JUDGMENT OF THE COURT (Second Chamber)

26 April 2007 *

In Case C-348/04,

REFERENCE for a preliminary ruling under Article 234 EC from the Court of Appeal (England and Wales) (Civil Division) (United Kingdom), made by decision of 17 June 2004, received at the Court on 12 August 2004, in the proceedings

Boehringer Ingelheim KG,

Boehringer Ingelheim Pharma GmbH & Co. KG

v

Swingward Ltd,

* Language of the case: English.

and

Boehringer Ingelheim KG,

Boehringer Ingelheim Pharma GmbH & Co. KG

v

Dowelhurst Ltd,

and

Glaxo Group Ltd

v

Swingward Ltd,

and

Glaxo Group Ltd,

The Wellcome Foundation Ltd,

v

Dowelhurst Ltd,

and

SmithKline Beecham plc,

Beecham Group plc,

SmithKline & French Laboratories Ltd

v

Dowelhurst Ltd,

and

Eli Lilly and Co.

v

Dowelhurst Ltd,

THE COURT (Second Chamber),

composed of C.W.A. Timmermans, President of the Chamber, J. Klučka, J. Makarczyk, G. Arestis and L. Bay Larsen (Rapporteur), Judges,

Advocate General: E. Sharpston,
Registrar: K. Sztranc-Sławiczek, Administrator,

having regard to the written procedure and further to the hearing on 26 January 2006,

after considering the observations submitted on behalf of:

— Boehringer Ingelheim KG and Boehringer Ingelheim Pharma GmbH & Co. KG, by R. Subiotto, solicitor, and by E. Gonzalez Diaz and I. McGrath, legal advisers,

— Eli Lilly and Co., by S. Thorley and G. Hobbs QC, and by G. Pritchard, barrister,

— Glaxo Group Ltd, The Wellcome Foundation Ltd, SmithKline Beecham plc, Beecham Group plc and SmithKline & French Laboratories Ltd, by M. Silverleaf QC and R. Hacon, barrister,

— Swingward Ltd and Dowelhurst Ltd, by N. Green and R. Arnold QC, instructed by C. Tunstall, solicitor,

— the Commission of the European Communities, by N. Rasmussen and M. Shotter, acting as Agents,

after hearing the Opinion of the Advocate General at the sitting on 6 April 2006,

gives the following

Judgment

1 This reference for a preliminary ruling concerns the interpretation of Article 7(2) of the 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; 'Directive 89/104').

2 The reference was made in the course of proceedings between Boehringer Ingelheim KG, Boehringer Ingelheim Pharma GmbH & Co. KG, Glaxo Group Ltd, The Wellcome Foundation Ltd, SmithKline Beecham plc, Beecham Group plc, Smith-

Kline and French Laboratories Ltd and Eli Lilly and Co. (together 'Boehringer Ingelheim and Others'), which are manufacturers of pharmaceutical products, and Swingward Ltd ('Swingward') and Dowelhurst Ltd ('Dowelhurst'), which are parallel importers and dealers in such products, concerning medicinal products manufactured by Boehringer Ingelheim and Others and which were the subject of parallel importation and marketed in the United Kingdom by Swingward and Dowelhurst, after being repackaged and relabelled.

Community law

3 Under Article 28 EC quantitative restrictions on imports and measures having equivalent effect are prohibited between Member States. However, according to Article 30 EC, prohibitions or restrictions on imports between Member States which are justified on grounds of the protection of industrial and commercial property are authorised so long as they do not constitute a means of arbitrary discrimination or a disguised restriction on trade between Member States.

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, read in conjunction with point 4 of Annex XVII thereto, Article 7(1) of Directive 89/104 was amended for the purposes of that Agreement, the expression 'in the Community' being replaced by 'in a Contracting Party'.

The main proceedings, the reference in Case C-143/00 and the questions referred by the national court in this case

6 The medicinal products concerned by the disputes in the main proceedings were marketed under various trade marks by Boehringer Ingelheim and Others in the Community, where they were bought by Swingward and Dowelhurst and imported into the United Kingdom. In order to market them in that Member State, Swingward and Dowelhurst altered to a certain extent the packaging of those products and the information leaflets which were included with them.

7 The alterations made vary from one case to the next. In some cases, a label setting out certain critical information, such as the name of the parallel importer and its parallel import licence number, was attached to the original packaging. On such

packaging, wording in languages other than English thus remained visible and the trade mark was not covered over. In other cases, the product was repackaged in boxes designed by the parallel importer on which the original manufacturer's trade mark was reproduced. Finally, in some cases, the product was repackaged in boxes designed by the parallel importer and which did not bear the trade mark of the manufacturer but the generic name of the product. Where this was the case, the packaging inside the box bore the original trade mark but a self-adhesive label was attached indicating the generic name of the product as well as the identity of the manufacturer and of the parallel import licence holder.

8 Boehringer Ingelheim and Others objected to those alterations and therefore brought actions for infringement of trade marks before the High Court of Justice (England and Wales), Chancery Division.

9 As 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 decided to stay the proceedings and to refer the following questions to the Court of Justice 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?'

10 That reference for a preliminary ruling gave rise to the judgment in Case C-143/00 *Boehringer Ingelheim and Others* [2002] ECR I-3759, in which the Court ruled:

'1 Article 7(2) of First Council Directive 89/104 ... 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.'

11 The High Court of Justice (England and Wales) applied the judgment in *Boehringer Ingelheim and Others*, cited above, and ruled in favour of the claimants in the main proceedings.

12 However, the High Court's decisions formed the subject-matter of an appeal before the Court of Appeal and, in its judgment of 5 March 2004, that court set out a number of findings which differ from those of the High Court.

13 In those circumstances, the Court of Appeal (England and Wales) (Civil Division) decided to stay the proceedings and to refer the following questions to the Court of Justice for a preliminary ruling:

'Reboxed products

(1) Where a parallel importer markets in one Member State a pharmaceutical product imported from another Member State in its original internal packaging

but with a new exterior carton printed in the language of the Member State of importation (a "reboxed" product):

(a) does the importer bear the burden of proving that the new packaging complies with each of the conditions set out in Joined Cases C-427/93, C-429/93 and C-436/93 *Bristol-Myers Squibb* [*and Others*] [1996] ECR I-3457 or does the trade mark proprietor bear the burden of proving that those conditions have not been complied with or does the burden of proof vary from condition to condition, and if so how?

(b) does the first condition set out in *Bristol-Myers Squibb* as interpreted in Case C-379/97 *Upjohn* ... [1999] ECR I-6927 and *Boehringer Ingelheim and Others*, namely that it must be shown that it is necessary to repackage the product in order that effective market access is not hindered, apply merely to the fact of reboxing (as held by the Court of Justice of the European Free Trade Association in Case E-3/02 *Paranova* v *Merck*) or does it also apply to the precise manner and style of the reboxing carried out by the parallel importer, and if so how?

(c) is the fourth condition set out in *Bristol-Myers Squibb and Others*, namely that the presentation of the repackaged product is not such as to be liable to

damage the reputation of the trade mark or its owner, only infringed if the packaging is defective, of poor quality or untidy or does it extend to anything which damages the reputation of the trade mark?

(d) if the answer to Question 1(c) is that the fourth condition is infringed by anything which damages the reputation of the trade mark and if either (i) the trade mark is not affixed to the new exterior carton ("de-branding") or (ii) the parallel importer applies either his own logo or a house-style or get-up or a get-up used for a number of different products to the new exterior carton ("co-branding") must such forms of box design be regarded as damaging to the reputation of the trade mark or is that a question of fact for the national court?

(e) if the answer to Question 1(d) is that it is a question of fact, on whom does the burden of proof lie?

Overstickered products

(2) Where a parallel importer markets in one Member State a pharmaceutical product imported from another Member State in its original internal and external packaging to which the parallel importer has applied an additional

external label printed in the language of the Member State of importation (an "overstickered" product):

(a) do the five conditions set out in *Bristol-Myers Squibb and Others* apply at all?

(b) if the answer to Question 2(a) is yes, does the importer bear the burden of proving that the overstickered packaging complies with each of the conditions set out in *Bristol-Myers Squibb and Others* or does the trade mark proprietor bear the burden of proving that those conditions have not been complied with or does the burden of proof vary from condition to condition?

(c) if the answer to Question 2(a) is yes, does the first condition set out in *Bristol-Myers Squibb and Others* as interpreted in *Upjohn* ... and *Boehringer Ingelheim and Others*, namely that it must be shown that it is necessary to repackage the product in order that effective market access is not hindered, apply merely to the fact of overstickering or does it also apply to the precise manner and style of overstickering adopted by the parallel importer?

(d) if the answer to Question 2(a) is yes, is the fourth condition set out in *Bristol-Myers Squibb and Others*, namely that the presentation of the repackaged product is not such as to be liable to damage the reputation of the trade mark or its owner, only infringed if the packaging is defective, of poor quality or untidy or does it extend to anything which damages the reputation of the trade mark?

(e) if the answer to Question 2(a) is yes and the answer to Question 2(d) is that the fourth condition is infringed by anything which damages the reputation of the trade mark, is it damaging to the reputation of a trade mark for this purpose if either (i) the additional label is positioned so as wholly or partially to obscure one of the proprietor's trade marks or (ii) the additional label fails to state that the trade mark in question is a trade mark owned by the proprietor or (iii) the name of the parallel importer is printed in capital letters?

Notice

(3) Where a parallel importer has failed to give notice in respect of a repackaged product as required by the fifth condition of *Bristol-Myers Squibb and Others*, and accordingly has infringed the proprietor's trade mark(s) for that reason only:

(a) is every subsequent act of importation of that product an infringement or does the importer only infringe until such time as the proprietor has become aware of the product and the applicable notice period has expired?

(b) is the proprietor entitled to claim financial remedies (i.e. damages for infringement or the handing over of all profits made by infringement) by reason of the importer's acts of infringement on the same basis as if the goods had been spurious?

(c) is the granting of financial remedies to the proprietor in respect of such acts of infringement by the importer subject to the principle of proportionality?

(d) if not, upon what basis should such compensation be assessed given that the products in question were placed on the market within the [European Economic Area] by the proprietor or with his consent?'

Preliminary observations

14 It must be borne in mind 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 (see *Boehringer Ingelheim and Others*, paragraph 29).

15 According to the case-law of the Court, 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 (see *Boehringer Ingelheim and Others*, paragraph 30).

16 Under Article 7(2) of Directive 89/104, the trade mark proprietor's opposition to repackaging, in that it constitutes a derogation from free movement of goods, 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 (see, to that effect, *Boehringer Ingelheim and Others*, paragraphs 18 and 31).

17 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 (see *Boehringer Ingelheim and Others*, paragraph 32).

18 A trade mark proprietor's opposition to repackaging of pharmaceutical products contributes 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 (*Boehringer Ingelheim and Others*, paragraph 33).

19 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 (*Bristol-Myers Squibb and Others*, paragraph 57, and *Boehringer Ingelheim and Others*, paragraph 34).

20 Moreover, 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. 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, and *Boehringer Ingelheim and Others*, paragraph 61).

21 Thus, the Court held, in paragraph 79 of *Bristol-Myers Squibb and Others*:

'... Article 7(2) of Directive [89/104] is to be interpreted as meaning 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. ...

— it is shown that the repackaging cannot affect the original condition of the product inside the packaging. ...

— the new packaging clearly states who repackaged the product and the name of the manufacturer ...

— 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.'

Question 2(a): the concept of 'repackaging'

22 It is appropriate to examine Question 2(a) first of all.

23 In paragraph 6 of *Boehringer Ingelheim and Others*, the Court stated that the packaging of each of the pharmaceutical products concerned by the main proceedings, and the instruction leaflets going with them, had been to some extent altered for the purposes of importation into the United Kingdom.

24 In paragraph 7 of the judgment, it was observed that the manner in which the different products concerned had been repackaged varied. In some cases, a label setting out certain critical information, such as the name of the parallel importer and

its parallel import licence number, had been attached to the original package. On such packages, wording in languages other than English therefore remained visible and the trade mark was not covered up. In other cases, the product had been repackaged in boxes designed by the parallel importer on which the trade mark was reproduced. Finally, in some cases, the product had been repackaged in boxes designed by the parallel importer which did not bear the trade mark. Instead, the generic name of the product had been marked on the box. Inside this box, the inner packaging bore the original trade mark but was overstickered with a label which indicated 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 contained an information leaflet for the patient written in English which bore the trade mark.

25 It must also be pointed out that the seventh question referred by the High Court of Justice in *Boehringer Ingelheim and Others* was aimed expressly at ascertaining whether the requirement to give prior notice, as set out in paragraph 20 of the present judgment, applies to all uses of the mark, including relabelling of the product, or whether that condition only applies to some of those uses.

26 The Court stated in paragraph 55 of *Boehringer Ingelheim and Others* that, by its fifth to seventh questions, the national court was seeking 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.

27 In paragraph 68 of that judgment, it was held 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.

28 It follows from the foregoing that in *Boehringer Ingelheim and Others* the Court included in the concept of repackaging the relabelling which was undoubtedly one of the forms envisaged by the referring court in which the packaging of the medicinal products in question was altered.

29 In that regard, it should be borne in mind that the relabelling of the trade-marked medicinal products, just like the reboxing of those products, are prejudicial to the specific subject-matter of the mark and it is not necessary in that context to assess the actual effects of the activity performed by the parallel importer.

30 The change brought about by any new carton or relabelling of a trade-marked medicinal product creates by its very nature real risks for the guarantee of origin which the mark seeks to protect. Such a change may thus be prohibited by the trade mark proprietor unless the new carton or relabelling is necessary in order to enable the marketing of the products imported in parallel and the legitimate interests of the proprietor are also safeguarded.

31 It follows that the five requirements set out in *Bristol-Myers Squibb and Others* in respect of the interpretation of Article 7(2) of Directive 89/104, requirements which, if met, prevent the proprietor from opposing further commercialisation of a pharmaceutical product which has been repackaged by the importer, also apply when the repackaging consists in the attachment of a label to the original packaging.

32 Accordingly, the answer to Question 2(a) must be that Article 7(2) of Directive 89/104 must be construed as meaning that the proprietor may legitimately oppose further commercialisation of a pharmaceutical product imported from another Member State in its original internal and external packaging with an additional external label applied by the importer, unless

— it is established that reliance on trade mark rights by the proprietor in order to oppose the marketing of the overstickered product under that trade mark would contribute to the artificial partitioning of the markets between Member States;

— it is shown that the new label cannot affect the original condition of the product inside the packaging;

— the packaging clearly states who overstickered the product and the name of the manufacturer;

— the presentation of the overstickered product is not such as to be liable to damage the reputation of the trade mark and of its proprietor; thus, the label must not be defective, of poor quality, or untidy; and

— the importer gives notice to the trade mark proprietor before the overstickered product is put on sale, and, on demand, supplies him with a specimen of that product.'

Questions 1(b) and 2(c): the application, as regards the manner and style of repackaging, of the condition that there be a need to repackage the product

33 As is clear from the discussion in relation to Question 2(a), the proprietor can legitimately oppose further commercialisation of a pharmaceutical product when the parallel importer has either reboxed the new product and re-applied the trade

mark or applied a label to the packaging containing the product, unless five conditions have been fulfilled, including that of establishing that reliance on trade mark rights by the proprietor in order to oppose the marketing of products thus repackaged would contribute to the artificial partitioning of the markets between Member States.

34 According to Boehringer Ingelheim and Others, the requirement that the repackaging be necessary to market the product in the importing Member State also applies to the manner and style in which it is repackaged by the parallel importer. Conversely, Swingward and Dowelhurst and the Commission of the European Communities maintain that that requirement is only directed at the fact of repackaging and not at the manner and style of that repackaging.

35 As was pointed out in paragraph 19 of the present judgment, the change brought about by any repackaging of a trade-marked medicinal 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.

36 That condition that repackaging be necessary is fulfilled if the rules or practices in the importing Member State prevent the product in question from being marketed in that State in the same packaging as that in which those products are marketed in the exporting Member State (see, to that effect, *Upjohn*, paragraphs 37 to 39 and 43).

37 Conversely, the condition that it be necessary is not fulfilled if repackaging of the product is explicable solely by the parallel importer's attempt to secure a commercial advantage (see *Upjohn*, paragraph 44).

38 Therefore, the condition that packaging be necessary is directed only at the fact of repackaging the product — and the choice between a new carton and oversticking — for the purposes of allowing that product to be marketed in the importing State and not at the manner or style in which it has been repackaged (see also the judgment of the EFTA Court in Case E-3/02 *Paranova* v *Merck* [2003] EFTA Court Report 2004, p. 1, paragraphs 41 to 45).

39 The answer to Questions 1(b) and 2(c) must therefore be that the condition that the repackaging of the pharmaceutical product, either by reboxing the product and re-applying the trade mark or by applying a label to the packaging containing the product, be necessary for its further commercialisation in the importing Member State, as one of the conditions which, if fulfilled, prevent the proprietor under Article 7(2) of Directive 89/104 from opposing such commercialisation, is directed solely at the fact of repackaging and not at the manner and style of the repackaging.

Questions 1(c) and 2(d): the condition that the presentation of the repackaged product must not be such as to be liable to damage the reputation of the trade mark

40 It is clear from paragraphs 21 and 32 of the present judgment that Article 7(2) of Directive 89/104 must be interpreted as meaning that the trade mark proprietor may

legitimately oppose further commercialisation of a pharmaceutical product, when the parallel importer has either re-boxed the product and re-applied the trade mark or applied a label to the packaging containing the product, unless five conditions have been fulfilled, including the condition that the presentation of the repackaged product must not be such as to be liable to damage the reputation of the trade mark and of its proprietor. Thus, the carton or the label must not be defective, of poor quality, or untidy.

41 It must be observed, as maintained by Boehringer Ingelheim and Others and the Commission, that the condition that the presentation of the repackaged product must not be such as to be liable to damage the reputation of the trade mark and of its proprietor cannot be limited only to the case where repackaging is defective, of poor quality, or untidy.

42 The Court, in holding in paragraph 76 of the judgment in *Bristol-Myers Squibb and Others* that defective, poor quality or untidy packaging could damage the trade mark's reputation, merely referred to certain cases in which inappropriate presentation of the repackaged product is liable to damage the reputation of the trade mark and of its proprietor.

43 Accordingly, a repackaged pharmaceutical product could be presented inappropriately and, therefore, damage the trade mark's reputation in particular where the

carton or label, while not being defective, of poor quality or untidy, are such as to affect the trade mark's value by detracting from the image of reliability and quality attaching to such a product and the confidence it is capable of inspiring in the public concerned (see, to that effect, *Bristol-Myers Squibb and Others*, paragraph 76, and Case C-337/95 *Parfums Christian Dior* [1997] ECR I-6013, paragraph 45).

44 Accordingly, the answer to Questions 1(c) and 2(d) must therefore be that the condition that the presentation of the pharmaceutical product must not be such as to be liable to damage the reputation of the trade mark and of its proprietor — as a necessary condition for preventing the proprietor, pursuant to Article 7(2) of Directive 89/104, from legitimately opposing further commercialisation of a pharmaceutical product, where the parallel importer has either reboxed the product and re-applied the trade mark or applied a label to the packaging containing the product — is not limited only to cases where the repackaging is defective, of poor quality, or untidy.

Question 1(d) and Question 2(e): circumstances likely to damage the trade mark's reputation

45 As the Commission correctly argues in its written observations, the fact that a parallel importer does not affix the trade mark to the new exterior carton ('de-branding') or applies either his own logo or a house-style or get-up or a get-up used

for a number of different products ('co-branding'), or positions the additional label so as wholly or partially to obscure the proprietor's trade mark, or fails to state on the additional label that the trade mark in question belongs to the proprietor, or prints the name of the parallel importer in capital letters is, in principle, liable to damage the trade mark's reputation.

46 However, precisely as with the question whether advertising is liable to create the impression that there is a commercial connection between the reseller and the trade mark proprietor and, therefore, constitute a legitimate reason within the meaning of Article 7(2) of Directive 89/104 (see Case C-63/97 *BMW* [1999] ECR I-905, paragraphs 51 and 55), the question whether the circumstances referred to in the previous paragraph of the present judgment are liable to damage the trade mark's reputation is a question of fact for the national court to decide in the light of the circumstances of each case.

47 Accordingly, the answer to Questions 1(d) and 2(e) must be that the question whether the fact that a parallel importer:

— fails to affix the trade mark to the new exterior carton ('de-branding'), or

— applies either his own logo or a house-style or a get-up or a get-up used for a number of different products ('co-branding'), or

— positions the additional label so as wholly or partially to obscure the proprietor's trade mark, or

— fails to state on the additional label that the trade mark in question belongs to the proprietor, or

— prints the name of the parallel importer in capital letters,

is liable to damage the trade mark's reputation is a question of fact for the national court to decide in the light of the circumstances of each case.

Questions 1(a) and (e) and 2(b): the burden of proof

48 As stated in paragraphs 2 and 8 of the present judgment, the main proceedings are between manufacturers of pharmaceutical products, on the one hand, and parallel

importers and dealers in pharmaceutical products on the other, against which the manufacturers have brought actions for infringement of their trade mark rights on the ground that medicinal products manufactured by them were the subject of parallel importation and marketed in the United Kingdom by the importers after being repackaged and relabelled.

49 As stated in paragraph 15 of the present judgment, it is the repackaging of the trade-marked medicinal 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 repackaging by the parallel importer.

50 It is clear, in particular, from paragraphs 31 to 33 of the present judgment that, pursuant to Article 7(2) of Directive 89/104, the proprietor can legitimately oppose further commercialisation of a pharmaceutical product, where the parallel importer has repackaged the product either by reboxing it and re-applying the trade mark or by applying a label to the original packaging, unless the conditions set out in paragraph 32 of the present judgment are fulfilled.

51 If it were a matter for the national law of the Member States to determine the question of the onus of proving the existence of those conditions, which, if fulfilled, would prevent the proprietor from opposing further commercialisation of a

repackaged pharmaceutical product, the consequence for trade mark proprietors could be that protection would vary according to the legal system concerned. The objective of 'the same protection under the legal systems of all the Member States' set out in the ninth recital in the preamble to Directive 89/104, and described as 'fundamental', would not be attained (see, to that effect, Case C-405/03 *Class International* [2005] ECR I-8735, paragraph 73).

52 In the light of the foregoing, it must be stated that, in situations such as those in the main proceedings, where it is established that the medicinal products which are the subject of parallel importation have been repackaged, it is for the parallel importers to prove the existence of the conditions referred to in paragraph 32 of the present judgment which, if fulfilled, would prevent the proprietors from lawfully opposing further commercialisation of those medicinal products (see, by analogy, *Class International*, paragraph 74).

53 As regards the condition that it must be shown that the repackaging cannot affect the original condition of the product inside the packaging, it is sufficient, however, that the parallel importer furnishes evidence that leads to the reasonable presumption that that condition has been fulfilled. This applies a fortiori also to the condition that the presentation of the repackaged product must not be such as to be liable to damage the reputation of the trade mark and of its proprietor. Where the importer furnishes such initial evidence that the latter condition has been fulfilled it will then be for the proprietor of the trade mark, who is best placed to assess whether the repackaging is liable to damage his reputation and that of the trade mark, to prove that they have been damaged.

54 The answer to Questions 1(a) and (e) and 2(b) must therefore be that, in situations such as those in the main proceedings, it is for the parallel importers to prove the existence of the conditions that:

— reliance on trade mark rights by the proprietor 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;

— the repackaging cannot affect the original condition of the product inside the packaging;

— the new packaging clearly states who repackaged the product and the name of the manufacturer;

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

— the importer must give notice to the trade mark proprietor before the repackaged product is put on sale and, on demand, supply him with a specimen of the repackaged product,

and which, if fulfilled, would prevent the proprietor from lawfully opposing the further commercialisation of a repackaged pharmaceutical product.

As regards the condition that it must be shown that the repackaging cannot affect the original condition of the product inside the packaging, it is sufficient that the parallel importer furnishes evidence that leads to the reasonable presumption that that condition has been fulfilled. This applies a fortiori also to the condition that the presentation of the repackaged product must not be such as to be liable to damage the reputation of the trade mark and of its proprietor. Where the importer furnishes such initial evidence that the latter condition has been fulfilled, it will then be for the proprietor of the trade mark, who is best placed to assess whether the repackaging is liable to damage his reputation and that of the trade mark, to prove that they have been damaged.

The third question: the consequences of the absence of prior notice

55 According to the case-law of the Court, 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 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 (*Boehringer Ingelheim and Others*, paragraphs 63 and 64).

56 It follows that if a parallel importer has failed to give prior notice to the trade mark proprietor concerning a repackaged pharmaceutical product, he infringes the right of that proprietor on the occasion of any subsequent importation of that product, so long as he has not given the proprietor such notice.

57 As regards the question whether the trade mark proprietor is entitled to claim financial remedies by reason of the importer's acts of infringement on the same basis as if the goods had been spurious, *Boehringer Ingelheim and Others* maintain that the failure to give prior notice must be penalised in the same way as for the marketing of spurious goods. According to Swingward and Dowelhurst, the failure to give prior notice cannot give rise to financial remedies assessed in the same way as if the goods had been spurious. The Commission states that compensation for failure to give prior notice must be determined in accordance with principles of national law on financial remedies provided that those principles are compatible with Community and international law, and in particular, with the principles of equivalence, effectiveness and proportionality.

58 In that respect, it must be borne in mind that the Member States are required, within the bounds of the freedom left to them by the third paragraph of Article 249

EC, to choose the most appropriate forms and methods to ensure the effectiveness of directives, in the light of their objective (see Case 48/75 *Royer* [1976] ECR 497, paragraph 75, and Joined Cases C-58/95, C-75/95, C-112/95, C-119/95, C-123/95, C-135/95, C-140/95, C-141/95, C-154/95 and C-157/95 *Gallotti and Others* [1996] ECR I-4345, paragraph 14, and Case C-212/04 *Adeneler and Others* [2006] ECR I-6057, paragraph 93).

59 Accordingly, where, as in the case in the main proceedings, Community law does not lay down any specific sanctions where infringements have been committed, it is incumbent on the national authorities to adopt appropriate measures to deal with such a situation. Those measures must be not only proportionate, but also sufficiently effective and a sufficient deterrent to ensure that Directive 89/104 is fully effective (see, to that effect, *Adeneler and Others*, paragraph 94).

60 It should be recalled, as is clear, in particular, from paragraph 21 of the present judgment, that for the trade mark proprietor to be able lawfully to oppose further marketing of a repackaged pharmaceutical product it is sufficient that one of the conditions set out in paragraph 79 of *Bristol-Myers Squibb and Others* is not fulfilled.

61 It follows that the trade mark owner's right to prevent parallel importation of pharmaceutical products which, while not spurious, have been marketed in breach of the requirement to give prior notice to that proprietor is not different from that enjoyed by the proprietor in respect of spurious goods.

62 In both cases, the products ought not to have been marketed on the market concerned.

63 Thus, a national measure under which, where a parallel importer has marketed goods which are not spurious without giving prior notice to the trade mark proprietor that proprietor is entitled to claim financial remedies on the same basis as if the goods had been spurious, is not in itself contrary to the principle of proportionality. However, it is for the national court to determine the amount of the financial remedies according to the circumstances of each case, in the light of, in particular, the extent of damage to the trade mark proprietor caused by the parallel importer's infringement and in accordance with the principle of proportionality.

64 In the light of the foregoing, the answer to the third question must be that, where a parallel importer has failed to give prior notice to the trade mark proprietor concerning a repackaged pharmaceutical product, he infringes that proprietor's rights on the occasion of any subsequent importation of that product, so long as he has not given the proprietor such notice. The sanction for that infringement must be not only proportionate, but also sufficiently effective and a sufficient deterrent to ensure that Directive 89/104 is fully effective. A national measure under which, in the case of such an infringement, the trade mark proprietor is entitled to claim financial remedies on the same basis as if the goods had been spurious, is not in itself contrary to the principle of proportionality. It is for the national court, however, to determine the amount of the financial remedies according to the circumstances of each case, in the light in particular of the extent of damage to the trade mark proprietor caused by the parallel importer's infringement and in accordance with the principle of proportionality.

Costs

65 Since these proceedings are, for the parties to the main proceedings, a step in the actions pending before the national court, the decision on costs is a matter for that court. Costs incurred in submitting observations to the Court, other than the costs of those parties, are not recoverable.

On those grounds, the Court (Second Chamber) hereby rules:

1. **Article 7(2) of the 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, is to be interpreted as meaning that the trade mark owner may legitimately oppose further commercialisation of a pharmaceutical product imported from another Member State in its original internal and external packaging with an additional external label applied by the importer, unless**

   — **it is established that reliance on trade mark rights by the proprietor in order to oppose the marketing of the overstickered product under that trade mark would contribute to the artificial partitioning of the markets between Member States;**

— **it is shown that the new label cannot affect the original condition of the product inside the packaging;**

— **the packaging clearly states who overstickered the product and the name of the manufacturer;**

— **the presentation of the overstickered product is not such as to be liable to damage the reputation of the trade mark and of its proprietor; thus, the label must not be defective, of poor quality, or untidy; and**

— **the importer gives notice to the trade mark proprietor before the overstickered product is put on sale, and, on demand, supplies him with a specimen of that product.**

2. **The condition that the repackaging of the pharmaceutical product, either by reboxing the product and re-applying the trade mark or by applying a label to the packaging containing the product, be necessary for its further commercialisation in the importing Member State, as one of the conditions which, if fulfilled, prevent the proprietor under Article 7(2) of Directive 89/104, as amended by the Agreement on the European Economic Area,**

from opposing such commercialisation, is directed solely at the fact of repackaging and not at the manner and style of the repackaging.

3. **The condition that the presentation of the pharmaceutical product must not be such as to be liable to damage the reputation of the trade mark and of its proprietor — as a necessary condition for preventing the proprietor, pursuant to Article 7(2) of Directive 89/104, as amended by the Agreement on the European Economic Area, from legitimately opposing further commercialisation of a pharmaceutical product where the parallel importer has either reboxed the product and re-applied the trade mark or applied a label to the packaging containing the product — is not limited to cases where the repackaging is defective, of poor quality, or untidy.**

4. **The question whether the fact that a parallel importer:**

   — **fails to affix the trade mark to the new exterior carton ('de-branding'), or**

   — **applies either his own logo or house-style or get-up or a get-up used for a number of different products ('co-branding'), or**

— **positions the additional label so as wholly or partially to obscure the proprietor's trade mark, or**

— **fails to state on the additional label that the trade mark in question belongs to the proprietor, or**

— **prints the name of the parallel importer in capital letters,**

is liable to damage the trade mark's reputation is a question of fact for the national court to decide in the light of the circumstances of each case.

5. **In situations such as those in the main proceedings, it is for the parallel importers to prove the existence of the conditions that**

— **reliance on trade mark rights by the proprietor 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;**

— **the repackaging cannot affect the original condition of the product inside the packaging;**

— **the new packaging clearly states who repackaged the product and the name of the manufacturer;**

— **the presentation of the repackaged product is not such as to be liable to damage the reputation of the trade mark and of its proprietor; thus, the repackaging must not be defective, of poor quality, or untidy; and**

— **the importer must give notice to the trade mark proprietor before the repackaged product is put on sale and, on demand, supply him with a specimen of the repackaged product,**

and which, if fulfilled, would prevent the proprietor from lawfully opposing the further commercialisation of a repackaged pharmaceutical product.

As regards the condition that it must be shown that the repackaging cannot affect the original condition of the product inside the packaging, it is

sufficient, however, that the parallel importer furnishes evidence that leads to the reasonable presumption that that condition has been fulfilled. This applies a fortiori also to the condition that the presentation of the repackaged product must not be such as to be liable to damage the reputation of the trade mark and of its proprietor. Where the importer furnishes such initial evidence that the latter condition has been fulfilled, it will then be for the proprietor of the trade mark, who is best placed to assess whether the repackaging is liable to damage his reputation and that of the trade mark, to prove that they have been damaged.

6. **Where a parallel importer has failed to give prior notice to the trade mark proprietor concerning a repackaged pharmaceutical product, he infringes that proprietor's rights on the occasion of any subsequent importation of that product, so long as he has not given the proprietor such notice. The sanction for that infringement must be not only proportionate, but also sufficiently effective and a sufficient deterrent to ensure that Directive 89/104, as amended by the Agreement on the European Economic Area, is fully effective. A national measure under which, in the case of such an infringement, the trade mark proprietor is entitled to claim financial remedies on the same basis as if the goods had been spurious, is not in itself contrary to the principle of proportionality. It is for the national court, however, to determine the amount of the financial remedies according to the circumstances of each case, in the light in particular of the extent of damage to the trade mark proprietor caused by the parallel importer's infringement and in accordance with the principle of proportionality.**

[Signatures]