European Court of Justice, 23 April 2002, MSD v Paranova

TRADEMARK LAW - FREE MOVEMENT OF GOODS

Repackaging of pharmaceutical products

- **Replacement packaging of pharmaceutical products is objectively necessary if effective access to the market is hindered as the result of strong resistance from a significant proportion of consumers to relabelled pharmaceutical products.**

Replacement packaging of pharmaceutical products is objectively necessary within the meaning of the Court's case-law if, without such repackaging, effective access to the market concerned, or to a substantial part of that market, must be considered to be hindered as the result of strong resistance from a significant proportion of consumers to relabelled pharmaceutical products.

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European Court of Justice, 23 April 2002

(G.C. Rodríguez Iglesias, P. Jann, C. Gulmann, D.A.O. Edward, M. Wathelet, R. Schintgen, V. Skouris, J.N. Cunha Rodrigues and C.W.A. Timmermans)

JUDGMENT OF THE COURT

23 April 2002 (1)

(Trade marks - Directive 89/104/EEC - Article 7(2) - Exhaustion of the rights conferred by the trade mark - Pharmaceutical products - Parallel importation - Repackaging of the trade-marked product)

In Case C-443/99,

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

Merck, Sharp & Dohme GmbH

and

Paranova Pharmazeutika Handels GmbH,

on the interpretation of Article 7(2) of First Council Directive 89/104/EEC of 21 December 1988 to approximate the laws of the Member States relating to trade marks (OJ 1989 L 40, p. 1), as amended by the Agreement on the European Economic Area of 2 May 1992 (OJ 1994 L 1, p. 3),

THE COURT,

composed of: G.C. Rodríguez Iglesias, President, P. Jann (President of Chamber), C. Gulmann (Rapporteur), D.A.O. Edward, M. Wathelet, R. Schintgen, V. Skouris, J.N. Cunha Rodrigues and C.W.A. Timmermans, Judges,

Advocate General: F.G. Jacobs,

Registrar: D. Louterman-Hubeau, Head of Division,

after considering the written observations submitted on behalf of:

- Merck, Sharp & Dohme GmbH, by R. Subiotto, solicitor, and C. Annacker, Rechtsanwältin,
- Paranova Pharmazeutika Handels GmbH, by R. Schneider, Rechtsanwalt,
- the Belgian Government, by A. Snoecx, acting as Agent,
- the Norwegian Government, by B. Ekeberg, acting as Agent,
- the Commission of the European Communities, by K. Banks and by S. Rating and M. Desantes Real, acting as Agents,

having regard to the Report for the Hearing,

after hearing the oral observations of Merck, Sharp & Dohme GmbH, represented by R. Subiotto and C. Annacker, of Paranova Pharmazeutika Handels GmbH, represented by R. Schneider and by E.B. Pfeiffer, Geschäftsführer, of the Norwegian Government, represented by B. Ekeberg, and of the Commission, represented by K. Banks and S. Rating, at the hearing on 3 April 2001,

after hearing the **Opinion of the Advocate General** at the sitting on 12 July 2001,

gives the following

Judgment

1. By order of 5 November 1999, received at the Court on 22 November 1999, the Oberlandesgericht Wien (Higher Regional Court, Vienna) referred to the Court for a preliminary ruling under Article 234 EC a question on the interpretation of Article 7(2) of First Council Directive 89/104/EEC of 21 December 1988 to approximate the laws of the Member States relating to trade marks (OJ 1989 L 40, p. 1), as amended by the Agreement on the European Economic Area of 2 May 1992 (OJ 1994 L 1, p. 3; 'the Directive').

2. That question was raised in the context of proceedings between Merck, Sharp & Dohme GmbH ('Merck'), an Austrian company belonging to the pharmaceutical group Merck & Co. Inc. ('the Merck group'), established in the United States, and Paranova Pharmazeutika Handels GmbH ('Paranova') concerning the marketing in Austria of pharmaceutical products which were manufactured by the Merck group and were the subject of parallel importation by Paranova.

Community law

3. Under Article 28 EC, quantitative restrictions on imports and measures having equivalent effect are to be prohibited between Member States. Article 30 EC, however, authorises prohibitions and restrictions on imports between Member States which are justified on grounds of the protection of industrial and commercial

property, on condition that they do not constitute a means of arbitrary discrimination or a disguised restriction on intra-Community trade.

4. Article 7 of Directive 89/104, entitled 'Exhaustion of the rights conferred by a trade mark', provides:

'1. The trade mark shall not entitle the proprietor to prohibit its use in relation to goods which have been put on the market in the Community under that trade mark by the proprietor or with his consent.

2. Paragraph 1 shall not apply where there exist legitimate reasons for the proprietor to oppose further commercialisation of the goods, especially where the condition of the goods is changed or impaired after they have been put on the market.'

5. In accordance with Article 65(2) of the Agreement on the European Economic Area, in conjunction with Annex XVII, point 4, thereto, Article 7(1) of Directive 89/104 has been amended for the purposes of that agreement, the expression 'in the Community' having been replaced by 'in a Contracting Party'.

The main proceedings and the question referred for preliminary ruling

6. Merck markets in Austria, in particular, pharmaceutical products which are intended for the treatment of benign prostatic hyperplasia and are sold under the trade mark Proscar, a mark registered by the Merck group.

7. Paranova, whose sole shareholder is the Danish group Paranova A/S ('the Paranova group'), trades, like its parent company, in original pharmaceutical products and specialises in parallel importation. It purchases pharmaceutical products in Member States where prices are comparatively low in order to sell them in other Member States where prices are higher, thus exploiting the price differences within the Community.

8. On 23 November 1997, Paranova was authorised by the Austrian authorities to place on the Austrian market the pharmaceutical product Proscar imported in parallel from Spain. Following that authorisation, it purchased the pharmaceutical product in Spain and had it repackaged in Denmark by Paranova-Pack A/S, a company also belonging to the Paranova group. The repackaging involved giving the product new outer packaging, namely a new box, and attaching to it new annexes translated into German, setting out the information and precautions for use. The particulars required for marketing in Austria were also attached. The packaging used in Austria contained, as in Spain, two blister strips of 14 tablets each.

9. On 15 July 1998, Paranova notified Merck of its intention to put on the market parallel imports of Proscar. At its request, Merck received a sample of the repackaged product, enclosed with a letter of 22 July 1998 in which it was requested to make known any objections it might have.

10. By letter of 9 October 1997 to Paranova, the Austrian authorities, referring to Community case-law, drew attention to the decisive importance of the appearance of pharmaceutical products for compliance by patients with their treatment, which might be jeopardised if the packaging were over-stickered.

11. Merck opposed use of the trade mark Proscar by placing it on the packaging where the product is presented and sold in the Member State of origin in the same arrangement (number of tablets) as in Austria. It claimed that that repackaging constituted unlawful interference with its trade mark rights.

12. Paranova contended that the pharmaceutical product could be marketed only if a number of particulars in German were shown on its outer packaging, in accordance with Paragraph 7(1) of the Arzneimittelgesetz (Austrian Law on pharmaceutical products). It also relied on the fact that the Austrian authorities had recommended replacement packaging and not mere over-stickering. According to Paranova, attaching labels would have had an appreciable influence on the sale of the pharmaceutical products, because relabelled foreign packs engender reactions of mistrust and rejection from both pharmacists and consumers.

13. The Handelsgericht Wien (Commercial Court, Vienna), to which Merck had applied on 22 July 1999 for an order to desist, granted such an order by decision of 16 August 1999. It held that it was possible for the packs of the pharmaceutical product Proscar to be provided with labels on all six sides without this impeding the marketing of that product.

14. On 7 September 1999, Paranova appealed against that decision to the referring court.

15. Since it took the view that the resolution of the dispute depended on the interpretation of Community law, the Oberlandesgericht Wien decided to stay proceedings and to refer the following question to the Court for a preliminary ruling:

'Must Article 7(2) of the First Council Directive of 21 December 1988 to approximate the laws of the Member States relating to trade marks (89/104/EEC) be interpreted as meaning that a trade mark owner may oppose the marketing of a pharmaceutical product put on the market under his trade mark where the importer has repackaged it and reaffixed the trade mark and has complied with the other requirements set forth in the **Court of Justice judgment in Joined Cases C-427/93, C-429/93 and C-436/93 [Bristol-Myers Squibb and Others [1996] ECR I-3457]** (the product inside the packaging must not be affected, the manufacturer and origin must be clearly indicated, the reputation of the trade mark or its owner must not be damaged as a consequence of poor packaging, and the trade mark owner must be given notice before the repackaged pharmaceutical product is put on sale), but the marketability of the product would be jeopardised without such repackaging solely because a significant proportion of the consumers of pharmaceutical products in the State of importation is suspicious of pharmaceutical products which have clearly been produced for the market of another State (in which a different language is spoken) and are inside packagings which have been adapted merely by means of self-stick labels to the domestic provisions governing the sale of pharmaceutical products?'

The question referred for preliminary ruling

16. By its question, the national court seeks essentially to ascertain whether a trade mark proprietor may oppose the repackaging, by a parallel importer and without its authorisation, of a pharmaceutical product bearing that trade mark on the ground that the repackaging is not necessary for the product to be able to be marketed in the importing State even if, without such repackaging, the marketability of the product would be jeopardised solely because a significant proportion of the consumers in that State is suspicious of pharmaceutical products clearly intended for the market of another State.

17. The national court states that Austrian consumers are not accustomed to being offered pharmaceutical products which have clearly been put on the market in another State, where a different language is used. It states that it is perfectly conceivable that a significant number of consumers would regard such a product with the same suspicion as products with untidy or poor-quality packaging. Even attaching labels, in particular in the case before it, would scarcely mitigate that suspicion. If it were to emerge that a significant proportion of consumers would in fact be suspicious in that way, it would be entirely possible, in the view of the national court, to consider that prohibition of the repackaging would contribute to artificial partitioning of the markets.

Observations submitted to the Court

18. Merck submits that the Court has already answered the question referred and that it did so most recently in **Case C-379/97 Upjohn [1999] ECR I-6927**. Inconvenience, consisting for example in having to overcome the resistance of consumers to relabelled pharmaceutical products, cannot justify a parallel importer in repackaging an imported product. In the alternative, Merck claims that a trade mark proprietor's prohibition of the replacement of packaging is justified where it is possible for the importer merely to adapt the original packaging, even if consumers prefer products whose packaging has been replaced. In a market economy it is for the parallel importer to overcome that consumer tendency. The importer's commercial interests are subjective and cannot be used as a basis for the assessment of the validity of its conduct without offending the principle of legal certainty. Moreover, the principle of proportionality requires that a restriction on a fundamental right must not go beyond what is sufficient and necessary to achieve the objective pursued.

19. According to Paranova, the obligation to attach labels constitutes an obstacle to sale and leads to an unacceptable partitioning of markets. Replacement of the packaging of medicinal products from other Member States is in principle lawful, provided that the importer complies with the conditions imposed by the Court in its case-law. The Court stated in Bristol-Myers Squibb and Others that medicinal products fall within a sensitive area where the presentation of the product may be capable of inspiring or destroying public confidence. On a market where the national authorities prefer replacement packaging of medicinal products to over-stickering, to require over-stickering amounts to an obstacle to trade which is much more significant than that arising from different sizes of packaging, as in **Bristol-Myers Squibb and Others**. The requirement of the 'necessity' of repackaging is unclear and does not constitute the decisive criterion. If, however, it were held to be applicable, that requirement should be broadly understood so as to enable effective access to the market, which precludes solely matters subjective to the parallel importer itself.

20. The Norwegian Government submits that the requirement of necessity is satisfied where a significant proportion of consumers has a tendency not to purchase products which are not repackaged because it is suspicious of medicinal products manifestly intended for the market of another State, where another language is used.

21. The Commission submits that the 'necessity' which objectively justifies repackaging by a parallel importer may be the result of circumstances of law or of fact. Since it is the basis for a derogation from the principle prohibiting trade mark infringement which is enshrined in Community law, that concept must be strictly interpreted. The parallel importer should cause as little damage as possible to the specific subject-matter of the mark. It cannot, for example, replace the packaging where it is possible to attach labels. According to the Court's case-law, a prohibition on repackaging contributes unjustifiably to an artificial partitioning of the markets only if the suspicion of the products imported is such that the parallel importer is thereby refused effective access to the market of the importing State. It therefore seems that even considerable suspicion on the part of consumers is not sufficient in that regard. There is nothing to suggest that, in the main proceedings, the replacement of the packaging satisfies in law or in fact a 'necessity' thus defined.

Findings of the Court

22. It should be noted as a preliminary point that the question referred relates to a situation in which a trade mark proprietor has opposed repackaging consisting in replacement of the original packaging by new packaging designed by the importer and required that the importer restrict itself to relabelling by means of self-adhesive stickers.

23. It is clear from paragraph 14 of the judgment in **Case 102/77 Hoffmann-La Roche [1978] ECR 1139** that the proprietor of a trade mark right which is protected in two Member States at the same time is justified, for the purposes of the first sentence of Article 30 EC, in preventing a product to which the trade mark has lawfully been applied in one of those States from being put on the market in the other Member State after it has been repacked in new packaging to which the trade mark has been affixed by a third party. That paragraph also states, however, that such prevention of marketing will constitute a disguised restriction on trade between Member States, within the meaning of the second sentence of Article 30 EC, where it is established, in particular, that the use of the trade mark right by the proprietor, having regard to the marketing system which he has adopted, will contribute to the

artificial partitioning of the markets between Member States.
24. In cases subsequent **to Hoffmann-La Roche**, in particular in **Bristol-Myers Squibb and Others** and **Upjohn**, the Court clarified what may constitute artificial partitioning of the markets between Member States. In certain circumstances, where repackaging is necessary to allow the product imported in parallel to be marketed in the importing State, opposition of the trade mark proprietor to the repackaging of pharmaceutical products is to be regarded as constituting artificial partitioning of markets.
25. The Court has found in that respect that it is necessary to take account of the circumstances prevailing at the time of marketing in the importing Member State which make repackaging objectively necessary in order that the pharmaceutical product can be placed on the market in that State by the parallel importer. The trade mark proprietor's opposition to the repackaging is not justified if it hinders effective access of the imported product to the market of that State (see, to that effect, **Upjohn, paragraph 43**).
26. Such an impediment exists, for example, where pharmaceutical products purchased by the parallel importer cannot be placed on the market in the Member State of importation in their original packaging by reason of national rules or practices relating to packaging, or where sickness insurance rules make reimbursement of medical expenses depend on a certain packaging or where well-established medical prescription practices are based, inter alia, on standard sizes recommended by professional groups and sickness insurance institutions. In that regard, it is sufficient for there to be an impediment in respect of one type of packaging used by the trade mark proprietor in the Member State of importation (**see Bristol-Myers Squibb and Others**, paragraphs 53 and 54).
27. In contrast, the trade mark proprietor may oppose the repackaging if it is based solely on the parallel importer's attempt to secure a commercial advantage (see, to that effect, **Upjohn, paragraph 44**).
28. In that context, it has also been held that the trade mark proprietor may oppose replacement packaging where the parallel importer is able to reuse the original packaging for the purpose of marketing in the Member State of importation by affixing labels to that packaging (**see Bristol-Myers Squibb and Others**, paragraph 55).
29. Thus, while the trade mark proprietor may oppose the parallel importer's use of replacement packaging, that is conditional on the relabelled pharmaceutical product being able to have effective access to the market concerned.
30. Resistance to relabelled pharmaceutical products does not always constitute an impediment to effective market access such as to make replacement packaging necessary, within the meaning of the Court's case-law.
31. However, there may exist on a market, or on a substantial part of it, such strong resistance from a significant proportion of consumers to relabelled pharmaceutical products that there must be held to be a hindrance to effective market access. In those circumstances, repackaging of the pharmaceutical products would not be explicable solely by the attempt to secure a commercial advantage. The purpose would be to achieve effective market access.
32. It is for the national court to determine whether that is the case.
33. The answer to the question referred must therefore be that replacement packaging of pharmaceutical products is objectively necessary within the meaning of the Court's case-law if, without such repackaging, effective access to the market concerned, or to a substantial part of that market, must be considered to be hindered as the result of strong resistance from a significant proportion of consumers to relabelled pharmaceutical products.

Costs

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

On those grounds,

THE COURT,
in answer to the question referred to it by the Oberlandesgericht Wien by order of 5 November 1999, hereby rules:

Replacement packaging of pharmaceutical products is objectively necessary within the meaning of the Court's case-law if, without such repackaging, effective access to the market concerned, or to a substantial part of that market, must be considered to be hindered as the result of strong resistance from a significant proportion of consumers to relabelled pharmaceutical products.

OPINION OF ADVOCATE GENERAL
JACOBS
delivered on 12 July 2001(1)
Case C-443/99
Merck, Sharp & Dohme GmbH
v
Paranova Pharmazeutika Handels GmbH
and Case C-143/00
Boehringer Ingelheim KG and Boehringer Ingelheim Pharma KG and Others
v
Swingward Ltd and Others

Introduction

1. These cases raise a number of questions concerning the circumstances in which a trade mark owner may rely on his trade mark rights to prevent the repackaging of his branded products by a parallel importer.
2. The cases were heard together and it is convenient to consider them in one Opinion. Since Case C-143/00 Boehringer Ingelheim and Others raises broader issues and refers a series of questions, including in effect the question referred in Case C-443/99 Merck, Sharp & Dohme, I will take it first.

The facts in Boehringer Ingelheim

3. The claimants in the main proceedings in Boehringer Ingelheim, Boehringer Ingelheim KG, Boehringer Ingelheim Pharma KG (together, 'Boehringer Ingelheim'), Glaxo Group Ltd, The Wellcome Foundation Ltd (together, 'Glaxo Wellcome'), Eli Lilly and Company ('Eli Lilly') and SmithKline Beecham plc, Beecham Group plc, SmithKline and French Laboratories Limited (together, 'SmithKline Beecham'), are well-known pharmaceutical companies which manufacture and sell pharmaceutical products. The defendants in the main proceedings, Swingward Ltd and Dowelhurst Ltd ('Swingward'), are parallel importers of pharmaceutical products, including, under licence from the United Kingdom authorities, products manufactured by the claimants.

4. In the order for reference, the referring court explains that various pharmaceutical products (inhalers and tablets) have been marketed by one of the claimants within the Community under a trade mark, bought by one of the defendants and imported into the United Kingdom. In each case, the defendants have interfered to some extent with the packaging of the products and with the instruction leaflets inside the packages.

5. It is apparent that the different products have been repackaged in various ways. In some instances, the original package has had a sticker attached to it (without obscuring the trade mark) which includes the trade mark and sets out certain critical information, such as the name of the parallel importer and its parallel import licence number. On such packages, non-English wording remains visible. In other instances, the product has been re-boxed in boxes designed by the parallel importer on which the original trade mark is reproduced. Finally, in some instances the product has been re-boxed in a box designed by the parallel importer which does not bear the trade mark. Instead the generic name of the product is marked on the box. Inside that box, in the case of tablets the inner packaging (blister packs) bears the original trade mark but is over-stickered with a label which indicates the generic name of the product and the identity of the parallel import licence holder. In one such case, the label repeats the trade mark. In another such case, it repeats (in English) the names of the days of the week, each adjacent to a blister containing a tablet. Where the product which has been repackaged under its generic name is an inhaler, the canister, originally labelled with the trade mark, has been over-stickered with the generic name. In all instances, the boxes contain a patient information leaflet in English which bears the trade mark and in the case of tablets the trade mark also appears on the tablets themselves.

6. The claimants object to all the above forms of presentation of their products and take the view that such repackaging and over-stickering is not necessary to enable the imported goods to be marketed in the United Kingdom and that therefore, according to the case-law of the Court of Justice, the parallel importers are not entitled so to repackage their products. The claimants have therefore brought proceedings before the High Court of Justice of England and Wales for trade mark infringement.

7. I would note at this point that in this Opinion I use the term 'repackaging' in general to refer globally to all the above types of operation, namely over-stickering with the trade mark, reboxing with the trade mark and reboxing without the trade mark, except where the context makes it clear that a more specific meaning is intended.

8. The reference has been prompted by the referring court's doubts as to the correct interpretation of the relevant Community legislation and the Court's case-law in this area. Before turning to the eight detailed questions to which the referring court seeks an answer and to the facts and question referred in Merck, Sharp & Dohme, it is helpful to set out that legislation and summarise that case-law.

The Community legal framework

9. Thirty years ago, the Court established the principle that, although the Treaty does not affect the existence of rights recognised by the legislation of a Member State with regard to industrial and commercial property, the exercise of those rights may nevertheless fall within the prohibitions laid down by the Treaty. (2)

10. Article 28 EC prohibits quantitative restrictions on imports in trade between Member States and measures equivalent in effect. According to the first sentence of Article 30 EC, Article 28 does not preclude prohibitions or restrictions which are justified on grounds of the protection of industrial or commercial property. According to the second sentence of Article 30, such prohibitions or restrictions may not constitute a means of arbitrary discrimination or a disguised restriction on trade between Member States.

11. It is clear that if a trade mark owner is allowed to use his trade mark to prevent the importation and sale of goods that have been placed on the market with his consent in another Member State, that will amount to a quantitative restriction or a measure having equivalent effect within the meaning of Article 28. At an early stage the Court held that the exercise by a trade mark owner of his trade mark rights to prevent such parallel trade could not be justified under Article 30. (3)

12. That principle of Community exhaustion was subsequently enshrined in Article 7(1) of the Trade Marks Directive (4) which provides as follows:

'The trade mark shall not entitle the proprietor to prohibit its use in relation to goods which have been put on the market in the Community under that trade mark by the proprietor or with his consent.'

13. The Court also recognised however that there are circumstances in which a trade mark owner may be justified by virtue of Article 30 in opposing the import from another Member State of products which had been put on the market by him or with his consent. Those circumstances, in so far as relevant to the present case, will be discussed in the following sections. That qualification to the principle of exhaustion of rights is reflected in Article 7(2) of the Trade Marks Directive, which provides:

'Paragraph 1 shall not apply where there exist legitimate reasons for the proprietor to oppose further commercialisation of the goods, especially where the

condition of the goods is changed or impaired after they have been put on the market.'

14. The referring court's analysis of the applicable law in this area concentrates on Articles 28 and 30 EC rather than Article 7 of the Directive. The Court has made it clear however - as the referring court notes - that Article 7 comprehensively regulates the question of the exhaustion of trade mark rights for products traded in the Community, (5) while repeatedly affirming that Article 30 EC and Article 7 of the Directive are to be interpreted in the same way. (6)

The relevant case-law

15. In its order for reference the national court is critical of the Court's case-law in this area and in effect asks the Court to reverse certain aspects of its previous decisions. (7) The referring court's criticisms and the observations submitted to the Court can best be evaluated after a relatively detailed account of the development of that case-law.

The early cases

16. The Court established the principle of exhaustion of rights in relation to trade marks in Centrafarm. (8) That case concerned an attempt by the owner of a trade mark to rely on his rights under national law to prevent the parallel import of pharmaceutical products in their original packaging. The Court ruled that, as an exception to one of the fundamental principles of the common market, Article 36 of the Treaty (the predecessor of Article 30 EC) admits of derogations from the free movement of goods only where such derogations are justified for the purpose of safeguarding rights which constitute the specific subject-matter of the trade mark. The specific subject-matter of the trade mark is the guarantee that the owner has the exclusive right to use that mark for the purpose of putting products protected by the trade mark into circulation for the first time, and is therefore intended to protect him against competitors wishing to take advantage of the status and reputation of the trade mark by selling products illegally bearing that trade mark. Where a product had been put onto the market in a legal manner in the Member State from which it had been imported, by the trade mark owner or with his consent, so that there could be no question of abuse or infringement of the mark, there was no justification for permitting the trade mark owner to prevent such trade. (9)

17. In Hoffmann-La Roche (10) the Court was asked to rule on the application of the principle of exhaustion of trade mark rights where a parallel importer of pharmaceutical products had repackaged them and reaffixed the trade mark to the new packaging without the consent of the owner of the trade mark. The repackaging was undertaken because the product was marketed in different quantities in the Member States of export and import.

18. In its judgment the Court repeated its statements in Centrafarm as to the scope of derogations under Article 36 from the free movement of goods and as to the meaning of the specific subject-matter of the trade mark (11) and continued that, in order to answer the question whether the specific subject-matter of the mark involves the right to prevent a third party from affixing the trade mark after repackaging - and hence whether such an action is justified under Article 36 - regard must be had to the essential function of the trade mark. That essential function is to guarantee the identity of origin of the trade-marked product to the consumer or ultimate user, enabling him without risk of confusion to distinguish that product from products of another origin. The effect of that guarantee of origin is that the consumer or ultimate user can be certain that without the authorisation of the proprietor of the mark there has been no third-party involvement in a trade-marked product such as to affect its original condition. The proprietor's right to prevent any use of the mark which is liable to impair the guarantee of origin so understood is therefore part of the specific subject-matter of the trade mark right. (12)

19. The Court reasoned that under the first sentence of Article 36 the proprietor of a trade mark accordingly had the right to prevent an importer of the trade-marked product, following repackaging of the product, from affixing the trade mark to the new packaging without the authorisation of the proprietor. (13)

20. The Court then qualified that proposition, stating that it was still however necessary to consider whether the exercise of that right may constitute a disguised restriction on trade between Member States within the meaning of the second sentence of Article 36. Such a restriction could arise if the proprietor of the trade mark marketed in various Member States an identical product in different packaging and invoked the trade mark in order to prevent repackaging even if that repackaging was done in such a way that the identity of origin of the trade-marked product and its original condition could not be affected. (14) That may be so where for example the repackaging affected only the outer of double packaging, leaving the inner packaging intact. Where the essential function was so protected, the exercise by the trade mark owner of his rights could constitute a disguised restriction if, having regard to the marketing system which he has adopted, it would contribute to the artificial partitioning of the markets between Member States. (15)

21. The Court added that, given the trade mark proprietor's interest that the consumer should not be misled as to the origin of the product, the trader should be allowed to sell the repackaged product only on condition that he give the proprietor prior notice and that he state on the new packaging that the product had been repackaged by him. (16)

22. The Court accordingly made the following ruling:

'(a) The proprietor of a trade mark right which is protected in two Member States at the same time is justified pursuant to the first sentence of Article 36 of the EEC Treaty in preventing a product to which the trade mark has lawfully been applied in one of those States from being marketed in the other Member State after it has been repacked in new packaging to which the trade mark has been affixed by a third party.

(b) However, such prevention of marketing constitutes a disguised restriction on trade between Member

States within the meaning of the second sentence of Article 36 where:
- It is established that the use of the trade mark right by the proprietor, having regard to the marketing system which he has adopted, will contribute to the artificial partitioning of the markets between Member States;
- It is shown that the repackaging cannot adversely affect the original condition of the product;
- The proprietor of the mark receives prior notice of the marketing of the repackaged product; and
- It is stated on the new packaging by whom the product has been repackaged.'

23. After Hoffmann-La Roche, therefore, the legality of parallel imports of repackaged pharmaceutical products to which the trade mark had been affixed was to be assessed as follows, leaving aside the conditions of advance notice, which I will discuss separately, (17) and of information on the new packaging, which is not at issue in the present cases.

24. First, since repackaging is liable to impair the guarantee of origin and since the trade mark owner's right to prevent any use of the mark which is so liable is part of the specific subject-matter of the trade mark right, the trade mark owner is prima facie justified under the first sentence of Article 36 in preventing an importer from affixing the mark to new packaging.

25. The exercise of that right may however in certain circumstances constitute a disguised restriction within the meaning of the second sentence of Article 36 and hence be unlawful.

26. That might be the case if the trade mark owner used different packaging in different Member States and used his trade mark rights to oppose repackaging which could not in fact affect the identity of origin and original condition of the trade marked product. In that case the exercise of the trade mark rights would contribute to the artificial partitioning of the markets between Member States.

27. Shortly after the reference was made in Hoffmann-La Roche, the Court was asked in American Home Products (18) to rule in a case where the importer sought not merely to repackage but also to affix a different trade mark. American Home Products was the proprietor of the trade marks Seresta, registered in Benelux, and Serenid D, registered in the United Kingdom, both in respect of tranquillisers with identical therapeutic properties which it marketed in the Netherlands as Seresta and in the United Kingdom as Serenid D. Centrafarm purchased tranquillisers in the United Kingdom and marketed them in the Netherlands in new packaging and under the mark Seresta. American Home Products sought an order prohibiting such conduct; the Court was asked whether Articles 30 and 36 prevented the trade mark owner from asserting his rights under national law to oppose such marketing.

28. The Court delivered its judgment in October 1978, five months after its judgment in Hoffmann-La Roche. The Court repeated its statement in the earlier case as to the specific subject-matter and essential function (as guarantee of origin) of a trade mark. It continued:

'This guarantee of origin means that only the proprietor may confer an identity upon the product by affixing the mark.

The guarantee of origin would in fact be jeopardised if it were permissible for a third party to affix the mark to the product, even to an original product.

...

The right granted to the proprietor to prohibit any unauthorised affixing of his mark to his product accordingly comes within the specific subject-matter of the trade mark.' (19)

29. The Court then turned to the question whether the exercise of that right could constitute a disguised restriction on trade between Member States within the meaning of the second sentence of Article 36. Its conclusion on that point has now been redefined by the Court in Upjohn (20) so as to bring the case-law on rebranding (namely replacing one trade mark with another in the same ownership) into line with that on reaffixing a trade mark to a repackaged product. (21)

Bristol-Myers Squibb and the related cases

30. Bristol-Myers Squibb and the two related cases Eurim-Pharm and MPA Pharma (22) similarly concerned the circumstances in which the owner of a trade mark could prevent a parallel importer from repackaging its trade-marked pharmaceutical products. The Court used its judgment in Hoffmann-La Roche as a starting point, further refining the ruling in that case. (23)

31. The Court first made it clear that adoption of the Trade Marks Directive had not altered the substance of the case-law discussed above. Thus, save in the circumstances defined in Article 7(2), Article 7(1) of the directive precludes the owner of a trade mark from relying on his rights as owner to prevent an importer from marketing a product which was put on the market in another Member State by the owner or with his consent, even if that importer has repackaged the product and reaffixed the trade mark to it without the owner's authorisation. (24) The Court's case-law under Article 36 must be taken as the basis for determining whether, under Article 7(2) of the directive, a trade mark owner may oppose the marketing of repackaged products to which the trade mark has been reaffixed. (25)

32. The Court, having referred to Hoffmann-La Roche, restated the basic principle of the exhaustion of rights, (26) then reiterated the principles laid down in that case concerning the essential function and the specific subject-matter of the trade mark, (27) concluding that Article 7(2) of the directive therefore meant that 'a trade mark owner may legitimately oppose the further marketing of a pharmaceutical product where the importer has repackaged it and reaffixed the trade mark, unless the four conditions set out in the Hoffmann-La Roche judgment ... have been met'. (28) By way of reminder, those four conditions define the circumstances where the exercise by the trade mark owner of his trade mark rights to prevent marketing constitutes a disguised restriction on trade between Member States within the meaning of the second sentence of Article 30; they are (i) that use of the trade mark right will,

given the trade mark owner's marketing system, contribute to the artificial partitioning of the markets; (ii) that the repackaging cannot adversely affect the original condition of the product; (iii) that the trade mark owner receive prior notice and (iv) that the new packaging state by whom the product has been repackaged.
33. The Court then analysed in more detail each of those four requirements.
34. With regard to the concept of artificial partitioning of the markets between Member States, the Court stated:
'Reliance on trade mark rights by their owner in order to oppose marketing under that trade mark of products repackaged by a third party would contribute to the partitioning of markets between Member States in particular where the owner has placed an identical pharmaceutical product on the market in several Member States in various forms of packaging, and the product may not, in the condition in which it has been marketed by the trade mark owner in one Member State, be imported and put on the market in another Member State by a parallel importer.
The trade mark owner cannot therefore oppose the repackaging of the product in new external packaging when the size of packet used by the owner in the Member State where the importer purchased the product cannot be marketed in the Member State of importation by reason, in particular, of a rule authorising packaging only of a certain size or a national practice to the same effect, sickness insurance rules making the reimbursement of medical expenses depend on the size of the packaging, or well-established medical prescription practices based, inter alia, on standard sizes recommended by professional groups and sickness insurance institutions.
...
The owner may ... oppose the repackaging of the product in new external packaging where the importer is able to achieve packaging which may be marketed in the Member State of importation by, for example, affixing to the original external or inner packaging new labels in the language of the Member State of importation ...
The power of the owner of trade mark rights protected in a Member State to oppose the marketing of repackaged products under the trade mark should be limited only in so far as the repackaging undertaken by the importer is necessary in order to market the product in the Member State of importation.
Finally, contrary to the argument of the plaintiffs in the main actions, the Court's use of the words "artificial partitioning of the markets" does not imply that the importer must demonstrate that, by putting an identical product on the market in varying forms of packaging in different Member States, the trade mark owner deliberately sought to partition the markets between Member States. By stating that the partitioning in question must be artificial, the Court's intention was to stress that the owner of a trade mark may always rely on his rights as owner to oppose the marketing of repackaged products when such action is justified by the need to safeguard the essential function of the trade mark, in which case the resultant partitioning could not be regarded as artificial.' (29)
35. The Court thus clarified two aspects of the first condition for a disguised restriction on trade it had laid down in Hoffmann-La Roche, namely that the use of the trade mark by the owner will contribute to the artificial partitioning of the markets.
36. First, whereas in the earlier case there was a general reference to 'having regard to the marketing system which [the trade mark owner] has adopted', the later rulings give an example of such a marketing system - namely where the owner has placed an identical pharmaceutical product on the market in several Member States in various forms of packaging and the product may not, in the condition in which it has been marketed by the trade mark owner in one Member State, be imported and put on the market in another Member State by a parallel importer. The Court stressed that what is relevant for determining whether the trade mark owner loses on this ground his prima facie right to oppose the marketing of repackaged products is whether the repackaging is necessary in order to market the product in the Member State of importation.
37. Second, the Court confirmed that, as implicitly suggested in Hoffmann-La Roche, use by the trade mark owner of his rights in order to safeguard the essential function of the mark will not be regarded as contributing to the artificial partitioning of the markets between Member States.
38. With regard to the condition that the repackaging must not be able adversely to affect the original condition of the product, the Court emphasised first that it was the condition of the product inside the packaging which was at issue. The trade mark owner may therefore oppose any repackaging involving a risk of the product inside the package being exposed to tampering or to influences affecting its original condition. That is not the case where the repackaging affects only the external of two layers, leaving the inner packaging intact. The mere removal of blister packs, flasks, phials, ampoules or inhalers from their original external packaging and their replacement in new external packaging cannot therefore affect the original condition of the product inside the packaging. (30)
39. The Court concluded that, if the repackaging is carried out in conditions which cannot affect the original condition of the product inside the packaging, the essential function of the trade mark as a guarantee of origin is safeguarded: the consumer or end user is not misled as to the origin of the products and does in fact receive products manufactured under the sole supervision of the trade mark owner. The trade mark owner may not therefore rely on his rights as owner in order to oppose the marketing under his trade mark of products repackaged by an importer. That conclusion however confers on the importer certain rights which, in normal circumstances, are reserved for the trade mark owner himself. In the interests of the owner as proprietor of the trade mark, and to protect him against any misuse, those rights must therefore, as the Court held in Hoff-

mann-La Roche, be recognised only in so far as the importer complies with a number of other requirements. (31)

40. First, the Court confirmed that, since it is in the trade mark owner's interest that the consumer or end user should not be led to believe that the owner is responsible for the repackaging, the new packaging must clearly state who repackaged the product and the name of the manufacturer. (32)

41. Even if that condition is met, however, the presentation of a repackaged product may be liable to damage the reputation of the trade mark and of its owner: the trade mark owner then has a legitimate interest, related to the specific subject-matter of the trade mark right, in being able to oppose the marketing. In assessing whether the presentation of the repackaged product is liable to damage the reputation of the trade mark, account must be taken of the nature of the product and the market for which it is intended. In the case of pharmaceutical products, the requirements to be met by presentation when repackaged vary according to whether the product is sold to hospitals or, through pharmacies, to consumers. In the former case, the products are administered to patients by professionals, for whom the presentation of the product is of little importance. In the latter case, the presentation of the product is of greater importance for the consumer, even if the fact that the products in question are subject to prescription by a doctor may in itself give consumers some degree of confidence in the quality of the product. (33)

42. Finally, the Court confirmed that the importer must give notice to the trade mark owner before the repackaged product is put on sale, and, on demand, supply him with a specimen of the repackaged product. That would enable the owner to check that the repackaging is not carried out in such a way as directly or indirectly to affect the original condition of the product and that the presentation after repackaging is not likely to damage the reputation of the trade mark; it also affords the trade mark owner a better possibility of protecting himself against counterfeiting. (34)

43. In all three decisions the Court went on to rule that the effect of Article 7(2) of the Trade Marks Directive or Article 36 of the Treaty was that the trade mark owner may legitimately oppose the further marketing of a pharmaceutical product where the importer has repackaged the product and reaffixed the trade mark unless:

‘- it is established that reliance on trade mark rights by the owner in order to oppose the marketing of repackaged products under that trade mark would contribute to the artificial partitioning of the markets between Member States; such is the case, in particular, where the owner has put an identical pharmaceutical product on the market in several Member States in various forms of packaging, and the repackaging carried out by the importer is necessary in order to market the product in the Member State of importation, and also carried out in such conditions that the original condition of the product cannot be affected by it; that condition does not, however, imply that it must be established that the trade mark owner deliberately sought to partition the markets between Member States;

- it is shown that the repackaging cannot affect the original condition of the product inside the packaging; such is the case, in particular, where the importer has merely carried out operations involving no risk of the product being affected, such as, for example, the removal of blister packs, flasks, phials, ampoules or inhalers from their original external packaging and their replacement in new external packaging, the fixing of self-stick labels on the inner packaging of the product, the addition to the packaging of new user instructions or information, or the insertion of an extra article; it is for the national court to verify that the original condition of the product inside the packaging is not indirectly affected, for example, by the fact that the external or inner packaging of the repackaged product or new user instructions or information omits certain important information or gives inaccurate information, or the fact that an extra article inserted in the packaging by the importer and designed for the ingestion and dosage of the product does not comply with the method of use and the doses envisaged by the manufacturer;

- the new packaging clearly states who repackaged the product and the name of the manufacturer in print such that a person with normal eyesight, exercising a normal degree of attentiveness, would be in a position to understand; similarly, the origin of an extra article from a source other than the trade mark owner must be indicated in such a way as to dispel any impression that the trade mark owner is responsible for it; however, it is not necessary to indicate that the repackaging was carried out without the authorisation of the trade mark owner;

- the presentation of the repackaged product is not such as to be liable to damage the reputation of the trade mark and of its owner; thus, the packaging must not be defective, of poor quality, or untidy; and

- the importer gives notice to the trade mark owner before the repackaged product is put on sale, and, on demand, supplies him with a specimen of the repackaged product.’ (35)

44. The Court in Bristol-Myers Squibb thus further clarified the circumstances in which the proprietor of a trade mark may rely on his trade mark rights to oppose repackaging by a parallel importer: such reliance is not permitted where it contributes to the artificial partitioning of the markets - for example where the repackaging is necessary for marketing - and where the repackaging takes place in such a way that the legitimate interests of the trade mark owner are observed. Protection of those legitimate interests means in particular that the original condition of the product must not be affected and that the repackaging is not done in such a way that it may damage the reputation of the mark and its owner; (36) the importer must moreover comply with the requirements as to informing the trade mark owner of the repackaging, supplying him with a specimen of the repackaged product and stating on that product the person responsible for the repackaging.

Loendersloot and Upjohn

45. More recently, the case-law summarised above has been approved (subject to one point) and further built on by the Court in its judgments in Loendersloot (37) and Upjohn. (38)

46. In Loendersloot (which was not itself concerned with pharmaceutical products) the Court stated that it had held in that case-law that a trade mark owner may in principle legitimately oppose the further marketing of a pharmaceutical product where the importer has repackaged it and reaffixed the trade mark: in such cases the product bearing the trade mark has been subject to interference by a third party without the authorisation of the trade mark owner, which is liable to impair the guarantee of origin provided by the trade mark. (39)

47. In Upjohn the Court stated that in accordance with the earlier case-law the capacity of a trade mark owner under national law to oppose repackaging of products with reaffixing of the original trade mark was regarded as justified in the light of Article 36 unless it was established in particular that such opposition contributed to the artificial partitioning of the markets between Member States. (40) It summarised the judgment in American Home Products as holding that the essential function of the trade mark would be jeopardised if it were permissible for a third party to affix the mark to the product, even the original product, and that the right granted to the proprietor of the mark to prohibit any unauthorised affixing of that mark to his product accordingly came within the specific subject-matter of the trade mark. The proprietor was accordingly justified, pursuant to the first sentence of Article 36, in preventing the parallel importer from so acting. (41)

The requirement of necessity

48. In discussing the concept of artificial partitioning of the markets where the trade mark owner had marketed an identical product in different packaging in different Member States, the Court in Bristol-Myers Squibb stated that the power of the trade mark owner to oppose the marketing of repackaged products should be limited only in so far as the repackaging was necessary in order to market the product in the State of importation. (42) The Court reiterated that notion in Loendersloot, (43) where it stated that in cases involving the repackaging of pharmaceutical products the national courts must consider whether circumstances in the markets of their own States made repackaging objectively necessary.

49. Guidance as to the circumstances in which repackaging by the importer may be regarded as 'necessary' may be found in Bristol-Myers Squibb. The Court in its judgment in that case referred to the impossibility of marketing in the Member State of importation by reason, in particular, of rules or national practices, sickness insurance rules governing the reimbursement of medical expenses, and well-established medical prescription practices. (44) The Court did not however consider that repackaging would be necessary where the importer could 'achieve packaging which may be marketed in the Member State of importation by, for example, affixing to the original external or inner packaging new labels in the language of the Member State of importation, or by adding new user instructions or information in the language of the Member State of importation ...' (45)

50. Further guidance as to the meaning of 'objectively necessary' has since been given by the Court in Upjohn (46) and Loendersloot. (47)

51. Upjohn concerned the question whether a parallel importer could lawfully use on imported goods the trade mark which the proprietor used in the importing State for identical goods, even though that mark differed from the mark under which the goods in question were put on the market by the proprietor in the exporting State. Although that issue is different from repackaging in the sense discussed above, the Court made it clear that for the purpose of determining whether the trade mark owner's conduct contributed to the artificial partitioning of markets there was no difference between the two situations. (48)

52. The Court in Upjohn stated that the condition of necessity was satisfied if, in a specific case, the prohibition imposed on the importer against replacing the trade mark [repackaging] hindered effective access to the markets of the importing Member State; that would be the case if the rules or practices in the importing Member State prevented the product in question from being marketed in that State under its trade mark in the exporting Member State [in the packaging used in the exporting Member State]. In contrast, the condition of necessity would not be satisfied if replacement of the trade mark [repackaging] was explicable solely by the parallel importer's attempt to secure a commercial advantage. (49)

53. In Loendersloot the Court stated that, even where relabelling (at issue rather than repackaging as such) was necessary for marketing in the State of import, it must be done in such a way as to make parallel trade feasible while causing as little prejudice as possible to the specific subject-matter of the trade mark right. Thus if the original labels comply with the relevant rules of the State of import but those rules require additional information to be given, it is not necessary to remove and reaffix or replace the original labels, since the mere application to the bottles in question of a sticker with the additional information may suffice. (50)

The order for reference and the questions referred in Boehringer Ingelheim

54. It is apparent from the extremely long and detailed order for reference that the High Court is not convinced that the case-law summarised above has in all respects been correctly decided. There are two specific issues with regard to which it considers that case-law incoherent or incorrect or both.

55. First, the referring court considers that there is a conflict between, on the one hand, the principle, expressed first in Hoffmann-La Roche, that reliance by a trade mark owner on his trade mark rights to oppose the parallel import of repackaged trade-marked goods will be justified where it is for the purpose of safeguarding the rights which constitute the specific subject-matter of the trade mark and, on the other hand, the principle, expressed first in Bristol-Myers Squibb, that the power

of the trade mark owner to oppose the parallel import of such goods should be limited only in so far as the repackaging is necessary in order to market the product. The referring court does not see why the criterion of necessity should be a factor: if the marketing of the repackaged goods cannot harm the specific subject-matter of the trade mark, then on the basis of the early case-law it should not be lawful for the trade mark owner to oppose it.

56. If however - contrary to its view as to what the law should be - the criterion of necessity is a factor, the referring court considers that there is insufficient guidance in the case-law of the Court as to the meaning of that concept. In particular, can it be said to be 'necessary' to rebox pharmaceutical products when overstickering would achieve the same ends but would make the products significantly less competitive in a given market?

57. Second, the referring court does not consider that the requirement of advance notice of repackaging, developed by the Court in its case-law, is intellectually sound. It invites the Court to reconsider that requirement. If however the requirement of notice survives, the referring court seeks guidance as to the form and length of such notice and the consequences of failure to give it.

58. It has accordingly referred the following questions to the Court:

'1. Can a proprietor of a trade mark use his trade mark rights to stop or hinder the import of his own goods from one Member State into another or to hinder their subsequent marketing or promotion when the importation, marketing or promotion causes no, or no substantial, harm to the specific subject-matter of his rights?

2. Is the answer to the previous question different if the ground relied on by the proprietor is that the importer or subsequent dealer is using his mark in a way which, although not prejudicial to its specific subject-matter, is not necessary?

3. If an importer of the proprietor's goods or a dealer in such imported goods needs to show that his use of the proprietor's mark is "necessary", is that requirement met if it is shown that the use of the mark is reasonably required to enable him to access (a) part only of the market in the goods, or (b) the whole of the market in the goods; or does it require that the use of the mark was essential to enabling the goods to be placed on the market and if none of these, what does "necessary" mean?

4. If the proprietor of a mark is, prima facie, entitled to enforce his national trade mark rights against any use of his mark on or in relation to goods which is not necessary, is it abusive conduct and a disguised restriction on trade in accordance with the second sentence of Article 30 [EC], to use that entitlement in order to hinder or exclude parallel imports of his own goods which do not threaten the specific subject matter or essential function of the trade mark?

5. Where an importer or someone dealing in imported goods intends to use the proprietor's trade mark on or in relation to those goods and such use does and will not prejudice the specific subject matter of the mark, must he nevertheless give the proprietor advance notice of his intended use of the mark?

6. If the answer to the previous question is in the affirmative, does that mean that failure of the importer or dealer to give such notice has the effect of entitling the proprietor to restrain or hinder the importation or further commercialisation of those goods even though such importation or further commercialisation will not prejudice the specific subject-matter of the mark?

7. If an importer or someone dealing in imported goods must give prior notice to the proprietor in respect of uses of the trade mark which do not prejudice the specific subject-matter of the mark,

(a) does that requirement apply to all such uses of the trade mark, including in advertising, re-labelling and repackaging or, if only some uses, which?

(b) must the importer or dealer give notice to the proprietor or is it sufficient that the proprietor receives such notice?

(c) how much notice must be given?

8. Is a national court of a Member State entitled, at the suit of the proprietor of trade mark rights, to order injunctions, damages, delivery up and other relief in respect of imported goods or the packaging or advertisements therefor where the making of such an order (a) stops or impedes the free movement of goods placed upon the market within the EC by the proprietor or with his consent but (b) is not for the purpose of preventing harm to the specific subject-matter of the rights and does not help to prevent such harm?'

The facts and the question referred in Merck, Sharp & Dohme

59. The claimant in the main proceedings in Case C-443/99, Merck, Sharp & Dohme GmbH ('Merck'), markets in Austria pharmaceutical products bearing its trade mark PROSCAR. The defendant in the main proceedings, Paranova Pharmazeutika Handels GmbH ('Paranova'), is a parallel importer of pharmaceutical products, including, under licence from the Austrian authorities, PROSCAR. Paranova purchased PROSCAR tablets in Spain and repackaged them with a view to marketing in Austria. The repackaging involved repacking the blister packs of tablets in new outer packaging on which the trade mark was reaffixed, producing or adapting (in particular translating) the other printed materials such as the information on use, and affixing on the new packaging any particulars required for marketing the product in Austria.

60. Merck sought and obtained an interim order restraining Paranova from so using its trade mark on the ground that the repackaging (and thus the reaffixing of the trade mark) by Paranova constituted unlawful interference with its trade mark rights, the first instance court (51) observing that replacing the original packaging with new packaging would be permissible only if the pharmaceutical product could not be adapted to the requirements of Austrian legislation by means of self-adhesive labels.

61. On appeal, the Oberlandesgericht Wien (Higher Regional Court, Vienna) referred the following question to the Court for a preliminary ruling:
'Must Article 7(2) of the First Council Directive of 21 December 1988 to approximate the laws of the Member States relating to trade marks (89/104/EEC) be interpreted as meaning that a trade mark owner may oppose the marketing of a pharmaceutical product put on the market under his trade mark where the importer has repackaged it and reaffixed the trade mark and has complied with the other requirements set forth in the Court of Justice judgment in Joined Cases C-427/93, C-429/93 and C-436/93 (the product inside the packaging must not be affected, the manufacturer and origin must be clearly indicated, the reputation of the trade mark or its owner must not be damaged as a consequence of poor packaging, and the trade mark owner must be given notice before the repackaged pharmaceutical product is put on sale), but the marketability of the product would be jeopardised without such repackaging solely because a significant proportion of the consumers of pharmaceutical products in the State of importation is suspicious of pharmaceutical products which have clearly been produced for the market of another State (in which a different language is spoken) and are inside packagings which have been adapted merely by means of self-stick labels to the domestic provisions governing the sale of pharmaceutical products?'
62. It is clear from the order for reference that the Oberlandesgericht Wien has doubts as to the correct interpretation of the case-law of the Court of Justice set out above, and in particular the judgment in Bristol-Myers Squibb, similar to those which prompted the High Court of Justice of England and Wales to refer the questions in Boehringer Ingelheim.
63. In particular, the Oberlandesgericht states that it now appears uncertain, in the case of pharmaceutical products in particular, in what circumstances reliance on a trade mark right by its owner in order to oppose the marketing of repackaged products under the trade mark would contribute to the artificial partitioning of markets between Member States. If - as appears to be the case - a significant proportion of consumers would be suspicious of pharmaceutical products which had been adapted to the requirements of Austrian legislation on the presentation of pharmaceutical products by the use of self-adhesive labels, it could certainly be said that prohibition of the repackaging of such pharmaceutical products would contribute to an artificial partitioning of the markets. It therefore needs to be decided whether such products may be repackaged only if that is the only way of complying with the legislation of the State of importation or also where the use of self-adhesive labels would, while satisfying legal requirements, in fact adversely affect sales of the product in comparison with the 'original product'. In other words, what precisely is meant by the requirement that repackaging must be 'necessary' in order to market the imported product? That question is essentially the same as the issue raised by the High Court and summarised in paragraph 56 above.

Observations of the parties

64. In Merck, Sharp & Dohme written observations were submitted by Merck, Paranova, the Belgian Government and the Commission. Merck, Paranova and the Commission were represented at the hearing.
65. In Boehringer Ingelheim written observations were submitted by Boehringer Ingelheim, Glaxo Wellcome, Eli Lilly and SmithKline Beecham (jointly), Swingward, the German and Norwegian (52) Governments and the Commission, all of whom were represented at the hearing.
66. The written observations in particular are in part taken up with the facts underlying the main proceedings. The referring courts have however in both cases correctly framed the questions referred on the basis of general principles, so that the answers given by the Court may be applied in other contexts. I shall similarly seek to avoid being diverted by the factual details since I consider that it is both possible and appropriate to answer the questions on the basis of general principles.
67. In so far as they deal with relevant general principles, the gist of the observations may be summarised as follows. The observations of the parties on the questions relating to the requirement of advance notice are referred to below, in the context of the discussion of that requirement.
68. Merck submits that the question referred by the Oberlandesgericht, Vienna, has already been answered by the Court's case-law, most recently Upjohn: a commercial advantage - such as overcoming consumer resistance to over-stickering - cannot authorise a parallel importer to repackage an imported product. If the Court does not accept that submission, Merck submits that a prohibition on re-boxing is not a restriction on trade if the importer can adapt the original packaging, even if consumers prefer reboxed products. In a market economy it is for the parallel importer to overcome that resistance. The importer's commercial interests are subjective, and may not be used in assessing the legality of his conduct without infringing the principle of legal certainty. Moreover the principle of proportionality requires that a restriction of a fundamental right must not go beyond what is appropriate and necessary to attain the desired objective.
69. Boehringer Ingelheim submits that the prohibition against the use of a trade mark by a party other than the trade mark owner does not constitute an impediment to free trade between Member States for the purposes of Article 28 EC if the parallel trader can have effective access to the markets of the State of importation without interfering with the trade mark owner's rights. In the alternative, Community law does not prevent the trade mark owner from opposing interference with his trade mark rights unless that interference is necessary for access to the market of the importing State and causes as little prejudice as possible to the specific subject-matter of the trade mark and other legitimate interests of the trade mark owner are assured. Interference with the trade mark owner's rights will be

necessary only if the legal rules in force in the importing State and practices having a similar effect would prevent the importer, without such interference, from marketing the product in the State of importation. The trade mark proprietor may therefore legitimately oppose interference prompted by local consumer preferences for a certain packaging where the rules and practices in force in that State allow the parallel importer to market the product without it.

70. Glaxo submits that the repackaging of a trade mark owner's goods and the reaffixing of the trade mark without the owner's consent is an interference with the specific subject-matter of the trade mark. The fact of that interference in itself justifies an action for infringement of the trade mark, subject only to the four conditions laid down in Hoffmann-La Roche. In particular, there is no further requirement of proof that the repackaging is damaging, or harmful or prejudicial to the specific subject-matter of the trade mark.

71. With regard to the condition of necessity, Glaxo submits that the Court intended to draw a distinction between changes to packaging which are required to enable the goods to be placed on the market and changes which are 'necessary' to maximise the commercial acceptability of those goods to the market, such as changes whose purpose is to enable parallel traders to charge higher prices for their goods or otherwise make them more attractive to their customers, or increase sales. If it is not shown that the repackaging was necessary in order to market the product in the importing Member State, then there is no artificial partitioning of the market by the trade mark proprietor. Provided that the importer can repackage if necessary for marketing, then the principle of free movement is satisfied.

72. SmithKline Beecham submits that it is clear from the case-law of the Court that the issue of proof of damage to the reputation of the mark may be a consideration relevant to the second sentence of Article 30 EC, but that it is not a precondition for the application of the first sentence of that article. Harm and necessity are two different things. If it is necessary to permit repackaging, in any given form, in order to avoid a disguised restriction, the fact that such repackaging causes harm to the proprietor remains a relevant consideration. The fact that the repackaging would cause no harm cannot of itself render the repackaging necessary. 'Necessary' means essential in order to market the product, in the sense that without the repackaging the product could not be put on the market. Overcoming the reluctance of customers to accept an over-stickered product is not a legitimate reason for repackaging.

73. Paranova submits that a requirement to over-sticker rather than rebox PROSCAR would be an obstacle to its sale and would lead to an undesirable partitioning of the markets. Reboxing of pharmaceutical products coming from other Member States is in principle permissible provided that the importer respects the requirements imposed by the Court in its case-law. The Court in Bristol-Myers Squibb stressed that pharmaceutical products were a sensitive area where presentation of the product could inspire (and hence destroy) public confidence. Regard must be had to the particular situation of the market in such products without giving weight to the commercial or non-commercial character of the different aspects of presentation. In the context of a market where the national authorities prefer pharmaceutical products which are reboxed rather than over-stickered, insisting on the latter would constitute an obstacle to trade much greater than that arising from the different package sizes at issue in Bristol-Myers Squibb.

74. With regard to the condition of necessity, Paranova submits that it is unclear and in any event not the decisive criterion. The interpretation given by the Court in Upjohn conflicts with the earlier case-law. In order to reconcile the cases, the question of 'necessity' should arise only if the specific subject-matter of the trade mark has been prejudiced. If however the condition were regarded as applicable, it should be interpreted broadly so as to permit effective access to the market, thus excluding only circumstances falling within the subjective sphere of the parallel importer himself.

75. Swingward submits that it is clear from the case-law of the Court that a trademark can be invoked only where there is specific and material harm to the specific subject-matter of the mark. The only circumstances in which conduct in respect of a trade mark is not necessary is where it is explicable solely by the parallel importer's attempts to secure a commercial advantage. A commercial advantage in the sense of Upjohn is an unfair or abusive commercial advantage.

76. The German Government submits in Boehringer Ingelheim that it is clear from the Court's case-law that to repackage or relabel trade-marked goods can affect the trade mark owner's rights including those constituting the specific subject-matter of the trade mark right and that there is no reason to depart from that settled case-law. The Court has also given clear guidelines on the circumstances in which repackaging and relabelling of trade-marked pharmaceutical products are permissible, by reference to the concept of necessity. Mere economic advantages, such as further increasing sales of a product, are not sufficient for repackaging or relabelling to be deemed necessary. Accordingly, there is, for example, no objective need to repackage where over-stickered or foreign packaging is less well received. If, on the other hand, the market for potential sales actually makes it very significantly harder to sell an imported product unaltered, repackaging must be regarded as necessary.

77. The Norwegian Government submits in Boehringer Ingelheim that the wording of Article 30 EC presupposes that restrictions on imports are justified only if the industrial or commercial property would otherwise be jeopardised; a condition of necessity would moreover be a breach of Article 30 EC, since it would constitute an undue restriction on imports. Passages in the Court's case-law relied on in support of the contrary argument do not support the conclusion that a trade mark owner can oppose the importation of repackaged products which do not adversely affect the original condition of the product or damage the reputation of

the trade mark and its owner. If the four conditions laid down in Hoffmann-La Roche are satisfied, there remains no legitimate reason for the proprietor of the trade mark to oppose the importation of the repackaged product. Consequently, the Norwegian Government concludes that no condition of necessity can be deduced from the case-law of the Court. If however such a condition were to be established, it should be considered to be fulfilled if the parallel importer finds repackaging necessary in order to market the product.

78. The Norwegian Government adds in Merck, Sharp & Dohme that the condition of necessity will be satisfied where a large part of the public is not inclined to purchase the products without reboxing because a significant proportion of customers and users are suspicious of pharmaceutical products which have clearly been produced for the market of another State where another language is spoken.

79. The Commission submits in Merck, Sharp & Dohme that the 'necessity' objectively justifying repackaging by a parallel importer may be legal (as in Loendersloot) or factual (as in Bristol-Myers Squibb). Since recognition of objective necessity derogates from the principle that a trade mark may not be infringed, enshrined by Community law, it must be interpreted restrictively. The parallel importer must cause as little prejudice as possible to the specific subject-matter of the trade mark. He cannot for example rebox if over-stickering is possible. There is no suggestion that reboxing is as a matter of either law or fact necessary in the present case. According to the Court's case-law there will not be artificial partitioning of the markets unless resistance to the imported products is such that the parallel importer is denied effective access to the markets of the importing State; even significant consumer resistance thus seems insufficient. Even if the national court were to find that sales of over-stickered products were greatly inferior, or even negligible, it would have to consider the reasons for the resistance; if it was in fact due to insufficient information, the national court should consider whether the importer should not rather seek to educate consumers and pharmacists.

80. The Commission submits in Boehringer Ingelheim that the essential question is whether the requirement of necessity has to be combined with the conditions relating to protection of the specific subject-matter of a trade mark. Although Bristol-Myers Squibb is not entirely without ambiguity in that regard, if the Court had wished to alter the nature of the list of conditions laid down in Hoffmann-La Roche by making some of them alternatives, it could perfectly well have done so in that judgment. The Commission thus considers the requirement of 'necessity' to be additional to the criteria concerning protection of the specific subject-matter of a trade mark. Over-stickering is easier to justify in terms of necessity than re-boxing under the trade mark, but still requires such justification. As for re-boxing without affixing the mark, since there is no use of the trade mark beyond that which is indispensable to reselling the goods, it would seem superfluous to impose a condition of 'necessity'. In that type of case, only the last four conditions laid down in Bristol-Myers Squibb relating to specific subject-matter should apply. With regard to the meaning of 'necessity', the Commission submits that consumer resistance does not make repackaging necessary within the meaning of the Court's case-law unless it is of a kind which cannot be overcome by lower prices and greater information.

81. It may be noted that the Commission submits in its written observations in Boehringer Ingelheim that the High Court's first, fifth, seventh and eighth questions are inadmissible in so far as they relate to the use of a trade mark by way of advertising, since nothing in the order for reference indicates that the disputes between the various parties to the national proceedings concern advertising. That submission was not disputed at the hearing. The conclusion therefore seems unavoidable that the national court does not require clarification of Community law as it relates to that issue in order to dispose of the cases before it. I accordingly do not propose to deal with the questions referred in so far as they refer to advertising or promotion by parallel importers.

The relationship between the specific subject-matter of a trade mark and the necessity of repackaging

82. The first, second, fourth and eighth questions referred in Boehringer Ingelheim all ask essentially whether a trade mark owner can use his trade mark rights to prevent a parallel importer from carrying out various repackaging operations treated by national law as infringements of his trade mark if there is no threat to the specific subject-matter or the essential function of the trade mark and/or if it is not necessary for the parallel importer to undertake such repackaging.

83. As mentioned above, it is clear from the order for reference that the national court considers that the Court has not been consistent in imposing the separate requirements relating to the specific subject-matter of a trade mark and the necessity of repackaging.

84. In my view however there is no inconsistency or incoherence in the imposition of the different requirements since those requirements are relevant at different stages in the analysis of the question whether a trade mark owner may use his trade mark rights to prevent a parallel importer from repackaging trade marked goods.

85. First, it is clear from the case-law that a trade mark owner is prima facie justified under the first sentence of Article 30 EC or under Article 7(2) of the Directive in opposing the unauthorised reaffixing of his trade mark after repackaging. (53)

86. In my view that principle applies to all the types of repackaging at issue in the present cases, because (i) each of those repackaging operations is in principle liable to prejudice the guarantee provided by a trade mark that a product bearing that mark has not been affected by a third party without the trade mark owner's authorisation and (ii) the specific subject-matter of the trade mark includes the right to prevent any use of it which is likely to impair that guarantee of origin, and each of those repackaging operations is likely so to do. (54)

87. Second, however, if the exercise of that right to oppose constitutes a disguised restriction on trade between Member States, then by virtue of the second sentence of Article 30 it will not be justified.
88. The Court in its case-law summarised above has given guidance for assessing whether the exercise by the trade mark owner of his trade mark rights constitutes a disguised restriction on trade within the meaning of the second sentence of Article 30.
89. It is in particular clear from that case-law that the exercise by the trade mark owner of his trade mark rights will constitute a disguised restriction if it will contribute to the artificial partitioning of the markets. (55)
90. One circumstance in which the exercise by the trade mark owner of those rights will contribute to the artificial partitioning of the markets is where the owner uses different packaging in the different Member States and repackaging is necessary for effective access to the market in the importing State. (56)
91. Thus the question whether repackaging is necessary may arise in assessing whether the exercise by the trade mark owner of his trade mark rights, although prima facie justified by virtue of the first sentence of Article 30, is on the facts prohibited by virtue of the second sentence.
92. The referring court and the defendants in Boehringer Ingelheim, however, are of the view that, if the above is a correct account of the case-law of the Court, that case-law should be revised.
93. The referring court notes that the Court in Bristol-Myers Squibb stated:
'The Court's case-law shows that Article 36 allows derogations from the fundamental principle of the free movement of goods within the common market only in so far as such derogations are justified in order to safeguard the rights which constitute the specific subject-matter of the industrial and commercial property in question.' (57)
. Since the referring court finds as a fact that the repackaging operations at issue in the main proceedings do not harm or even put at risk the specific subject-matter of the claimants' trade marks, it considers that no derogation from the principle of the free movement of goods should be justified. The concept of necessity is extraneous to the above-stated fundamental principle.
95. However in my view there is no contradiction between on the one hand the above-quoted statement of the Court and on the other the proposition that the claimants may in principle (hence subject to the second sentence of Article 30) assert their trade mark rights even in the absence of actual harm or risk of harm. The statement of the Court was made in the context of a line of reasoning on the interpretation of Article 7(2) of the Trade Marks Directive. The following paragraphs of the judgment show that the Court was endorsing the view it had expressed in Hoffmann-La Roche to the effect that, since repackaging was liable to impair the guarantee of origin, the trade mark owner may in principle rely on his rights to prevent the marketing of repackaged products. (58)
96. Such an interpretation means of course that there may be cases where the trade mark owner can so rely on his rights even if it might appear in a particular case that there is no actual harm to the specific subject-matter or essential function of his mark. I do not share the apparent view of the referring court however that that is necessarily an unpalatable or illogical consequence.
97. It is clear from the terms of the relevant provisions of the Treaty as interpreted by the Court that interference by a third party, such as a parallel importer, with intellectual property rights, such as the rights of a trade mark owner, will be capable of justification by virtue of Community law only where the unfettered exercise of those rights would have an adverse effect on the free movement of goods. By importing the criterion of necessity, and hence justifying all such interference which is necessary for effective access to the market in the importing State, the Court has developed a formula which precisely reflects that balance.
98. It must be borne in mind that repackaging a product which bears a trade mark, whether or not the trade mark is reaffixed to the new external packaging or simply removed and not replaced, is a particularly intrusive form of trade mark infringement.
99. It must also not be forgotten that most of the 'repackaging cases' discussed above concern pharmaceutical products, and that the pharmaceutical market, for reasons discussed further below, (59) has certain features not shared by the market in many other goods.
100. The referring court and the defendants in Boehringer Ingelheim have expressed concern at what they regard as one inevitable consequence of endorsement of the necessity criterion coupled with a strict interpretation of the notion of necessity: namely that trade mark owners will be able to enforce trade marks even though their corporate strategy is designed to partition markets. But that consequence does not follow. It must be borne in mind that the criterion of necessity was introduced by the Court solely in the context of an example of conduct which would contribute to the artificial partitioning of the markets and which would hence constitute a disguised restriction on trade between Member States within the meaning of the second sentence of Article 30 of the Treaty. It is not to my mind the only example. As I stated in my Opinion in Upjohn, if it can be shown that the trade mark owner's practice of using different marks in different Member States was intended to partition markets, that will in itself be sufficient to preclude reliance by him on his trade mark rights to oppose affixing of a different mark by the importer; (60) the same applies where reaffixing a mark after repackaging is at issue rather than rebranding. (61)
101. The defendants in Boehringer Ingelheim also invoke the judgment of the Court in SABEL (62) in support of their view that trade mark owners cannot rely on their rights in the absence of properly substantiated evidence that the subject-matter of the mark has been harmed. SABEL however concerned Article

4(1)(b) of the Directive which provides that a mark shall not be registered or, if registered, shall be liable to be declared invalid 'if because of its identity with, or similarity to, the earlier trade mark and the identity or similarity of the goods or services covered by the trade marks, there exists a likelihood of confusion on the part of the public ...'. Thus that provision explicitly requires that a likelihood of confusion be established. The main proceedings in Boehringer Ingelheim however do not concern similar marks or similar goods: they concern (at least in part) the use of an identical mark on identical goods. Infringement in that case is under Article 5(1)(a), which does not require proof of any risk of confusion (or other harm).

102. The referring court in Boehringer Ingelheim states in the order for reference that it has assumed that the claimants have made out a good case of trade mark infringement under domestic law. I would note in passing that, as suggested in the previous paragraph, the concept of infringement has now been harmonised by the Trade Marks Directive; (63) national law consequently no longer has an unfettered discretion as to which conduct it will treat as infringement.

103. I accordingly conclude that a trade mark owner may use his trade mark rights to prevent the parallel importer of a pharmaceutical product from repackaging that product provided that such use of his rights does not contribute to the artificial partitioning of the markets between Member States or otherwise constitute a disguised restriction on trade between Member States. A trade mark owner who uses his trade mark rights to prevent a parallel importer from necessary repackaging contributes to such artificial partitioning. That is the inescapable conclusion of the case-law considered above and I see no reason to depart from that case-law. That conclusion however raises the question how 'necessary' is to be interpreted, to which I now turn.

The meaning of 'necessary'

104. The third question in Boehringer Ingelheim and the question in Merck, Sharp and Dohme concern the scope of the concept of 'necessary' developed by the Court as a criterion for determining whether reliance by a trade mark owner on his trade mark rights contributes to the artificial partitioning of the markets and hence constitutes a disguised restriction on trade within the meaning of the second sentence of Article 30 EC.

105. Various interpretations of the concept have been advanced. The referring court in Boehringer Ingelheim suggests in its third question that it may mean either 'reasonably required to enable [the importer] to access' the market (I will consider below the question which market is relevant, also raised in the third question) or 'essential' therefor. The claimants understandably argue that 'necessary' means nothing less than 'essential', while the defendants, equally understandably, argue that (on the assumption that the criterion is relevant at all) it must be defined by reference to effective access to the market understood in the broadest sense.

106. It is clear from the observations submitted to the Court that the parties' differences concerning the correct interpretation of the concept of necessity are largely attributable to statements made by the Court in its judgment in Upjohn, (64) and in particular the following paragraphs:

'The view that the condition of market partitioning defined in Bristol-Myers Squibb applies to the case where a trade mark is replaced also implies, contrary to what Paranova argues, that this replacement of the trade mark must be objectively necessary within the meaning of that judgment if the proprietor is to be precluded from opposing it.

It follows that it is for the national courts to examine whether the circumstances prevailing at the time of marketing made it objectively necessary to replace the original trade mark by that of the importing Member State in order that the product in question could be placed on the market in that State by the parallel importer. This condition of necessity is satisfied if, in a specific case, the prohibition imposed on the importer against replacing the trade mark hinders effective access to the markets of the importing Member State. That would be the case if the rules or practices in the importing Member State prevent the product in question from being marketed in that State under its trade mark in the exporting Member State. This is so where a rule for the protection of consumers prohibits the use, in the importing Member State, of the trade mark used in the exporting Member State on the ground that it is liable to mislead consumers.

In contrast, the condition of necessity will not be satisfied if replacement of the trade mark is explicable solely by the parallel importer's attempt to secure a commercial advantage.

It is for the national courts to determine, in each specific case, whether it was objectively necessary for the parallel importer to use the trade mark used in the Member State of import in order to enable the imported products to be marketed.' (65)

107. Merck seeks to deduce from the above, and in particular from the second paragraph set out above, (66) that the Court has stated that 'to hinder' means 'to prevent', which in turn means to make impossible; thus repackaging is permissible only where marketing would otherwise be impossible. That statement is in my view too narrow. It is of course correct that a rule or practice which prevents market access, or makes it impossible, must be regarded as 'hindering' such access. That does not however mean that only such rules or practices may properly be regarded as 'hindering' access. The Court in that paragraph of its judgment in Upjohn was simply giving an example of circumstances where repackaging would be regarded as necessary: it was not purporting to be exhaustive.

108. It is clear from the Court's dicta that repackaging must be 'objectively' necessary. It cannot thus be for the parallel importer to determine what is necessary, as the Norwegian Government submits. The statement by the referring court in Boehringer Ingelheim that there are always alternative ways of repackaging so that no one way can be necessary is in my view misconceived for the same reason.

109. It has been suggested by Paranova that in certain Member States - it mentions Austria, Denmark and Finland (and also Norway, in the European Economic Area) - pharmaceutical products in over-stickered packaging will not receive marketing authorisation or approval. If correct, that is clearly an example of a situation where repackaging would be objectively necessary for market access.
110. In my view however repackaging may correctly be regarded as objectively necessary in other, less black and white situations. If the national court finds as a fact - as did the referring court in Boehringer Ingelheim - that there is 'widespread and substantial resistance' to over-stickered boxes by the relevant consumers, and if the effect of such resistance is that the parallel importer would be effectively excluded from the market unless permitted to repackage, repackaging would to my mind certainly be regarded as objectively necessary for effective market access in the sense that it is reasonably required for such access. Although it is clear that 'rules [and] practices' (67) cannot embrace mere patterns of consumer preference, none the less if such patterns are sufficiently strongly held, widespread and widely recognised that, for example, doctors' prescription practices or pharmacists' purchasing practices are affected and 'effective access' denied, then repackaging may correctly be regarded as objectively necessary.
111. It is also to my mind clear from the case-law of the Court reviewed above that a particular method of repackaging cannot be regarded as necessary if another method which interferes less with the trade mark owner's rights will suffice to give the parallel importer effective access to the market in the importing State. (68) If therefore the national court finds on the facts that over-stickered packages have effective access to that market, then it cannot be necessary for the parallel importer to undertake more intrusive types of repackaging such as reboxing.
112. It may furthermore be noted that all the cases referred to above, with the exception of Loendersloot which is mentioned only in so far as it confirms those earlier decisions, involved pharmaceutical products. The market in pharmaceutical products has a number of features which distinguish it in important respects from the markets in many other products. In particular, prices are as a general rule set or affected by national regulators and do not reflect the normal play of supply and demand: wholesale and retail suppliers of pharmaceutical products cannot freely adjust prices in a given national market in order to increase sales. Moreover, the consequences of careless repackaging of pharmaceutical products may have repercussions on public health and hence go beyond damage to the trade mark owner's rights.
113. Those features of the market perhaps underlie the Court's apparent reluctance unduly to limit the trade mark owner's entitlement to oppose repackaging. Thus for example the limited effect of normal market forces in a highly regulated market means that different prices in different national markets are not necessarily attributable to the owner's taking advantage of divided national markets; equally it may mean that parallel importers cannot, like importers of most other products, use lower prices to overcome any consumer resistance to their imported products. Again it seems to me that the Court's case-law accommodates the conflicting condiderations: on the one hand for example the trade mark owner's right to invoke the first sentence of Article 30 EC to oppose any repackaging should prevent the marketing of imported pharmaceutical products which have suffered in the repackaging process; on the other hand the importer is in general entitled carefully to repackage to the extent necessary to obtain effective access to the market, and may therefore use suitable repackaging as a tool for overcoming consumer resistance.
114. Swingward has argued that, where the Court stated in Upjohn that the condition of necessity would not be satisfied if replacement (or reaffixing) of the trade mark was explicable solely by the parallel importer's attempt to secure a commercial advantage, that must be understood as an unfair or abusive commercial advantage; only in those circumstances will use of the mark in packaging not be necessary.
115. It is clear however from the context of its statement in Upjohn that the contrast which the Court was seeking to draw was between on the one hand factors beyond the parallel importer's control, such as national rules and practices, and on the other hand the importer's desire to maximise sales. Interference by the importer which is not necessary to overcome objective factors but which the importer considers would enhance sales is not 'necessary' within the meaning of Upjohn. There is no suggestion in the judgment that the Court intended that interference seen as conferring a 'fair' (in contrast to 'unfair' or 'abusive') commercial advantage should be regarded as necessary. (69)
116. With regard to the second aspect of the third question referred in Boehringer Ingelheim, namely whether use of the mark by the parallel importer must be necessary to enable him to access (a) part only of the market in the goods or (b) the whole of the market in the goods, it is in my view clear from the case-law of the Court that denial of access to part of the market in the goods cannot be permitted. That follows from the judgment in Bristol-Myers Squibb, (70) in which the Court stated:
'Where, in accordance with the rules and practices in force in the Member State of importation, the trade mark owner uses many different sizes of packaging in that State, the finding that one of those sizes is also marketed in the Member State of exportation is not enough to justify the conclusion that repackaging is unnecessary. Partitioning of the markets would exist if the importer were able to sell the product in only part of [the market for that product].' (71)
117. The referring court states that, on the evidence before it, there is no doubt that some pharmacists will not purchase over-stickered products because of a perception, frequently based on experience, that some of their customers will not accept them, which means that there is a part of the market from which an over-stickered

product is excluded completely. I would accept that, if the product is thereby excluded from the market, reboxing is necessary in order for the defendants to have effective access to the relevant market.

118. I accordingly conclude that a parallel importer will be justified by virtue of Community law in repackaging pharmaceutical products in so far as such repackaging is reasonably required to enable the importer to obtain effective access to the market of the importing Member State (or to a significant part of it) and in so far as other, less intrusive, methods of repackaging will not enable him to obtain effective access to that market (or to a significant part of it); for that purpose account must be taken not only of obstacles which exist in law - such as the regulatory requirements of the importing Member State - but also of obstacles which exist in fact, including resistance of consumers, for example to overstickered boxes, which is such as to affect prescription or dispensing practice.

119. That conclusion, like my conclusion on the first issue, (72) to my mind correctly interprets the case-law so as fairly to balance the competing interests of on the one hand the parallel importer in benefiting from the free movement of goods and on the other hand the trade mark owner in safeguarding his intellectual property rights. I would note however that that balance will be upset, to the detriment of the fundamental principle of the free movement of goods, if national procedural rules or practices on the burden of proof effectively prevent the parallel importer from demonstrating the necessity of repackaging in particular circumstances.

The requirement of notice

120. The fifth, sixth and seventh questions referred in Boehringer Ingelheim essentially invite the Court to reconsider the requirement of advance notice of repackaging imposed by the Court in its earlier case-law. In particular the referring court asks whether, where the proposed repackaging does not harm the specific subject-matter of the mark, notice is none the less required and, if so, how much notice is required, must it be given by the importer or is it sufficient that the trade mark owner receives it from another source, and what is the effect of failure to give notice.

121. Boehringer Ingelheim submits that there is no good reason to reconsider the requirement of advance notice developed by the Court. That requirement does not impose an unreasonable burden on the parallel importer, impede the free movement of goods, delay the marketing of the imported products or render their commercialisation appreciably more difficult. Since the requirement does not depend on the use of the trade mark causing prejudice to the specific subject-matter of the trade mark, the owner of the mark may oppose any use of his mark by a parallel importer unless the importer has given him advance notice.

122. Glaxo submits that the requirement of prior notice is not onerous and is reasonable. It should be enforced as the Court of Justice has consistently required since Hoffmann-La Roche. Prior notice must be given by the parallel importer. It must precede the marketing sufficiently to enable objections to be considered and there must be a penalty on the parallel importer for failing to give notice, since otherwise there is no incentive for compliance with the requirement and notice would in practice never be given. Advance notice of 28 days would be reasonable.

123. Swingward submits that it follows from the case-law of the Court that the requirement that an importer give notice to a trade mark owner is a procedural requirement designed to place the owner in a position whereby its legitimate rights can be supervised; it is a means to an end, but not an end in its own right. In Community parlance it is a secondary, procedural right. As such, the principle of proportionality applies. Where there is no harm to the specific subject-matter of the trade mark, a failure to provide notice will not have been at all prejudicial to the trade mark owner. Accordingly, it would be disproportionate to the object of the requirement that a failure should transform an innocuous use of the trade mark into an infringing use of the trade mark. As to the two-day period suggested by the referring court, Swingward considers it reasonable. Finally, Swingward argues that the requirement of notice is met where the proprietor receives notice, whether or not from the importer.

124. The German Government submits that if the trade mark owner has not been given adequate information about the type of repackaging before the repackaged goods are put on the market, in sufficient time for him to be able to examine whether the requirements laid down by the Court for repackaging are satisfied, that is a ground for preventing the repackaging parallel importer from relying on exhaustion of the trade mark rights. Notice must be given in enough time to enable the trade mark owner to assess the method used. The notice must be given by the parallel importer.

125. The Commission submits that the notice requirement, combined with the possibility for the trade mark owner to require the parallel importer to supply him with a specimen of the repackaged or relabelled product before it goes on sale, enables the trade mark proprietor to ensure that the specific subject-matter of his right is protected. The requirement is therefore an instrument for the protection of the specific subject-matter of the trade mark rights. The case-law shows that the Court intended each of the conditions laid down to be fulfilled before a trade mark proprietor could be deprived of his right to oppose the further marketing of a repackaged pharmaceutical product. It follows from that case-law that a trade mark proprietor may oppose such further marketing where he has not been given notice of the intended use of his mark. The notice period must be calculated only by reference to the rights of the trade mark proprietor, and will therefore normally be rather short. It will be longer if the parallel importer chooses to notify without simultaneously sending a sample. In this case, extra time will be needed for the trade mark proprietor to decide to ask for a sample and to receive it.

126. I would point out that the notice requirement dates from the judgment in Hoffmann-La Roche, (73) in which the Court stated that, given the trade mark pro-

prietor's interest that the consumer should not be misled as to the origin of the product, the trader should be allowed to sell the repackaged product only on condition that he give the proprietor prior notice and that he state on the new packaging that the product had been repackaged by him.
127. The Court in Bristol-Myers Squibb (74) affirmed that 'the trade mark owner must be given advance notice of the repackaged product', specifying that it must be given by the importer. In Loendersloot (75) it reiterated that affirmation in the specific context of pharmaceutical products, adding that even in the broader context of the facts of that case (relabelling of whisky) 'the interests of the trade mark owner, and in particular his need to combat counterfeiting, are given sufficient weight if [the importer] gives him prior notice that the relabelled products are to be put on sale'. (76)
128. The requirement that the parallel importer gives the trade mark owner advance notice before the repackaged product is put on sale thus has a solid pedigree and is based on cogent reasons.
129. The referring court in Boehringer Ingelheim however doubts whether it is appropriate where there is no prejudice to the specific subject-matter of the trade mark.
130. In my view, the requirement of notice cannot depend on whether there is actual prejudice to the specific subject-matter of the mark. As discussed above, it is clear from the Court's case-law that the mere act of repackaging is regarded by the Court as liable to prejudice the specific subject-matter of the mark. Advance notice to the trade mark owner gives him an opportunity to verify whether there is actual prejudice to the specific subject-matter or the essential function of the mark. Abolishing the requirement of notice would confer on the parallel importer the right to decide at the outset whether the type of repackaging undertaken in fact prejudiced those legitimate interests of the owner of the mark. That would go against the very clear indications given by the Court since the introduction of the requirement of notice in Hoffmann-La Roche, the first repackaging case, in 1978. I can see no argument for so altering the case-law.
131. Nor do I see any ground for departing from the Court's clear indications that the notice should be given by the parallel importer. It has been argued by Swingward that, since the Medicines Control Agency (MCA) in the United Kingdom notifies the trade mark owner when it grants a product licence (parallel import), the trade mark owner thereby receives sufficient notice of proposed parallel imports. I do not accept that argument on two grounds.
132. First, it appears from the sample annexed to Boehringer Ingelheim's observations that an MCA notification contains no information about how the product in question has been repackaged. It cannot therefore in any event constitute notice within the meaning of the Court's case-law.
133. Second, parallel importers throughout the Union must be aware of their obligations and how to fulfil them. Satisfaction of a requirement imposed by the Court cannot be tied to the regulatory framework in one Member State. A requirement that the importer give notice to the trade mark owner is simple to apply and simple to observe, thus contributing to the uniform application of Community law.
134. With regard to the period of notice required, it is axiomatic that it must be reasonable. In particular, the period must be sufficient to enable the trade mark owner - which in the case of pharmaceutical products will normally be a large company with several departments, possibly in more than one country, legitimately concerned with the issue - to assess the acceptability of the proposed packaging. I would consider that in general a period of three to four weeks would be reasonable. I would mention that, according to Boehringer Ingelheim, the British Association of Parallel Importers has proposed three weeks. There may perhaps be exceptional circumstances justifying a shorter or a longer period in a particular case; whether that is so is a matter for the national court.
135. Finally, the national court asks what the consequence of failure to give notice should be. It was argued before that court that it would be absurd for a trade mark owner to be able to block parallel imports in such circumstances since, even if there is a notice requirement, it would be entirely disproportionate to allow a trade mark owner to prevent further marketing of parallel imports because of a failure to observe a procedural requirement in a case where no harm was done to the specific subject-matter of the mark.
136. The conclusion however seems inescapable that, if a parallel importer fails to give the trade mark owner reasonable advance notice of the repackaging, that repackaging constitutes infringement. The formulation adopted by the Court in Hoffmann-La Roche and Bristol-Myers Squibb shows that it intended each of the conditions laid down in those cases, including the requirement of advance notice, to be fulfilled before a trade mark owner loses his right to oppose repackaging. There is in addition the pragmatic argument that liability for infringement is the only realistic sanction for failure by a parallel importer to give advance notice and no purpose would be served by the Court's imposing a requirement without a sanction.

Conclusion

137. I am accordingly of the opinion that the questions referred to the Court in the present cases should be answered as follows:

In Case C-443/99 Merck, Sharp & Dohme:

Article 7(2) of the First Council Directive of 21 December 1988 to approximate the laws of the Member States relating to trade marks (89/104/EEC) does not entitle a trade mark owner to oppose the marketing of a pharmaceutical product put on the market under his trade mark where the importer has repackaged it and reaffixed the trade mark and has complied with the other requirements set forth in the Court of Justice judgment in Joined Cases C-427/93, C-429/93 and C-436/93 Bristol-Myers Squibb and Others (the product inside the packaging must not be affected, the manufac-

turer and origin must be clearly indicated, the reputation of the trade mark or its owner must not be damaged as a consequence of poor packaging, and the trade mark owner must be given notice before the repackaged pharmaceutical product is put on sale) if such repackaging and reaffixing of the trade mark are reasonably required to enable the importer to obtain effective access to the market of the importing Member State (or to a significant part of it) and in so far as other, less intrusive, methods of repackaging will not enable him to obtain effective access to that market (or to a significant part of it); for that purpose account must be taken not only of obstacles which exist in law - such as the regulatory requirements of the importing Member State - but also of obstacles which exist in fact, including resistance of consumers, for example to overstickered boxes, which is such as to affect prescription or dispensing practice.

In Case C-143/00 Boehringer Ingelheim and Others:

(1) Neither Articles 28 and 30 EC nor Article 7(2) of the First Council Directive of 21 December 1988 to approximate the laws of the Member States relating to trade marks (89/104/EEC) precludes a trade mark owner from using his trade mark rights to prevent the parallel importer of a pharmaceutical product from repackaging that product provided that such use of his rights does not contribute to the artificial partitioning of the markets between Member States or otherwise constitute a disguised restriction on trade between Member States. A trade mark owner who uses his trade mark rights to prevent a parallel importer from necessary repackaging contributes to such artifical partitioning.

(2) Repackaging is necessary if it is reasonably required to enable the importer to obtain effective access to the market of the importing Member State (or to a significant part of it) and in so far as other, less intrusive, methods of repackaging will not enable him to obtain effective access to that market (or to a significant part of it); for that purpose account must be taken not only of obstacles which exist in law - such as the regulatory requirements of the importing Member State - but also of obstacles which exist in fact, including resistance of consumers, for example to over-stickered boxes, which is such as to affect prescription or dispensing practice.

(3) A parallel importer intending to market repackaged goods bearing a trade mark must in all circumstances give the owner of the trade mark reasonable advance notice. Three to four weeks' notice will normally be regarded as reasonable. A parallel importer who has failed to give the trade mark owner reasonable advance notice cannot rely on Article 30 EC or on Article 7(2) of the Directive in proceedings brought against him for infringement.

1: - Original language: English.

2: - Case 78/70 Deutsche Grammophon [1971] ECR 487, paragraph 11 of the judgment.

3: - Case 16/74 Centrafarm v Winthrop [1974] ECR 1183, paragraph 12 of the judgment.

4: - First Council Directive 89/104/EEC of 21 December 1988 to approximate the laws of the Member States relating to trade marks, OJ 1989 L 40, p. 1.

5: - Joined Cases C-427/93, C-429/93 and C-436/93 Bristol-Myers Squibb and Others [1996] ECR I-3457, paragraphs 25 to 26 of the judgment; Case C-352/95 Phytheron International [1997] ECR I-1729, paragraph 17.

6: - Bristol-Myers Squibb, cited in note 5, paragraph 40 of the judgment; Joined Cases C-71/94, C-72/94 and C-73/94 Eurim-Pharm [1996] ECR I-3603, paragraph 27; Case C-232/94 MPA Pharma [1996] ECR I-3671, paragraph 13; Case C-337/95 Parfums Christian Dior [1997] ECR I-6013, paragraph 53; Case C-349/95 Loendersloot [1997] ECR I-6227, paragraph 18.

7: - For further discussion see paragraphs 54 to 57 below.

8: - Cited in note 3.

9: - Paragraphs 7, 8 and 10 of the judgment.

10: - Case 102/77 [1978] ECR 1139.

11: - Paragraphs 6 and 7 of the judgment.

12: - Paragraph 7 of the judgment.

13: - Paragraph 8 of the judgment.

14: - Paragraph 9 of the judgment.

15: - Paragraph 10 of the judgment.

16: - Paragraph 12 of the judgment.

17: - See paragraphs 120 to 136 below.

18: - Case 3/78 [1978] ECR 1823.

19: - Paragraphs 13, 14 and 17 of the judgment.

20: - Case C-379/97 [1999] ECR I-6927.

21: - See paragraph 51 below.

22: - Cited in notes 5 and 6.

23: - Footnote references are to paragraph numbers in the judgment in Bristol-Myers Squibb; the judgments in the other two cases are to the same substantive effect.

24: - Paragraph 37 of the judgment.

25: - Paragraph 41 of the judgment.

26: - Paragraphs 42 to 45 of the judgment.

27: - Paragraphs 47 and 48 of the judgment.

28: - Paragraph 50 of the judgment.

29: - Paragraphs 52 to 57 of the judgment.

30: - Paragraphs 58 to 61 of the judgment.

31: - Paragraphs 67 to 69 of the judgment.

32: - Paragraphs 70 to 74 of the judgment.

33: - Paragraphs 75 to 77 of the judgment.

34: - Paragraph 78 of the judgment.

35: - Paragraph 79 and operative part of the judgment.

36: - See Loendersloot, cited in note 6, paragraphs 28 to 30 of the judgment, and Upjohn, cited in note 20, paragraph 17.

37: - Cited in note 6.

38: - Cited in note 20.

39: - Paragraphs 26 and 27 of the judgment.

40: - Paragraph 31 of the judgment.

41: - Paragraph 21 of the judgment.

42: - Paragraph 56 of the judgment.

43: - Cited in note 6, paragraph 38 of the judgment.

44: - Paragraph 53 of the judgment.

45: - Paragraph 55 of the judgment.

46: - Cited in note 20, paragraphs 43 and 44 of the judgment.
47: - Cited in note 6.
48: - See paragraphs 37 to 39 of the judgment.
49: - Paragraphs 43 and 44 of the judgment.
50: - Paragraphs 45 and 46 of the judgment.
51: - The Handelsgericht Wien (Commercial Court, Vienna).
52: - Pursuant to the third paragraph of Article 20 of the Statute of the Court of Justice.
53: - Hoffmann-La Roche, cited in note 10, paragraph 8 of the judgment, summarised in paragraph 19 above; Bristol-Myers Squibb, cited in note 5, paragraph 50, quoted in paragraph 32 above.
54: - Hoffmann-La Roche, paragraph 7 of the judgment, summarised in paragraph 18 above.
55: - Paragraph 10 of the judgment in Hoffmann-La Roche, summarised at paragraph 20 above.
56: - Bristol-Myers Squibb, paragraph 52 of the judgment, quoted in paragraph 34 above.
57: - Paragraph 42 of the judgment.
58: - See in particular paragraphs 47 to 49 of the judgment in Bristol-Myers Squibb.
59: - Paragraphs 112 and 113.
60: - Paragraph 42.
61: - See paragraph 51 above.
62: - Case C-251/95 [1997] ECR I-6191, paragraphs 22 to 26 of the judgment.
63: - Cited in note 4.
64: - Cited in note 20.
65: - Paragraphs 42 to 45 of the judgment.
66: - Paragraph 43 of the judgment.
67: - Upjohn, paragraph 43 of the judgment, set out in paragraph 106 above.
68: - See paragraph 55 of the judgment in Bristol-Myers Squibb, set out in paragraph 34 above, and paragraph 46 of the judgment in Loendersloot, summarised in paragraph 53 above.
69: - See also paragraph 54 of my Opinion in Upjohn.
70: - Cited in note 5, paragraph 54 of the judgment.
71: - The words in square brackets are mistranslated in the judgment as ‘his market’.
72: - See paragraph 103 above.
73: - Cited in note 10, paragraph 12 of the judgment.
74: - Cited in note 5, paragraph 78 of the judgment, summarised in paragraph 42 above, and paragraph 79 and operative part of the judgment, set out in paragraph 43 above.
75: - Cited in note 6.
76: - Paragraphs 30, 47, 48 and 49 of the judgment.