JUDGMENT OF THE COURT (Sixth Chamber)
8 May 2003 *

In Case C-113/01,

REFERENCE to the Court under Article 234 EC by Högsta förvaltningsdomstolen (Finland) for a preliminary ruling in the proceedings pending before that court brought by

Paranova Oy

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

THE COURT (Sixth Chamber),

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

Advocate General: F.G. Jacobs,
Registrar: H.A. Rühl, Principal Administrator,

* Language of the case: Swedish.

after considering the written observations submitted on behalf of:

— the Finnish Government, by E. Bygglin, acting as Agent,

— the Danish Government, by J. Molde, acting as Agent,

— the Netherlands Government, by H.G. Sevenster, acting as Agent,

— the Norwegian Government, by T. Nordby, acting as Agent,

— the Commission of the European Communities, by L. Ström, acting as Agent,

having regard to the Report for the Hearing,

after hearing the oral observations of the Finnish Government, represented by E. Bygglin, of the Danish Government, represented by J. Molde, of the Netherlands Government, represented by J. Bakel, acting as Agent, of the Norwegian Government, represented by T. Nordby, and of the Commission, represented by L. Ström, at the hearing on 10 October 2002,

after hearing the Opinion of the Advocate General at the sitting on 12 December 2002,

gives the following

Judgment

1 By order of 8 March 2001, received at the Court on 14 March 2001, the Högsta förvaltningsdomstolen (Supreme Administrative Court, Finland) referred to the Court for a preliminary ruling under Article 234 EC three questions on the interpretation of Article 28 EC and Article 30 EC.

2 Those questions were raised in proceedings between Paranova Oy ('Paranova') and the Läkemedelsverket (Finnish Medical Products Agency) concerning the consequences of the withdrawal of a marketing authorisation on the parallel import into Finland by Paranova of a medicinal product.

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 between Member States 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 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 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 Chapter Va 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 in 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 Article 101 of the Läkemedelslagen (Finnish Medicinal Products Law No 395/1987), the Läkemedelsverket may prohibit the importation, manufacture, distribution and sale or any other transfer for consumption of a medicinal product if the conditions for a marketing authorisation or for a registration or the requirements or obligations that concern the manufacture or the importation of the medicinal product are no longer fulfilled or if there is reason to believe that such is the case.

9 Under Regulation 1/1997 of the Läkemedelsverket on the parallel importation of medicinal products, parallel imports are possible only of medicinal products which are already covered by a marketing authorisation valid in Finland. Such products must also be covered by a marketing authorisation valid in the country of supply. That country must belong to the European Economic Area. When dealing with an application for the parallel import of a medicinal product, the Läkemedelsverket has to establish that the medicinal products are sufficiently similar to be considered to be identical produts.

10 Under the first subparagraph of paragraph 4.3 of that regulation, authorisation for parallel imports (a 'parallel import licence') is granted for five years. However, the validity of that licence depends on that of the marketing authorisations granted both in Finland and in the country of supply for the directly imported medicinal product and it remains in force only so long as those authorisations themselves remain valid. It is for the parallel importer to ensure

that each consignment imported to Finland is covered by a marketing authorisation valid in that Member State and in the country of supply. If the marketing authorisation expires in the country of supply, the parallel importer must inform the Läkemedelsverket immediately.

The main proceedings and the questions referred

11 Suomen Astra Oy ('Astra') held the marketing authorisation in Finland for the medicinal product known as 'Losec enterokapslar' (Losec enteric capsules, hereinafter the 'capsules' or 'the old version of the product'), while Paranova held a parallel import licence for the capsules. The product is used to treat conditions caused by stomach acid.

12 By letter sent to the Läkemedelsverket on 28 September 1998, Astra sought revocation of the marketing authorisation granted to it for the capsules, explaining that it intended to sell in Finland a new variant of that product called 'Losec MUPS enterotabletter' (Losec MUPS enteric tablets, hereinafter the 'tablets') in place of the capsules. Subsequently, the Läkemedelsverket withdrew the marketing authorisation held by Astra for the capsules with effect from 30 September 1998.

13 The capsules continued to be sold in other Member States, under the marketing authorisations granted in those States.

14 The two versions of Losec are therapeutic equivalents, that is to say that both versions contain the same dose of the active ingredient which is absorbed by the body at the same rate and to the same extent when taken orally.

15 The active ingredient of the capsules contains omeprazole acid. The tablets contain magnesium salt of omeprazole acid. The salt dissolves more easily in water and is more stable. It is thus easier to manufacture tablets than capsules.

16 In a letter sent to Paranova on 8 October 1998, the Läkemedelsverket gave notice that it had withdrawn the marketing authorisation held by Astra for the capsules and that the validity of the licence which Paranova held for the capsules expired on the same date, that is to say, 30 September 1998.

17 On 24 November 1998 the Läkemedelsverket gave notice that the parallel import licence held by Paranova for the capsules was no longer valid, with immediate effect, regardless of any objection by Paranova. In the grounds for the decision the Läkemedelsverket pointed out that the parallel import licence did not meet the conditions set out in Regulation 1/1997, since the validity of the parallel import licence depends on that of the marketing authorisation granted for the medicinal product at issue in Finland and remains in force only as long as that authorisation is itself valid.

18 Paranova appealed against that decision before the Högsta förvaltningsdomstolen, claiming that it is incompatible with Article 28 EC and Article 30 EC. It argued that it became aware of the revocation of the marketing authorisation which Astra held when its own parallel import licence became invalid. It thus did not have the time necessary to adapt its stock and sale contracts concluded before the new situation arose. For parallel importers, securing a supply which is consistent with consumption of the medicinal product constitutes one of the most important commercial criteria.

19 The Läkemedelsverket countered that parallel import licences are granted for five years. However, their validity is limited by that of the marketing authorisation of reference in Finland and in the country of origin of the medicinal product imported as a parallel import. It is thus for the parallel importer to check that each consignment imported is covered by a marketing authorisation in both States. The Läkemedelsverket also contends that the two medicinal products are essentially the same if they have the same qualitative and quantitative composition in terms of active principles, if they have the same pharmaceutical form and, where appropriate, if they are 'bioequivalent'. However, as the capsules and the tablets have different pharmaceutical forms, they cannot constitute the same medicinal product.

20 It is against that background that the Högsta förvaltningsdomstolen decided to stay proceedings and refer the following questions to the Court of Justice for a preliminary ruling:

'1. Is it compatible with Articles 28 EC and 30 EC for a national agency to decide that a marketing authorisation for a medicinal product imported as a parallel import automatically comes to an end if the original marketing authorisation for the medicinal product has been withdrawn at the holder's request for reasons unconnected with the effectiveness or the safety of the medicinal product and despite the fact that the product has a valid marketing authorisation in the Member State from which the parallel imports come?

2. If Community law imposes restrictions or conditions on the right of a national agency to decide that a marketing authorisation for parallel imports comes to an end in the situation referred to in Question 1, what importance should be accorded to the facts that

(a) the holder of the original marketing authorisation has obtained a new marketing authorisation for a medicinal product designed to replace the original medicinal product but that new product is not in the same pharmaceutical form (tablets instead of capsules) and the active

ingredient is not exactly the same (magnesium Omeprazole instead of Omeprazole); on the other hand, the national agency considers that the medicinal products are bioequivalent and that they have the same therapeutic effect;

(b) subsequent control of the effectiveness and safety of the medicinal product is possibly made more difficult by the fact that the marketing authorisation for the original medicinal product has been withdrawn;

(c) the medicinal product imported as a parallel import has been widely used over many years in Member States and it is improbable that its continued sale presents a danger to public health?

3. If, in the situation referred to in Question 1, Articles 28 EC and 30 EC allow it to be found that the marketing authorisation granted for a parallel import has expired, may it be decided that the marketing authorisation for the parallel import expired immediately the original marketing authorisation was withdrawn, without allowing the parallel importer any time to adapt his activity? Do any of the circumstances referred to in Question 2 affect the question whether it may be decided that the marketing authorisation for a parallel import expires immediately?'

The questions referred for a preliminary ruling

21 As a preliminary point it must be observed that:

— the parallel import licence for the capsules (the old version of the medicinal product) was issued by reference to the marketing authorisation granted by the national authorities for that same medicinal product;

— that marketing authorisation was withdrawn at the request of its holder for reasons unconnected with the safety of the product;

— that holder obtained a marketing authorisation for a new variant of that medicinal product, and

— the old version of the medicinal product is still marketed legally in other Member States under marketing authorisations which have not been revoked.

22 In those circumstances, the question arises as to whether Article 28 EC and Article 30 EC preclude national legislation under which the withdrawal, at the request of its holder, of the marketing authorisation granted for the old version of a medicinal product of itself entails the withdrawal of the parallel import licence for that same product.

23 It must be noted at the outset 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 (Case C-172/00 *Ferring* [2002] ECR I-6891, paragraph 33).

24 However, such a restriction may be justified by reasons relating to the protection of public health, in accordance with the provisions of Article 30 EC (*Ferring*, cited above, paragraph 33).

25 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. 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 (*Ferring*, paragraph 34).

26 No reason has been put before the Court to justify why the mere fact that a marketing authorisation of reference was withdrawn at the request of its holder should entail the automatic withdrawal of the parallel import licence issued for the medicinal product in question (see, to that effect, *Ferring*, paragraph 35).

27 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 of the medicinal product 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 (*Ferring*, paragraph 36).

28 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 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 (*Ferring*, paragraph 37).

29 Although adequate monitoring of the old version of the medicinal product 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 (*Ferring*, paragraph 38).

30 In that connection, it must be observed that the 'Note for Guidance on Procedure for Competent Authorities on the Undertaking of Pharmacovigilance Activities' (CPMP/PhVWP/175/95), published in June 1995 by the European Agency for the Evaluation of Medicinal Products, requires, in its paragraph 3.1.4, that the terminologies used to code medicinal products, adverse reactions to them and diseases should ensure compatibility of reports between Member States and in particular ensure that reports entered into a database should be coded according to internationally approved terminologies or with mutually accepted terms allowing connections to be made with such terminologies.

31 Finally, it must also be observed that, while it cannot be ruled out that there are reasons relating to the protection of public health which require a parallel import licence for medicinal products to be linked to a marketing authorisation of reference, no such reasons are apparent from the observations put before the Court.

32 If there are no reasons of a general nature which could explain why the withdrawal of the marketing authorisation of reference should entail that of the parallel import licence, that does not preclude the existence, in specific circumstances, of reasons relating to the protection of public health which could justify the withdrawal of the parallel import licence.

33 As the Court has held, such reasons could arise, for example, where there is in fact a risk to public health arising from the coexistence of two versions of the same medicinal product on the market of the importing Member State (*Ferring*, paragraph 43).

34 In the light of those considerations the answer to the first question should be that Article 28 EC and Article 30 EC preclude national legislation under which the withdrawal, at the request of its holder, of the marketing authorisation of reference of itself entails the withdrawal of the parallel import licence granted for the medicinal product in question. However, those provisions do not preclude restrictions on parallel imports of the medicinal product in question if there is in fact a risk to the health of humans as a result of the continued existence of that medicinal product on the market of the importing Member State.

35 In the light of that reply, there is no need to reply to the second question. Similarly, it is not necessary to consider the third question in which the referring court essentially seeks to know whether the parallel import licence loses its validity immediately on withdrawal of the marketing authorisation of reference.

Costs

36 The costs incurred by the Finnish, Danish, Netherlands and Norwegian Governments 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 action 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 Högsta förvaltningsdomstolen by order of 8 March 2001, hereby rules:

Article 28 EC and Article 30 EC preclude national legislation under which the withdrawal, at the request of its holder, of a marketing authorisation of reference of itself entails the withdrawal of the parallel import licence granted for the medicinal product in question. However, those provisions do not preclude restrictions on parallel imports of the medicinal product in question where there is in fact a risk to the health of humans as a result of the continued existence of that medicinal product on the market of the importing Member State.

Puissochet Gulmann Macken

Colneric Cunha Rodrigues

Delivered in open court in Luxembourg on 8 May 2003.

R. Grass

Registrar

J.-P. Puissochet

President of the Sixth Chamber