorities in other Member States in which the old version of the medicinal product is still marketed.

31 During the hearing, the Swedish Government argued that the rules governing the marketing of medicinal products cannot be interpreted in a more restrictive manner than is required for the protection of public health. That means that there is no reason to restrict the free movement of a medicinal product which has been the subject of a previous examination by the competent authorities of the Member State of importation and for which a marketing authorisation has been issued, as long as the pharmacovigilance system is maintained.

32 According to the Commission, where a marketing authorisation of reference is withdrawn at the request of its holder the parallel import of a medicinal product identical to that for which the marketing authorisation was issued must be allowed, in accordance with Article 28 EC. The competent authorities of the Member State of importation have the necessary documents and, in particular, those concerning the manufacturing process and the qualitative and quantitative composition of the medicinal product of reference. The withdrawal of the marketing authorisation for that product at the request of the holder is a purely formal act which changes nothing in relation to the medicinal product concerned. The Commission emphasises that a parallel import licence cannot depend on the wishes of the holder of the marketing authorisation for the medicinal product of reference. An arbitrary withdrawal entailing the lapse of the parallel import licence would lead to a compartmentalisation of the market and would be contrary to the proper functioning of the internal market.

Findings of the Court

33 It is common ground that the cessation of the validity of a parallel import licence following the withdrawal of the marketing authorisation of reference constitutes

a restriction on the free movement of goods contrary to Article 28 EC, unless it is justified by reasons relating to the protection of public health, in accordance with the provisions of Article 30 EC.

34 It is for the national authorities responsible for the operation of the legislation governing the production and marketing of medicinal products — legislation which, as is made clear in the first recital of Directive 65/65, has as its primary objective the safeguarding of public health — to ensure that it is fully complied with. Nevertheless, the principle of proportionality, which is the basis of the last sentence of Article 30 EC, requires that the power of the Member States to prohibit imports of products from other Member States be restricted to what is necessary in order to achieve the aims concerning the protection of health that are legitimately pursued (see Case 174/82 *Sandoz* [1983] ECR 2445, paragraph 18). Thus, national legislation or practice cannot benefit from the derogation laid down in Article 30 EC when the health and life of humans can be protected equally effectively by measures less restrictive of intra-Community trade.

35 In a situation such as that in point in the main proceedings in which, at the request of its holder, a marketing authorisation of reference is withdrawn for reasons other than the protection of public health there do not appear, as the Swedish Government and the Commission in particular have pointed out, to be any reasons to justify the automatic cessation of the validity of the parallel import licence.

36 First, it must be observed that the withdrawal of a marketing authorisation of reference does not mean in itself that the quality, efficacity and non-toxicity of the old version is called into question. In that respect it must be noted that that version continues to be lawfully marketed in the Member State of exportation under the marketing authorisation issued in that State.

37 Next, although the competent authorities of the Member State of importation can, and indeed must, adopt the measures necessary for the purpose of verifying the quality, efficacity and non-toxicity of the old version of the medicinal product, it does not appear from the information before the Court that that objective cannot be attained by other measures having a less restrictive effect on the import of medicinal products than the automatic cessation of the validity of the parallel import licence in consequence of the withdrawal of the marketing authorisation of reference.

38 Although adequate monitoring of the old version remains necessary and may in certain cases mean that information is requested from the importer, it must be pointed out that pharmacovigilance satisfying the relevant requirements of Directive 75/319 as amended can ordinarily be guaranteed for medicinal products that are the subject of parallel imports, such as those in question in the main proceedings, through cooperation with the national authorities of the other Member States by means of access to the documents and data produced by the manufacturer or other companies in the same group, relating to the old version in the Member States in which that version is still marketed on the basis of a marketing authorisation still in force (see *Rhône-Poulenc Rorer and May & Baker*, cited above, paragraph 46).

39 Finally, it must also be pointed out that, although it is conceivable that there may be reasons relating to the protection of public health which require that a parallel import licence for medicinal products be necessarily linked to a marketing authorisation of reference, no such reasons emerge from the observations which have been submitted to the Court.

40 In the light of the foregoing considerations, it must be held that national legislation under which the withdrawal of the marketing authorisation of

reference for a medicinal product on application by the holder thereof means that a parallel import licence for that product automatically ceases to be valid does not comply with the requirements resulting from Article 28 EC.

41 In view of that answer, there is no need to examine the second question on the possible importance of the fact that for the holder of the marketing authorisation for the old version of the medicinal product there was, under national law, another possibility, which would enable it to waive that authorisation in such a way that the old version would remain marketable for a transitional period.

42 In relation to the third question, it need merely be observed that nothing has been put before the Court to show that the fact that the new version has been placed on the market of the Member State of importation alone or is also found on the market in other Member States has any relevance to the answer to the first question.

43 As to the fourth question, concerning the fact that two versions of the same medicinal product on the market of the Member State of importation entails the risk of improper conservation of the old version, it must be held that if it can be demonstrated that there is in fact a risk to public health arising from the coexistence of the two versions such a risk may justify restrictions on the importation of the old version.

44 It must be pointed out, however, that the question of the existence and the reality of the risk is a matter which is primarily for the competent authorities of that Member State to determine, and the mere assertion by the holder of the marketing authorisation for the new and old versions that there is such a risk is not sufficient to justify prohibition of the importation of the old version.

45 In that respect, while it is not open to the Court to rule on the question relating to the existence and reality of a risk to public health linked to the coexistence of the two versions of the medicinal product in question on the German market, it is conceivable that the risk mentioned by Ferring may be of such a nature that it cannot be averted satisfactorily by appropriate labelling.

46 The questions referred to the Court must therefore be answered as follows:

— Article 28 EC precludes national legislation under which the withdrawal of the marketing authorisation of reference for a medicinal product on application by the holder thereof means that the parallel import licence for that product automatically ceases to be valid;

— the fact that the new version of the medicinal product has been placed on the market of the Member State of importation alone or is also found on the market in other Member States does not alter the answer to the first question;

— if it is demonstrated that there is in fact a risk to public health arising from the coexistence of two versions of the same medicinal product on the market in a Member State such a risk may justify restrictions on the importation of the old version of the medicinal product in consequence of the withdrawal of the marketing authorisation of reference by the holder thereof in relation to that market.

Costs

47 The costs incurred by the Swedish Government and by the Commission, 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 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 questions referred to it by the Landgericht Köln by order of 14 April 2000, hereby rules:

1. **Article 28 EC precludes national legislation under which the withdrawal of the marketing authorisation of reference for a medicinal product on application by the holder thereof means that the parallel import licence for that product automatically ceases to be valid.**

2. The fact that the new version of the medicinal product has been placed on the market of the Member State of importation alone or is also found on the market in other Member States does not alter the answer to the first question.

3. If it is demonstrated that there is in fact a risk to public health arising from the coexistence of two versions of the same medicinal product on the market in a Member State such a risk may justify restrictions on the importation of the old version of the medicinal product in consequence of the withdrawal of the marketing authorisation of reference by the holder thereof in relation to that market.

Macken Gulmann Puissochet

Skouris Cunha Rodrigues

Delivered in open court in Luxembourg on 10 September 2002.

R. Grass

Registrar

F. Macken

President of the Sixth Chamber