JUDGMENT OF THE COURT

23 April 2002 *

In Case C-143/00,

REFERENCE to the Court under Article 234 EC by the High Court of Justice of England and Wales, Chancery Division (United Kingdom), for a preliminary ruling in the proceedings pending before that court between

Boehringer Ingelheim KG,

Boehringer Ingelheim Pharma KG

and

Swingward Ltd,

and between

Boehringer Ingelheim KG,

Boehringer Ingelheim Pharma KG

* Language of the case: English.

and

Dowelhurst Ltd,

and between

Glaxo Group Ltd

and

Swingward Ltd,

and between

Boehringer Ingelheim KG,

Boehringer Ingelheim Pharma KG

and

Dowelhurst Ltd,

and between

Glaxo Group Ltd,

The Wellcome Foundation Ltd

and

Dowelhurst Ltd,

and between

SmithKline Beecham plc,

Beecham Group plc,

SmithKline & French Laboratories Ltd

and

Dowelhurst Ltd

and between

Eli Lilly and Co.

and

Dowelhurst Ltd,

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), and of Articles 28 EC and 30 EC,

THE COURT,

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

Advocate General: F.G. Jacobs,
Registrar: D. Louterman-Hubeau, Head of Division,

after considering the written observations submitted on behalf of:

— Boehringer Ingelheim KG and Boehringer Ingelheim Pharma KG, by R. Subiotto, solicitor, and C. Annacker, Rechtsanwältin,

— SmithKline Beecham plc, Beecham Group plc, SmithKline & French Laboratories Ltd and Eli Lilly and Co., by S. Thorley QC and M. Brealey, barrister,

— Glaxo Group Ltd, by M. Silverleaf QC and R. Hacon, barrister,

— Swingward Ltd and Dowelhurst Ltd, by N. Green and H. Carr QC,

— the German Government, by B. Muttelsee-Schön and A. Dittrich, acting as Agents,

— the Norwegian Government, by B. Ekeberg, acting as Agent,

— the Commission of the European Communities, by K. Banks, acting as Agent,

having regard to the Report for the Hearing,

after hearing the oral observations of Boehringer Ingelheim KG and Boehringer Ingelheim Pharma KG, represented by R. Subiotto and C. Annacker, of SmithKline Beecham plc, Beecham Group plc, SmithKline & French Laboratories Ltd and Eli Lilly and Co., represented by S. Thorley and M. Brealey, of Glaxo Group Ltd, represented by M. Silverleaf and R. Hacon, of Swingward Ltd and Dowelhurst Ltd, represented by N. Green and H. Carr, of the German Government, represented by A. Dittrich, of the Norwegian Government, represented by B. Ekeberg, and of the Commission, represented by K. Banks and by S. Rating, acting as Agent, 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 7 March 2000, received at the Court on 17 April 2000, the High Court of Justice of England and Wales, Chancery Division, referred to the Court for a preliminary ruling under Article 234 EC eight questions 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'), and of Articles 28 EC and 30 EC.

2 Those questions were raised in the context of proceedings between Boehringer Ingelheim KG and Boehringer Ingelheim Pharma KG (together, 'Boehringer'),

Glaxo Group Ltd ('Glaxo'), SmithKline Beecham plc, Beecham Group plc and SmithKline & French Laboratories Ltd (together, 'SmithKline'), The Wellcome Foundation Ltd ('Wellcome') and Eli Lilly and Co. ('Eli Lilly') ('the claimants'), on the one hand, and Swingward Ltd ('Swingward') and Dowelhurst Ltd ('Dowelhurst') ('the defendants'), on the other, concerning the marketing of pharmaceutical products manufactured by Boehringer, Glaxo, SmithKline, Wellcome and Eli Lilly, which were the subject of parallel importation into the United Kingdom by Swingward and Dowelhurst.

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 questions referred for preliminary ruling

6 Each of the pharmaceutical products concerned by the main proceedings has been marketed under a trade mark by one of the claimants within the Community, where it was purchased by one of the defendants and imported into the United Kingdom. For the latter purpose, the defendants have to some extent altered the packaging of the products and the instruction leaflets going with them.

7 The manner in which the different products concerned have been repackaged varies. In some cases, a label setting out certain critical information, such as the name of the parallel importer and its parallel import licence number, has been attached to the original package. On such packages, wording in languages other than English therefore remains visible and the trade mark is not covered up. In other cases, the product has been repackaged in boxes designed by the parallel importer on which the trade mark is reproduced. Finally, in some cases, the product has been repackaged in boxes designed by the parallel importer which do

not bear the trade mark. Instead the generic name of the product is marked on the box. Inside this box, the inner packaging bears the original trade mark but is over-stickered with a label which indicates the generic name of the product as well as the identity of the manufacturer and of the parallel import licence holder. In all these cases of repackaging, the boxes contain an information leaflet for the patient written in English which bears the trade mark.

8 Boehringer, Glaxo, SmithKline, Wellcome and Eli Lilly object to these changes in packaging and claim that they are not necessary to enable the products concerned to be put on the market in the United Kingdom. According to them, it follows from the case-law of the Court that the parallel importers are not entitled to make such changes. The claimants have therefore brought proceedings before the national court for trade mark infringement.

9 Since it took the view that the resolution of the disputes in the main proceedings was dependent on the interpretation of Community law, the High Court of Justice of England and Wales, Chancery Division, decided to stay proceedings and to refer the following eight questions to the Court for a preliminary ruling:

'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 cases 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?'

Preliminary observations

10 By its questions, the national court seeks to obtain clarification on a number of aspects of the Court's case-law relating to the repackaging of trade-marked pharmaceutical products by parallel importers without authorisation from the trade mark proprietor.

11 Accordingly, the essential elements of that case-law must be recalled.

12 First of all, it is clear from the Court's case-law, in particular from Case 102/77 *Hoffmann-La Roche* [1978] ECR 1139, paragraphs 6 and 7, that:

— Article 30 EC allows derogations from the fundamental principle of the free movement of goods between Member States only to the extent to which such derogations are justified in order to safeguard the rights which constitute the specific subject-matter of the industrial property concerned;

— in that context, account must be taken of the essential function of the trade mark, which is to guarantee to the consumer or end user the identity of the trade-marked product's origin by enabling him to distinguish it without any risk of confusion from products of different origin;

— that guarantee of origin means that the consumer or end user can be certain that a trade-marked product offered to him has not been subject at a previous stage of marketing to interference by a third party, without the authorisation of the trade mark proprietor, in such a way as to affect the original condition of the product.

13 The right attributed to a trade mark proprietor of preventing any use of the trade mark which is likely to impair the guarantee of origin so understood is therefore part of the specific subject-matter of the trade mark rights. It is therefore justifiable under the first sentence of Article 30 EC to recognise that the proprietor of a trade mark is entitled to prevent an importer of a trade-marked product, following repackaging of that product, from affixing the trade mark to the new packaging without the authorisation of the proprietor (*Hoffmann-La Roche*, paragraphs 7 and 8).

14 It is clear from paragraph 14 of *Hoffmann-La Roche* 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 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.

15 Next, in cases subsequent to *Hoffmann-La Roche*, in particular in Joined Cases C-427/93, C-429/93 and C-436/93 *Bristol-Myers Squibb and Others* [1996] ECR I-3457 and Case C-379/97 *Upjohn* [1999] ECR I-6927, 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.

16 In that case-law, the Court also elaborated on and clarified the other requirements which the parallel importer must meet in order to be able to repackage trade-marked pharmaceutical products. It stated, in particular, that the presentation of the repackaged product must not be such as to damage the reputation of the trade mark.

17 Finally, it should be remembered that, before Directive 89/104 was adopted, the Court's case-law on those issues had been developed on the basis of the provisions of the EEC Treaty relating to intra-Community trade. Following adoption of that directive, Article 7 of which comprehensively regulates the question of the exhaustion of trade mark rights for products traded in the Community, the Court held that national rules on the subject had to be assessed in the light of that article (see *Bristol-Myers Squibb and Others*, paragraph 26).

18 However, Article 7 of the Directive, like Article 30 EC, is intended specifically to reconcile the fundamental interest in protecting trade mark rights with the fundamental interest in free movement of goods between Member States, so that those two provisions, which pursue the same result, must be interpreted in the same way. The Court's case-law under Article 36 of the EEC Treaty (subsequently Article 36 of the EC Treaty and now, after amendment, Article 30 EC) must therefore be taken as the basis for determining whether, under Article 7(2) of the Directive, a trade mark proprietor may oppose the marketing of repackaged products to which the trade mark has been reaffixed (see *Bristol-Myers Squibb and Others*, paragraphs 40 and 41).

The specific subject-matter of the trade mark

19 By its first, second, fourth and eighth questions, the national court seeks to obtain clarification of the concept of the specific subject-matter of the trade mark, as used in the Court's case-law, in order to determine the circumstances in which a trade mark proprietor may rely on its trade mark rights in order to prevent a parallel importer from repackaging pharmaceutical products.

20 The national court seeks to ascertain, in particular, whether it is possible to take the view, as some courts in other Member States have done, that repackaging is prejudicial to the specific subject-matter of the trade mark for the purposes of the Court's case-law, so that the trade mark proprietor may oppose repackaging as a matter of principle even if, in reality, that repackaging does not constitute a threat to its proprietary interests. According to the national court, the repackaging in question in the present case concerns authentic goods marketed with the proprietor's consent and does not harm the original condition of the products,

their reputation or the essential functions of the mark. The court raises the question whether, in circumstances where the mark is not used in such a way as to deceive consumers as to the origin and quality of the goods, such repackaging must be permitted even if it is not established that repackaging is necessary in order to allow the parallel importer effective access to the market.

Observations submitted to the Court

21 Boehringer submits that a trade mark proprietor may always legitimately oppose the further marketing of a pharmaceutical product where the parallel importer has repackaged the product and used the trade mark on, or in relation to, the product or interfered with the trade mark proprietor's rights in any other way, unless this interference is essential in the circumstances prevailing at the time of marketing in the Member State of importation in order for the product to be marketed in that State by the importer and such interference causes as little harm as possible to the trade mark proprietor's rights.

22 Glaxo submits that the repackaging of a trade mark proprietor's products without its consent is an interference with the specific subject-matter of the trade mark. Such conduct in itself would attract a sanction pursuant to an action for infringement of the trade mark, subject only to the four conditions laid down in the Court's case-law and set out in paragraph 14 above. There is no further requirement of proof that the repackaging is damaging or prejudicial to the specific subject-matter of the trade mark.

23 SmithKline claims that, according to the order for reference, the onus is on the trade mark proprietor to demonstrate some additional 'harm' in order to prevent

the parallel importation of goods bearing that trade mark. It submits that that approach is wrong having regard to the Court's case-law on the subject.

24 Swingward and Dowelhurst submit that it is clear from the case-law of the Court that trade mark rights can be relied on only where there is specific and material harm to the specific subject-matter of the trade mark.

25 The German Government submits that it is clear from the Court's case-law that to repackage or relabel goods can adversely affect the trade mark proprietor's rights, including those constituting the specific subject-matter of the mark, and that there is no reason to depart from that settled case-law.

26 The Norwegian Government submits that the wording of Article 30 EC presupposes that restrictions on imports are justified only if industrial or commercial property is jeopardised. It cannot be deduced from the Court's case-law that a trade mark proprietor may 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 proprietor.

27 The Commission submits 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. *Bristol-Myers Squibb and Others* is not entirely without ambiguity in that regard. However, 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. 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.

Findings of the Court

28 Although it is possible to derogate from the fundamental principle of free movement of goods where the proprietor of a mark relies on the mark to oppose the repackaging of pharmaceutical products imported in parallel, that is only to the extent necessary to enable the proprietor to safeguard rights which form part of the specific subject-matter of the mark, as understood in the light of its essential function.

29 It is not in dispute that the specific subject-matter of a mark is to guarantee the origin of the product bearing that mark and that repackaging of that product by a third party without the authorisation of the proprietor is likely to create real risks for that guarantee of origin.

30 Thus, in paragraphs 7 and 8 of *Hoffmann-La Roche*, the Court considered that the proprietor's right to oppose the repackaging of pharmaceutical products bearing its mark is, having regard to that risk to the guarantee of origin, related to the specific subject-matter of the mark. According to that case-law, it is the repackaging of the trade-marked pharmaceutical products in itself which is prejudicial to the specific subject-matter of the mark, and it is not necessary in that context to assess the actual effects of the repackaging by the parallel importer.

31 However, it is clear from paragraph 9 of *Hoffmann-La Roche* that the derogation from free movement of goods which is the consequence of the trade mark proprietor's opposition to repackaging cannot be accepted if the proprietor's exercise of that right constitutes a disguised restriction on trade between Member States within the meaning of the second sentence of Article 30 EC.

32 A disguised restriction within the meaning of that provision will exist where the exercise by a trade mark proprietor of its right to oppose repackaging contributes to artificial partitioning of the markets between Member States and where, in addition, the repackaging is done in such a way that the legitimate interests of the proprietor are respected. This means, in particular, that the repackaging must not adversely affect the original condition of the product and must not be such as to harm the reputation of the mark.

33 As was recalled in paragraph 15 above, the Court has found that a trade mark proprietor's opposition to repackaging of pharmaceutical products must be regarded as contributing to artificial partitioning of the markets between Member States where the repackaging is necessary in order to enable the product imported in parallel to be marketed in the importing State.

34 Thus it is clear from settled case-law that the change brought about by any repackaging of a trade-marked pharmaceutical product — creating by its very nature the risk of interference with the original condition of the product — may be prohibited by the trade mark proprietor unless the repackaging is necessary in order to enable the marketing of the products imported in parallel and the legitimate interests of the proprietor are also safeguarded (see, to that effect, *Bristol-Myers Squibb and Others*, paragraph 57).

35 The answer to the first, second, fourth and eighth questions must therefore be that Article 7(2) of the Directive must be interpreted as meaning that a trade mark proprietor may rely on its trade mark rights in order to prevent a parallel importer from repackaging pharmaceutical products unless the exercise of those rights contributes to artificial partitioning of the markets between Member States.

The need for repackaging

36 By its third question, the national court asks the Court in what circumstances repackaging by a parallel importer in order to market pharmaceutical products in the importing State may be considered to be necessary for the purposes of the Court's case-law. It seeks more specifically to ascertain whether repackaging may be considered necessary on the sole ground that, without it, the commercial success of the product would be adversely affected on the market of the importing State because a significant proportion of the consumers in that State mistrust pharmaceutical products which are manifestly intended for the market of another State.

37 The national court considers that repackaging should be regarded as necessary where it enables a real or potential impediment to the marketing of the products to be overcome. That issue is important since the claimants contend that repackaging by parallel importers, which consists in replacing the packaging of the products, is not necessary because marketing would still be possible simply by relabelling the products. According to the national court, there is real market resistance to relabelling and replacement of packaging is necessary to overcome that resistance.

Observations submitted to the Court

38 Boehringer submits that interference with the proprietor's trade mark rights is necessary only where, without such interference, the rules or practices in force in the importing State prevent the importer from selling the product in that State.

The trade mark proprietor may therefore legitimately oppose repackaging dictated by consumer preference in that State for a particular presentation of the product, so long as the rules and practices of the importing State allow it to be marketed without such interference.

39 Glaxo submits that the Court intended to draw a distinction between changes to packaging which are required to enable the goods to reach the market and changes which serve to maximise the acceptability of those goods on the market. It places in the second category changes whose purpose is to enable parallel importers to charge higher prices, to make the products more attractive to consumers or to increase sales. In so far as it is not established that the repackaging is necessary for the product to be sold in the importing Member State, the proprietor's opposition does not constitute artificial partitioning of the market. The principle of free movement of goods is observed so long as the importer can repackage the product where that is necessary in order to reach the market.

40 SmithKline submits that 'necessary' repackaging must be understood as meaning that without which the product could not be placed on the market. To overcome the reluctance of consumers to accept over-stickered products is not a legitimate reason for repackaging.

41 Swingward and Dowelhurst identify only one case where repackaging cannot be regarded as necessary, namely where it is explicable solely by the parallel importer's attempts to secure a commercial advantage in the sense of *Upjohn*, that is, an unfair or abusive commercial advantage.

42 The German Government submits that the Court has clearly indicated the circumstances in which repackaging of trade-marked pharmaceutical products is

permissible, by reference to the concept of necessity. Mere economic advantages, such as increasing sales, are not sufficient for repackaging to be deemed necessary. Accordingly, there is, for example, no objective need to repackage the product where relabelling or the use of foreign packaging is regarded less favourably. However, if the characteristics of the market make it very significantly harder to sell a product which has not been repackaged, then repackaging is to be regarded as necessary.

43 The Norwegian Government submits that no requirement of necessity can be deduced from the Court's case-law. If, however, such a requirement were to exist, it should be considered to be satisfied if the parallel importer finds repackaging necessary in order to sell the product.

44 The Commission considers that consumer resistance does not give rise to 'necessity' 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.

Findings of the Court

45 According to the Court's case-law, where a trade mark proprietor relies on its trade mark rights to prevent a parallel importer from repackaging where that is necessary for the pharmaceutical products concerned to be marketed in the importing State, that contributes to artificial partitioning of the markets between Member States, contrary to Community law.

46 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).

47 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).

48 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).

49 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).

50 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.

51 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.

52 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.

53 It is for the national court to determine whether that is the case.

54 The answer to the third question 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.

Advance notice to the trade mark proprietor

55 By its fifth to seventh questions, the national court seeks to obtain clarification of the requirement that the parallel importer must give advance notice to the trade mark proprietor that the repackaged product is to be put on sale. It seeks in particular to ascertain whether, as long as the intended repackaging does not in the particular case prejudice the specific subject-matter of the mark, notice is nevertheless necessary; whether the importer himself must give notice or it is sufficient that the proprietor receive such notice from another source; the length of notice to be given; and the consequence of failure to give notice.

Observations submitted to the Court

56 Boehringer submits that there is no valid reason to reconsider the requirement of notice identified by the Court. That requirement does not impose an unreasonable burden on the parallel importer, does not impede free movement of goods, does not delay marketing of the imported products and does not render their marketing appreciably more difficult. Since that requirement is not dependent on a use of the mark interfering with its specific subject-matter, the proprietor can oppose any use of its mark by a parallel importer unless the importer has given it notice.

57 According to Glaxo, the requirement of notice is not onerous and it is reasonable. It should be enforced in accordance with the principles which were identified in *Hoffmann-La Roche* and have been consistently applied by the Court. The parallel importer itself should give notice to the proprietor prior to marketing,

allowing a reasonable time for objections to be taken into account. The parallel importer should be penalised for failure to give notice, since otherwise there is simply no incentive for him to comply with that requirement. Advance notice of 28 days would be reasonable.

58 Swingward and Dowelhurst submit that it follows from the Court's case-law that the requirement that an importer give notice to the proprietor is a procedural requirement designed to place the proprietor in a position to safeguard its rights. Where there is no harm to the specific subject-matter of the trade mark, failure to give notice is not at all prejudicial to the proprietor. Accordingly, it would not be consistent with the principle of proportionality for failure to give notice to transform a legitimate use of the trade mark into an infringement of the trade mark rights. Swingward and Dowelhurst consider a period of two days before the repackaged product is placed on the market to be reasonable. They further submit that the obligation of notice is fulfilled so long as the proprietor receives notice, whether it was sent by the importer or a third party. Since the United Kingdom authorities responsible for controlling pharmaceutical products notify the proprietor when they issue a parallel import licence, the proprietor is adequately informed about intended parallel imports.

59 The German Government submits that if a trade mark proprietor has not received adequate information about the type of repackaging intended before the repackaged goods are placed on the market, in sufficient time for it to be able to check that the requirements for repackaging laid down by the Court are satisfied, it is justified in preventing the importer from relying on exhaustion of the trade mark rights. Notice should be given by the parallel importer.

60 The Commission submits that it follows from the Court's case-law that a trade mark proprietor may oppose marketing by a parallel importer where it has not

been given prior notice of the use of its mark. The notice period should allow the proprietor a reasonable opportunity to carry out the necessary examination and to determine whether it should raise an objection. The period will be longer if the parallel importer chooses to notify without simultaneously sending a sample. In this case, an additional period must enable the proprietor to request, and receive, a sample.

Findings of the Court

61 According to the Court's case-law, a parallel importer which repackages a trade-marked pharmaceutical product must give prior notice to the trade mark proprietor that the repackaged product is being put on sale (see *Hoffmann-La Roche*, paragraph 12). At the request of the trade mark proprietor, the importer must also supply it with a sample of the repackaged product before it goes on sale. That requirement enables the proprietor 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 such as to damage the reputation of the trade mark. It also affords the trade mark proprietor a better possibility of protecting himself against counterfeiting (see *Bristol-Myers Squibb and Others*, paragraph 78).

62 The purpose of the requirements set out in the preceding paragraph is to safeguard the legitimate interests of trade mark proprietors. As the claimants point out, satisfying those requirements scarcely poses any real practical problems for parallel importers provided that the proprietors react within a reasonable time to the notice. Adequate functioning of the notice system presupposes that the interested parties make sincere efforts to respect each other's legitimate interests.

63 As regards the requests for clarification from the national court as to those requirements, first, it follows from the reply to the first, second, fourth and eighth questions that a parallel importer must, in any event, in order to be entitled to repackage trade-marked pharmaceutical products, fulfil the requirement of prior notice. If the parallel importer does not satisfy that requirement, the trade mark proprietor may oppose the marketing of the repackaged pharmaceutical product.

64 Second, it is incumbent on the parallel importer itself to give notice to the trade mark proprietor of the intended repackaging. It is not sufficient that the proprietor be notified by other sources, such as the authority which issues a parallel import licence to the importer.

65 Third, the Court has not yet ruled on the period of notice to be given to the proprietor to react to the intended repackaging of the pharmaceutical product bearing its mark.

66 In that regard, it is self-evident that while, having regard to the purpose of notice to the trade mark proprietor, it is appropriate to allow a reasonable time for it to react to the intended repackaging, consideration must also be given to the parallel importer's interest in proceeding to market the pharmaceutical product as soon as possible after obtaining the necessary licence from the competent authority.

67 In the event of dispute, it is for the national court to assess, in the light of all the relevant circumstances, whether the trade mark proprietor had a reasonable time

to react to the intended repackaging. On the basis of the evidence before the Court, a period of 15 working days seems likely to constitute such a reasonable time where the parallel importer has chosen to give notice to the trade mark proprietor by supplying it simultaneously with a sample of the repackaged pharmaceutical product. That period being purely indicative, it remains open to the parallel importer to allow a shorter time and to the proprietor to ask for a longer time to react than that allowed by the parallel importer.

68 In the light of the foregoing, the answer to the fifth to seventh questions must be that a parallel importer must, in any event, in order to be entitled to repackage trade-marked pharmaceutical products, fulfil the requirement of prior notice. If the parallel importer does not satisfy that requirement, the trade mark proprietor may oppose the marketing of the repackaged pharmaceutical product. It is incumbent on the parallel importer himself to give notice to the trade mark proprietor of the intended repackaging. In the event of dispute, it is for the national court to assess, in the light of all the relevant circumstances, whether the proprietor had a reasonable time to react to the intended repackaging.

Costs

69 The costs incurred by the German 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 proceedings pending before the national court, the decision on costs is a matter for that court.

On those grounds,

THE COURT,

in answer to the questions referred to it by the High Court of Justice of England and Wales, Chancery Division, by order of 7 March 2000, hereby rules:

1. 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, as amended by the Agreement on the European Economic Area of 2 May 1992, must be interpreted as meaning that a trade mark proprietor may rely on its trade mark rights in order to prevent a parallel importer from repackaging pharmaceutical products unless the exercise of those rights contributes to artificial partitioning of the markets between Member States.

2. 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.

3. A parallel importer must, in any event, in order to be entitled to repackage trade-marked pharmaceutical products, fulfil the requirement of prior notice. If the parallel importer does not satisfy that requirement, the trade mark proprietor may oppose the marketing of the repackaged pharmaceutical product. It is incumbent on the parallel importer himself to give notice to the trade mark proprietor of the intended repackaging. In the event of dispute, it is for the national court to assess, in the light of all the relevant circumstances, whether the proprietor had a reasonable time to react to the intended repackaging.

Rodríguez Iglesias	Jann	Gulmann
Edward	La Pergola	Wathelet
Schintgen	Skouris	Cunha Rodrigues

Delivered in open court in Luxembourg on 23 April 2002.

R. Grass — Registrar

G.C. Rodríguez Iglesias — President