European Court of Justice, 10 September 2002, Ferring

FREE MOVEMENT OF GOODS

Parallel import licence

- **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**

It is common ground that the cessation of the validity of a parallel import licence following the withdrawal of the marketing authorisation of reference constitutes a restriction on the free movement of goods contrary to Article 28 EC, unless it is justified by rea-sons relating to the protection of public health, in accordance with the provisions of Article 30 EC.

- **If it can be demonstrated that there is in fact a risk to public health arising from the coexistence of the two versions such a risk may justify restrictions on the importation of the old version.**

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European Court of Justice, 10 September 2002
(F. Macken, President of the Chamber, C. Gulmann, J.-P. Puissochet, V. Skouris and J.N. Cunha Rodrigues)
JUDGMENT OF THE COURT (Sixth Chamber)
10 September 2002 (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 by the holder of that authorisation)
In Case C-172/00,
REFERENCE to the Court under Article 234 EC by the Landgericht Köln (Germany) for a preliminary ruling in the proceedings pending before that court between
Ferring Arzneimittel GmbH
and
Eurim-Pharm Arzneimittel GmbH,
on the interpretation of Article 28 EC and Article 30 EC,
THE COURT (Sixth Chamber),
composed of: F. Macken, President of the Chamber, C. Gulmann (Rapporteur), J.-P. Puissochet, V. Skouris and J.N. Cunha Rodrigues, Judges,
Advocate General: L.A. Geelhoed,
Registrar: L. Hewlett, Administrator,
after considering the written observations submitted on behalf of:
- Ferring Arzneimittel GmbH, by G. Hess, Rechtsanwältin,
- Eurim-Pharm Arzneimittel GmbH, by M. Epping, Rechtsanwältin,
- the Commission of the European Communities, by J.C. Schieferer, acting as Agent,

having regard to the Report for the Hearing,
after hearing the oral observations of Ferring Arzneimittel GmbH, represented by G. Hess, Eurim-Pharm Arzneimittel GmbH, represented by W.A. Rehmann, Rechtsanwalt, the Swedish Government, represented by A. Kruse, acting as Agent, and the Commission, represented by J.C. Schieferer, at the hearing on 22 November 2001,
after hearing the **Opinion of the Advocate General** at the sitting on 7 February 2002,
gives the following
Judgment
1. By order of 14 April 2000, received at the Court on 10 May 2000, the Landgericht Köln (Regional Court, Cologne) referred to the Court for a preliminary ruling under Article 234 EC four questions on the interpretation of Article 28 EC and Article 30 EC.
2. Those questions were raised in proceedings between Ferring Arzneimittel GmbH ('Ferring') and Eurim-Pharm Arzneimittel GmbH ('Eurim-Pharm') concerning the parallel import into Germany by Eurim-Pharm of a medicinal product manufactured by Ferring.
Legal framework
Community law
3. Under Article 28 EC quantitative restrictions on imports and all measures having equivalent effect are prohibited between Member States. However, according to Article 30 EC prohibitions or restrictions on import which are justified on the ground, inter alia, of the protection of health of humans are authorised so long as they do not constitute a means of arbitrary discrimination or a disguised restriction on trade between Member States.
4. According to the first paragraph of Article 3 of Directive 65/65/EEC of the Council of 26 January 1965 on the approximation of provisions laid down by law, regulation or administrative action relating to proprietary medicinal products (OJ, English Special Edition 1965-1966 (I), p. 17), as amended by Council Directive 93/39/EEC of 14 June 1993 (OJ 1993 L 214, p. 22, 'Directive 65/65'), no medicinal product may be placed on the market in a Member State unless a marketing authorisation has been issued by the competent authority of that Member State.
5. Article 4 of Directive 65/65 defines in detail the procedure, documents and information necessary for the issue of a marketing authorisation.
6. Article 5 of Directive 65/65 states that the marketing authorisation is to be refused if after verification of the particulars and documents listed in Article 4 it appears that the medicinal product is harmful in the normal conditions of use, or that its therapeutic efficacy is lacking or is insufficiently substantiated by the applicant, or that its qualitative and quantitative composition is not as declared.
7. According to Article 29a of the Second Council Directive 75/319/EEC of 20 May 1975 on the

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

National law

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

9. Under Paragraph 31(1)(2) of the AMG a marketing authorisation lapses on written notice of waiver. Under subparagraph 4 of that provision, in its original version, the medicinal product concerned could still, notwithstanding such waiver, be sold for a period of two years to allow stocks to be cleared. That rule also applied to medicinal products benefiting from an implied authorisation. The eighth law amending the AMG removed, with effect from 11 September 1998, the possibility of benefiting from a two-year clearance period in the case of waiver of an implied authorisation. On the other hand, under Paragraph 105(5)(c) of the AMG it was possible to postpone the lapse of the implied authorisation until 31 December 2004 by withdrawing the application for its renewal.

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

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

The main proceedings and the questions referred for a preliminary ruling

12. Ferring marketed in Germany, under reference number 10545, a medicinal product known as 'Minirin Spray' ('the old version') which is an antidiuretic consisting of an active substance known as 'Desmopressin' on the basis of an implied authorisation issued under Paragraph 105 of the AMG.

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

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

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

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

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

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

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

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

- which hitherto, and for several years, has been brought by way of parallel importation from Member State B into Member State A and has been placed on the market there by reference to the abovementioned implied authorisation,
- which the manufacturer and authorisation holder is replacing with a new preparation Y [which it] is placing on the market in Member State A on the basis of a separate authorisation, and,
- where preparation Y differs from preparation X only in respect of modified excipients, leading to improved temperature stability and thus making storage in the refrigerator unnecessary?

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

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

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

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

The questions referred for a preliminary ruling

Preliminary observations

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

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

21. Those rules, as interpreted by the Court, mean in particular that an operator who has bought a medicinal product lawfully marketed in one Member State under a marketing authorisation issued in that State can import that medicinal product into another Member State where he already has a marketing authorisation without having to obtain such an authorisation in accordance with Directive 65/65, and without having to provide information about the verification, prescribed by the directive, of efficacity and non-toxicity of the medicinal product. It is not necessary for the protection of public health to subject parallel importers to such requirements, as the competent authorities of the Member State of importation already have all the information necessary to carry out that verification (see in particular **Case 104/75 De Peijper [1976] ECR 613, paragraphs 21 and 36** and Case C-201/94 Smith & Nephew and Primecrown [1996] ECR I-5819, paragraph 22).

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

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

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

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

24. A similar situation has already been the subject of questions referred to the Court for a preliminary ruling in Rhône-Poulenc Rorer and May & Baker, cited above. However, in that case the point in issue was whether, taking account of the fact that the United Kingdom authorities had accepted that the parallel import licences of an old version of a medicinal product may be annexed to the marketing authorisation issued for the new version, the imports of the old version could be regarded as parallel imports, so that the ordinary authorisation procedure laid down by Directive 65/65 did not apply.

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

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

Observations submitted to the Court

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

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

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

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

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

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

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

Findings of the Court

33. It is common ground that the cessation of the validity of a parallel import licence following the withdrawal of the marketing authorisation of reference constitutes a restriction on the free movement of goods contrary to Article 28 EC, unless it is justified by reasons relating to the protection of public health, in accordance with the provisions of Article 30 EC.

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

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

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

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

38. Although adequate monitoring of the old version remains necessary and may in certain cases mean that information is requested from the importer, it must be pointed out that pharmacovigilance satisfying the rele-

vant requirements of Directive 75/319 as amended can ordinarily be guaranteed for medicinal products that are the subject of parallel imports, such as those in question in the main proceedings, through cooperation with the national authorities of the other Member States by means of access to the documents and data produced by the manufacturer or other companies in the same group, relating to the old version in the Member States in which that version is still marketed on the basis of a marketing authorisation still in force (see Rhône-Poulenc Rorer and May & Baker, cited above, paragraph 46).

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

40. In the light of the foregoing considerations, it must be held that national legislation under which the withdrawal of the marketing authorisation of reference for a medicinal product on application by the holder thereof means that a parallel import licence for that product automatically ceases to be valid does not comply with the requirements resulting from Article 28 EC.

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

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

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

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

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

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

- Article 28 EC precludes national legislation under which the withdrawal of the marketing authorisation of reference for a medicinal product on application by the holder thereof means that the parallel import licence for that product automatically ceases to be valid;
- the fact that the new version of the medicinal product has been placed on the market of the Member State of importation alone or is also found on the market in other Member States does not alter the answer to the first question;
- if it is demonstrated that there is in fact a risk to public health arising from the coexistence of two versions of the same medicinal product on the market in a Member State such a risk may justify restrictions on the importation of the old version of the medicinal product in consequence of the withdrawal of the marketing authorisation of reference by the holder thereof in relation to that market.

Costs

47. The costs incurred by the Swedish Government and by the Commission, which have submitted observations to the Court, are not recoverable. Since these proceedings are, for the parties to the main proceedings, a step in the proceedings pending before the national court, the decision on costs is a matter for that court.

On those grounds,

THE COURT (Sixth Chamber),

in answer to the questions referred to it by the Landgericht Köln by order of 14 April 2000, hereby rules:

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

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

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

OPINION OF ADVOCATE GENERAL GEELHOED
delivered on 7 February 2002 (1)
Case C-172/00
Ferring Arzneimittel GmbH
v

Eurin-Pharm Arzneimittel GmbH
(Reference for a preliminary ruling from the Landgericht Köln (Regional Court, Cologne))
(Reference for a preliminary ruling - Interpretation of Articles 28 EC and 30 EC - National legislation prohibiting parallel imports of a medicinal product for which a licence no longer exists as a result of its surrender by the holder - Obligation on the part of the holder to have regard to the interests of the parallel importer)

I - Introduction

1. In the present case the Regional Court, Cologne (First Commercial Chamber) has referred four questions concerning the interpretation of Articles 28 and 30 EC in the matter of parallel imports of medicinal products.

2. Essentially the questions relate to the situation where the marketing authorisation (hereinafter: 'MA') (2) for a medicinal product has been withdrawn at the request of the licence holder because he no longer markets the product. Instead he markets a similar product. The point at issue is therefore whether it is compatible with Articles 28 and 30 EC for parallel imports of the old preparation, from another Member State - by someone other than the former licence holder - to be prohibited. A particular circumstance in this case is that the old preparation was marketed on the basis of a so-called implied licence. The question therefore also arises as to whether this implied licence can be regarded as being an MA.

II - Legal background

European Law

3. Parallel imports of medicinal products are to a large degree governed by Articles 28 and 30 EC. Furthermore, the marketing of medicinal products is regulated by a number of Community Directives.

4. According to Article 3 of Council Directive 65/65/EEC of 26 January 1965 on the approximation of provisions laid down by law, regulation or administrative action relating to proprietary medicinal products (3) only medicines that have an MA may be placed on the market. I quote: '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 in accordance with this Directive or an authorisation has been granted in accordance with 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 ....'

5. The second paragraph of Article 4 of Directive 65/65 provides an overview of the particulars and documents that should accompany the application for an MA. Among other things, this concerns qualitative and quantitative particulars of all the constituents of the proprietary product (point 3), results of the physio-chemical, biological or microbiological tests and of the pharmacological and toxicological tests and clinical trials (point 8) and one or more specimens or mock-ups of the sales presentation of the proprietary product (point 9).

6. Point 8 of the second paragraph of Article 4 of Directive 65/65 (4) mentions a number of instances in which the applicant is not required to provide the results of pharmacological and toxicological tests or the results of clinical trials. He must demonstrate:

'(i) either that the proprietary medicinal product is essentially similar to a product authorised in the country concerned by the application and that the person responsible for the marketing of the original proprietary medicinal product has consented to the pharmacological, toxicological or clinical references contained in the file on the original proprietary medicinal product being used for the purpose of examining the application in question;

(ii) or by detailed references to published scientific literature ... that the constituent or constituents of the proprietary medicinal product have a well established medicinal use, with recognised efficacy and an acceptable level of safety;

(iii) or that the proprietary medicinal product is essentially similar to a product which has been authorised within the Community, in accordance with Community provisions in force, for not less than six years and is marketed in the Member State for which the application is made ....'

7. Article 5 of Directive 65/65 provides as follows:

'The authorisation provided for in Article 3 shall be refused if, after verification of the particulars and documents listed in Article 4, it [appears] that the proprietary 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. Authorisation shall likewise be refused if the particulars and documents submitted in support of the application do not comply with Article 4.'

8. Article 7 of Directive 65/65 (5) provides that the procedure for granting an authorisation must be completed within 210 days. In the event that another Member State has already granted an authorisation, the Directive provides for a period of 90 days following receipt of the assessment report from the other Member State.

9. Under Article 29a of the Second Council Directive 75/319/EEC of 20 May 1975 on the approximation of provisions laid down by Law, Regulation or Administrative action relating to proprietary medicinal products (hereafter: 'Second Directive'), (6) 'the Member States shall establish a pharmacovigilance system. This system shall 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.'

10. As at 18 December 2001 the various Directives concerning medicinal products have been brought together in one consolidated text: 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. (7) The preamble of this Directive sets out the objective and the scope of the system. The second and third recitals read:
'The essential aim of any rules governing the production, distribution and use of medicinal products must be to safeguard public health.
However, this objective must be attained by means which will not hinder the development of the pharmaceutical industry or trade in medicinal products within the Community.'
There is, as is apparent from the fourth whereas, a direct link with the functioning of the internal market. In this connection the fourteenth whereas states that: 'This Directive represents an important step towards achievement of the objective of the free movement of medicinal products ... .'
11. The present case concerns parallel imports of medicinal products. The Court has marked out this area in three important cases. These cases are:
- the De Peijper Case of 20 May 1976; (8)
- the Smith & Nephew and Primecrown Case of 12 November 1996; (9)

and
- the Rhône-Poulenc Rorer and May & Baker Case of 16 December 1999. (10)

12. The basis in European law for the implied licence is to be found in Article 39(2) of the Second Directive.

National Law

13. According to Article 105 of the Arzneimittelgesetz (11) medicinal products may be marketed in Germany without an MA providing they were already on the market on 1 January 1978 when the Law came into force. Marketing takes place on the basis of a so-called implied licence consisting of a declaration from the competent authorities. These medicinal products were entitled to remain on the market as long as a request for renewal of the implied licence was made before 30 March 1990.
14. Paragraph 31(I) (2°) of the AMG provides that a marketing authorisation lapses on written notice of waiver. According to the original version of Paragraph 31(IV), medicinal products could still be sold for a further two years from such waiver in order to clear stocks. This time-limit also applied to medicinal products that were marketed under an implied licence. An amendment to the AMG, which came into force on 11 September 1998, abolished the two-year clearance time-limit for medicinal products marketed under an implied licence. In its place Paragraph 105(V)(c) of the AMG provided that it was possible to postpone the expiry of the implied licence until 1 January 2005, by withdrawing the application to extend the implied licence.
15. According to a Communication of 17 April 1996 from the Bundesinstitut für Arzneimittel und Medizinprodukte (12) (Federal Institute for Pharmaceutical and Medicinal Products) parallel importers have a right to market medicinal products following a notification to the competent authorities, if the medicinal products in question were already on the market on the basis of an implied licence. In such cases there is no verification of the identity of the medicinal products.
16. The communication also states that, according to German administrative practice, parallel imports remain authorised in the event of the extension of an implied licence, in so far as the imported medicinal products are identical to the product to which the implied licence relates. This applies until the procedure for extending the implied licence is terminated and until the medicinal product imported as a parallel import has obtained its own licence.

III - Facts and procedure

The main proceedings

17. The parties to the main proceedings, Ferring Arzneimittel GmbH (hereafter: 'Ferring') and Eurin-Pharm Arzneimittel GmbH (hereafter: 'Eurin-Pharm') are competitors in the marketing of medicinal products.
18. The main proceedings concern the importation into Germany by Eurin-Pharm of the medicinal product Minirin Spray. Since June 1996 Eurin-Pharm has been importing this preparation from elsewhere in the European Union and placing it on the market in Germany with German labelling with the registration number 10545. The preparation in question was first marketed under this number by Ferring, without an MA, because it was already on the market on 1 January 1978. In accordance with Paragraph 105 of the AMG Ferring had received an implied licence for the medicinal product. In a letter to the Bundesinstitut für Arzneimittel und Medizinprodukte (Federal Institute for Pharmaceutical and Medicinal Products) dated 14 July 1999 Ferring surrendered the implied licence. Ferring now markets the product Minirin Nasenspray 5 ml on the basis of a new licence with the number 32187.00.00. This medicinal product has supplanted the Minirin Spray preparation.
19. In the main proceedings Ferring takes the view that Eurin-Pharm can no longer rely on the implied licence because the implied licence no longer exists. Ferring states that that medicinal product, which it currently markets, contains other excipients so that its form is more temperature-stable. In this (new) form it is marketed in several Member States. In the main proceedings, Ferring is requesting that Eurin-Pharm be ordered, in order to avoid an administrative fine of up to DEM 500 000 for each infringement, to refrain from importing the medicinal product Minirin Spray and placing it on the market in the Federal Republic of Germany under registration number 10545.
20. Eurin-Pharm contends that Ferring's action should be dismissed. Eurin-Pharm denies the existence of therapeutically relevant differences between the old and the new preparations, since the only difference that Ferring puts forward is that the new preparation does not need to be kept cold. In view of the identical nature of Minirin Spray and Minirin Nasenspray the importation by Eurin-Pharm is, in law, to be regarded as a parallel import. In this connection Eurin-Pharm has in the interim also submitted an application for a parallel import licence.

21. Eurin-Pharm also contends that the two-year clearance time-limit under Paragraph 31(IV) of the AMG is applicable, although that is not strictly provided for by the letter of the law. Any other interpretation of this provision would run counter to the free movement of goods within the European Union. In this regard Eurin-Pharm refers to the judgment in Rhône-Poulenc Rorer and May & Baker. (13) This transitional marketability must be valid until a decision is taken on the application for a parallel import licence.
22. In interlocutory proceedings the Landgericht (Regional Court) Cologne upheld Ferring's claim for a prohibition on the marketing of the product; the present case concerns the substance of the case.

Preliminary questions

23. By an order of 14 April 2000, which was received at the Court Registry on 10 May 2000 the Landgericht Cologne sought a preliminary ruling on the following questions:

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

- for which there existed hitherto in Member State A an implied licence which has now expired because the licence holder has surrendered it,
- which for several years has been brought as a parallel import from Member State B to Member State A and has been placed on the market there with reference to the abovementioned implied licence,
- which the manufacturer and licence holder is replacing with a new preparation Y [which it] is placing on the market in Member State A on the basis of an independent licence, and
- [where preparation Y] differs from preparation X only in respect of modified excipients, so that those excipients lead to improved temperature stability and thus make storage in the refrigerator unnecessary?

2. Does it affect the judgment if there was available to the holder of the licence which has now expired a lawful means of surrendering that licence in such a way that the marketability of the medicinal product was preserved for a certain (transitional) period?

If yes, according to which criteria must the previous holder, when taking a decision on his action, take into consideration the European free movement of goods?

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

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

Explanations provided by the referring court

24. In its explanations of the questions the referring court alluded to the decision in the interlocutory proceedings. In that decision the Landgericht Cologne stated that national legislation was clear and that Eurin-Pharm's interpretation should be rejected. In accordance with Paragraph 105 of the AMG the two-year clearance time-limit (ex Paragraph 31(IV) of the AMG) does not apply to the surrender of an implied licence. Ferring could indeed have withdrawn the application to extend the implied licence with the result that it would have remained valid until the end of 2004. However, the referring court considers that Ferring was not obliged by law to take this step; nor did any other obligation exist compelling a licence holder to take into consideration the interests of a parallel importer.
25. In any event, the new medicinal product is distinct from the old medicinal product in regard to its temperature stability. This difference can also have an impact on the application of the medicinal product. The Landgericht Cologne indicates that the situation could arise where a patient is in possession of both preparations and uses them one after the other and thus fails to pay heed to the correct temperature. Thus, there are material differences from a therapeutic point of view between the old and the new preparations.
26. According to the Landgericht Cologne considerations of European law cannot entail a result favourable to Eurin-Pharm. The MA is tied to the product, which makes it possible for parallel importers to ‘tie into’ existing licences, including implied licences. If, however, there is no licence, then an importer cannot ‘tie into’ it. There is no perceptible restraint of trade, if only because it was submitted without contradiction at the hearing that Eurin-Pharm could obtain a licence itself within 90 days, under the simplified authorisation procedure.
27. The Landgericht is, however, not certain with regard to this interpretation of European law. Whatever the case may be in this respect, Eurin-Pharm cannot, at any rate, rely upon the judgment in the Rhône-Poulenc Rorer and May & Baker. (14) In that decision the particular problem of the lack of an MA was expressly left open.

The proceedings before the Court

28. The parties to the main proceedings, Ferring and Eurin-Pharm, and the Commission submitted written observations. They expounded their arguments at the hearing of 22 November. (15) The Swedish Government also made observations at this hearing.

IV - Remarks concerning the scope of the dispute and the presentation of this Opinion

29. According to Ferring the present case relates only to whether Eurin-Pharm may continue to import the ‘old’ preparation under the existing reference number, although the MA for this preparation no longer exists and the new preparation has not been compared to the old one. The proceedings do not concern the question whether Eurin-Pharm must undergo the entire authorisation procedure provided for in Directive 65/65, or whether a simplified procedure may suffice.
30. On its own merits I agree with Ferring's view regarding the scope of the proceedings. Nevertheless, the additional consequences of the withdrawal of the MA on the parallel importer must be taken into account. That is a question concerning the obligations which can be imposed on the parties in order to limit the effects of withdrawal.

31. A second preliminary remark relates to the German system, and in particular implied licences. At the hearing the Commission representative raised the issue of the compatibility of the German legislation with European law. In the Commission's view, as from 21 May 1990, implied licences could no longer serve as the basis for lawful marketing. The Commission refers to Article 39(2) of the Second Directive, which provides that within a given time-limit, the other provisions of the directive are to be applied progressively to proprietary medicinal products placed on the market under previous provisions. For that reason the Commission had at the time requested that the German legislation be adapted. In its view incompatibility of the implied licence with Community law is of decisive importance to the assessment of the questions before the Court.
32. In my view the Commission raises a relevant point in this connection. At the very least, there are doubts concerning the question whether the implied licence could still serve as the basis for marketing medicinal products after 21 May 1990. Nevertheless, I am of the view that the compatibility or otherwise with European law of the legal concept of the implied licence should not be of primordial importance in the Court's reply. Firstly, the referring court does not pose this question. Secondly - and I consider this to be of greater importance - the Commission's point of view essentially relates to the doctrine of the direct effect of directives in the event of incorrect transposition. According to the settled case-law of the Court a directive cannot of itself impose obligations on an individual and cannot therefore be relied upon as such against an individual. (16) In the present case, therefore, Eurin-Pharm was entitled to proceed on the assumption that the German legislation upon which the implied licence is based was valid. None the less, I shall take account of the fact that the question from the referring court relates to an implied licence and not to a ‘real’ MA under Article 3 of Directive 65/65.
33. This brings me to the questions posed by the referring court. In essence the referring court seeks to ascertain whether Articles 28 and 30 EC preclude national legislation whose consequence is that, in the event of the withdrawal of an MA at the request of the licence holder, parallel imports also cease to be permitted. This is in my view the nub of the present proceedings. In the event of an affirmative reply to this question, I must then consider the conditions that can be imposed on the parallel importer, who markets a medicinal product for which the original MA has been withdrawn. Thereafter, I shall consider two particular aspects of the present proceedings. The first is the question whether the licence holder, who requests its withdrawal, must take into account the interests of the parallel importer. The second aspect, already mentioned in the previous paragraph hereof, is that we are dealing here with an implied licence.
34. It should be noted that the main issue in the present case was already raised in the Rhône-Poulenc Rorer and May & Baker case. That case was more concerned with the question of the lawfulness, as regards free movement of goods, of the automatic revocation of parallel import licences as a result of the revocation of an MA at the request of the licence holder. That question did not require an answer in that case. (17)
35. Finally I shall examine the fact that Ferring has introduced a new variant (18) of the medicinal product on to the market. I shall conclude that it is irrelevant that the licence holder replaces the old variant by a new variant. However, the following questions must still be addressed:
- Can a variant of a medicinal product be described as new when the preparation concerned has the same therapeutic efficacy, but differs from the old variant in the manner in which it must be stored?
- Is it undesirable that the old and new variants be available simultaneously on the market?
- Is it of significance that the old variant is still marketed normally in other Member States?

These questions will be dealt with as subsidiary issues, in the event that the Court does not share my view on the main issue.

V - The context

Scope and content of the marketing authorisation

36. Community involvement with the marketing of medicinal products dates back to 1965. Directive 65/65 harmonised the national rules in this area. The Community system has been progressively extended. The last substantial expansion was under Directive 93/39. According to the preamble of Directive 65/65 the safeguarding of public health is paramount. However, this objective must be attained by means that will not hinder the development of the pharmaceutical industry or trade in medicinal products. With the extension of the system, the free movement of medicinal products, within the internal market, has taken on an increasingly important role. (19)
37. The key elements of the system that has thus arisen are the uniform procedure and the obligation for the national competent authorities to cooperate. The national authorities may refuse to grant an MA for a medicinal product on grounds of quality, safety or therapeutic efficacy. The Member States' competent authorities must be able to arrive at their decisions on the basis of uniform tests and by reference to uniform criteria. In this way differences in evaluation can be avoided. (20) In applying these uniform criteria the Member States have a very limited margin of evaluation.
38. For reasons of public health it is necessary for all medicinal products to have been duly tested before being placed on the market. This is the main provision of Directive 65/65, which the Court has confirmed in the Rhône-Poulenc Rorer and May & Baker judgment. (21) No medicinal product may be placed on the market in a Member State unless an MA has been issued under the Directive by the competent authority of that State. An application for a marketing authorisation 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.
39. However, unnecessary duplication during the course of this examination is to be avoided. (22) Thus Point 8 of the second paragraph of Article 4 of Directive 65/65 establishes an abridged procedure which, subject to certain conditions, relieves the manufacturers of medicinal products, which are essentially similar to medicinal products already authorised, from having to provide the results of pharmacological and toxicological tests and of clinical trials, thus saving the time and expense necessary to assemble such data, and avoiding the repetition of tests on humans or animals where these are not absolutely necessary. (23) In accordance with Article 7a of the Directive the abridged procedure must be completed within 90 days. Moreover, in the De Peijper (24) case the Court decided that a Member State may not require a trader to provide all the pharmaceutical particulars considered necessary for the purpose of checking that the medicinal preparation is effective and not harmful, if the authorities already have this data at their disposal from an earlier evaluation of the same preparation, carried out at the request of another trader.
40. Furthermore, the evaluation reports must be exchanged between the Member States. These reports must also be used for subsequent applications in the same Member State, for example in the case of parallel imports. The EC directives also impose deadlines on the competent national authorities. All these measures aim to promote the free movement of goods. However, concerns regarding the protection of public health also require that the marketing of medicinal products should not be dependent upon compliance with an excessively high number of formalities.

The parallel import

41. The phenomenon of parallel imports is not regulated in Directive 65/65 and subsequent Directives. In the judgment in Smith & Nephew and Newcrown (25) the Court stated: 'Consequently, the provisions of Directive 65/65 concerning the procedure for issue of marketing authorisations cannot apply to a proprietary medicinal product covered by a marketing authorisation in one Member State which is being imported into another Member State as a parallel import of a product already covered by a marketing authorisation in that other Member State. In such a case, the imported proprietary medicinal product cannot be regarded as being placed on the market for the first time in the Member State of importation.'
42. Parallel imports are governed by Articles 28 and 30 EC. A restriction on imports of medicinal products can be based on the protection of public health, but must always be necessary and proportionate. In this regard I would refer once again to the division of powers between the Union and the Member States in the field of public health. In accordance with Article 152(1) EC, Community action complements national policy. In the event of no Community action, the Member States are free to decide their own policy, as long as this remains within the limits of the Treaty (in this case Articles 28 and 30 EC in particular).
43. Protection of public health can indeed be a reason for not restricting parallel imports of medicinal products. Parallel importers are very often in a position to offer the medicinal product at a price lower than that charged by the producer or the duly appointed importer. It is in the interest of an effective protection of public health that medicinal products should be sold at reasonable prices. (26)
44. Furthermore, parallel imports of medicinal products mainly occur in the interests of the internal market. The existence of parallel imports prevents an unnecessary partitioning of the Member State's markets and ensures that the system of MA's does not lead to certain traders in medicinal products having a monopoly. On the contrary, parallel imports guarantee keen price competition as between economic operators. (27)
45. In short, both the wording and the objectives of the EC Treaty regard parallel imports of medicinal products as a desirable phenomenon.
46. Accordingly, the Court has decided that national authorities must not obstruct parallel imports, by requiring parallel importers to satisfy the same requirements, as those which are applicable to undertakings applying for an MA for a medicinal product for the first time. The national authorities are required to authorise a medicinal product, in accordance with the rules - Articles 28 and 30 EC - on parallel imports. These exceptions to the rules normally applicable to an MA application, are subject to the condition that the protection of public health is not undermined. (28)
47. In concrete terms, this means that if the authorities of the importing Member State already have all the pharmaceutical particulars relating to the medicinal product in question, it is clearly unnecessary, in order to protect the health and life of humans, for the parallel importer to produce the particulars again. (29)
48. Within these limits many of the Member States have a simplified authorisation procedure based on national law. The Commission has published guidelines for the Member States and the economic operators concerned. (30) According to these guidelines the simplified procedure must result in the granting of an authorisation within 45 days of the arrival of the application and accompanying documents.

Obligations of the licence holder and the parallel importer and their interrelationship

49. The legislation on the marketing of medicinal products is not solely concerned with market authorisation. Rules are also laid down concerning the marketing of medicinal products for which an MA has already been granted. These concern, for example, the requirement that only medicinal products complying with the specifications for which the MA is granted may be placed on the market (Article 10(2) of Directive 65/65). Directive 65/65 also contains an obligation to modify the methods of preparation and control, taking into account the technical and scientific progress (Article 9a). The responsibility for compliance with these rules lies with the licence holder.

50. An important issue for which the licence holder is responsible is the pharmacovigilance system set out in Chapter V of the Second Directive. (31) Article 29a provides that this system is to be used to collect information useful for the surveillance of medicinal products, with particular reference to adverse reactions in human beings, and to evaluate such information scientifically. One of the obligations of the licence holder is to report to the competent authorities all suspected serious adverse reactions that are brought to his attention by doctors.
51. I shall not dwell on all the obligations vested in the licence holder. The present case is not directly concerned with this matter. I shall restrict myself to two important considerations, which are in my view instrumental in the imposition of the obligations. Firstly, the safety of the medicinal product itself: within a system such as that laid down by Directive 65/65 and related directives it is not only important that approval be carefully regulated but it must also be guaranteed that the preparation is marketed and used in a safe manner once it has been approved. For this reason it must also be certain that the batches marketed are identical to the preparation for which the MA has been granted. Secondly, the developments after the granting of the authorisation mean that the situation that arises is not static. Science and technology advance and the use of the medicinal product can, in itself, lead to new insights, for example into the side-effects of the product.
52. It is possible that the authorisation must be suspended or withdrawn. The licence holder may also modify the medicinal product himself. Article 9a of the Directive may even oblige him to do so in some instances.
53. In the event of parallel imports certain obligations are also incumbent on the parallel importer. The obligations are not as far-reaching as those of the licence holder in view of the fact that the parallel importer cannot be held responsible for the further development of the medicinal product. Furthermore, the parallel importer does not have at his disposal all the pharmaceutical particulars relating to the medicinal product. Naturally, this situation must not be allowed to pose a public health risk.
54. However, there is nothing to prevent other obligations from being imposed on the parallel importer. Thus, under the Court's case-law, the national authority can have a legitimate interest in being able to verify, at any time, whether a certain batch is in conformity with the particulars in the file. For this purpose the parallel importer may be requested to prove the conformity of an imported batch with the description of the medicinal product.
However, Articles 28 and 30 EC set limits to the requirements that can be laid down in regard to the furnishing of proof by the parallel importer in such cases. (32)
55. With regard to pharmacovigilance, the Court adopted the following position in Rhône-Poulenc Rorer and May & Baker. Pharmacovigilance, satisfying the relevant requirements of the Second Directive, can be ensured for medicinal products imported as parallel imports through cooperation with the national authorities of the other Member States. The authorities of a Member State, where the old version is still marketed on the basis of a valid MA, must grant access to the documents and data relating to this version, produced by the manufacturer or other companies in the same group.
56. Cooperation between the national authorities can also remove many of the risks for public health in other instances. In its 1982 guidelines (33) the Commission stresses the obligation on national authorities to cooperate. It infers this obligation from Article 10 EC and also from Article 30 of the Second Directive. These provisions must ensure that the competent authorities provide each other with the necessary information in order to guarantee that the Community requirements are fulfilled.
57. Finally, I would refer to an obligation of a totally different nature, which affects the relationship between the licence holder and the parallel importer. The licence holder is obliged to cooperate with the competent authorities of the Member State where the parallel importation occurs. This authority has legislative and administrative means at its disposal, capable of compelling the manufacturer, his duly appointed representative or the licence holder to supply information in their possession, which the authority considers to be necessary. (34) Thus, anyone holding an MA in the importing Member State for a new variant of a medicinal product, but belonging to the group that holds an MA for the old variant in the other Member States, is obliged to supply any necessary information regarding the old variant. The Court has previously ruled in the De Peijper judgment that a rule which makes it possible for a manufacturer to refuse to produce the information necessary to evaluate a medicinal product for the purposes of a parallel import licence, must be regarded as being a measure of equivalent effect, not justified by Article 30 EC. (35)
58. In light of the foregoing I consider that it must be possible to require the licence holder to act in good faith with regard to the parallel importer.

When is the same medicinal product at issue?

59. In Smith & Nephew and Primecrown the Court clarified the circumstances involving parallel imports of the same medicinal product. (36) The Court established two requirements:

- the medicinal products must have a common origin by virtue of the fact that they are both manufactured pursuant to agreements concluded with the same licensor. It must be avoided that the behaviour of the licensor could lead to partitioning of the national markets of the various Member States.
- The medicinal products must have the same composition. They do not have to be identical in all respects, however, they must have been manufactured according to the same formulation, using the same active ingredient and they must also have the same therapeutic effects.

60. The second requirement is also associated with the risk that the manufacturer may partition markets by making small changes, of no therapeutic relevance, to the products that he markets in the various Member States. According to Advocate General La Pergola, if different variants of the same medicinal product are on the market, then the manufacturer must be able to demonstrate, to the full satisfaction of the competent national authority, that the difference in formulation is a response to genuine and objective public health concerns. The Advocate General then refers to the situation where a version withdrawn from the market in one Member State, is nevertheless still being manufactured and marketed by the same firm, or by a company in the same group, in other Member States. Convincing reasons must be given in such a situation, including an explanation of why public health concerns do not arise in relation to the countries where the old version is still marketed. Other factors may also play a role. (37)
61. The Rhône-Poulenc Rorer and May & Baker case concerned two variants of the same medicinal product, with the same active ingredients and the same therapeutic effect. The variants were only distinguishable from each other by differences in the excipients, (38) which had possible consequences on the shelf life and the bioavailability of the product, for example with regard to the speed at which the medicinal product dissolved or was absorbed. Such differences are not relevant in answering the question of whether the simplified procedure for parallel imports (which is based upon Articles 28 and 30 EC) may be applied, provided that the variant imported as a parallel import does not pose any problems as regards its quality, efficacy and safety. As I understand the Court's case-law, these problems must be related to the excipients contained in this variant. (39)
62. Finally, the Court's interpretation of the notion ‘essentially similar proprietary medicinal product’ is of importance; in accordance with point 8 of Article 4 of Directive 65/65 an abridged procedure is possible for these products. The Court refers to the minutes of a Council meeting. (40) These apply the following criteria: the same qualitative and quantitative composition in terms of active principles and the same pharmaceutical form, and, where necessary, bioequivalence of the two medicinal products has been established by appropriate bioavailability studies. (41) In fact, even in these circumstances, the variant must not present any public health problems linked to the excipients contained in it. In such a case the variant cannot be deemed to be essentially similar to the original proprietary product.

VI - Assessment: the legal consequences for parallel imports

The main point: the admissibility of an import ban

63. In essence the referring court is concerned with the admissibility of a ban on parallel imports of a medicinal product, when the MA in the importing country for the reference product has been withdrawn at the request of the licence holder. Under the applicable German law, the withdrawal of the MA at the request of the holder leads to the immediate expiry of the licence holder for parallel imports of the medicinal product. (42) The question now is whether Articles 28 and 30 preclude such national legislation.
64. In my view it is important to distinguish the issue of the admissibility of a ban on imports of a medicinal product from that of whether additional obligations can be imposed on the parallel importer, as a result of the fact that there is no longer an MA holder in the Member State concerned. The second question only arises once it has been established that parallel imports are in principle allowed.
65. With regard to the permissibility of parallel imports Ferring is of the view that with the withdrawal of the (implied) licence, the legal basis for the marketing of the old products ceases to subsist. Eurin-Pharm should therefore have requested a new licence for parallel imports, whereby it could have referred to the new MA. In the ensuing simplified procedure, the national authority should have verified whether there was a difference in therapeutic effect between the old product and the new product. In the intervening period, that is to say prior to the decision of the national authority, the medicinal product may not be marketed.
66. Eurin-Pharm maintains, on the contrary, that the old product may at least remain on the market during a transitional period. Eurin-Pharm considers it to be important that this situation should not endanger pharmacovigilance. The German authorities still have at their disposal all the information submitted in the course of the various authorisation procedures. Furthermore, they can apply to the authorities of other Member States, where the old product is still on the market.
67. The Swedish Government has pointed to the fact that the rules relating to the marketing of medicinal products may not be more strictly interpreted than is required for the protection of public health. This implies that there is no reason to limit the free movement of a medicine that has been previously assessed and for which an MA has been issued, providing that pharmacovigilance continues. The Swedish Government bases its comments on the Rhône-Poulenc Rorer and May & Baker Case.
68. It is, it seems to me, important to establish that the withdrawal of the parallel import licence should be regarded as a quantitative restriction on imports prohibited under Article 28 EC, in the absence of any justificatory ground provided for in the Treaty.
69. I further note that withdrawal of the MA for the reference medicinal product has nothing to do with product safety, or more generally with public health interests. Withdrawal is a direct result of the fact that the manufacturer no longer markets the product concerned in the Member State in question. The basis for the decision is quite simply the request of the licence holder, which is itself linked to the licence holder's own market strategy.
70. In light of the foregoing, I conclude that there is a restriction on imports prohibited under Article 28 EC in respect of which no justificatory ground is provided for under the Treaty, for example in the present case a pub-

lic-health ground. One of the reasons is that the medicinal product has been marketed in Germany for a considerable time and satisfies public-health requirements.
71. In substantiation of this conclusion I would make the following three points.
72. Firstly, withdrawal of the MA does not in itself compel the parallel importer to cease importing and request a licence in his own right. The reason why he was not obliged to follow the normal authorisation procedure, prior to withdrawal, was primarily that the Member State's national authority already possessed and had evaluated all the information regarding the medicinal product. This situation has in no way changed.
73. Secondly, from the perspective of the parallel importer the situation is as follows. He is confronted with the consequences of an administrative decision taken at the request of the licence holder. He was not involved in the adoption of the decision. The procedure does not provide for his interests to be taken into account. No means of redress are available to him. In fact, we are dealing with the withdrawal of the MA at the request of the licence holder himself, based, as stated previously, on the licence holder's own market strategy. Application of German legislation would imply that the parallel importer must immediately cease to import and distribute the medicinal product concerned, which could cause him considerable loss due to his inability to fulfil contractual obligations and to dispose of existing stocks.
74. Should Community law provide a ground for justifying an importation ban - quod non - then this ban, through lack of a transitional period and by offering no means of redress to the parallel importer, would be disproportionate in nature and therefore prohibited under Community law.
75. Thirdly, in my view parallel imports of medicinal products are per se a desirable phenomenon, from the point of view of both the internal market and the protection of public health. I refer to paragraph 40 et seq. of this Opinion. This implies that parallel imports cannot simply be terminated on the basis of a one-sided decision on the part of the holder of an MA.

Conditions that may be imposed on the parallel importer

76. None of the foregoing means that the parallel importer continues to enjoy an unlimited right of importation and distribution even after withdrawal of the MA. Withdrawal, however, means that the licence holder no longer bears any responsibilities with regard to the medicinal product. It is thus logical that these responsibilities should pass to the parallel importer. That increase in his responsibilities must serve to ensure adequate supervision of the imported medicinal products. The parallel importer has become the person marketing the medicinal product concerned in the Member State in question.
77. Nevertheless, not all obligations can simply be transferred to the parallel importer. On this aspect I would refer back to paragraph 53 of my Opinion.
78. That increased responsibility of the parallel importer, coupled with the fact that not all obligations can simply be transferred to him, can entail restrictions - or conditions - being attached to the right to effect parallel imports.
79. I consider such restrictions to be acceptable, provided that they are justified on a general-interest ground relating to public health (more specifically, supervision of the safety of the medicinal product) and are necessary and proportionate.
80. The Swedish Government has put forward a number of criteria, which the Court could take into consideration in its ruling on the question. It is important that safety checks be maintained and that information concerning the medicinal product be available to the authorities of the other Member States. Another relevant criterion is whether a medicinal product has already been marketed in the European Union for a sufficient period, without giving rise to any serious problems. Finally, the continuation of the parallel import licence could be limited as to time. In this respect the Swedish Government considers that a period equating to the normal period for extension of an MA would be appropriate.
81. In line in this regard with the Swedish Government, I believe that it is advisable for the Court to formulate criteria for the limitation by the Member States of the right to effect parallel imports. In this regard - likewise in agreement with the remarks of the Swedish Government - I can conceive of three types of restriction:
- those directly linked to the safety of the medicinal product;
- temporal limits;
- obligation on the parallel importer to request an MA within a reasonable period, failing which his parallel import licence may be withdrawn.

82. With regard to the first type of restriction, these restrictions or conditions are in addition to the obligations incumbent on the parallel importer in any event, in view of the fact that he will have marketed batches of medicinal products even before the withdrawal of the MA. The restrictions or conditions must not go beyond what is necessary to ensure the safety of the medicinal products, nor, in my view, must they render imports of medicinal products practically impossible. This is precluded by the principle of proportionality.
83. In instances where it is difficult to imagine the transfer of obligations to the parallel importer, for example those concerning the further development of the medicinal product, cooperation between the national authorities of the Member States can offer a solution. This is the direction that the Court recommended in the Rhône-Poulenc Rorer and May & Baker case for the pharmacovigilance system. Mandatory cooperation between the national authorities of the Member States must ensure that the authorities in the importing Member State possess sufficient information to guarantee the safety of a medicinal product. In fact, parallel imports always occur from another Member State where an MA for the product concerned still exists.

84. As a second type of restriction I mentioned temporal limits. In the same way as the market authorisation under Directive 65/65 is of a limited duration, so also the authorisation to effect parallel imports may be limited as to time. I would point out that under Article 10(1) of Directive 65/65, the authorisation is valid for five years and can be extended for a further period of five years. The Swedish Government recommends that the parallel import licence should be for the same term as the (in the meantime withdrawn) MA. I support this proposition. There is no reason to place the parallel importer in a more advantageous position, as regards the duration of the licence, than the position in which the licence holder would have found himself had he continued marketing the medicinal product. Moreover, the Member States must have a means of periodically reviewing whether the medicinal product still complies with the requirements applicable to it.
85. The third kind of restriction concerns the obligation to apply for the grant of an MA as a right within a reasonable period. I consider that such an obligation can be justified in the general interest and also complies with the requirements of necessity and proportionality. The authorities of a Member State have a legitimate interest in assigning to a specific person full liability for a medicinal product marketed on their territory. This enables them to perform their supervisory tasks in the field of public health in the best way possible although - as was already apparent from paragraph 53 and following of this Opinion - certain obligations may also be imposed on the parallel importer.
86. The parallel importer must be granted a reasonable period within which to request the MA. Furthermore, it appears to me, that the parallel importer may not be forced to market existing stocks under a new name or with a new registration number. Provided those conditions are met, it is not disproportionate to couple the obligation to request an MA in his own right with the sanction of withdrawal of the parallel import licence.
87. In short, in situations where the MA for the reference medicinal product in the importing country has not been withdrawn at the request of the licence holder in order to protect public health, it is permissible in this regard to impose restrictions on the parallel importer provided that such restrictions relate to the safety of the medicinal product or are intended to limit the duration of the right to effect parallel imports. The parallel importer may himself be obliged to request an MA within a reasonable period of time, or suffer withdrawal of his parallel import licence.

Must the interests of the parallel importer be taken into account?

88. Essentially, on this point, the referring court wishes to be informed as to whether the licence holder must take into account the interests of the parallel importer, if he has a choice between various administrative channels. In this regard, Ferring contends that it would not be legitimate to compel it to maintain the implied licence for the old variant for the benefit of the parallel importer. Eurin-Pharm recognises the legitimacy of Ferring's desire to replace the implied licence. However, Ferring could have used other channels, which would not have led to the immediate termination of importation.
89. The Commission maintains that this question is misplaced. It is not the licence holder, but rather the authorities of a Member State who must uphold the freedoms guaranteed by the EC Treaty - and thus the interests of the parallel importer. The Swedish Government has expressed the same viewpoint.
90. In paragraph 58, I stated that it must be possible to require the licence holder to act in good faith with regard to the parallel importer. It follows from the De Peijper case, that it must be possible to oblige him to provide information to render parallel imports possible. (43) In my view, the rationale behind this is that parallel imports would otherwise not in fact be possible, inasmuch as the licence holder is the only person in possession of certain information. In my opinion the obligations of the licence holder go no further. As the Commission and the Swedish Government correctly state, it is not the task of the licence holder to uphold the freedoms guaranteed by the EC Treaty. The responsibility of the licence holder implies that he may not impede parallel imports (by withholding information), but, on the other hand, he cannot be expected in his management decisions to take into account the interests of the parallel importer who is after all his competitor.

The fact that an implied licence is involved

91. In the Commission's view it is a determining factor that we are dealing here with an implied licence. This implied licence has been granted contrary to Community law. In this respect it is relevant that the identity of the old preparation has not been established in accordance with Directive 65/65. In such a situation Articles 28 and 30 do not preclude a ban on parallel imports.
92. As I already stated in paragraph 32, Eurin-Pharm was entitled to proceed on the assumption that the German legislation upon which its own and Ferrings' (implied) licences were based was valid. None the less, in the case of an implied licence, it is not certain that the product has been examined, in accordance with Articles 4 and 5 of Directive 65/65, with regard to its harmfulness and therapeutic efficacy. There could be public health reasons that would justify the product being examined once again if parallel imports are to continue. However, these reasons are unconnected with the moment in time of the withdrawal of the MA from the original licence holder.
93. It is therefore not permissible - in view of the fact that it is an implied licence with which we are dealing here and not a full MA - that parallel imports should be terminated without provision for a reasonable transitional period. Conversely, I consider it acceptable - in so far as required by public health and on condition that the preparation has not already been investigated - that the parallel importer should undergo the full procedure under Directive 65/65 when applying for an MA. The transitional period should take this into account where appropriate.

Conclusion

94. I come to the following conclusion.

- The withdrawal of an MA for the reference medicinal product in the importing country at the request of the licence holder cannot result in the immediate cessation of parallel imports, where the purpose of the withdrawal was not to protect public health.
- Such a legal consequence must be regarded as an import restriction prohibited under Article 28 EC for which no justificatory ground is provided for in the Treaty relating, for example in the present case, to public health. It should also be taken into consideration that the medicinal product has been marketed in Germany for a considerable time, and that it is not disputed that the product complies with public-health requirements.
- However, restrictions may be imposed on the parallel importer with a view to supervision of the medicinal product, provided that those restrictions are directly related to the safety of the medicinal product or are intended to limit the duration of the right to effect parallel imports.
- The parallel importer may himself be required to request an MA within a reasonable period, or suffer withdrawal of his parallel import licence.
- The fact that the case involves an implied licence is immaterial to the assessment of the case.

VII - Assessment: Is it important that a new variant has been placed on the market?

95. In the legal proceedings before the Court much attention has been paid to the fact that not only was the MA withdrawn at the request of the licence holder, but that the licence holder at the same time placed a similar medicinal product on the market.

96. The Swedish Government, amongst others, has gone into this point in considerable detail. The Swedish Government has looked into the acceptability of automatically terminating the parallel import licence until such time as it is established whether the two medicinal products are sufficiently similar. It considers this to be unacceptable. On the other hand, according to Ferring, the presence on the market of both variants side by side is liable to confuse consumers. Ferring considers the risk of confusion to be of decisive importance.

97. What is important, in my view, is this. The obligation to cease parallel imports immediately is - as I stated in my reply to the first question - contrary to Articles 28 and 30 EC. I see no reason why this conclusion should be any different due to the fact that the original licence holder has placed on the market a new variant of the same preparation. Nor do I consider that this situation should alter the conclusion as regards the acceptability of restrictions placed on parallel imports, with a view to supervision of the medicinal product.

98. The fact that Ferring has placed a new variant on the market, cannot be decisive in determining whether parallel imports should be terminated. However, this fact could possibly play a role in the following question. Under what conditions may the old variant remain on the market when a decision has been taken regarding the parallel importer's request for an MA?

99. In view of the fact that the referring judge's questions do not relate to this follow-up situation, I recommend that the Court should reply as follows: In the situation under examination it is not important that the original licence holder markets a similar product.

100. In the alternative, should the Court disagree with my assessment, I shall consider three further questions.

Is the same medicinal product involved?

101. This question comes down to this. Are medicinal products which differ as to temperature stability, but are otherwise similar, identical within the meaning of the applicable Community rules?

102. Ferring proposes that this question should be answered in the negative. Moreover, Ferring considers that the reply to this question is immaterial to the present case. Eurin-Pharm states that there is no difference in therapeutic effect between the old and new variants. The distinction relates purely to an excipient, not to the active ingredient.

103. In paragraph 59, I referred to Smith & Nephew and Primecrown in which the Court clarified the cases of parallel imports in which the same medicinal product is involved. In summary, both the origin and the composition must be the same. The origin is not at issue in this case.

104. As regards composition, the sameness must derive from the fact that both variants contain the same active ingredients and have the same therapeutic effect. In Rhône-Poulenc Rorer and May & Baker the Court stated that differences in excipients, which affect shelf-life for example, are immaterial. It can be otherwise only if the difference in excipients gives rise to public health problems.

105. In the present case we are concerned with a difference that, although it does not per se cause a change in shelf-life, is otherwise totally comparable. If the old variant is kept at room temperature, it loses its efficacy after a short period of time. The new variant marketed by Ferring includes an undeniable improvement over the old variant. It is an advantage for the consumer not to have to store the nasal spray in a refrigerator. This does not necessarily mean that use of the old variant can give rise to public-health problems. Having regard to the case-law of the Court, I consider that the distinction between the two variants is immaterial and that both variants can be regarded as the same medicinal product for the purposes of the Community rules on the marketing of medicinal products.

The (un)desirability of two variants being present side by side on the market

106. According to Ferring, consumers are confused if both variants are on the market side by side. The consequence may be that the old product will be stored at room temperature, which reduces the efficacy of the product. The risk that temperature stable and temperature unstable products would be on the market at the same time was a decisive reason for Ferring in surrendering the implied licence. Eurin-Pharm regards this argument as being principally an excuse to be able to prevent parallel imports. The packaging of the old product always states that it must be kept cool.

107. At the hearing Ferring also pointed out that the risk of confusion ceases as soon as the parallel importer

obtains a licence in his own right. From that point in time two different preparations exist marketed under different names.

108. The Commission points out that the question whether the presence of two variants of the same preparation on the market leads to confusion, is not relevant in this case. In the approval system for medicinal products, there is always a risk that two variants of the same product may be marketed. The parallel importer can always submit an application himself on the basis of Directive 65/65. The question raised in this connection does not therefore need to be examined in assessing whether it is permissible to maintain a parallel import licence.

109. Fundamentally, I agree with the Commission's position. The approval system for medicinal products does not exclude the possibility that two variants of the same medicinal product may be marketed, even when that may lead to confusion for the consumer. The consumer is not concerned by the title under which a parallel importer places a medicinal product on the market. When it is imported the parallel import variant - at least in the German system - is assigned the same registration number as the original variant. This registration number is in fact not something that the average consumer will notice.

110. At the hearing Ferring also pointed to the possibility that, should the parallel importer hold a separate authorisation, the variants would be on the market under different names. I do not fully understand this argument. In my opinion the original holder of an MA can give a new variant a new name if he wishes to alert the consumer to a difference with regard to the old variant. In the present case Ferring did this by marketing the new variant under the name 'Minirin Nasenspray 5 ml'. This is nothing to do with the parallel importer.

Old variant still available in other Member States

111. In my view the crux of the matter is that the possibility for a medicinal product manufacturer to market different variants of the same medicinal product in the various Member States can result in an unnecessary partitioning of the Member States' markets, (44) which runs counter to the interests of the internal market within the European Union.

112. Barring evidence to the contrary, the fact that the old variant is still marketed in other Member States reinforces the argument that this variant does not present any safety risks and that parallel imports of the old variant continue to be possible. Furthermore, according to Eurin-Pharm, the new product was not available in other countries from which it could have been exported. Eurin-Pharm states, therefore, that it was only able to import the old product into Germany.

113. In short, if a variant of a medicinal product is (still) lawfully marketed in one Member State, then these variants may also be imported into another Member State. It would be otherwise only in the event of exceptional and specific public health circumstances arising in the latter Member State.

VIII - Conclusion

114. In light of the foregoing considerations I propose that the Court should reply as follows to the questions from the Landgericht Köln (Regional Court, Cologne):

'(1) Withdrawal of an MA for the reference medicinal product in the importing country at the request of the licence holder cannot result in the immediate cessation of parallel imports, where the product was not withdrawn in order to protect public health. Such a legal consequence must be regarded as a restriction on imports prohibited under Article 28 EC and for which no justificatory ground is provided for by the Treaty relating, for example, in the present case to public health.

Restrictions may be imposed on the parallel importer with a view to supervision of the medicinal product, in so far as those restrictions are directly linked to the safety of the medicinal product or are intended to limit the duration of the right to effect parallel imports.

The parallel importer may himself be required to request an MA within a reasonable period of time, or suffer withdrawal of his parallel import licence.

The fact that an implied licence is at issue is immaterial to the assessment of the case.

(2) In the circumstances of the case the fact that the original licence holder markets a similar medicinal product is immaterial.'

1: - Original language: Dutch.

2: - In instances where it clarifies the discussion I shall use the term MA for the authorisation that is granted to the person who places a medicinal product on the market for the first time in a particular Member State. In cases such as the present the term 'parent-authorisation' is also used instead of MA.

3: - OJ 1965 L 22, p. 369. This Directive has been frequently amended. The most important amendments can be found in Council Directive 87/21/EEC of 22 December 1986 amending Directive 65/65/EEC on the approximation of provisions laid down by law, regulation or administrative action relating to proprietary medicinal products (OJ 1987 L 15, p. 36) and in Council Directive 93/39/EEC of 14 June 1993 amending Directives 65/65/EEC, 75/318/EEC and 75/319/EEC in respect of medicinal products (OJ 1993 L 214, p. 22).

4: - As amended by Directive 87/21.

5: - As amended by Directive 93/39.

6: - OJ 1975 L 147, p. 13, Article 29a is inserted by Directive 93/39 (cited in footnote 3).

7: - OJ 2001 L 311, p. 67.

8: - Case 104/75 De Peijper [1976] ECR 613.

9: - Case C-201/94 Smith & Nephew Pharmaceuticals and Primecrown v The Medicine Control Agency [1996] ECR I-5819.

10: - Case C-94/98 Rhône-Poulenc Rorer and May & Baker [1999] ECR I-8789.

11: - Law on Medicinal products 1976 (hereinafter: 'AMG').

12: - Hereinafter: 'Communication'.

13: - Cited in footnote 10.

14: - Cited in footnote 10.

15: - The Commission altered its point of view following fresh appraisals.
16: - The fundamental judgment in this field is the judgment of 14 July 1994, Paola Faccini Dori v Recreb (Case C-91/92 [1994] ECR I-3325, paragraphs 20 and following). Confirmed in, amongst others, the judgment of 26 September 2000 Unilever Italia v Central Food (Case C-443/98 [2000] ECR I-7535).
17: - Cited in footnote 10, paragraph 39 of the judgment. This question has also arisen in the case Paranova Läkemedel and others which is still pending before the Court.
18: - In the remainder of this Opinion I shall refer to the old and new variants of the medicinal product. The use of this term is more correct in view of the problem at issue.
19: - See the fourteenth recital of Directive 2001/83, cited in footnote 10 of this Opinion.
20: - See the fourth recital of Council Directive 75/318/EEC of 20 May 1975 on the approximation of the laws of Member States relating to analytical, pharmaco-toxicological and clinical standards and protocols in respect of the testing of proprietary medicinal products, OJ 1975 L 147, p. 1.
21: - Cited in footnote 10, paragraph 23.
22: - See also on this point the fifteenth recital of Directive 2001/83.
23: - See paragraph 25 of the judgment in Rhône-Poulenc Rorer and May & Baker (cited in footnote 10).
24: - Cited in footnote 8, paragraph 21.
25: - Cited in footnote 9, paragraph 21.
26: - See paragraph 25 of the judgment in De Peijper, cited in footnote 8.
27: - See also the Opinion of Advocate General La Pergola in Rhône-Poulenc Rorer and May & Baker (cited in footnote 10, paragraph 6).
28: - Judgment in Rhône-Poulenc Rorer and May & Baker (cited in footnote 10, paragraph 40 and 45).
29: - See the judgment in De Peijper (cited in footnote 8, paragraph 21).
30: - See Commission communication on parallel imports of proprietary medicinal products for which marketing authorisations have already been granted (OJ 1982 C 115, p. 5).
31: - As introduced by Directive 93/39.
32: - See the De Peijper judgment (cited in footnote 8, paragraphs 27-29).
33: - Cited in footnote 30.
34: - See amongst others the judgment in Smith & Nephew and Primecrown (cited in footnote 9, paragraph 27).
35: - Cited in footnote 8, paragraph 32.
36: - Cited in footnote 9, paragraphs 25 and 26. See also paragraph 28 of the Rhône-Poulenc Rorer and May & Baker case (cited in footnote 10).
37: - Opinion in the Rhône-Poulenc Rorer and May & Baker case (cited in footnote 10, paragraph 27).
38: - These form the main body of a medicinal product, apart from the active ingredient.
39: - See also judgment of 11 March 1999, British Agrochemicals Association (Case C-100/96, ECR I-1499, paragraph 40). This case related to plant protection products.
40: - The meeting referred to was in December 1986, at which Council Directive 87/21/EEC of 22 December 1986 amending Directive 65/65/EEC on the approximation of provisions laid down by law, regulation or administrative action relating to proprietary medicinal products (cited in footnote 3), was adopted.
41: - See judgment of 3 December 1998, Generics (UK) and Others (Case C-368/96, ECR I-1967, paragraph 25).
42: - I do not take into consideration the particular circumstance that it is an implied licence that is concerned here. See on this issue paragraphs 31-32 of this Opinion.
43: - Cited in footnote 8.
44: - I refer to the Opinion of Advocate General La Pergola in Rhône-Poulenc Rorer and May & Baker (cited in footnote 10).