EUROPEAN COMMISSION

ORIGINAL

Brussels, 14 December 2004
JURM(2004) 174

TO THE PRESIDENT AND MEMBERS OF THE
COURT OF JUSTICE OF THE EUROPEAN COMMUNITIES

WRITTEN OBSERVATIONS

submitted pursuant to Article 20 of the Protocol of the Statute of the Court of Justice by the Commission of the European Communities, represented by Niels Bertil Rasmussen and Michael Shotter, members of its Legal Service, with an address for service at the office of Luis Escobar Guerrero, also a member of its Legal Service, at the Centre Wagner, Kirchberg, Luxembourg

in Case **C-348/04**,

BOEHRINGER INGELHEIM e. a.

in which the Court of Appeal (United Kingdom) has requested a preliminary ruling, pursuant to Article 234 EC, concerning the interpretation of Article 7(2) of First Council Directive 89/104/EEC of 21 September 1988 to approximate the laws of the Member States relating to trade marks (OJ L 40, 11.2.1989, p.1) in particular, in relation to the reboxing or relabelling of parallel imported products.

Commission européenne, B-1049 Bruxelles / Europese Commissie, B-1049 Brussel - Belgium. Telephone: (32-2) 299 11 11.
Office: BERL . Telephone: direct line . Fax: (32-2) 296.53.29.

E-mail:

The Commission has the honour to submit the following written observations:

I. FACTS AND PROCEDURE

1. The litigation in the national court involves a number of linked disputes between various well-known pharmaceutical manufacturers ("the claimants") [1], on the one hand, and parallel importers and dealers in generic pharmaceuticals ("the defendants")[2], on the other; it concerns the reboxing or relabelling of parallel imports.

2. This litigation has already given rise to a reference for a preliminary ruling under Article 234 EC to which the Court responded in its judgment in Case C-143/00 Boehringer Ingelheim I[3]. The Commission refers to the grounds of that judgment for the earlier background to the dispute.

3. The High Court of Justice then applied the Court's preliminary ruling in Boehringer Ingelheim I. On the basis that re-packaging a product which bears a trade mark, whether or not the trade mark is reaffixed to the external packaging or simply removed and not replaced, is a particularly intrusive form of trade mark infringement, the High Court found in favour of the claimants, holding that "de-branding" and "co-branding" were objectionable. In particular, it was held that partial "*de-branding by removal of the mark from the outer packaging or significant diminution of its prominence may reduce the extent to which the proprietor can build up public awareness of and reputation in his mark. If such de-branding is not necessary to enable the importer to access the market, the proprietor can use his registered rights to prevent it.*" As to co-branding, it was held that:

> *"The second class consists of those cases where the importer reboxes in a livery which serves to build up his own reputation in his own mark or get-up on the back of the claimant's product. The use by an importer of his own mark or get-up*

---

[1] Boehringer Ingelheim KG, Boehringer Ingelheim Pharma GmbH & Co KG, Boehringer Ingelheim Limited, Glaxo Group Limited, Smithkline Beecham plc, Beecham Group plc, Smithkline and French Laboratories Limited, Eli Lilly and Company.

[2] Swingward Limited, Dowelhurst Limited.

[3] [2002] ECR I-3759

alongside the proprietor's mark on the new boxes was referred to as co-branding during the trial. The effect of this is likely to be to diminish to some extent the build up of the proprietor's exclusive reputation. To some extent, the goodwill generated by the use of the proprietor's mark will benefit the importer, not the proprietor. Once again, that adversely affects the proprietor's interest in his mark and, if it is not necessary to do this to enable the importer to access the market, it can be restrained."

4. The judgment of the High Court was appealed. The judgment of the Court of Appeal of 5 March 2004 made certain findings at variance with those of the High Court, but concluded that the law was not free from doubt and that there was a need for a second reference to the Court for a preliminary ruling under Article 234 EC. By order dated 17 June 2004 the following questions were referred to the Court:

"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 v Paranova or does the burden of proof vary from condition to condition, and if so how?

(b) does the first condition set out in Brystol-Myers Squibb v Paranova as interpreted in Case C-379/97 Upjohn v Paranova and Case C-143/00 Boehringer v Swingward, 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 Inc v Merck & Co Inc) 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 v Paranova, namely that the presentation of the repackaged product is not such as to be liable to damage the reputation of the trade mark or its owner, only infringed if the packaging is defective, of poor quality or untidy or does it extend to anything which damages the reputation of the trade mark?

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

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

Overstickered products

2. Where a parallel importer markets in one Member State a pharmaceutical product imported from another Member State in its original internal and external packaging to which the parallel importer has applied an additional external label printed in the language of the Member State of importation (an "overstickered" product):

(a) do the five conditions set out in Bristol-Myers Squibb v Paranova apply at all?

(b) if the answer in 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 v Paranova 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 in question 2(a) is yes, does the first condition set out in Bristol-Myers Squibb v Paranova as interpreted in Upjohn v Paranova and Boehringer v Swingward, 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 v Paranova, 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 in 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 v Paranova, 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 has 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?"

II. LAW

5. The questions referred by the national court relate, without mentioning these provisions expressly, to the following articles in Directive 89/104/EEC[4] (hereinafter "the Directive"):

"Article 5
Rights conferred by a trade mark

1. The registered trade mark shall confer on the proprietor exclusive rights therein. The proprietor shall be entitled to prevent all third parties not having his consent from using in the course of trade:

(a) any sign which is identical with the trade mark in relation to goods or services which are identical with those for which the trade mark is registered;"

6. Article 5(3) lists in a non-exhaustive fashion, a number of activities which may be prohibited under Article 5(1). These are:

(a) affixing the sign to the goods or to the packaging thereof;

(b) offering the goods, or putting them on the market or stocking them for these purposes under that sign, or offering or supplying services thereunder;

(c) importing or exporting the goods under the sign;

(d) using the sign on business papers and in advertising.

7. Article 7 of the Directive provides as follows:

---

[4] First Council Directive of 21 December 1988 to approximate the laws of the Member States relating to trade marks.

"Exhaustion of the rights conferred by a trade mark

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 commercialization of the goods, especially where the condition of the goods is changed or impaired after they have been put on the market."

8. The questions of the national court refer in particular to the case-law of the Court relating to the treatment of parallel imports under Articles 28-30 EC. In its judgment in Joined Cases C-427/93, C-429/93 and C-436/93 Bristol-Myers Squibb[5], the Court held:

"Where Community directives provide for the harmonization of measures necessary to ensure the protection of the interests referred to in Article [30] of the Treaty, any national measure relating thereto must be assessed in relation to the provisions of that directive and not Articles [28 to 30] of the Treaty" (paragraph 25).

It went on:

"Article 7 of the directive is worded in general terms and comprehensively regulates the question of the exhaustion of trade mark rights for products traded in the Community. Therefore, national rules on the subject must be assessed in the light of that article.

Like any secondary legislation, however, the directive must be interpreted in the light of the Treaty rules on the free movement of goods and in particular Article [30]" (paragraphs 26 and 27).

The Court concluded that:

"the reliance by a trade mark owner on his rights as owner in order to prevent an importer from marketing a product which was put on the market in another Member State by the owner or with his consent where that importer has repackaged the product and reaffixed the trade mark without the owner's authorization, is to be assessed on the basis of the combined provisions of national trade mark law and Article 7 of the directive, interpreted in the light of Article [30] of the Treaty" (paragraph 28).

The Court's caselaw concerning Article 30 is therefore to be used as a source of inspiration for the interpretation of Article 7(2) of the Directive.

---

[5] [1996] ECR I-3457

9. The questions referred by the national court make particular reference to the five conditions laid down by the Court in paragraph 3 of the operative part of its Bristol-Myers Squibb judgment ("the BMS criteria"):

> *"Article 7(2) of Directive 89/104 must 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 is carried out in such conditions that the original condition of the product cannot be affected by it; that condition does not, however, imply that it must be established that the trade mark owner deliberately sought to partition the markets between Member States;*
>
> ° *it is shown that the repackaging cannot affect the original condition of the product inside the packaging; such is the case, in particular, where the importer has merely carried out operations involving no risk of the product being affected, such as, for example, the removal of blister packs, flasks, phials, ampoules or inhalers from their original external packaging and their replacement in new external packaging, the fixing of self-stick labels on the inner packaging of the product, the addition to the packaging of new user instructions or information, or the insertion of an extra article; it is for the national court to verify that the original condition of the product inside the packaging is not indirectly affected, for example, by the fact that the external or inner packaging of the repackaged product or new user instructions or information omits certain important information or gives inaccurate information, or the fact that an extra article inserted in the packaging by the importer and designed for the ingestion and dosage of the product does not comply with the method of use and the doses envisaged by the manufacturer;*
>
> ° *the new packaging clearly states who repackaged the product and the name of the manufacturer in print such that a person with normal eyesight, exercising a normal degree of attentiveness, would be in a position to understand; similarly, the origin of an extra article from a source other than the trade mark owner must be indicated in such a way as to dispel any impression that the trade mark owner is responsible for it; however, it is not necessary to indicate that the repackaging was carried out without the authorization of the trade mark owner;*
>
> ° *the presentation of the repackaged product is not such as to be liable to damage*

the reputation of the trade mark and of its owner; thus, the packaging must not be defective, of poor quality, or untidy; and

° *the importer gives notice to the trade mark owner before the repackaged product is put on sale, and, on demand, supplies him with a specimen of the repackaged product."*

III. DISCUSSION OF THE QUESTIONS

10. The national court distinguishes in the questions asked between "*reboxed*" and "*overstickered*" products. A reboxed product is described there as a (pharmaceutical) product in its original internal packaging but with a new exterior carton printed in the language of the Member State of importation. An overstickered product is described as a (pharmaceutical) product 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. When it refers to reboxed and overstickered products, the Commission will do so using the same meaning as that applied by the national court.

11. It is clearly important not to lose sight of the two different types of products with which the national court is concerned, but it would simplify matters and avoid undue repetition were the two sets of questions concerning reboxed and overstickered products to be merged. However, such an approach would only be appropriate where the answer to be given to Question 2(a) of the national court on whether the BMS criteria apply at all, is answered in the affirmative. It is therefore proposed to examine this as a preliminary question.

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

12. The Commission considers that the considerations and principles underlying the Court's findings in the judgment in Bristol-Myers Squibb, and in particular, the five BMS criteria cited above, should apply both to reboxed and overstickered products. It is clear from that judgment that the products in question were repackaged in new

external packaging[6], that is, that they were reboxed. For two of the products concerned, new stickers were added, covering the label of the manufacturer, but to the internal packaging. In other words, there was no overstickering in the sense covered by the present reference. In its key passages, the judgment refers only to "repackaging". This is most clearly seen in paragraph 55 of the judgment where the Court held:

> *"The owner may, on the other hand, 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 ....."*

13. Accordingly, where the Court used the word "repackaging", this should be read as covering both reboxing and overstickering, even if overstickering was not directly at issue in that case. Even if the factual situation is different, the Commission submits that the Court has employed the term "repackaging" in such a general manner that it covers overstickering as well as reboxing.

14. Moreover, such a reading is appropriate in the light of the reasoning employed by the Court in its Bristol-Myers Squibb judgment and in subsequent judgments applying the BMS criteria[7]. In particular, the first of these conditions relates to the need to avoid partitioning markets between Member States. Reliance on trade mark rights by their owner in order to oppose marketing under that trade mark of products repackaged by a third party would contribute to the partitioning of markets between Member States[8]. Repackaging may be necessary to allow the product imported in parallel to be marketed in the importing State[9]. If that is the case, for example, because the existing packaging is not in the language of the Member State of importation, the parallel importer needs to repackage his product to obtain effective access to the market. That repackaging may consist of attaching a new label (overstickering) or of completely replacing the external package (reboxing) where a

---

[6] Paragraph 11 of the judgment.

[7] See, for example, Joined Cases C-71/94, C-72/94 and C-73/94 Eurim-Pharm v. Beiersdorf [1996] ECR I-3603, paragraph 17 of which indicates that a self-stick label was added to the front of the original packet.

[8] Paragraph 52 of the judgment in Bristol-Myers Squibb.

[9] See paragraphs 15 and 22 of the judgment in Boehringer Ingelheim I.

relabelled product would not be able to have effective access to the market concerned[10], but in both cases, the original product is being "repackaged" in order to gain access to the new market.

15. The point seems clear and is reflected in the following passage from the Opinion of the Advocate General in Boehringer Ingelheim I[11]:

> *"It is also in my mind clear from the case-law of the Court reviewed above that a particular method of repackaging cannot be regarded as necessary if another method which interferes less with the trade mark owner's rights will suffice to give the parallel importer effective access to the market in the importing State. If therefore the national court finds on the facts that overstickered packages have effective access to that market, then it cannot be necessary for the parallel importer to undertake more intrusive types of repackaging such as reboxing."*

16. The above passage highlights another reason why there is no good basis to distinguish overstickering from reboxing for the purposes of applying the BMS criteria. The specific subject matter of a mark is to guarantee the origin of the product bearing that mark and the 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[12]. Overstickering also in principle involves a risk of interference with the original condition of the product, even if it is less intrusive than reboxing. This explains why the change brought about by "any repackaging" of a trade-marked pharmaceutical product creates by its very nature the risk of interference with the original condition of the product[13]. This point is expressly made at paragraph 86 of the Advocate General's Opinion in Boehringer Ingelheim I[14]

17. In conclusion, the Commission considers that in principle there is no valid reason for distinguishing overstickering from reboxing for the purposes of applying the

---

[10] Paragraph 50 of Boehringer Ingelheim I.

[11] Paragraph 111.

[12] Paragraph 29 of Boehringer Ingelheim I.

[13] Paragraph 34 of Boehringer Ingelheim I.

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

BMS criteria to parallel imports of pharmaceutical products. Accordingly, the Commission proposes to merge its treatment of the first and second questions of the national court.

Does the first condition set out in Bristol-Myers Squibb, 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/ overstickering, or does it also apply to the precise manner and style of the reboxing/ overstickering carried out by the parallel importer and, if so how?

18. In order to answer the merged question set out above, it is necessary to consider whether the rationale, as it appears from the case law, is the same on the one hand for controlling the fact of repackaging, as it is on the other for controlling the precise manner and style in which the repackaged product is presented.

19. As a starting point, it is worth recalling that the specific subject matter or essential function of a trade mark is to guarantee the origin of the product bearing that mark. It is possible to identify two aspects of this function[15], namely to enable consumers and end-users:

> to distinguish the trade marked product from products which have another origin without any possibility of confusion (maintaining the distinct character);
>
> to be certain that a trade-marked product when it is sold has not been subject at a previous stage of marketing to interference by a third person (maintaining the integrity).

20. It is submitted that when the Court has applied the "necessity requirement" for repackaging, it has done so in relation to the interest of the trade mark proprietor to maintain the integrity of his product. This can be seen from a reading of paragraphs 29-34 of the judgment in Boehringer Ingelheim I, paragraph 34 of which reads as follows:

> *"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."*

---

[15] See paragraph 7 of the judgment in Case 102/77 Hoffman-La Roche v Centrafarm [1978] ECR 1139.

21. However, the Court in its Bristol-Myers Squibb judgment also added a further safeguard for the trade mark proprietor, namely that the consumer or end-user should not be led to believe that the owner of the trade mark is responsible for the repackaging, so an indication must be given on the packaging of who repackaged the product[16]. In other words, the Court has laid down requirements relating to the substance of how the repackaging is presented, but it has done so with a different rationale in mind. The requirement to indicate who carried out the repackaging is not intended to safeguard the integrity of the product, but rather to maintain the distinct character of the trade mark, which enables consumers to distinguish the commercial origin of the products from the process of repackaging. Regardless of how the presentation of the repackaged products differs from that of products marketed by the trade mark proprietor, in order to make it clear that the owner is not responsible for the repackaging, it is difficult to imagine how this *presentation* could ever interfere or create by it very nature the risk of interference with the original condition of the product. It is submitted that such a risk, which is evidently a key consideration for the Court in applying the necessity test, arises from the *fact of repackaging* as such, not the presentation of such repackaging.

22. Consequently, it is submitted that it is not justified by the case-law of the Court to apply the requirement of necessity to the presentation of the repackaged product and/or inclusion of the logo of the person responsible for the repackaging and/or of other graphic elements of the packaging. Thus, the trade mark proprietor cannot invoke "legitimate interests" to oppose such presentation on the mere basis that those elements cannot be considered to be "necessary" for the marketing of the goods. By way of final comment on this point, the Commission considers that this approach is confirmed by the twofold test that the Court applies in paragraph 34 of the Boehringer Ingelheim I judgment (cited above). In other words, *in addition to* applying the necessity test, the "legitimate interests of the proprietor" must also be safeguarded. The assessment of whether these interests have been safeguarded is not determined by the criterion of necessity.

23. At this juncture, the Commission recalls that the questions asked by the national court concern the validity of any distinction between "the fact of reboxing/

---

[16] Paragraph 70.

overstickering" and the "precise manner and style of reboxing/ overstickering". For its part, the Commission in its analysis above has expressed this in terms of a distinction between "the fact of repackaging" and the "the presentation of the repackaging" (the presentation of the repackaged product). For the sake of clear use of terminology, the Commission would stress that the manner of repackaging as such, that is the act undertaken by the parallel importer in either overstickering or reboxing the product (and not therefore the manner of presenting either the overstickering or reboxing) *is* subject to the necessity test. In this regard, the Court has held in Boehringer Ingelheim I (paragraphs 48-51) that:

> *"In contrast, the trade mark proprietor may oppose the repackaging if it is based solely on the parallel importer's attempt to secure a commercial advantage (see, to that effect, Upjohn, paragraph 44).*
>
> *In that context, it has also been held that the trade mark proprietor may oppose replacement packaging [**i.e. "reboxing"**] where the parallel importer is able to reuse the original packaging for the purpose of marketing in the Member State of importation by affixing labels to that packaging (see Bristol-Myers Squibb and Others, paragraph 55).*
>
> *Thus, while the trade mark proprietor may oppose the parallel importer's use of replacement packaging [**i.e. "reboxing"**], that is conditional on the relabelled [**i.e. "overstickered"**] pharmaceutical product being able to have effective access to the market concerned.*
>
> *Resistance to relabelled [**i.e. "overstickered"**] pharmaceutical products does not always constitute an impediment to effective market access such as to make replacement packaging [**i.e. "reboxing"**] necessary, within the meaning of the Court's case-law. [**explanation and emphasis added**]"*

24. It is only when as a matter of fact there is such strong resistance to overstickering of pharmaceutical products from a significant proportion of consumers that there would be a hindrance to effective market access, that reboxing can be considered as necessary[17].

25. Moreover, the result advocated above by the Commission, that it is not justified to apply the requirement of necessity to the presentation of the repackaged product, has now been upheld by the EFTA Court in its judgment in Case E-3/02 Paranova v Merck & Co[18]. The EFTA Court drew a distinction between the first of the BMS

---

[17] Paragraph 52 of Boehringer Ingelheim I

[18] Judgment of 8 July 2003.

conditions, namely that there is only a "right to repackage" if there is a need to avoid partitioning the market, and the remaining BMS criteria which determine conditions for the exercise of this right in order to safeguard the legitimate interests of the trade mark proprietor[19]. Accordingly, once it was established that there was a "right to repackage" on the part of the parallel importer in order to gain effective access to the market, the necessity requirement could not be decisive when interpreting the term "legitimate reasons" in Article 7(2) of the Directive[20]. The EFTA Court then held:

> *"Such a treatment of the parallel importer would not reflect its rights and functions under the fundamental principle of the free movement of goods in an appropriate way. After lawfully having repackaged the products and reaffixed the trade mark proprietor's trade mark, the parallel importer is to be considered as an operator on basically equal footing with the manufacturer and trade mark proprietor within the limits set by 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 product design, would constitute a disproportionate restriction on the free movement of goods.[21]"*

26. In conclusion, the first condition set out in the Bristol-Myers Squibb judgment, namely that it must be shown that it is necessary to repackage the product in order that effective market access is not hindered, applies merely to the fact of reboxing/ overstickering. It does not apply to the precise manner and style of the reboxing/ overstickering carried out by the parallel importer.

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?

27. The present question concerns the interpretation of the wording of the fourth of the BMS criteria. These concern the interpretation of Article 7(2) of the Directive, that is, the situations in which a trade mark proprietor may oppose further marketing because there are *"legitimate reasons"* to do so. In consequence, the Commission finds it appropriate to address the question in a broader manner, namely whether damage to the reputation of the trade mark or its owner may constitute "legitimate

---

[19] Paragraph 41.

[20] Paragraph 44.

[21] Paragraph 45.

reasons" to oppose the further marketing *only* when the packaging is defective, of poor quality or untidy or in *every* situation where the marketing of the repackaged product may damage the reputation of the trade mark.

28. The Commission considers that there is no good reason to limit the discussion concerning possible damage to the trade mark proprietor's reputation to matters of defective, poor quality or untidy packaging. It will be recalled that in Bristol-Myers Squibb, the Court held at paragraphs 75-77 that:

> *"Even if the person who carried out the repackaging is indicated on the packaging of the product, there remains the possibility that the reputation of the trade mark, and thus of its owner, may nevertheless suffer from an* ***inappropriate presentation*** *of the repackaged product. In such a case, the trade mark owner has a legitimate interest, related to the specific subject-matter of the trade mark right, in being able to oppose the marketing of the product. In assessing whether the presentation of the repackaged product is liable to damage the reputation of the trade mark, account must be taken of the nature of the product and the market for which it is intended.*
>
> *In the case of pharmaceutical products, that is certainly a sensitive area in which the public is particularly demanding as to the quality and integrity of the product, and the presentation of the product may indeed be capable of inspiring public confidence in that regard. It follows that defective, poor quality or untidy packaging could damage the trade mark's reputation.*
>
> *However, the requirements to be met by the presentation of a repackaged pharmaceutical product vary according to whether the product is sold to hospitals or, through pharmacies, to consumers. In the former case, the products are administered to patients by professionals, for whom the presentation of the product is of little importance. In the latter case, the presentation of the product is of greater importance for the consumer, even if the fact that the products in question are subject to prescription by a doctor may in itself give consumers some degree of confidence in the quality of the product.* ***[Emphasis added]*** *"*

29. In other words, the Court referred to defective, poor quality or untidy packaging as examples of presentation in the case of pharmaceutical products that might damage the reputation of the trade mark. However, it is submitted that anything that might damage the reputation of the trade mark, as a result of "*inappropriate presentation*[22]" depending on the nature of the product and the market for which it is intended, could constitute "legitimate reasons" to oppose the further marketing of the goods.

---

[22] Paragraph 75 of Bristol-Myers Squibb.

30. Furthermore, it follows from subsequent case-law that the trade mark proprietor may have "legitimate reasons" to oppose the use of the trade mark because of the possible damage to its reputation even in regard to the marketing of products when no repackaging has taken place. Firstly, it is worth mentioning that such damage to the reputation of the trade mark might result from the use of the trade mark to bring to the public's attention the further commercialisation of the goods. In the judgment in Case C-337/95 Christian Dior v Evora[23] the Court held, after having cited paragraph 75 of the judgment in Bristol-Myers Squibb, that:

> *"It follows that, where a reseller makes use of a trade mark in order to bring the public's attention to further commercialisation of trade-marked goods, a balance must be struck between the legitimate interest of the trade mark owner in being protected against resellers using his trade mark for advertising in a manner which could* ***damage the reputation*** *of the trade mark and the reseller's legitimate interest in being able to resell the goods in question by using advertising methods which are customary in his sector of trade. [Emphasis added]"*

31. The Court went on to conclude (at paragraph 48 of the judgment) that the trade mark proprietor could not rely on Article 7(2) of the Directive to oppose the use of a trade mark in ways customary in the reseller's sector of trade unless it was established that the use of the trade mark "*seriously damages the reputation of the trade mark*".

32. Secondly, reference is made to judgment in Case 63/97 BMW v. Deenik[24] in which the Court held in par. 51-52:

> *"The fact that the 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, and in particular that the reseller's business is affiliated to the trade mark proprietor's distribution network or that there is a special relationship between the two undertakings, may constitute a legitimate reason within the meaning of Article 7(2) of the directive.*
>
> *Such advertising is not essential to the further commercialisation of goods put on the Community market under the trade mark by its proprietor or with his consent or, therefore, to the purpose of the exhaustion rule laid down in Article 7 of the directive. Moreover, it is contrary to the obligation to act fairly in relation to the legitimate interests of the trade mark owner and it affects the value of the trade mark by taking unfair advantage of its distinctive character or repute. It is also incompatible*

---

[23] [1997] ECR I-6013, at paragraph 44.

[24] [1999] ECR I-905

with the specific object of a trade mark which is, according to the case-law of the Court, to protect the proprietor against competitors wishing to take advantage of the status and reputation of the trade mark (see, inter alia, Case C-10/89 HAG GF [1990] ECR I-3711, 'HAG II', paragraph 14)."

33. In the Commission's view it follows from this jurisprudence that the trade mark proprietor may have "legitimate reasons" in the sense of Article 7(2) of the Directive to oppose the further commercialisation of the goods, not only when the reputation of the trade mark is endangered by packaging which may be considered to be "defective, of poor quality or untidy" but in case of any "inappropriate presentation", either which may give rise to the impression that there is a commercial connection between the reseller and the trade mark proprietor (in the sense of the BMW judgment) or which may damage the reputation of the trade mark (in the sense of the Christian Dior judgment).

34. The Commission would also refer to paragraph 52 of the judgment of the EFTA Court in Paranova v Merck & Co:

> *"In order to establish whether there is a risk of damage to the reputation of the trade mark, the national court will have to take account of whether there is an inappropriate presentation of the repackaged product. In such a case, the trade mark proprietor has a legitimate interest, related to the specific subject matter of the trade mark right, in being able to oppose the marketing of the product. Apart from instances of defective, poor quality or untidy packaging, the national court may also take account of circumstances* ***outside the actual package design*** *such as advertisements published by the Appellant. The Court is not aware of anything that would indicate that affixing coloured stripes along the edges of the product packaging could damage the reputation of the trade mark, and thus that of the Respondents. [Emphasis added]"*

The words emphasised in the passage above illustrate the broad reading to be given to the fourth condition of the BMS criteria, which in the view of the Commission is justified by the case-law of the Court.

35. In conclusion, the Commission would answer that the fourth condition set out in the Bristol-Myers Squibb judgment, 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, extends to anything which damages the reputation of the trade mark as a result of inappropriate presentation, depending on the nature of the product and the market for which it is intended.

Is it damaging to the reputation of a trade mark for the purposes of the fourth condition set out in Bristol-Myers Squibb that:

> in the case of reboxed products the trade mark is not affixed to the exterior carton ("de-branding") or 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"); and,
>
> in the case of overstickered products (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?

36. As a general observation common to all the specific instances raised by the national court, the Commission considers that the point of departure should be an application of the principles discussed in answer to the national court's Questions 1(c) and 2(d). The application of these principles does not lead to the inevitable conclusion that in each of the circumstances raised by the national court there must necessarily be damage to the trade mark or its owner. It seems to the Commission that it is only possible to conclude that each of the circumstances is capable of having such an effect, but that in each case it is up to the national court to carry out the detailed factual appraisal necessary. However, in carrying that appraisal, the national court should take account of the factors discussed below.

37. In the case of "de-branded" products, the Commission recalls that the products and instruction leaflets inside the new boxes still bear the original trade mark (which led the referring court to suggest that the proper term would be "partial debranding"). One cannot therefore treat these cases as not involving a "use in the course of trade" of the relevant trade mark in relation to goods for which the mark is registered, as provided for in Article 5(1)(a) of the Directive. It is also to be observed that where a generic name is used on the outside of the pack and a brand name appears on the inner packaging or on the product itself, it is evident that consumer confusion can only be avoided if the instruction leaflet makes it clear that that the different terms refer to the same product.

38. As for co-branding, this seems to cover any number of situations where there is a parallel use of a distinctive sign of the parallel importer together with the trade mark. As a matter of principle, the Commission does not accept that co-branding must *per se* damage the reputation of the trade mark. Indeed, the BMS criteria

indicate that the identity of the manufacturer and that of the parallel importer should be clearly identified on the packaging. However, it is also the case that no impression should be created that there is a commercial connection or special relationship between the manufacturer and the parallel importer, bearing in mind the nature of the person purchasing or prescribing the product. In each case, it will be necessary for the national court to weigh the different circumstances in order to reach the final decision as to whether the reputation of the trade mark has been damaged. By way of example, it is helpful in this regard to refer to the discussion of the different factors that influenced the consideration of the use by the parallel importer of coloured stripes that was at issue in the judgment of the EFTA Court in Paranova v Merck & Co[25]:

> *"With regard to the suggestion that the Applicant is pursuing the goal of generating a "Paranova product range," the EFTA Surveillance Authority has rightly observed that the mere fact that a parallel importer gains additional advantage from a particular type of graphic design is, in itself, immaterial.*
>
> *The Respondents have observed that products under the same trade mark owned by them may be marketed by various parallel importers with various package designs. They have argued that this would evoke the risk of degeneration of the trade mark. The Court holds that such a risk may, in principle, constitute "legitimate reasons" within the meaning of Article 7(2) of the Directive. It is for the national court to make the necessary factual assessments. In its examination, the national court will have to take into account that the products in question are prescription drugs, and that decisions to use them are made by members of the medical profession on the basis of specialist knowledge and professional responsibility. Only if the coloured stripes constitute the main factor in creating the risk of degeneration, may that risk form a "legitimate reason" to oppose the use of those coloured stripes. This must be distinguished from other causes of degeneration, such as the trade mark owner's own conduct, or developments in the market. Furthermore, the common use of one trade mark by more than one undertaking is an inevitable consequence of the privilege conferred on parallel importers in recognition of their contribution to free trade.*
>
> *If coloured stripes affixed along the edges of the product repackaging could create a risk of confusion as to the identity of the manufacturer, that might in theory cause damage to the reputation of the trade mark. However, the repackager's duty to clearly state the name of the manufacturer as well as its own name is intended to counteract any blurring of the distinction between the manufacturer and the parallel*

---

[25] Paragraphs 54-56.

importer . Therefore, the use of coloured stripes could not alone constitute a "legitimate reason" within the meaning of Article 7(2) of the Directive, as long as the names of the manufacturer and the parallel importer are adequately stated, i.e. whether the names in question are printed in such a way as to be understood by a person with normal eyesight, exercising a normal degree of attentiveness (see, for comparison, Bristol-Myers Squibb, at paragraph 71)"

39. In the case of overstickering, the Commission would again highlight the essential nature of the specific factual circumstances of each case. Take the case of partial overstickering; the extent to which the trade mark is obscured will need to be taken into account by the national court in determining whether the reputation of the trade mark is damaged. Partial overstickering is a broad enough notion that it is capable of covering not merely where a minor or insignificant part of the trade mark is obscured, but also where there is a denaturising of the distinct features of the mark. A precise examination of each case will also be able to consider whether a partially obscured trade mark as a result of the overstickering in itself gives rise to an untidy presentation, depending on the manner in which the overstickering is carried out. As a final observation, the Commission would note that, to the extent that it proves impossible to guarantee (due, for example, to the size and particular lay-out of the original product) that no damage is caused by overstickering to the legitimate interests of the trade mark holder, this may of course have a bearing on the assessment whether reboxing is the necessary form of repackaging as opposed to overstickering.

40. As regards failure to state that the trade mark is the property of the manufacturer, it is not possible to conclude anything from this fact alone. No obligation to state such ownership has been established by the jurisprudence of the Court. The trade mark's ability to serve as an indication of origin does not depend on such additional indications, as it is the trade mark *in itself* which serves as an indication of origin of the products in hand. Moreover, the Court sets out in an exhaustive manner the information to be provided in the 3rd condition of the Bristol-Myers Squibb judgment. It is noted that the Court rejected the suggestion that the parallel importer should also state that the repackaging was carried out without the authorization of the trade mark owner. The above considerations lead to the conclusion that the absence of a statement that the trade mark is the property of the manufacturer cannot

in itself[26] damage the reputation of the trade mark within the meaning of the fourth condition set out in Bristol-Myers Squibb.

41. Finally, as regards the situation where the name of the parallel importer is printed in capital letters it is submitted it is does not appear possible to extrapolate any additional guiding principles from the case-law of the Court and that, accordingly, it is for the national court to assess whether the reputation of the trade mark is damaged contrary to the principles established by the Court and as considered in question 1(c).

42. By way of conclusion, the Commission would propose by way of answer to Questions 1(d) and 2(e) that the precise determination of what constitutes inappropriate presentation for the purpose of the fourth condition of Bristol-Myers Squibb ultimately depends on a detailed factual appraisal carried out by the national court.

Does the importer bear the burden of proving that the new packaging complies with each of the conditions set out in the judgment 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?

43. In answering the question above, the Commission thereby proposes to respond to Questions 1(a) and (e) and 2(b) of the national court.

44. The question of who should bear the burden of proof is a procedural matter and is thus governed in accordance with the principle of procedural autonomy by national law. However, this statement is subject to two conditions being met: that the procedural rules applicable to claims founded on Community law must not be less favourable than those governing similar actions of a domestic nature and that they must not be arranged in such a way that they render the exercise of rights flowing from Community law practically impossible or excessively difficult.

45. Notwithstanding the above, it is clear after the judgment of the Court in Case C-244/00 Van Doren & Co[27] that a national rule of evidence that is consistent with

---

[26] However, when combined with other elements, this may serve to give the impression that there is a commercial connection or a special relationship between the trade mark proprietor and the parallel importer in the sense of the BMW judgment.

[27] Judgment of 8 April 2003.

Community law, and in particular with Articles 5 and 7 of the Directive, should nevertheless be assessed in relation to the requirements enshrined in Articles 28-30 EC. These rules may mean that the rule of evidence "*needs to be qualified*[28]" where that rule would allow the proprietor of the trade mark to partition national markets and thus assist the maintenance of price differences between Member States. Accordingly, "*where a third party against whom proceedings have been brought succeeds in establishing that there is a real risk of partitioning national markets if he himself bears the burden of [proof]*[29]" a national rule of evidence can be qualified.

46. Therefore, as a starting point it is up to national procedural rules to determine who bears the burden of proving that the conditions laid down in the Bristol-Myers Squibb judgment have been satisfied. However, those national procedural rules, where they impose the burden on the parallel importer, may be qualified if the parallel importer is able to establish that the operation of such rules itself leads to a real risk of partitioning national markets.

47. It is not possible to set hard and fast rules as to when national procedural rules would be liable to partition markets, but the Commission would submit that a difficulty could well arise where the procedural rules compelled a parallel importer to adduce evidence with documents to which he does not have access. Likewise, if the national rules compelled the parallel importer to prove something which cannot be proved or only with the utmost difficulty[30]. There would also be a problem "*if national procedural rules or practices on the burden of proof effectively prevent the parallel importer from demonstrating the necessity of repackaging in particular circumstances*[31]".

48. Accordingly, provided that the parallel importer has been able to establish that the operation of national procedural rules leads to a real risk of partitioning national markets, a rule of thumb would suggest that the different conditions laid down in

---

[28] Paragraph 37.

[29] Paragraph 41.

[30] The Advocate General's Opinion in Bristol Myers Squibb, at paragraph 103.

[31] The Advocate General's Opinion in Boehringer Ingelheim I, at paragraph 119.

Bristol-Myers Squibb call for a differentiated approach depending on which party is the more likely to possess the information relevant to assessing each of the individual conditions. For example, concerning the first BMS condition, the holder of the trade mark who markets the trade marked goods in different Member States is likely to be the same company or one of a number of related companies and thus in a better position to assess the market conditions across several Member States than a parallel importer whose activities might be confined to a single Member State. It is the trade mark proprietor that has the relevant information concerning the second condition that the repackaging must not affect the condition of the product inside the packaging[32]. On the other hand, the third BMS condition, requiring that the new packaging indicate the person responsible and the origin of any extra articles not sourced by the trade mark holder would mean that the burden should fall on the parallel importer as the person responsible for repackaging. As for the fourth condition, that the presentation is not liable to damage the trade mark, it is the trade mark holder who is in a position to provide evidence of damage to the trade mark. Finally, the fifth BMS condition requires that the parallel importer gives notice and a product specimen to the trade mark holder, in which case it is the parallel importer that is in a position to furnish the evidence on this question.

49. In conclusion, it is up to national procedural rules to determine who bears the burden of proving that the conditions laid down in the Bristol-Myers Squibb judgment have been satisfied. However, those national procedural rules, where they impose the burden on the parallel importer, may be qualified if the parallel importer is able to establish that the operation of such rules itself leads to a real risk of partitioning national markets. Where that is the case, the different conditions laid down in Bristol-Myers Squibb call for a differentiated approach depending on which party is the more likely to possess the information relevant to assessing each of the individual conditions.

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 v Paranova*, and accordingly has infringed the proprietor's trade mark(s) for that reason only:

---

[32] See also the comments of the Advocate General referred to in footnote 30

(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 has 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?"

50. It seems clear to the Commission that the five BMS conditions are cumulative. There is nothing to suggest that the fifth condition is any less important than the other four. Its role is to enable the trade mark proprietor to ensure that the specific subject matter of his right is protected[33]. This requirement is therefore an instrument for the protection of the specific subject matter of trade mark rights. As has been observed[34], a requirement that the importer give notice to the trade mark owner is simple to apply and simple to observe, thus contributing to the uniform application of Community law. Accordingly, if the fifth BMS condition is not satisfied, the trade mark proprietor is fully entitled to oppose parallel importation of the repackaged goods[35]. The Court has also made it quite clear that:

> *"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[36]."*

51. In view of the above the Commission considers that the answer to the first part of Question 3 is straightforward, namely that the parallel importer cannot rely on the trade mark proprietor becoming aware, by whatever source, of the repackaging in order to avoid its obligation to notify the trade mark proprietor. Accordingly, each

---

[33] See paragraph 78 of Bristol-Myers Squibb.

[34] See the Opinion of the Advocate General in Boehringer Ingelheim I, paragraph 133.

[35] See paragraph 63 of Boehringer Ingelheim I.

[36] Paragraph 64 of Boehringer Ingelheim I.

subsequent act of importation, without notice having been duly given, will continue to infringe the rights of the trade mark holder.

52. The Commission proposes to treat the remaining three parts of Question 3 together. They all relate to the financial remedies available in the event of infringement due to failure to give advance notice in accordance with the fifth condition laid down in Bristol Myers Squibb. As such, in the absence of applicable harmonisation, national rules and modalities for the ordering of damages should apply, provided that the remedies are compatible with Community and international law[37]. In particular, national legal orders must provide individuals with the means necessary to assert the rights they enjoy under Community law; actions for infringement of Community law must not be treated less favourably than similar actions for infringement of national law (the principle of equivalence) and national provisions must not make it impossible in practice to exercise those rights (the principle of effectiveness)[38].

53. Paragraph (c) of the third question raises in particular the Community law requirement of proportionality. Behind such a question may well lie the same considerations that motivated the sixth question in Boehringer Ingelheim I, namely that it would be disproportionate to block parallel trade, or impose financial remedies, against a parallel trader, where even though there was a failure to comply with the notice condition there was no harm to the specific subject matter of the mark. In this regard, the Commission notes that whereas it is correct that Community law requires penalties to be proportionate to the nature of the infringement, the consistent formulation of the Court's judgments in repackaging cases nevertheless highlights the importance attached to each of the five conditions. As stated above, it is impossible to interpret those judgments otherwise than as an authorisation for the trade mark proprietor to oppose marketing where he has not been given advance notice of repackaging. Moreover, in the words of the Advocate General:

---

[37] Neither the EC Treaty nor Directive 89/104 provides for specific rules on damages for trade mark infringements. Article 13 of Directive 2004/48/EC of the European Parliament and of the Council on the enforcement of intellectual property rights (OJ L 157 of 30.4.2004, p45) contains provisions on damages in such cases, but it does not apply to the facts of the present dispute. It will also be necessary to comply with Article 45 of the Trade-Related Aspects of Intellectual Property (TRIPS) Agreement.

[38] See by way of analogy the judgment in Case C-326/96 Levez, [1998] ECR I-07835

"There is in addition the pragmatic argument that liability for infringement is the only realistic sanction for failure by a parallel importer to give advance notice and no purpose would be served by the Court's imposing a requirement without a sanction.[39]*"*

54. In conclusion, compensation for infringement of the notice condition laid down in Bristol Myers Squibb 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.

IV. CONCLUSION

55. In the light of the foregoing observations, the Commission suggests that the questions of the national court should be answered as follows:

"The five conditions in Bristol-Myers Squibb apply to both overstickering and reboxing;

The first condition set out in Bristol-Myers Squibb, namely that it must be shown that it is necessary to repackage the product in order that effective market access is not hindered, applies merely to the fact of reboxing/ overstickering. It does not apply to the precise manner and style of the reboxing/ overstickering carried out by the parallel importer.

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, extends to anything which damages the reputation of the trade mark as a result of inappropriate presentation, depending on the nature of the product and the market for which it is intended.

The precise determination of what constitutes inappropriate presentation ultimately depends on a detailed factual appraisal carried out by the national court.

It is up to national procedural rules to determine who bears the burden of proving that the conditions laid down in Bristol-Myers Squibb have been satisfied. However, those national procedural rules, where they impose the burden on the parallel importer, may be qualified if the parallel importer is able to establish that the operation of such rules itself leads to a real risk of partitioning national markets. Where that is the case, the different conditions laid down in Bristol-Myers Squibb call for a differentiated approach depending

---

[39] See paragraph 136 of the Opinion in Boehringer Ingelheim I.

on which party is the more likely to possess the information relevant to assessing each of the individual conditions.

The parallel importer cannot rely on the trade mark proprietor becoming aware, by whatever source, of the repackaging in order to avoid its obligation to notify the trade mark proprietor. Accordingly, each subsequent act of importation, without notice having been duly given, will continue to infringe the rights of the trade mark holder.

Compensation for infringement of the notice (fifth) condition laid down in Bristol-Myers Squibb 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."

[redacted] [redacted]

Niels Bertil RASMUSSEN Michael SHOTTER

Agents for the Commission