European Court of Justice, 26 April 2007, Boehringer Ingelheim v Swingward II

TRADEMARK LAW – FREE MOVEMENT

Additional external label

- **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.

Repackaging necessary

- **The repackaging of the pharmaceutical product be necessary for its further commercialisation, as one of the conditions is directed solely at the fact of repackaging and not at the manner and style of the repackaging.**

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.

Reputation trade mark not damaged

- **Damaged reputation is not limited only to cases where the repackaging is defective, of poor quality, or untidy.**

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.

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European Court of Justice, 26 April 2007
(C.W.A. Timmermans, J. Klučka, J. Makarczyk, G. Arestis and L. Bay Larsen)
JUDGMENT OF THE COURT (Second Chamber)
26 April 2007 (*)
(Industrial and commercial property – Trade mark rights – Pharmaceutical products – Parallel imports – Repackaging of the product bearing the trade mark)
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,
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, SmithKline 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-345**7 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 l(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 ("debranding") 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 l(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 Ingelheimand 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, cited above, 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 situa-

tion. 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, cited above, 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.

OPINION OF ADVOCATE GENERAL
Sharpston

delivered on 6 April 2006 (1)
Case C-348/04
Boehringer Ingelheim KG
Boehringer Ingelheim Pharma GmbH & Co. KG
Glaxo Group Ltd
v
Swingward Ltd
and
Boehringer Ingelheim KG
Boehringer Ingelheim Pharma GmbH |& Co. KG
Glaxo Group Ltd
Smithkline Beecham plc
Beecham Group plc
Smithkline and French Laboratories Ltd
Eli Lilly and Co.
The Wellcome Foundation Ltd
v
Dowelhurst Ltd
1. In the present case the Court of Appeal (England and Wales) (Civil Division) seeks further guidance from the Court of Justice on the effect of the latter's judgment in Boehringer Ingelheim and Others ('Boehringer I'). (2) That case concerned the circumstances in which a trade mark owner may rely on his trade mark rights to prevent a parallel importer who has repackaged products bearing the trade mark from marketing those products.
2. In the judgment of the Court of Appeal which led up to the order for reference, Lord Justice Jacob said: 'Sometimes I think the law may be losing a sense of reality in this area – we are, after all, only considering the use of the owner's trade mark for his goods in perfect condition. The pickle the law has got into would, I think, astonish the average consumer.'
3. I agree. It seems to me that after 30 years of case-law on the repackaging of pharmaceutical products it should be possible to distil sufficient principles to enable national courts to apply the law to the constantly replayed litigation between manufacturers and parallel importers. I will attempt to articulate such principles in this Opinion. I would then hope that national courts will play their part robustly in applying the principles to the facts before them without further requests to fine-tune the principles. Every judge knows that ingenious lawyers can always find a reason why a given proposition does or does not apply to their client's situation. It should not however in my view be for the Court of Justice to adjudicate on such detail for evermore. (3)
The legal framework

4. The development of the Court's case-law on repackaging was examined in some detail by both Advocate General Jacobs and the Court in Boehringer I. I will not repeat that analysis. I will merely set out the following points which in my view are particularly relevant to the present case.

5. The historical roots of this case-law are of course Articles 28 and 30 EC. Article 30 looms large in the pleadings in this case. Article 28 in contrast gets little mention. It must not however be forgotten that Article 30 is the exception to the fundamental rule enshrined in Article 28 that goods should be able to move freely between Member States. As a derogation from that basic rule, Article 30 is to be strictly construed. (4)

6. In so construing Article 30 in the context of intellectual and industrial property rights, the Court at an early stage developed the concept of the specific subject-matter of the right, ruling that Article 30 'only admits derogations from [the free movement of goods] to the extent to which they are justified for the purpose of safeguarding rights which constitute the specific subject-matter of such property'. (5) That principle makes it possible to determine, in relation to each type of intellectual property, the circumstances in which the exercise of the right will be permissible under Community law, even though in a cross-border context such exercise by definition impedes free movement. (6)

7. Also at an early stage the Court defined the specific subject-matter of a trade mark right as 'the guarantee that the owner of the trade mark has the exclusive right to use that trade mark, for the purpose of putting products protected by the trade mark into circulation for the first time'. (7) From that definition the doctrine of exhaustion of trade mark rights (8) followed naturally. The Court thus concluded that 'the exercise, by the owner of a trade mark, of the right which he enjoys under the legislation of a Member State to prohibit the sale, in that State, of a product which has been marketed under the trade mark in another Member State by the trade mark owner or with his consent is incompatible with the rules of the EEC Treaty concerning the free movement of goods within the Common Market'. (9)

8. The Court further developed the concept of the specific subject-matter of a trade mark right in Hoffmann-La Roche, (10) explaining that 'the essential function of the trade mark … is to guarantee the identity of the origin of the trade-marked product to the consumer or ultimate user, by enabling him without any possibility of confusion to distinguish that product from products which have another origin [and to] be certain that a trade-marked product … has not been subject at a previous stage of marketing to interference … such as to affect the original condition of the product'. Safeguarding the specific subject-matter of a trade mark therefore includes the right to prevent 'any use of the trade mark which is liable to impair the guarantee of origin'.

9. The specific subject-matter of a trade mark thus has two components. First, there is the right to use the mark for the purpose of putting products protected by it into circulation for the first time in the EC, after which that right is exhausted. Second, there is the right to oppose any use of the trade mark which is liable to impair the guarantee of origin, which comprises both a guarantee of identity of origin and a guarantee of integrity of the trade-marked product.

10. Those core rights are reflected in the Trade Marks Directive. (11) Article 5(1) provides that a trade mark confers on its proprietor 'exclusive rights therein', and in particular the right to prevent the use in the course of trade of (a) an identical sign in relation to identical goods or services and (b) an identical or confusingly similar sign with regard to identical or similar goods or services. (12)

11. Without qualification, Article 5(1)(a) would give the proprietor of a mark the right to prevent all such use in relation to the goods which it covers. Proprietors could thus prevent imports into one Member State of such goods from another Member State and negate the free movement of goods guaranteed by Article 28 EC. That would however be contrary both to the Treaty and to the stated objective of the Directive, which is intended 'to eliminate disparities between the trade mark laws of the Member States which may impede the free movement of goods and the freedom to provide services and distort competition within the common market' (13) and hence to safeguard the functioning of the internal market. (14) Article 7(1) therefore provides that the trade mark owner's right to prevent use of the mark 'shall not entitle the proprietor to prohibit its use in relation to goods which have been put on the market in the Community (15) under that trade mark by the proprietor or with his consent', thus encapsulating the doctrine of Community exhaustion of trade mark rights.

12. Although Article 7(1) has been described as an exception to the rule in Article 5(1), (16) I do not consider that that is a strictly accurate analysis of the relationship between the two provisions. It seems to me that it is more helpful to describe them as counterbalancing each other. If the language of rule and exception is invoked, then it would be more in the spirit of the interrelationship of Articles 28 and 30 EC for Article 5(1), which potentially restricts imports, to be construed as an exception to Article 7(1), which reflects the basic principle of the free movement of goods.

13. In contrast, Article 7(2) states that Article 7(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'. Article 7(2) therefore clearly is an exception to the basic principle of the free movement of goods. Accordingly, it should not be generously construed. (17) It follows that an overbroad interpretation should not be given either, in general, to the term 'legitimate reasons' or, in particular, to the notion of the 'condition' of the goods being 'changed or impaired'.

14. Articles 5 to 7 of the Directive (18) effect a complete harmonisation of the rules relating to the rights conferred by a trade mark and accordingly define the rights of proprietors of trade marks in the Commu-

nity. (19) The Court has nevertheless already stated that its previous case-law under Article 30 EC must be taken as the basis for determining whether a trade mark owner may under Article 7(2) oppose the marketing of repackaged products to which the trade mark has been reaffixed. (20) The same canons of interpretation must apply to other variants of repackaging to which trade mark owners take objection. The Directive must be construed in accordance with the Treaty framework and the core rights developed by the Court and defined above. (21)

15. Having said that, I do not consider that it is necessarily helpful or desirable for the Court to continue to cast its judgments in terms of Article 30 EC (or indeed for parties to plead their case on that basis). The Directive has been with us since 1988. It is surely time to move on.

16. Against that background it may be helpful to reformulate certain propositions derived from the Court's decision in Bristol-Myers Squibb, (22) which colour the questions referred in the present case.

17. In that case, the Court ruled that, under Article 7(2) of the Directive, a trade mark owner may legitimately oppose the further marketing of a repackaged pharmaceutical product unless

(1) that would contribute to the artificial partitioning of the markets between Member States; such is the case, in particular, where the repackaging 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;

(2) the repackaging cannot affect the original condition of the product inside the packaging;

(3) the new packaging clearly states who repackaged the product and the name of the manufacturer;

(4) 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

(5) 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.

18. I will refer to those five conditions, which permeate the questions referred in the present case, as 'the BMS conditions'.

19. Although the Court in Bristol-Myers Squibb interprets Article 7(2) as meaning that the trade mark owner may oppose further marketing unless the criteria are met, I do not consider that that provision creates an independent right of action. As the Court stated in Silhouette, (23) 'while it is undeniable that the Directive requires Member States to implement provisions on the basis of which the proprietor of a trade mark, when his rights are infringed, must be able to obtain an order restraining third parties from making use of his mark, that requirement is imposed, not by Article 7, but by Article 5 of the Directive'.

20. To summarise the BMS conditions in a way that fits clearly within the structure and language of the Directive, repackaging – or at least certain types of repackaging – will constitute a 'legitimate reason' within the meaning of Article 7(2) unless (i) the repackaging is necessary for market access; (ii) the repackaging cannot affect the original condition of the product; (iii) the new packaging shows the name of the importer and the manufacturer; (iv) the presentation is not such as to be liable to damage the reputation of the mark and its owner; and (v) the importer gives notice to the owner.

The main proceedings and the questions referred

21. The claimants are manufacturers of pharmaceuticals and the defendants parallel importers of pharmaceutical products (inhalers or tablets) manufactured and marketed within the Community under a trade mark by one of the claimants. The dispute concerns the circumstances in which the defendants may lawfully oversticker (24) or rebox (25) those pharmaceuticals.

22. More specifically, questions have been put in the present case on two methods of reboxing the products in new exterior cartons designed by one of the defendants and bearing some or all of its own logo or trade mark or a house style or get-up. The first is described by the referring court as 'cobranding': the parallel importer reaffixes the original trade mark (26) to the new exterior carton. The second is described by the referring court as 'debranding': the original trade mark is not reaffixed to the new exterior carton, although it will remain on the pills and inhalers themselves and on any blister packs; instead, the generic name of the drug is indicated. (27)

23. In its first judgment in the national proceedings, (28) the High Court found (i) that there was 'widespread and substantial resistance to parallel-imported pharmaceuticals supplied in overstickered boxes' as opposed to reboxed products and (ii) that the defendants' activities did not harm or even put at risk the 'specific subject-matter' of the claimants' trade mark rights: '[t]he use of the claimants' registered marks has in all cases been accurate, in the sense that they are used to convey without deception or harm the truthful message of source and responsibility for quality'. It also noted that it had not been suggested that the defendants' activities to which objection is taken have adulterated or in any other way compromised the quality of the claimants' products.

24. The High Court referred a series of questions to the Court seeking clarification of principles developed by the Court in its earlier case-law. The questions concerned in part the scope of the principle that parallel importers of pharmaceutical products should be permitted to repackage the products if that was necessary in order to enable the marketing of the products; and in part the scope of the requirement that a parallel importer must give notice to a trade mark proprietor of his intended use of the mark.

25. In Boehringer I, the Court answered those questions as follows:

'1. Article 7(2) of [the Trade Marks 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.

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.'

26. In its second judgment (29) the High Court considered that two propositions followed from the judgment of the Court of Justice: first, that damage to the specific subject-matter of the trade mark proprietor's rights must be assumed to result from repackaging, even where there was in fact no damage either to the quality of the goods or to the mark's function as an indication of origin; and second, that the necessity test applied not only to determine whether the importers could repackage at all but also, if so, to determine the type of repackaging which was permissible, so that the only permissible repackaging was that which from a trade mark point of view was as unobtrusive as possible. The High Court accordingly concluded that both debranding and cobranding infringed the claimants' trade marks.

27. The defendants appealed to the Court of Appeal. The claimants cross-appealed to that court against the finding in the High Court's first judgment that there was widespread and substantial resistance to overstickered boxes. The Court of Appeal confirmed that finding, concluding that if parallel importers could not rebox they faced a substantial hindrance to sale. With regard to the appeal against the High Court's second judgment, the Court of Appeal, although robustly expressing certain views of its own, concluded that the law was not acte clair in certain respects. (30) In particular, it had continuing doubts concerning the meaning of 'necessary', the burden of proof and the consequences of failure to give notice. It has accordingly referred a further series of questions, as follows:

'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 [Bristol-Myers Squibb] 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 [Pharmacia & Upjohn (31)] and [Boehringer I], 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 EFTA Court 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], 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 l(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 ("debranding") 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] apply at all?

(b) if the answer is 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] 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] as interpreted in [Pharmacia & Upjohn] and [Boehringer I], 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 over-

stickering 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], 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 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 EEA by the proprietor or with his consent?'

28. Written observations have been submitted by the claimants, the defendants and the Commission, all of whom were represented at the hearing.

Do the five conditions set out in Bristol-Myers Squibb apply to overstickered products?

29. As the Commission points out, if this question (32) is answered in the affirmative, then questions 2(b) to 2(e) can in effect be merged with questions 1(a) to 1(d). If it is answered in the negative, questions 2(b) to (e) do not arise. It therefore seems sensible to consider question 2(a) first.

30. The High Court in its second judgment had interpreted the Court's judgment in Boehringer I as limited to reboxing, on the basis that only the latter was inherently harmful to the specific subject-matter of the trade mark. The referring court agrees that overstickering does no harm to the reputation of the claimants or their marks.

31. The claimants and the Commission submit that the Court has confirmed that the BMS conditions apply to overstickered packaging. (33) The defendants submit that it follows from the Court's case-law (34) that the BMS conditions do not apply to overstickering.

32. As the defendants correctly point out, the earlier cases were all on various types of reboxing. The issue of overstickering in the context of pharmaceutical products only came before the Court in Boehringer I, but in that case, contrary to what the claimants suggest, was not a central issue.

33. It seems to me that the defendants' point of view is better supported by the case-law and the principles underlying it than the claimants' and the Commission's.

34. In Bristol-Myers Squibb, the Court stated:

'The [trade mark] owner may … oppose the repackaging of the product in new external packaging where the importer is able to achieve packaging which may be marketed in the Member State of importation by, for example, affixing to the original external or inner packaging new labels in the language of the Member State of importation …' (35)

35. Similarly in Loendersloot:

'The person carrying out the relabelling must … use means which make parallel trade feasible while causing as little prejudice as possible to the specific subject-matter of the trade mark right. Thus if the statements on the original labels comply with the rules on labelling in force in the Member State of destination, but those rules require additional information to be given, it is not necessary to remove and reaffix or replace the original labels, since the mere application to the bottles in question of a sticker with the additional information may suffice.' (36)

36. Although those statements by the Court do not explicitly answer the question whether affixing new labels amounts to 'repackaging' in the context of the Court's case-law on Article 30 EC, they strongly suggest that the trade mark owner cannot oppose overstickering. Logically, therefore, they imply that it does not.

37. It is true that in Phytheron, (37) which preceded Loendersloot, the Court ruled that 'the mere addition on the label of [a number of statements designed to comply with the legislative requirements of the Member State of import] cannot constitute a legitimate reason within the meaning of Article 7(2) of the Trade Marks Directive, provided that the label so altered does not omit important information or give inaccurate information and its presentation is not liable to damage the reputation of the trade mark and that of its owner (see Bristol-Myers Squibb, paragraphs 65, 75 and 76)'. (38)

38. It is clear from the Court's citation of Bristol-Myers Squibb in the above quote that the caveat relating to information is a reference to the second BMS condition, namely that the repackaging cannot affect the original condition of the product. Although that

may seem surprising, the Court in Bristol-Myers Squibb expressed the view that in the case of pharmaceutical products the provision of inadequate information may 'indirectly affect' the original condition of the product; whether it does so is a question of fact for the national court. (39)Phytheron therefore suggests that the second and fourth (no damage to reputation) BMS conditions apply to overstickering. In Bristol-Myers Squibb itself, however, it was accepted that the second condition was not breached by overstickering the inner packaging. (40) It might therefore be thought a fortiori that overstickering the outer packaging, as the defendants have done in the present case, would not breach that condition. Moreover Phytheron did not concern pharmaceutical products. I am accordingly not inclined to regard Phytheron as authority for the proposition that the second BMS condition applies to overstickering.

39. Given the conflicting indications in the more recent case-law (illustrated by the fact that both the claimants and the defendants rely on Loendersloot and Boehringer I), it seems to me that the answer must be found by reference to basic principles.

40. The original source of the BMS conditions, Hoffmann-La Roche, (41) refers to the proprietor's right to prevent any use of the trade mark which is liable to impair the guarantee of origin. (42) Whatever the Court's historical approach to the risks attached to replacing external packaging, the overstickering at issue in the present case does not appear to me to constitute such use of the trade mark. The mark is being affixed to genuine goods with no risk of affecting the original condition of the product itself. That view is borne out by the findings of fact made by the High Court and upheld on appeal by the referring court. In my view, where there is no risk that the guarantee of origin is impaired, as in the case of applying an additional external label to the original external packaging while retaining the original internal packaging, (43) the BMS conditions do not apply.

41. That approach to my mind best reflects the appropriate balance between the primary Treaty principle of free movement of goods and the rights of trade mark owners in relation to parallel imports. Where there is no risk to the guarantee of origin as defined by the Court, free movement of goods must prevail. Where on the facts a trade mark owner can demonstrate that overstickering risks impairing the guarantee of origin as so understood, then by way of derogation from the free movement of goods, the trade mark owner's rights may exceptionally prevail. That follows from the Court's definitions of the core rights and specific subject-matter of a trade mark.

42. I accordingly conclude on question 2(a) that the BMS conditions do not apply 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. Given that conclusion, questions 2(b) to (e) do not arise.

Does the requirement that repackaging be necessary apply merely to the fact of reboxing or to the precise manner and style of the reboxing and if so, how?

43. This question (44) arises because the High Court in its second judgment held that the necessity test applied not only to repackaging as such but also to the details of the manner of repackaging. It accordingly concluded that repackaging should be as unobtrusive from a trade mark view as possible. The referring court disagrees with that analysis.

44. The claimants, again citing Boehringer I and Loendersloot, (45) submit that the requirement of necessity applies to the precise manner and style of reboxing. (46) The defendants and the Commission, also citing those cases, take the contrary view.

45. Essentially the question on necessity has arisen because of the High Court's view that the Court's case-law on repackaging establishes an 'irrebuttable legal fiction' that even where (as found as facts in the main proceedings) the repackaging at issue did not and could not adversely affect the quality of the goods, and had no real adverse impact on the mark's function as an indication of origin, damage or prejudice to the specific subject-matter must be assumed. That proposition derives from the Court's statement in Boehringer I that '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'. (47)

46. That statement in fact was paraphrasing Hoffmann-La Roche. (48) With respect, I am not convinced that the summary is wholly correct. What the Court actually said in Hoffmann-La Roche was that the guarantee of origin enables the consumer to be certain that a trade-marked product has not been subject to unauthorised interference by a third party 'such as to affect [its] original condition'. (49) That suggests that the precise manner and style of reboxing which affects only the outer packaging would not impair the guarantee of origin.

47. Moreover as I have already indicated (50) I do not consider that the notion of the 'condition of the goods [being] changed or impaired' (the wording of Article 7(2) of the Trade Marks Directive, which reflects the Hoffmann-La Roche conditions) should be broadly interpreted.

48. The travaux préparatoires (51) also suggest that the Commission originally intended the necessity requirement to apply to the fact of repackaging; and envisaged that the parallel importer should enjoy a degree of freedom as to how precisely he repackaged, provided that he met the requirements laid down in Hoffman-La Roche. (52) There is nothing to suggest that that intention did not survive the legislative process.

49. The referring court and the defendants contend that the decision of the EFTA Court in Paranova v Merck (53) endorses the view that the necessity condi-

tion applies merely to the fact of reboxing and not to the precise manner and style thereof. I am not convinced that that judgment is quite as clear-cut as is suggested. It is however certainly relevant.

50. In that case, the EFTA Court was asked inter alia whether the criterion of necessity that the Court of Justice had applied in interpreting 'legitimate reasons' within the meaning of Article 7(2) applied also to the more specific design of the packaging or whether the more specific design of the packaging was to be assessed solely on the basis of the condition that the repackaging must not adversely affect the reputation of the trade mark proprietor or the trade mark.

51. The EFTA Court reviewed the case-law of the Court of Justice and in particular the BMS conditions. It considered that on the basis of the first condition 'it will be established whether the parallel importer has a right to repackage the product and reaffix the manufacturer's trade mark, whereas the other criteria determine conditions for the exercise of this right in order to safeguard legitimate interests of the trade mark proprietor'. Citing Bristol-Myers Squibb, Merck Sharpe & Dohme, (54)Boehringer I and Pharmacia & Upjohn, (55) the EFTA Court stated that '[p]ermitting parallel imports and repackaging are means which aim at securing the free movement of goods. … The parallel importer's right to repackage is, in other words, justified because it makes an important contribution to overcoming the partitioning of the EEA market along national boundaries. It is against this background that the Court of Justice [has] established the necessity test … It follows that the [test] is relevant to the issue of establishing the parallel importer's right to repackage as such, where the conduct of the trade mark proprietor and factual or legal trade barriers hinder effective access to the market of the State of importation. Where … the right to repackage is beyond doubt and the parallel importer has, in exercising it, achieved effective access to the market, the necessity requirement cannot be decisive when interpreting the term "legitimate reasons" in Article 7(2) of the Directive. … Imposing the necessity requirement on the market conduct of the parallel importer after having gained market access, in particular on its strategy of product presentation, such as advertising or packaging design, would constitute a disproportionate restriction on the free movement of goods'. (56)

52. That reasoning seems to me to be correct. The scheme of the BMS conditions (and indeed of the original conditions laid down in Hoffmann-La Roche) also lends itself to that analysis. It is furthermore borne out by the approach of the Court in Pharmacia & Upjohn, (57) in which it is stated that the 'condition of necessity is satisfied if … the rules or practices in the importing Member State prevent the product in question from being marketed in that State'.

53. It has been suggested (58) that the judgment of the EFTA Court gives insufficient weight to 'the right of a trade mark proprietor to present his trade mark as he wished' and on that basis is not good law. A trade mark proprietor of course has such a right. But it is exhausted once the products have been put on the market in the Community by him or with his consent. That is the point of the rule of exhaustion, which seeks to ensure that intellectual property rights are not used to impede the free movement of goods. In my view there must be very cogent reasons for displacing it.

54. There is moreover a forceful pragmatic argument (which in my view is at least as important as the conceptual coherence of the law) against the view that the necessity test applies to the precise manner and style of repackaging. Such an interpretation would place an intolerable burden on national courts, which would have to take numerous decisions on trivial details of pattern and colour which are not obviously within their judicial remit.

55. I accordingly conclude that the requirement that repackaging be necessary applies merely to the fact of reboxing and does not extend to the precise manner and style thereof.

Is the fourth BMS condition infringed only if the packaging is defective, of poor quality or untidy or does it extend to anything which damages the reputation of the trade mark?

56. The fourth BMS condition is that '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'.

57. This question (59) was prompted by the defendants' submission that the fourth BMS condition was limited to poor packaging. The referring court disagrees, considering that any damage to the reputation of the mark means non-compliance with the condition, but presumably felt that the issue was not beyond doubt.

58. I agree with the claimants and the Commission that there is no reason to limit the fourth BMS condition to matters of defective, poor quality or untidy packaging. It is clear from paragraphs 75 to 77 of the judgment in BMS that the Court referred to such packaging as examples of 'inappropriate presentation' in the case of pharmaceutical products that might damage the reputation of the trade mark.

59. The Court has moreover since BMS recognised other examples of damage to reputation which could in principle constitute a 'legitimate reason' within the meaning of Article 7(2) allowing the proprietor to oppose further commercialisation of goods which have been put on the market in the Community by him or with his consent. (60) Thus in Dior (61) the Court stated generally that damage to the reputation of a trade mark may be a legitimate reason; and indicated more specifically that use of a trade mark in advertising which seriously damaged the reputation of the mark could be a legitimate reason. In BMW (62) the Court stated that the fact that a trade mark is used in a reseller's advertising in such a way that it may give rise to the impression that there is a commercial connection between the reseller and the trade mark proprietor may constitute a legitimate reason.

60. The defendants do not in my view convincingly deal with this case-law. They rely on the inclusion of

the word 'thus' (63) in the fourth BMS condition as suggesting that it is only where the packaging is defective, of poor quality or untidy that the fourth condition is infringed. The word 'thus' is a perilously fragile thread on which to hang that interpretation. In any event it could equally mean 'by way of example' and hence support the opposite view.

61. I accordingly conclude that the fourth BMS condition is not limited to defective, poor quality or untidy packaging: the issue is whether there is a serious risk that the reputation of the trade mark will be damaged.

Are certain (specified) methods of repackaging necessarily damaging to the reputation of a trade mark or is damage to reputation a question of fact?

62. By this question (64) the national court asks whether it is necessarily damaging to the reputation of a trade mark if (i) the trade mark is not affixed to the new exterior carton ('debranding') 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 ('cobranding'), or whether damage to reputation is a question of fact.

63. As explained above, the High Court took the view in its second judgment that any repackaging must be assumed to be damaging to the reputation of the mark. The referring court disagrees. It states that in some cases cobranding may cause such damage, for example if it creates a perception that the cobrand's proprietor is the manufacturer or that the importer and manufacturer are in some sort of joint venture. That is not the case however in the present proceedings. As regards debranding the referring court also sees no damage to reputation: a trade mark owner has no right that requires subsequent dealers to keep his trade mark on the product.

64. The claimants submit that debranding and cobranding are both inherently damaging to the reputation of the trade mark. The defendants submit that debranding is not an infringement at all since it does not amount to 'using' the trade mark within the meaning of Article 5(1). With regard to cobranding, there was no suggestion in BMS that the parallel importer's adoption of a house style for its packaging would be damaging to the trade mark's reputation. (65) The Commission submits that, while each of the circumstances posited may in principle damage the reputation of a trade mark, in each case the national court must carry out a detailed factual appraisal in order to determine whether it actually does so.

65. I agree with the position adopted by the Commission. It is clear (see points 58 and 59 above) that both inappropriate presentation of the mark and incorrect suggestion of commercial link with the trade mark owner are capable in principle of damaging the mark's reputation (although it is also clear from Dior that only serious damage to reputation will amount to a legitimate reason within the meaning of Article 7(2) (66)). The Court confirmed in BMW that whether advertising may create the impression that there is a commercial connection between the reseller and the trade mark proprietor is a question of fact for the national court to decide in the light of the circumstances of each case. (67) It seems to me that the same logic should apply in other circumstances which might amount to 'legitimate reasons' within the meaning of Article 7(2). Whether a given circumstance (e.g. damage to reputation) may in principle constitute a 'legitimate reason' is a question of law, but whether in a given case that circumstance obtains is a question of fact.

66. I accordingly conclude that both inappropriate presentation of the trade mark and incorrect suggestion of a commercial link are capable in principle of damaging the trade mark's reputation. Whether particular forms of repackaging cause such damage and whether the damage is sufficiently serious to amount to a 'legitimate reason' within the meaning of Article 7(2) of the Directive is a question of fact for the national court.

What is the effect of failing to give notice as required by the fifth BMS condition?

67. The fifth BMS condition requires the importer to give notice to the trade mark owner before the repackaged product is put on sale and, on demand, to supply him with a specimen thereof.

68. In Boehringer I the Court ruled that if the parallel importer does not himself satisfy the requirement of prior notice, the trade mark proprietor may oppose the marketing of the repackaged product and that, 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. The Court suggested on a 'purely indicative' basis that 15 working days would be a reasonable period. (68)

69. The High Court in its second judgment considered that it was not clear from Boehringer I what the appropriate remedy would be where the importer has failed to give notice but has complied with the other BMS conditions. The referring court accordingly asks, (69) on the assumption that that is the case, (a) whether the importer infringes by every subsequent importation or only until the proprietor has become aware of the product and the notice period has expired; (b) whether the proprietor is entitled to claim damages or an account on the same basis as if the goods had been spurious; (c) whether the granting of such remedies is subject to the principle of proportionality and (d) if not, upon what basis compensation should be assessed.

70. The claimants submit that every act subsequent to a failure to give notice is an infringement regardless of the proprietor's awareness since each act misleads consumers as to the origin of the product. Remedies are to be determined by national law. The defendants submit that the proprietor is entitled to relief only until the expiry of 15 days after he has actually become aware of the packaging in question, by whatever means. The principle of proportionality applies to remedies as well as to substantive measures. The Commission agrees with the claimants that question 3(a) has already been answered in the sense of the first alternative put by the national court: see Boehringer I. Compensation is to be determined in accordance with national principles relating to financial remedies provided that these are

compatible with Community and international law, in particular that they comply with the principles of equivalence, effectiveness and proportionality.

71. The referring court correctly points out that the requirement for notice does not appear to have any Treaty basis. It was introduced in the judgment in Hoffmann-La Roche on the footing that it reduced the risk of consumers being misled as to the origin of the product. (70) That rationale was further developed in Bristol-Myers Squibb, where the Court explained that the requirement for notice together with the possibility (introduced in that judgment) for the trade mark proprietor to require a sample of the repackaged product is to enable the proprietor to check that the repackaging does not affect the original condition of the product and that the presentation is not likely to damage the reputation of the mark. It also affords the proprietor a better possibility of protecting himself against counterfeiting. (71)

72. The requirement is therefore, in contrast to the first four BMS conditions which may be described as substantive, in the nature of a procedural requirement. It accordingly follows, in my view, that breach of the notice requirement attracts a sanction distinct from the sanctions applicable if the other, substantive, BMS conditions are breached.

73. That is not to minimise the importance of the notice requirement. It may be essentially procedural, but it is none the less an important safeguard for the trade mark proprietor. Failure to give notice is not trivial.

74. It may also be worth pointing out that, save in very rare cases, failure to give notice will be deliberate. The parallel importer knows who the trade mark owner is and how to contact him. As noted in the Opinion of Advocate General Jacobs in Boehringer I, the notice requirement 'is simple to apply and simple to observe, thus contributing to the uniform application of Community law'. (72)

75. Two scenarios may be envisaged: no (or inadequate) notice but compliance with the first four BMS conditions and no (or inadequate) notice but non-compliance with one or more of the first four BMS conditions.

76. In the first of those scenarios, which forms the basis of the referring court's question, it seems to me that it would be disproportionate to sanction the parallel importer for failure to give notice as severely as if, in addition to failing to give notice, he had breached one or more of the substantive conditions. A sanction is none the less appropriate because, as explained above, giving notice is an important procedural requirement; and by failing to give notice the parallel importer has (deliberately) deprived the trade mark owner of the opportunity to effect the prior control that Community law allows him. The sanction should thus be effective and dissuasive. It should not however be equal to the sanction that would apply if the substantive conditions had also been breached, because that would be disproportionate.

77. The defendants express concern that the trade mark owner may, after becoming aware from another source of a repackaged product, deliberately delay commencing proceedings with a view to increasing any financial award for infringement. It would in my view similarly be disproportionate and indeed unjust for the trade mark owner to benefit in such a manner from his own delay.

78. Likewise, because the parallel importer is (in fact) exercising Community law rights, the sanction must not discriminate against him because he is exercising Community rights rather than national law rights; and must not make it in practice impossible for him to exercise those rights.

79. In any given case, it is for the national judge to set an appropriate sanction which respects those parameters.

80. The second scenario described above is, of course, hypothetical in the present case. Nevertheless, I mention it for the sake of completeness. Here, the situation is significantly different. The failure to give notice will in such cases be an aggravating factor, because it makes it more difficult for the trade mark owner legitimately to object to the use of repackaging (whether generally on the basis that it is not necessary to repackage at all, or specifically on the basis that the actual repackaging used falls short of the second, third and/or fourth BMS condition). If, as is probable, the failure to give notice is deliberate, the purpose will presumably be to enable the parallel importer to get a foothold in the market before the trade mark owner is in a position to enforce his rights. In such circumstances, I consider that the national court should apply its normal sanctions under national law for breach of the substantive conditions, and should impose a separate and additional sanction for the failure to give notice.

Who bears the burden of proof?

81. The referring court asks (73) whether the importer bears the burden of proving that the new packaging complies with each BMS condition, or whether the burden of proof varies from condition to condition, and if so, how. In the context of the fourth BMS condition (damage to reputation), the referring court also asks (74) who bears the burden of proving that a particular form of box design damages the reputation of the trade mark if (as I suggest is the case) the question whether such design is so damaging is a question of fact.

82. Clearly the impact of the five BMS conditions, and whether in practice they operate in a way that respects the proper relationship between Article 7(1) and Article 7(2) of the Directive, will depend significantly upon which party bears the burden of showing that those conditions are satisfied. The guidance given in Boehringer I, namely that the burden of proof should be a procedural matter determined by the national court as long as the effect is non-discriminatory, has proved insufficiently precise, as the present reference demonstrates. Depending upon which party is required by the national court to discharge the burden of proof in a particular Member State, the same factual circum-

stances may lead to different outcomes in different Member States, a result that would be contrary to the harmonisation that the Directive seeks to achieve. (75)

83. In deciding on the respective roles played here by Community law and national law, it is important to distinguish between determining where the burden of proof should fall, and determining how that burden of proof is to be discharged. I agree with the referring court that it is appropriate for this Court to indicate to national courts where the burden of proof lies in respect of the five BMS conditions. How that burden is discharged in respect of any individual conditions will then be a matter for national procedural and evidential rules.

84. The claimants submit that the burden of proof for all five conditions should lie on the defendants, because of the inherent exposure to harm of the trade mark owner's rights through repackaging.

85. The defendants advance two submissions. Primarily, they suggest that the burden of proof for all five conditions should lie with the trade mark owner. Such an interpretation cannot be squared with the way in which the Court's judgment in Bristol-Myers Squibb is framed, (76) and I do not consider it further.

86. Alternatively, they suggest that the burden of proof for each condition should be assigned according to which party substantially asserts the affirmative of the issue in question (in order to avoid the risk of being required to prove a negative). They would therefore accept that the burden of proof with regard to the first condition (necessity to repackage in order to market the product), the third condition (clear identification of manufacturer and importer) and the fifth condition (notice) should fall upon the parallel importer. They contend, however, that the trade mark owner should be required to make good any claim that the repackaging does not satisfy the second condition (no effect on original condition, proper instructions) or the fourth condition (non-damaging presentation).

87. The Commission submits that, as a starting point, it is up to national procedural rules to determine who bears the burden of proving compliance with the BMS conditions. However, national procedural rules which impose the burden of proof on the parallel importer may be qualified if the importer is able to establish that their operation leads to a real risk of partitioning national markets. (77) In such a case, the burden of proving each of the BMS conditions lies on the party who is the more likely to possess the information relevant to assessing that condition.

88. Once one examines the five BMS conditions, it becomes apparent that they are not homogeneous. The first condition is potentially complex. Depending on the circumstances, detailed analysis of the legal and factual circumstances of the market in the Member State of importation may sometimes be required in order to decide whether repackaging is necessary in order to permit the parallel importer to access and to sell effectively in that market. Superficially, the second and fourth conditions appear complex. To my mind, however, each requires evaluation of what is essentially a relatively simple issue: does what has been done to the product by way of repackaging carry with it a real risk that the original condition of the product will be adversely affected (second condition); and is the new presentation of the product such that there is a real risk of serious damage to the reputation of the trade mark (fourth condition). The third and fifth conditions are rather more straightforward.

89. Depending upon which of the conditions is at issue, it may be more or less practicable for the parallel importer or the trade mark owner to marshal the necessary material to prove that a particular condition is (or is not) satisfied, and hence reasonable to require him to do so in order to discharge the burden of proof.

90. More fundamentally, the effect of requiring the parallel importer to discharge all five conditions would be to tilt the balance further away from free movement of goods (the fundamental principle) and towards protection of intellectual property rights (the exception to that principle). Conversely, requiring the trade mark owner to discharge all five conditions would make it correspondingly more difficult for him ever to invoke his rights under Article 7(2) of the Directive and (as I have already indicated) runs counter to Bristol-Myers Squibb.

91. To my mind, both those options are therefore unacceptable; and one should consider each condition in turn.

The first condition: necessity

92. The Court indicated in Bristol-Myers Squibb that the 'power of the owner of trade mark rights protected in a Member State to oppose the marketing of repackaged products under the trade mark should be limited only in so far as the repackaging undertaken by the importer is necessary in order to market the product in the Member State of importation'. (78) It seems to me to be implicit in the logic of that statement that the parallel importer must demonstrate necessity in order to displace the presumption that the trade mark owner retains the power to oppose the marketing of repackaged products. It hardly makes sense for the person possessing power to be required to demonstrate that he may not, in the circumstances, exercise it.

93. It also seems to me that the parallel importer is the party most likely to possess the information to discharge the burden of proving necessity. In the normal course of events, he will have familiarised himself with the regulatory requirements governing the distribution and marketing of pharmaceutical products in the Member State of importation. He will be aware of such matters as what is required, in what language, on a patient information leaflet and the sizes of product packaging that are (or are not) routinely prescribed and/or routinely reimbursed by the social security system. He also has the commercial incentive to do the necessary work to discover whether (for example) there is patient resistance in a particular Member State to packs with overstickering, (79) so that it is necessary to rebox rather than to oversticker in order to market the product successfully.

94. I therefore consider that the parallel importer should bear the burden of proving necessity.

The second condition: no adverse effect on condition of product

95. It is the parallel importer who chooses the extent to which he repackages the product and by what method, and who has supervision of (and hence control over) the repackaging process. He knows that the trade mark owner may legitimately 'oppose any repackaging involving a risk of the product inside the packaging being exposed to tampering or to influences affecting its original condition' (80) and that the repackaging must therefore be carried out 'in circumstances not capable of affecting the original condition of the product'. (81) It is thus for the parallel importer to show that what he has chosen to do, and how he has chosen to do it, will maintain the integrity of the trade-marked product. This does not seem to me to be tantamount to proving a negative, as the defendants submit. Moreover, in the context of pharmaceutical products, the parallel importer will of course almost certainly already have had to satisfy the relevant regulatory authorities that his repackaging process carries no risk of damage to the condition of the products. The Court has already explained (82) that, in the context of the second BMS condition, the risk in question must be a real risk, as opposed to a hypothetical or abstract risk.

96. In my view, it is therefore for the parallel importer to discharge the burden of proving that there is no adverse effect.

The third condition: clear identification of importer and manufacturer

97. The parallel importer both determines and controls the repackaging. He specifies such matters as the colour, size and typeface used to display information and the location of the information on the package. It is therefore for the parallel importer to discharge the burden of showing that both the trade mark owner and the parallel importer are clearly identified on the repackaged product.

The fourth condition: presentation not damaging to reputation

98. I have already indicated that, in my view, the fourth BMS condition is infringed if the packaging is such as to give rise to a serious risk that the reputation of the trade mark will be damaged. (83) It follows that the burden of proving that that is the case should be borne by the trade mark owner. He is in the best position to assess whether the repackaging presents no risk, or a possible risk, of damaging the trade mark's reputation. Should he consider that the risk is serious, he is best placed to present evidence to make good that assertion. He should therefore bear the positive burden of proving interference with his trade mark rights. (84)

The fifth condition: notice

99. The parallel importer by definition controls whether, when and by what means he informs the trade mark owner that he intends to repackage the trade-marked product and to sell it in the Member State of importation. It follows that he should bear the burden of proving that he has taken all reasonable steps to give due notice. (85)

Conclusion

100. For the reasons given above, I consider that the questions referred by the Court of Appeal (England and Wales) (Civil Division) should be answered as follows:

– The five conditions set out in Joined Cases C-427/93, C-429/93 and C-436/93 Bristol-Myers Squibb [1996] ECR I-3457 ('the BMS conditions') do not apply 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.

– The requirement that repackaging be necessary (the first BMS condition) applies merely to the fact of reboxing and does not extend to the precise manner and style thereof.

– The requirement that the presentation of the repackaged product be not such as to be liable to damage the reputation of the trade mark or its owner (the fourth BMS condition) is not limited to defective, poor quality or untidy packaging: the issue is whether there is a serious risk that the reputation of the trade mark will be damaged.

– Both inappropriate presentation of the trade mark and incorrect suggestion of a commercial link are capable in principle of damaging the trade mark's reputation. Whether particular forms of repackaging cause such damage and whether the damage is sufficiently serious to amount to a 'legitimate reason' within the meaning 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 is a question of fact for the national court.

– In circumstances where the importer has failed to give notice but has complied with the other BMS conditions, he infringes by every subsequent importation. It is for the national court to determine the appropriate sanction, which should be effective and dissuasive. It should also be proportionate and therefore should not be equal to the sanction that would apply if the other BMS conditions had also been breached.

– The parallel importer bears the burden of proving compliance with the first, second, third and fifth BMS conditions. The trade mark owner bears the burden of proving serious risk of damage to the reputation of the trade mark or himself (the fourth BMS condition).

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1 – Original language: English.

2 – Case C-143/00 [2002] ECR I-3759.

3 – It may be noted that Advocate General Jacobs made a similar point nine years ago in point 33 of his Opinion in Case C-349/95 Loendersloot [1997] ECR I-6227, where he expressed the view that 'this Court would … be going beyond its functions under Article [234 EC] if it were to rule on all aspects of repackaging and relabelling which might be undertaken by parallel importers in relation to different types of product. Once

the Court has spelt out the essential principle or principles, it must be left to the national courts to apply those principles in the cases before them'.
4 – Case 113/80 Commission v Ireland [1981] ECR 1625, paragraph 7.
5 – Case 78/70 Deutsche Grammophon [1971] ECR 487, paragraph 11. 'Specific subject-matter' is the rather infelicitous translation of the French 'objet spécifique'. See chapter 6 of D. Keeling, Intellectual Property Rights in EU Law (2003) for an interesting historical and linguistic discussion.
6 – Point 14 of the Opinion of Advocate General Jacobs in Case C-10/89 HAG [1990] ECR I-3711 (HAG II).
7 – Case 16/74 Centrafarm v Winthrop [1974] ECR 1183, paragraph 8.
8 – There were analogous developments in the context of other intellectual property rights: see Deutsche Grammophon, cited in footnote 5, concerning rights related to copyright, Case 15/74 Centrafarm v Sterling Drug [1974] ECR 1147 concerning patents and Case 58/80 Dansk Supermarked [1981] ECR 181 concerning copyright.
9 – Centrafarm v Winthrop, cited in footnote 7, paragraph 12.
10 – Case 102/77 [1978] ECR 1139, paragraph 7.
11 – 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).
12 – Since the present case does not concern services, I shall restrict future discussion to goods.
13 – First recital in the preamble as rephrased by the Court in Case C-206/01 Arsenal Football Club [2002] ECR I-10273, paragraph 46.
14 – Case C-355/96 Silhouette [1998] ECR I-4799, paragraph 27.
15 – In accordance with Article 65(2), in conjunction with Annex XVII, point 4, of the Agreement on the European Economic Area of 2 May 1992 (OJ 1994 L 1, p. 3), Article 7(1) has been amended for the purposes of the Agreement so that the expression 'in the Community' has been replaced by 'in a Contracting Party'. Since however the present proceedings concern intra-Community trade, I will continue to refer to the Community rather than the European Economic Area in discussing the scope of Article 7(1).
16 – Case C-16/03 Peak Holding [2004] ECR I-11313, paragraph 34 and the case-law there cited.
17 – See point 5 above.
18 – Article 6 concerns limitations on the effects of a trade mark which are not relevant in the present case.
19 – Peak Holding, cited in footnote 16, paragraph 30 and the case-law there cited.
20 – Joined Cases C-427/93, C-429/93 and C-436/93 Bristol-Myers Squibb [1996] ECR I-3457, paragraph 41.
21 – Points 7 to 9.
22 – Cited in footnote 20.
23 – Cited in footnote 14, paragraph 35.
24 – The order for reference defines an overstickered product as a 'product imported from another Member State in its original internal and external packaging to which the parallel importer has applied an additional label printed in the language of the Member State of importation'.
25 – The order for reference defines a reboxed product as a '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'.
26 – Or in some cases marks, where the manufacturer's name and logo have also been registered as such.
27 – Some of the blister packs and inhalers are themselves overstickered, but not so as completely to cover the original trade marks, and it does not appear that any issue is taken with this.
28 – Judgment of Laddie J delivered on 28 February 2000, [2000] 2 CMLR 571.
29 – Judgment of Laddie J delivered on 6 February 2003, [2003] EWHC 110 (Ch).
30 – Corroborated perhaps by the fact that each side argued that, as a result of the Court's 'clarification', it had in whole or large part won the trade mark part of the action.
31 – Case C-379/97 [1999] ECR I-6927.
32 – Question 2(a).
33 – Bristol-Myers Squibb, cited in footnote 20, paragraph 55, Joined Cases C-71/94, C-72/94 and C-73/94 Eurim-Pharm [1996] ECR I-3603, Loendersloot, cited in footnote 3, paragraph 27, and Boehringer I.
34 – Hoffmann-La Roche, cited in footnote 10, Case 1/81 Pfizer [1981] 2913, Bristol-Myers Squibb, cited in footnote 20, Pharmacia & Upjohn, cited in footnote 31, Loendersloot, cited in footnote 3, paragraph 27, and Boehringer I.
35 – Paragraph 55.
36 – Paragraph 46.
37 – Case C-352/95 [1997] ECR I-1729.
38 – Paragraph 23.
39 – See paragraphs 65 and 66.
40 – See paragraph 64.
41 – Cited in footnote 10.
42 – Paragraph 7.
43 – As the wording of the question assumes.
44 – Question 1(b). (Question 1(a) is considered below, at points 81 to 99.)
45 – Cited in footnote 3, paragraph 46.
46 – It is perhaps worth pointing out that the question is limited to changes to the outer packaging. For that reason, the claimants' attempted analogy with the marketing of branded cars in China (described by the Commission at the hearing as 'frankly silly') does not seem to me to be particularly helpful. If anything, in fact, the example of car marketing undermines the claimants' case, since dealers frequently co-brand by, for example, ensuring that their name is on the number plate or elsewhere on the car.
47 – Paragraph 30.
48 – Cited in footnote 10.
49 – Paragraph 7. The Court then went on (in paragraphs 9 to 12) to develop the forerunner of what has

become the necessity test, and touched more briefly on what are now the other BMS conditions.
50 – Point 13 above.
51 – See the Explanatory Memorandum to the Proposal for a first Council Directive to approximate the laws of the Member States relating to trade marks (COM(80) 635 final, 19 November 1980), commentary on Article 6.
52 – Cf. Pfizer, cited in footnote 34, where the parallel importer followed the Hoffmann-LaRoche requirements to the letter, and the Court endorsed his approach.
53 – Case E-3/02, judgment of 8 July 2003, ETMR 2004, p. 1.
54 – Case C-443/99 [2002] ECR I-3703.
55 – Cited in footnote 31.
56 – Paragraphs 41 to 45.
57 – Cited in footnote 31, paragraph 43. Although the passage cited refers to removal and replacement of the trade mark rather than repackaging more generally, it is clear from paragraphs 37 to 39 of the judgment that the Court considers the two situations to be governed by the same principles.
58 – By Eli Lilly, one of the claimants.
59 – Question 1(c).
60 – Notwithstanding that wording, Article 7(2) does not itself confer a right of action. The trade mark owner who wishes to oppose an alleged infringement must still bring himself within Article 5(1) of the Directive: see point 19 above.
61 – Case C-337/95 [1997] ECR I-6013, paragraphs 43 and 46.
62 – Case C-63/97 [1999] ECR I-905, paragraph 51.
63 – 'Ainsi' in the French text.
64 – Question 1(d).
65 – See also Pfizer, cited in footnote 34.
66 – Paragraph 46.
67 – Paragraph 55.
68 – Operative part and paragraph 67.
69 – Question 3.
70 – Paragraph 12.
71 – Paragraph 78, echoed in Boehringer I, paragraph 61. See also Loendersloot, cited in footnote 3, paragraph 49.
72 – Point 133.
73 – Question 1(a).
74 – Question 1(d).
75 – See Case C-405/03 Class International, paragraph 73 of the judgment of 18 October 2005.
76 – See, e.g., the phrasing of paragraphs 49, 50, 69, 73, 74 and 78 of Bristol-Myers Squibb.
77 – Case C-244/00 Van Doren [2003] ECR I-3051, paragraphs 37 and 41.
78 – Paragraph 56.
79– For example, because such packs still display, partially, information in a language that elderly patients do not know and may distrust, or, more generally, because patients may suspect that such packs have been tampered with.
80 – Paragraph 59 of Bristol-Myers Squibb.
81 – Paragraph 60 of Bristol-Myers Squibb.
82 – See paragraphs 61 to 63 of Bristol-Myers Squibb.
83 – Point 61 above.
84 – Cf. Van Doren, cited in footnote 77, paragraph 41. The Court held that, in circumstances where there is a real risk of market partition if the importer bears the burden of proving that the goods were placed on the market in the EEA by or with the consent of the trade mark owner, the latter has first to prove that the goods were initially placed on the market outside the EEA, in order to claim interference with the rights conferred upon him by Article 5(1) of the Directive, before the parallel importer has to demonstrate subsequent marketing within the EEA by the trade mark owner or with his consent. See also Class International, cited in footnote 75, paragraphs 70 to 75 for an illustration of the Court determining where the onus of proving interference with trade mark rights lies.
85 – I put it in those terms because I do not consider that the importer should be penalised if he took all reasonable steps to give notice but for some reason, for example a failure of communication within the trade mark owner's organisation, the notice failed to reach the relevant department.