JUDGMENT OF THE COURT (Sixth Chamber)

8 May 2003 *

In Case C-15/01,

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

Paranova Läkemedel AB,

Farmagon A/S,

Medartuum AB,

Net Pharma KG AB,

Orifarm AB,

Trans Euro Medical AB,

Cross Pharma AB,

MedImport Scandinavia AB

and

Läkemedelsverket,

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

* Language of the case: Swedish.

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,

after considering the written observations submitted on behalf of:

— Paranova Läkemedel AB, Farmagon A/S, Medartuum AB, Net Pharma KG AB, Orifarm AB, Trans Euro Medical AB, Cross Pharma AB and MedImport Scandinavia AB, by U. Rutgersson Langenius, advokat,

— the Läkemedelsverket, by A. Åslundh-Nilsson and B. Lindström, acting as Agents,

— the Swedish Government, by A. Kruse, 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 Paranova Läkemedel AB, Farmagon A/S, Medartuum AB, Net Pharma KG AB, Orifarm AB, Trans Euro Medical AB, Cross Pharma AB and MedImport Scandinavia AB, represented by C. Bus, advokat, of the Läkemedelsverket and of the Swedish Government, represented by A. Kruse, of the Danish Government, represented by J. Molde, of the Netherlands Government, represented by J. van 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 21 December 2000, received at the Court on 15 January 2001, the Regeringsrätten (Supreme Administrative Court, Sweden) referred to the Court for a preliminary ruling under Article 234 EC two questions on the interpretation of Article 28 EC and Article 30 EC.

2 Those questions were raised in proceedings brought by Paranova Läkemedel AB, Farmagon A/S, Medartuum AB, Net Pharma KG AB, Orifarm AB, Trans Euro Medical AB, Cross Pharma AB and MedImport Scandinavia AB ('Paranova and Others') against the Läkemedelsverket (Swedish Medical Products Agency) concerning the consequences of the withdrawal of a marketing authorisation on the parallel import into Sweden by Paranova and Others 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 The Läkemedelslagen (Swedish Medicinal Products Law) (1992:859), the Läkemedelsförordningen (Medicinal Products Order) (1992:1752) and the regulations drawn up by the Läkemedelsverket (1994:22) contain provisions implementing Directive 65/65.

9 Under the regulations of the Läkemedelsverket a marketing authorisation from that agency is required in the case of parallel imports of medicinal products. The Läkemedelsverket investigates in order to establish whether the directly imported medicinal product and the medicinal product to be imported as a parallel import are the same. The withdrawal or suspension by the Swedish authorities or by those of the country of export of the marketing authorisation for the directly imported medicinal product entails the withdrawal or suspension of the authorisation for the parallel import into Sweden of the medicinal product. However, on application the Läkemedelsverket can authorise the continued validity of that authorisation if the marketing authorisation is withdrawn or suspended for economic reasons and not for reasons relating to the effects or the safety of the medicinal product concerned.

The main proceedings and the questions referred

10 Hässle Läkemedel AB ('Hässle') held the marketing authorisation in Sweden for the medicinal product known as 'Losec enterokapslar' (Losec enteric capsules,

hereinafter the 'capsules' or 'the old version of the product'), while Paranova and Others held marketing authorisations for parallel imports ('parallel import licences') of the capsules. The product is used to treat conditions caused by stomach acid.

11 The Läkemedelsverket decided, at Hässle's request, that the marketing authorisation granted to Hässle ceased to be valid on 1 January 1999. Hässle made its request for withdrawal of the marketing authorisation granted to it for the capsules because it intended to sell in Sweden a new variant of that product called 'Losec MUPS enterotabletter' (Losec MUPS enteric tablets, hereinafter the 'tablets') in place of the capsules.

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

13 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.

14 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.

15 On 1 September 1998 the Läkemedelsverket decided that the parallel import licences granted to Paranova and Others would expire on the same date as the marketing authorisation which Mr Hässle held. On 25 September 1998 the date on which those authorisations expired was, however, postponed until 30 June 1999. The Läkemedelsverket gave as the reason for its decision the fact that the capsules and the tablets had to be considered as two distinct medicinal products, both because the production methods differed and because the active ingredient, that is to say, omeprazole acid, of the capsules, had been replaced by another active ingredient in the tablets, that is to say, magnesium salt of omeprazole acid. It pointed out that if the parallel import licence for the capsules did not expire, that product would be put on the market in Sweden without it being possible to meet the necessary safety requirements.

16 Paranova and Others appealed to the Länsrätten i Uppsala Län (County Administrative Court for Uppsala, Sweden), against the decision of the Läkemedelsverket of 1 September 1998. The Länsrätten upheld that appeal by judgment of 7 December 1998.

17 The Läkemedelsverket appealed against that judgment to the Kammarrätten i Stockholm (Administrative Court of Appeal, Stockholm, Sweden), which, by judgment of 26 February 1999, upheld that appeal, and held that the two medicinal products at issue were not sufficiently similar to be covered by the same marketing authorisation.

18 Paranova and Others have appealed against that judgment to the Regeringsrätten, which, in the order for reference, pointed out that although the application was made in the form of a dispute as to whether a marketing authorisation granted for directly imported tablets can be the basis for a right to sell the capsules imported as parallel imports, it must first be decided whether the fact that the marketing

authorisation held by Hässle for the capsules was withdrawn at its request must automatically entail the withdrawal of the authorisation granted to the parallel importers.

19 It is against that background that the Regeringsrätten referred the following questions to the Court for a preliminary ruling:

'1. Is it compatible with Articles 28 EC and 30 EC to revoke a marketing authorisation for a medicinal product imported as a parallel import on the ground that the marketing authorisation for the directly imported medicinal product has been revoked at the request of the holder of the authorisation for reasons unconnected with the safety of the medicinal product? Does the answer depend on what specific reasons have given rise to that request or on whether the holder of the authorisation or companies belonging to the same group in other Member States continue to sell the medicinal product to which the parallel imports relate on the basis of marketing authorisations granted there?

2. If the parallel importers rely on a new marketing authorisation for a directly imported medicinal product rather than on the old marketing authorisation, is authorisation for the continued marketing of the medicinal product imported as a parallel import precluded by the fact that that medicinal product and the directly imported medicinal product which is covered by the new marketing authorisation are different in the sense that the medicinal product imported as a parallel import is sold in the form of a capsule containing a certain acid (omeprazole) while the directly imported medicinal product is sold in the form of a tablet containing a magnesium salt of the acid?'

The questions referred for a preliminary ruling

20 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.

21 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.

22 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).

23 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).

24 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).

25 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).

26 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 (*Ferring*, paragraph 36).

27 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).

28 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).

29 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.

30 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.

31 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.

32 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).

33 In the light of those considerations the answer to the first part of 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.

34 In the light of that reply, there is no need to reply to the second part of the first question. Similarly, it is not necessary to consider the second question in which the referring court essentially seeks to know whether the parallel import licence can be linked to the new marketing authorisation granted for the tablets.

Costs

35 The costs incurred by the Swedish, 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 Regeringsrätten by order of 21 December 2000, hereby rules:

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.

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