European Court of Justice, 8 May 2003, Paranova

FREE MOVEMENT OF GOODS - PHARMACEUTICAL LAW

The mere fact that a marketing authorisation of reference was withdrawn at the request of its holder should not entail the automatic withdrawal of the parallel import licence issued for the medicinal product in question, unless there is in fact a risk to the health of humans

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.

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European Court of Justice, 8 May 2003
(J.-P. Puissochet, C. Gulmann, F. Macken, N. Colneric and J.N. Cunha Rodrigues)
JUDGMENT OF THE COURT (Sixth Chamber)
8 May 2003 (1)
(Interpretation of Article 28 EC and Article 30 EC - Medicinal products - Withdrawal of parallel import licence in consequence of waiver of the marketing authorisation for the medicinal product of reference)
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,
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 appli-

cant, 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 products.

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.

OPINION OF ADVOCATE GENERAL
JACOBS
delivered on 12 December 2002(1)
Case C-15/01
Paranova Läkemedel AB and Others
v
Läkemedelsverket
and
Case C-113/01
Paranova Oy

1. These cases raise a number of questions concerning the consequences for a parallel importer of medicinal products benefiting from a marketing authorisation in the Member State of import where that authorisation is withdrawn at the request of the company holding it.

2. Case C-15/01 Paranova Läkemedel AB is a reference from the Swedish Regeringsrätten (Supreme Administrative Court); Case C-113/01 Paranova Oy is a reference from the Finnish Högsta Förvaltningsdomstolen (Supreme Administrative Court).

The Community legal context

3. The marketing of medicinal products in the Community was at the material time (2) principally governed by Council Directive 65/65/EEC of 26 January 1965 on the approximation of provisions laid down by law,

regulation or administrative action relating to medicinal products. (3)

4. Article 3 of Directive 65/65 provides that no medicinal product may be placed on the market of a Member State unless a marketing authorisation has been issued by the competent authorities of that Member State or an authorisation has been granted in accordance with Regulation (EEC) No 2309/93. (4)

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

6. It is clear from the case-law of the Court that parallel imports of medicinal products are not covered by Directive 65/65. That case-law was recently summarised by the Court in Ferring(5) as follows:

'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).

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.

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 it 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 efficacy 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).

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').'

7. Although, as appears from the case-law cited above, Member States may not require parallel importers of medicinal products to obtain a full marketing authorisation within the meaning of Directive 65/65, they frequently provide for a simplified authorisation procedure for parallel imports. The Commission recognised that practice in its guidelines (6) published in 1982, subject to limitations designed to ensure that the inevitable restrictions on imports flowing from any monitoring system are justified for the purpose of protecting the health and life of humans pursuant to Article 30 EC. Thus for example the Commission envisages that the parallel importer may be required to supply the competent authorities of the Member State of import with information enabling them to check that the medicinal product to be imported is in fact covered by the marketing authorisation of reference relied on by the parallel importer.

8. In the context of such a system, many Member States - including, it appears from the orders for reference, Sweden and Finland - issue separate authorisations to parallel importers. For convenience, I shall refer to such an authorisation as a 'licence' or 'parallel import licence', as distinct from the 'marketing authorisation' within the meaning of Directive 65/65 for the reference product.

9. Finally, Chapter Va of Council Directive 75/319/EEC (7) requires the Member States to set up a pharmacovigilance system which, among 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.

The proceedings before the national courts

10. Both cases concern the medicinal product Losec. Losec, reportedly the world's largest-selling pharmaceutical, is used to treat and prevent peptic ulcers and reflux oesophagitis (heartburn). It contains omeprazole, a substance called a proton-pump inhibitor which works by blocking a particular mechanism in the stomach called the proton pump which controls acid production, thereby reducing the amount of stomach acid produced.

11. Losec was initially marketed in capsules. Case C-15/01 ('the Swedish case') concerns Sweden, where the marketing authorisation for Losec capsules was held by Hässle Läkemedel AB ('Hässle') whilst Paranova Läkemedel AB and several other pharmaceutical companies ('Paranova AB') held the licence for capsules imported as a parallel import. Case C-113/01 ('the Finnish case') concerns Finland, where the marketing authorisation for Losec capsules was held by Suomen Astra Oy ('Astra') whilst Paranova Oy held the licence for capsules imported as a parallel import. I shall refer to the parallel importers collectively as 'Paranova'.

12. Subsequently Hässle and Astra ('the manufacturers') each gave notice to the relevant national medical products agency (the competent authority for the purpose of Directive 65/65, in each case called the Läkemedelsverket) that it was withdrawing Losec capsules from the market and at the same time surrendering or seeking revocation of the marketing authorisation for those products.

13. The reason for the manufacturers' actions was that they intended to sell a new variant of Losec called Losec MUPS tablets. The capsules however were to continue to be sold in other Member States under authorisations granted there. It appears to be accepted that Losec MUPS tablets and Losec capsules are what are known as therapeutic equivalents - that is to say, they contain the same active ingredient (omeprazole) - and are bioequivalent in that that ingredient is absorbed by the body at the same rate and to the same extent when taken orally. They differ however according to the Läkemedelsverket in pharmaceutical form (capsule as opposed to tablet) and form of the active ingredient (magnesium salt of omeprazole acid as opposed to omeprazole acid).
14. The Läkemedelsverket gave notice to Paranova that the manufacturers' marketing authorisations for the capsules were no longer valid and that as a consequence and in accordance with the relevant national regulations Paranova's parallel import licences were also no longer valid.
15. Paranova sought annulment of the decisions of the Läkemedelsverket on the ground that, inter alia, they were incompatible with Articles 28 and 30 EC. The application was made in the Swedish case to the Länsrätten (County Administrative Court), Uppsala, with an appeal to the Kammarrätten (Administrative Court of Appeal), Stockholm, and thence to the referring court and in the Finnish case directly to the referring court.
16. The Läkemedelsverket is in each case of the view that the fact that there is no marketing authorisation for the capsules in the Member State of importation (Sweden or Finland) means that capsules cannot lawfully be imported by parallel trade from another Member State since in such circumstances it would be unable properly to comply with its duty of pharmacovigilance.
17. The referring courts have accordingly referred the following questions for a preliminary ruling.
18. In the Swedish case:
‘1. Is it compatible with Articles 28 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?’
19. In the Finnish case:
‘1. Is it compatible with Articles 28 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
20.
(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 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 recent case-law of the Court

21. The Court delivered its judgment in Ferring(8) after the orders for reference had been made in the present cases. In that case the Court was asked to rule on the lawfulness of national legislation under which the withdrawal of the marketing authorisation of reference for a medicinal product on application by the holder thereof meant that the parallel import licence for that product automatically ceased to be valid. It was accepted that - as in the present cases - the holder of the

marketing authorisation of reference sought withdrawal of that authorisation not for reasons connected with public health but because it intended to market a new version of the product.
22. The Court started from the premiss that the cessation of the validity of a parallel import licence following the withdrawal of the marketing authorisation of reference constituted a restriction on the free movement of goods contrary to Article 28 EC unless justified by reasons relating to the protection of public health in accordance with Article 30 EC. It stated that the principle of proportionality, which was the basis of the last sentence of Article 30 EC, required that the power of the Member States to prohibit imports of products from other Member States be restricted to what was necessary in order to achieve legitimately pursued aims concerning the protection of health. National legislation or practice could not therefore benefit from the derogation laid down in Article 30 EC when the health and life of humans could be protected equally effectively by measures less restrictive of intra-Community trade. (9)
23. The Court continued by stating that where a marketing authorisation of reference was withdrawn at the request of its holder for reasons other than the protection of public health there did not appear to be any grounds justifying the automatic cessation of the validity of the parallel import licence. First, the withdrawal of a marketing authorisation of reference did not mean in itself that the quality, efficacy and non-toxicity of the old version - which continued to be lawfully marketed in the Member State of exportation under the marketing authorisation issued in that State - was called into question. Second, pharmacovigilance satisfying Directive 75/319 (10) could ordinarily be guaranteed for medicinal products that were the subject of parallel imports 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 was still marketed on the basis of a marketing authorisation still in force. (11)
24. The Court accordingly concluded that national legislation under which the withdrawal of the marketing authorisation of reference for a medicinal product on application by the holder thereof meant that a parallel import licence for that product automatically ceased to be valid did not comply with Article 28 EC. (12)
25. The Court had acknowledged that it was conceivable that there could be reasons relating to the protection of public health which required that a parallel import licence for medicinal products be necessarily linked to a marketing authorisation of reference. In particular, a demonstrated risk to public health arising from the coexistence of two versions of the same medicinal product on the market in a Member State could 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. (13)

Observations of the parties

26. Written observations have been submitted in the Swedish case by Paranova AB, the Danish, Netherlands, Norwegian and Swedish Governments and the Commission and in the Finnish case by the Danish, Finnish, Netherlands and Norwegian Governments and the Commission. Paranova, all the aforementioned governments and the Commission were represented at the hearing, which was common to both cases.
27. The written observations were in all cases submitted before the Court delivered its judgment in Ferring and to that extent, as was acknowledged at the hearing by, in particular, the Danish and Netherlands Governments and the Commission, have in effect been overtaken by events as may be seen below.

The first question referred

28. By their respective first questions, the referring courts in the present cases ask essentially whether it is compatible with Articles 28 and 30 EC for a licence for a medicinal product imported as a parallel import to be revoked on the sole ground that the marketing authorisation of reference has been withdrawn at the holder's request for reasons unconnected with the safety of the product.
29. In my view, that question has now been answered in the negative by the judgment of the Court in Ferring for the reasons summarised above. (14)
30. In the Swedish case the referring court asks in addition whether the answer to that question depends on what specific reasons have given rise to the request by the holder of the marketing authorisation of reference for the withdrawal of that authorisation.
31. As explained above, (15) revocation of the parallel import licence constitutes a restriction on the free movement of goods contrary to Article 28 EC; as such it will be lawful only if it can be justified in accordance with Article 30 EC, which provides that measures may be justified on grounds of, inter alia, ‘the protection of health and life of humans’. The Swedish referring court's question is explicitly based on the premiss that the reasons for the withdrawal of the marketing authorisation of reference are unconnected with the safety of the product. In those circumstances, the answer to the first question cannot therefore depend on what those other reasons - presumably dictated by commercial considerations - may be.
32. The Swedish referring court also asks whether the answer to the first question depends on whether the holder of the marketing authorisation of reference (or companies belonging to the same group) continues to sell the product which is the subject of parallel imports - namely the capsules - in other Member States on the basis of marketing authorisations granted there.
33. It is not entirely clear what has prompted the Swedish referring court to raise that point. In one sense, it seems irrelevant, since the phenomenon of parallel import pre-supposes that the imported product is on the market in at least one Member State other than the State of import; that product will moreover frequently have been placed on the other market by the holder of the marketing authorisation of reference or a company

belonging to the same group. The Swedish court may however be asking whether the situation there described will make the pharmacovigilance duties of the competent authority of the State of import easier to discharge where a parallel import licence survives revocation of the marketing authorisation of reference.

34. The Court stated in Rhône-Poulenc Rorer and May & Baker(16) that with regard to pharmacovigilance it was 'possible to compel the holder of the marketing authorisation in the Member State of importation, who belongs to the group of companies which is in possession of the marketing authorisations for the old version in the other Member States, to supply the necessary information'. It is clear from the context (17) that the Court was responding to the argument that the pharmacovigilance system would not work where a marketing authorisation of reference was revoked since the obligation on the holder of that authorisation to submit information regularly as required by Directive 75/319 would also lapse, so that the competent authorities in the State of import could not be sure that the use of the old product imported in parallel was still safe according to the latest scientific data. The Court must therefore have meant in the passage cited above that it was possible to compel the holder of the marketing authorisation for the new version of the product in the Member State of import, who belongs to the group of companies which is in possession of the marketing authorisations for the old version in the other Member States (including ex hypothesi the State of export), to supply the necessary information relating to the old version.

35. Even where the situation described by the Swedish court does not obtain, however, it will in my view be only in exceptional circumstances that the competent authority of the State of import will be able to rely on difficulty in discharging its pharmacovigilance duties as a justification for withdrawing the parallel import licence. I set out my reasons for that view in paragraphs 39 to 45 below, in the context of the second question referred by the Finnish court which directly raises this issue.

The second question referred in the Finnish case

36. The referring court in the Finnish case also asks in effect whether it is relevant that (a) the holder of the marketing authorisation of reference has obtained a new marketing authorisation for a replacement product which, albeit in a different pharmaceutical form and with a slightly different active ingredient, is regarded as bioequivalent and as having the same therapeutic effect; (b) subsequent control of the effectiveness and safety of the product may be more difficult because the marketing authorisation of reference has been withdrawn; and (c) the imported product has been widely used over many years so that it is unlikely to present a danger to public health.

37. It appears from the order for reference that Paranova Oy raised those points before the referring court in the context of its argument that a prohibition on imports based on health reasons in accordance with Article 30 EC must respect the principle of proportionality. Paranova Oy argued that that assessment must be made with regard to the circumstances of the case in question. It stressed that the fact that the products were, in principle, identical and that they were well known, both to national agencies in charge of evaluation of medicinal products in the European Union and to doctors and patients, had to be taken into account and that Losec capsules, having been available on the world market for some time and being one of the most widely sold medicines, had been used by such a significantly large number of people and for such a significant period of time that national agencies in charge of evaluation of medication in the European Union had been able to develop a very clear opinion of how they worked and their effects.

38. Under (a), the Finnish referring court asks whether it is relevant that the holder of the marketing authorisation of reference has obtained a new marketing authorisation for a replacement product which, albeit in a different pharmaceutical form and with a slightly different active ingredient, is regarded as bioequivalent and as having the same therapeutic effect. In my view, that factor is not relevant given the conclusion of the Court in Ferring, since in any event the competent authority of the Member State of import is not entitled to revoke the parallel import licence unless there is a demonstrated risk to public health.

39. Under (b), the Finnish referring court mentions possible problems with pharmacovigilance. It is concerned in particular that subsequent control of the effectiveness and safety of the product may be more difficult after revocation of the marketing authorisation of reference.

40. The Court made it clear in Ferring that if it can be demonstrated that there is in fact a risk to public health arising from the coexistence on the market of the Member State of import of the two versions of the medicinal product at issue (in the present case, the capsules and the tablets), such a risk may justify restrictions on the importation of the old version. (18) That statement was restricted to the specific alleged health risk referred to in the questions referred in that case. It is however clearly of broader application. If therefore it can be demonstrated that there is in fact a risk to public health arising from the continued marketing of the imported capsules in Finland after withdrawal of the marketing authorisation of reference, restrictions on import may be justified.

41. However, the Court added in Ferring that the question of the existence and the reality of the risk is a matter which is primarily for the competent authorities of the Member State of import 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. (19) The determination by the competent authority of the existence and reality of the risk must in my view be substantiated: the mere assertion by the competent authority concerned that, for example, it would not be possible to carry out the necessary safety checks if parallel imports of the capsules

continued after revocation of the marketing authorisation of reference would not be sufficient if the authority could not demonstrate that that concern was justified.
42. In that context, it is worth repeating the points made by the Court in Ferring. First, it gave weight to the fact that the old version of the medicinal product continued to be lawfully marketed in the Member State of exportation under the marketing authorisation issued in that State. Second, it noted that, although adequate monitoring of the old version remained necessary in the State of import, pharmacovigilance satisfying Directive 75/319 could ordinarily be guaranteed 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 was still marketed on the basis of a marketing authorisation still in force. (20) It may be added that, as discussed above, (21) it is clear from the case-law of the Court that the manufacturer in that situation may be compelled to supply the necessary information. (22)
43. At the time of the events giving rise to the main proceedings in the present cases, (23) Chapter Va of Directive 75/319 (24) as amended in particular by Directive 93/39 (25) imposed a series of obligations concerning pharmacovigilance. In particular, Article 29a required Member States to establish a pharmacovigilance system to be used to collect information useful in the surveillance of medicinal products, with particular reference to adverse reactions in human beings, and to evaluate such information scientifically. Articles 29c and 29d required the person responsible for placing the medicinal product on the market to establish and maintain a system ensuring that information about all suspected adverse reactions reported to the company and to medical representatives was collected and collated at a single point within the Community, to answer fully and promptly any request from the competent authorities for additional information necessary for the evaluation of the benefits and risks of a medicinal product and to record and promptly report to the competent authorities all suspected serious adverse reactions brought to its attention by health care professionals. Article 29f required the Member States to ensure that reports of suspected serious adverse reactions were immediately brought to the attention of the European Agency for the Evaluation of Medicinal Products established by Regulation No 2309/93 (26) ('the Agency').
44. With effect from 30 June 2000, those obligations have been further strengthened by Directive 2000/38, (27) which amended Chapter Va of Directive 75/319. The marketing authorisation holder must now in addition provide to the competent authorities any other information relevant to the evaluation of the benefits and risks of a medicinal product, including appropriate information on post-authorisation safety studies, (28) maintain detailed records of all suspected adverse reactions occurring either in the Community or in a third country (29) and record and promptly report to the competent authority of the Member State in whose territory the incident occurred all suspected serious adverse reactions of which he has or can reasonably be expected to have knowledge. (30) Furthermore, Member States are to ensure that reports of suspected serious adverse reactions that have taken place on their territory are promptly made available to the Agency and the other Member States. (31)
45. The Finnish Government stated at the hearing that reliance on the pharmacovigilance requirements of Directive 75/319 was undermined by the fact that different Member States used different languages: a report of a suspected serious adverse reaction which took place in Greece, for example, would be forwarded to the Finnish competent authority in Greek. I am not however convinced that that is as serious a problem as it may appear at first sight. The 'Note for Guidance on Procedure for Competent Authorities on the Undertaking of Pharmacovigilance Activities'(32) issued by the Agency requires that the terminologies used to code medicinal products, diseases and adverse drug reactions should ensure compatibility of reports between Member States and in particular that reports entered into a database should be coded according to internationally approved terminologies or with mutually accepted terms enabling connections with internationally approved terminologies.
46. In my view the combined effect of the abovementioned pharmacovigilance requirements is such that it would be only in exceptional cases that the competent authority of the Member State into which a medicinal product was imported in circumstances such as those of the present case could prohibit such imports on the ground that it could not ensure pharmacovigilance.
47. Finally, the factor referred to by the Finnish referring court at (c) - namely the history of widespread use of the capsules - is essentially part of the same pharmacovigilance point: although there is no formal requirement that the competent authority of the Member State of import take such a factor into account, it will inevitably mean that the recording and reporting system imposed by the legislation and summarised above (33) is unlikely to be triggered.
48. I accordingly conclude on the Finnish court's second question that, where a marketing authorisation of reference has been withdrawn for reasons unconnected with the safety of the product, restrictions on the continued import of medicinal products previously imported as parallel imports will be justified only if it can be demonstrated that there is in fact a risk to public health arising from the continued marketing of the imported capsules in the Member State of import.

The second question referred in the Swedish case and the third question referred in the Finnish case

49. It is clear from the order for reference in the Swedish case and from the terms of the third question referred in the Finnish case that each of those questions arises only if the first question is answered in the affirmative, namely to the effect that it is compatible with Articles 28 and 30 EC for the parallel import licence to be revoked on the ground that the marketing authorisa-

tion of reference has been withdrawn. Since in the light of the judgment of the Court in Ferring I propose that the first question should be answered in the negative, the second question referred in the Swedish case and the third question referred in the Finnish case do not arise.

Conclusion

50. I am accordingly of the view that the questions referred by the Swedish Regeringsrätten and the Finnish Högsta Förvaltningsdomstolen should be answered as follows:

It is not compatible with Articles 28 and 30 EC for a licence for a medicinal product imported as a parallel import to be revoked on the sole ground that the marketing authorisation of reference has been withdrawn at the holder's request for reasons unconnected with the safety of the product unless there is a demonstrated risk to public health arising from the continued marketing of the imported product after withdrawal of that authorisation.

1: Original language: English

2: - The legislation has with effect from 18 December 2001 been codified and consolidated in 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. However, the relevant provisions have not been amended in their substance.

3: - OJ, English Special Edition 1965-1966, p. 20, as amended in particular by Council Directive 87/21/EEC of 22 December 1986, OJ 1987 L 15, p. 36, Council Directive 89/341/EEC of 3 May 1989, OJ 1989 L 142, p. 11, and Council Directive 93/39/EEC of 14 June 1993, OJ 1993 L 214, p. 22.

4: - Council Regulation (EEC) No 2309/93 of 22 July 1993 laying down Community procedures for the authorisation and supervision of medicinal products for human and veterinary use and establishing a European Agency for the Evaluation of Medicinal Products, OJ 1993 L 214, p. 1. Community-wide marketing authorisations are not at issue in the present cases.

5: - Case C-172/00 Ferring Arzneimittel, judgment delivered on 10 September 2002, paragraphs 19 to 22 of the judgment; see also the extremely helpful discussion of the Community regulation of parallel imports of medicinal products in the Opinion in that case of Advocate General Geelhoed delivered on 7 February 2002.

6: - Commission communication on parallel imports of proprietary medicinal products for which marketing authorisations have already been granted, OJ 1982 C 115, p. 5.

7: - Second Council Directive of 20 May 1975 on the approximation of provisions laid down by law, regulation or administrative action relating to medicinal products, OJ 1975 L 147, p. 13, as amended in particular by Directive 93/39, cited in note 3. Chapter Va of Directive 75/319 was amended with effect from 30 June 2000 by Commission Directive 2000/38/EC of 5 June 2000, OJ 2000 L 139, p. 28.

8: - Cited in note 5.

9: - Paragraphs 33 and 34 of the judgment.

10: - Cited in note 7.

11: - Paragraphs 35 to 38 of the judgment, citing Rhône-Poulenc Rorer and May & Baker, cited in paragraph 6 above, paragraph 46 of the judgment.

12: - Paragraph 40 and operative part of the judgment.

13: - Paragraphs 39, 43 and 46 and operative part of the judgment.

14: - See paragraphs 21 to 23.

15: - See paragraph 21.

16: - Cited in paragraph 6 above, paragraph 46 of the judgment.

17: - See in particular paragraphs 33 and 38 of the judgment.

18: - Paragraph 43 of the judgment.

19: - Paragraph 44 of the judgment.

20: - Paragraphs 36 and 38 of the judgment, citing Rhône-Poulenc Rorer and May & Baker, paragraph 46.

21: - See paragraph 33.

22: - Rhône-Poulenc Rorer and May & Baker, cited in paragraph 6, paragraph 46 of the judgment.

23: - 1998.

24: - Cited in note 7.

25: - Cited in note 3.

26: - Cited in note 4.

27: - Cited in note 7.

28: - Article 29c(d).

29: - Article 29d(1).

30: - Article 29d(2) and (3).

31: - Article 29f(2).

32: - CPMP/PhVWP/175/95 issued in June 1995; see paragraph 3.1.4.

33: - See paragraphs 42 and 43.
