JUDGMENT OF THE COURT
8 July 2003*

(Parallel imports – Article 7(2) of Directive 89/104/EEC – Use of coloured stripes on the parallel importer's repackaging design – Legitimate reasons)

In Case E-3/02,

REQUEST to the Court by *Norges Høyesterett* (the Supreme Court of Norway) for an Advisory Opinion under Article 34 of the Agreement between the EFTA States on the Establishment of a Surveillance Authority and a Court of Justice in the case pending before it between

Paranova AS

and

Merck & Co., Inc. and Others

on the interpretation of Article 7(2) of First Council Directive 89/104/EEC of 21 December 1988 to approximate the laws of the Member States relating to trade marks (OJ 1989 L 40, p 1), as referred to in point 4 of Annex XVII to the EEA Agreement (hereinafter "the Directive"),

THE COURT,

composed of: Carl Baudenbacher, President and Judge-Rapporteur, Per Tresselt and Thorgeir Örlygsson, Judges,

Registrar: Lucien Dedichen,

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* Language of the Request: Norwegian.

having considered the written observations submitted on behalf of:

– Paranova AS, represented by Jonas W. Myhre, Høyesterettsadvokat;

– Merck & Co., Inc. and Others, represented by Aase Gundersen, Advokat;

– the EFTA Surveillance Authority, represented by Elisabethann Wright, Senior Officer, and Dóra Sif Tynes, Officer, Legal and Executive Affairs, acting as Agents;

– the Commission of the European Communities, represented by Niels Bertil Rasmussen, Member of its Legal Service, acting as Agent,

– the Kingdom of Norway, represented by Inger Holten, Adviser, Ministry of Foreign Affairs, and Thomas Nordby, Advokat, Office of the Attorney-General (Civil Affairs), acting as Agents,

having regard to the Report for the Hearing,

having heard oral argument of Paranova AS, represented by Jonas W. Myhre; Merck & Co., Inc. and Others, represented by Aase Gundersen; the EFTA Surveillance Authority, represented by Elisabethann Wright; the Commission of the European Communities, represented by Niels Bertil Rasmussen, and the Kingdom of Norway, represented by Inger Holten at the hearing on 21 May 2003,

gives the following

Judgment

I Facts and procedure

1 By a reference dated 17 December 2002, registered at the Court on 24 December 2002, *Norges Høyesterett* made a request for an Advisory Opinion in the case pending before it between Paranova AS (hereinafter the "Appellant") and Merck & Co., Inc., USA, Merck Sharp & Dohme B.V., the Netherlands, and MSD Norge AS (hereinafter, jointly the "Respondents").

2 The dispute before the national court concerns the parallel import of pharmaceutical products and the question of whether the parallel importer may use its own packaging design with vertical or horizontal coloured stripes or other graphic elements for the repackaging, to which the pharmaceutical producer's trade mark is reaffixed.

3 The Appellant is part of Paranova-Gruppen A/S, which has its main office in Denmark. Paranova-Gruppen A/S has specialised in the parallel importation of

pharmaceutical products to the Scandinavian countries as well as Finland and Austria, via subsidiaries in these countries. The Appellant repackages the pharmaceutical products in new outer packaging or affixes stickers to the original packaging. The actual repackaging takes place in Denmark.

4 The Respondents belong to the Merck group, a worldwide group of companies in the pharmaceutical industry. In these proceedings, the Merck group is represented by: the parent company, Merck & Co., Inc., USA, which is the proprietor of the trade mark that is the subject of this case; the subsidiary, Merck Sharp & Dohme B.V., the Netherlands, the company holding the marketing rights and selling the group's products from the Netherlands to the Norwegian market; and, the Norwegian subsidiary, MSD Norge AS, which conducts the marketing in Norway.

5 The Appellant launched the sale of parallel imported pharmaceutical products in Norway for the first time on 1 May 1995. Since then, the Appellant has gradually expanded its product range. The Appellant sells, in the Norwegian market, original pharmaceutical products purchased in other EEA States, mostly from countries in southern Europe, where prices for pharmaceutical products are lower. In Norway the Appellant sells only to wholesalers, who in turn sell to pharmacies and hospitals. The parallel imported pharmaceutical products are sold in direct competition with the producer's/direct importer's own sales in the Norwegian market. They are, however, only available by prescription.

6 The packaging the Respondents utilised in the country where the Appellant purchases the product is most often different from that utilised in Norway, in respect of appearance and often also of volume. When making purchases abroad, the Appellant and other parallel importers are usually only able to purchase pharmaceutical products in small packages, e.g. with 30 tablets: while in Norway, they are mainly sold in larger packages of around 100 tablets. Therefore, prior to sale in Norway, the Appellant packs the pharmaceutical products in new outer boxes with Norwegian text. The inner packaging, so-called blister packs containing e.g. 7 or 10 tablets per pack, are marked by the parallel importer, but are otherwise not affected by the repackaging. According to *Høyesterett*, it is established that the condition of the goods has not been changed or impaired, and that the pharmaceutical market is partitioned along national boundaries.

7 The outer packaging indicates that the pharmaceutical product is produced by the Respondents and that the Appellant is the re-packager and parallel importer. The Respondents' product trade mark, which is also the product's trade name, is reaffixed by the Appellant to its new packaging.

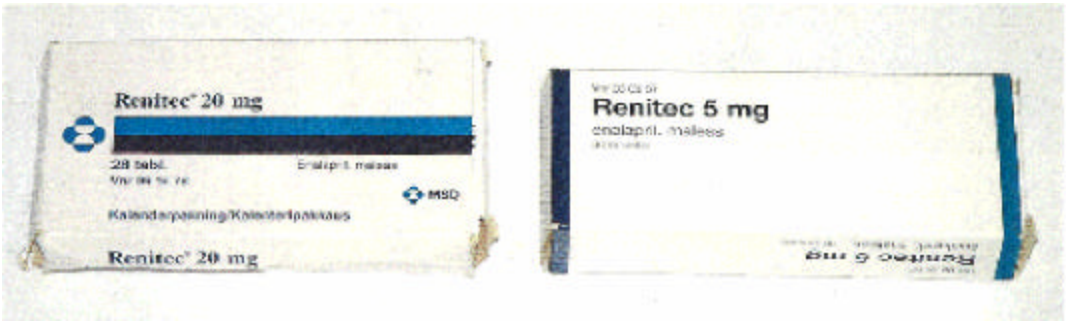
8 When it first started marketing in Norway in 1995, the Appellant also affixed to the repackaged boxes its own trade mark in a particular font as well as its own logo, a multi-coloured pentagon. Moreover, the Appellant affixed vertical or horizontal coloured stripes to the edges of the repackaging. The colour of the stripes varied depending on the producer – the Respondents or others – as the

Appellant employed colours reminiscent of those used by the producer itself in the Scandinavian market. Whether the stripes were vertical or horizontal depended on the shape of the packaging.

9 By a writ of summons dated 15 August 1995, the Respondents brought suit against the Appellant before the Asker and Bærum *herredsrett* (county court), demanding that the Appellant be prohibited from marketing "Renitec" and "Sinemet," which were at that time the only Merck-produced pharmaceutical products that the Appellant sold in Norway. The case was later expanded to include all those Merck-produced pharmaceutical products that the Appellant sold in Norway for which the Respondents have registered the product name as a trade mark. The *herredsrett* rendered judgment on 21 January 1999 in favour of the Respondents.

10 Following the *herredsrett's* judgment, the Appellant changed its packaging by removing its own trade mark and the pentagon logo. The vertical or horizontal stripes along the edges of the packaging remained, but the Appellant changed the colours from dark green and light green to dark green and charcoal grey, so that they became more similar to the Respondents' own colour scheme (dark green and grey). That colour scheme is also protected as a Community Trade Mark, registered at the OHIM under No. 000077701 for Merck & Co., Inc., USA.

11 The following picture, submitted by the Respondents without objection, shows an example of the front side of an original packaging of the Respondents (left) and of a repackaging used by the Appellant subsequent to the *herredsrett's* judgment (right).



12 The Appellant appealed the judgment to Borgarting *lagmannsrett* on 23 March 1999. The Respondents opposed the new packaging in preparatory appellate procedure. At what point in time the Respondents first lodged an objection to the Appellant's use of coloured stripes is disputed.

13 Borgarting *lagmannsrett* rendered judgment on 14 January 2002 in favour of the Respondents. In its reasons, the *lagmannsrett* found that *"by employing its own design – including coloured stripes – on the packaging of products produced by others, in this case Merck, Paranova contributes to blurring the distinction between producer and distributor/importer*." The *lagmannsrett* further found that the Appellant's use of coloured stripes on the new packaging "… *on the whole merely (contributes) to recognition of Paranova itself*." In paragraph 2 of the

operative part of the *lagmannsrett*'s judgment the Appellant *"is prohibited from marketing repackaged products that are labelled with the trade marks "Aldomet," "Blocadren," "Clinoril," "Indocid," "Mevacor," "Renitec," "Sinemet" or "Zocor" when the products' new packaging is labelled with a trade mark and/or logo of Paranova AS and/or other graphic elements that make up a part of the packaging's design and that are affixed by or for Paranova AS. Correspondingly, Paranova AS is prohibited from marketing products that are not repackaged, but on which a label has been affixed to the original packaging."*

14 Even though the Appellant disputed the correctness of the *lagmannsrett*'s prohibition, it chose to comply with the prohibition pending a final decision. It therefore notified both the Respondents and the market that it would shift to white packaging with black writing, the package design which is still used at present.

15 The Appellant notified *Statens Legemiddelverk* (the Norwegian Medicines Control Authority) in order to obtain the mandatory marketing license and approval of the packaging. In a decision of 26 February 2002, the Authority refused to approve the Appellant's use of white packaging with black lettering. The Authority found that extensive use of such packaging could lead to increased confusion and incorrect usage of pharmaceuticals. On administrative appeal, the Ministry of Health agreed with the Authority's reasoning, but found that the relevant national regulation did not authorise the denial of approval on those grounds. On that basis, the Authority then granted a temporary approval of the simplified packaging. The Authority has subsequently proposed to amend the regulation, so as to give the Authority express powers to require the inclusion of graphic elements and colours in the packaging of pharmaceuticals, with a view to reducing the danger of confusion or erroneous use.

16 The Appellant appealed paragraph 2 of the operative part of the *lagmannsrett*'s judgment to *Høyesterett*. *Høyesterett* seeks to clarify whether packaging onto which have been affixed vertical or horizontal coloured stripes along the edges can be prohibited by virtue of the exclusive right of the trade mark proprietor, *i.e.* whether in accordance with Article 7(2) of the Directive the Respondents had "legitimate reasons" for opposing the Appellant's use of coloured stripes. It referred the following questions to the Court:

> 1. *Do "legitimate reasons" exist within the meaning of Article 7(2) of Council Directive 89/104/EEA, cf. Articles 11 and 13 EEA, in a case where the conditions for permitting a parallel importer to undertake repackaging of pharmaceutical products and reaffixing of the trade mark have been met, but where the trade mark proprietor opposes the marketing of the repackaged product with the trade mark reaffixed in a packaging that the parallel importer has equipped with coloured stripes and/or other graphic elements that make up a part of the design of the packaging?*

2. In answering the question, it should be indicated whether the criterion of necessity that the Court of Justice of the European Communities has applied in interpreting "legitimate reasons" within the meaning of Article 7(2) of Council Directive 89/104/EEA applies also to the more specific design of the packaging, or if the more specific design of the packaging is 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.

17 As *Høyesterett* has stressed, the case before it does not concern the parallel importer's repackaging and reaffixing of a trade mark in itself, but rather the question of whether the proprietor of a trade mark, by invoking its trade mark rights, is entitled to prohibit the use of the trade mark on the new packaging on grounds of the characteristics of the packaging's design.

18 The Court notes that the questions referred to it are solely related to the use of the vertical or horizontal stripes. As has been confirmed by both parties to the main proceedings in the oral hearing before the Court, the use of other graphic elements on the package design is no longer of relevance in the proceedings before *Høyesterett.*

19 The Court notes furthermore that similar cases have been brought before national courts of Member States of the European Communities. Judgments by the Supreme Court of Denmark delivered on 4 January 2002 in Case II 51/2000 *Orifarm* v *AstraZeneca*; on 22 April 2002 in Case II 146/2000 *Orifarm* v *Hoechst Marion Roussel*; and, on 19 December 2002 in Case 214/2001 *Handelsselskabet af 5. januar 2002* v *Løvens Kemiske Fabrik*, show that the legal issues facing the Court are being dealt with in the judiciary of other Contracting Parties to the EEA Agreement. Reference is also made to the judgment of the English High Court of Justice of 6 February 2002, [2003] EWHC 110 (Ch).

II Legal background

20 Article 11 of the EEA Agreement reads:

> "Quantitative restrictions on imports and all measures having equivalent effect shall be prohibited between the Contracting Parties."

21 Article 13 of the EEA Agreement reads:

> "The provisions of Articles 11 and 12 shall not preclude prohibitions or restrictions on imports, exports or goods in transit justified on grounds of public morality, public policy or public security; the protection of health and life of humans, animals or plants; the protection of national treasures possessing artistic, historic or archaeological value; or the protection of industrial and commercial property. Such prohibitions or restrictions shall not, however, constitute a means of arbitrary discrimination or a disguised restriction on trade between the Contracting Parties."

22 Article 7 of the Directive reads:

> "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."

23 Pursuant to Article 65(2) of the EEA Agreement and point 4(c) of Annex XVII thereto, Article 7(1) of the Directive was, in the EEA context, replaced by the following:

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

24 Reference is made to the Report for the Hearing for a fuller account of the legal framework, the facts, the procedure and the written observations submitted to the Court, which are mentioned or discussed hereinafter only in so far as is necessary for the reasoning of the Court.

III Observations submitted to the Court

25 The Appellant submits that there are no legitimate reasons for the trade mark proprietor to oppose its use of coloured stripes on the packaging. It questions the suitability of the necessity criterion for the assessment of the packaging design. Pursuant to the necessity concept, as derived from the case law of the Court of Justice of the European Communities, the decisive issue would be whether the packaging design was necessary in order for the parallel importer to gain market access in the Member State of importation. If that criterion were applicable, the Appellant argues, the trade mark proprietor would have unrestricted control over whatever design the parallel importer might choose and could force the latter to remove all elements of design from the packaging. Instead, the assessment should be solely based on the criterion of whether the use of these stripes is liable to damage the reputation of the trade mark. In addition, the Appellant stresses the importance of its packaging design to avoid confusion on the part of the consumer and thus to contribute to the protection of public health. At the oral hearing the Appellant added that the use of colours for identification purposes is a common practice in the trade of pharmaceuticals. Finally, the Appellant submits that the Respondents had lost their right to rely on their trade mark rights due to passivity.

26 The Respondents claim that they are entitled to oppose the use of coloured stripes on the parallel importer's packaging in order to safeguard the essential function of the trade mark and in compliance with the necessity test. By opposing only the marketing of the products in the repackaging in question, they do not deny

market access for the parallel imported products. The Respondents furthermore submit that the Appellant's trade dress leads to association with the original product and deprives them of the goodwill generated by the sale and use of their goods. The uniform style of the packaging design for a whole series of products marketed by the Appellant creates the impression of a "Paranova product range" comprising products from different manufacturers. At the oral hearing, the Respondents stated that the main reason to oppose the use of coloured stripes was to prevent the Appellant from establishing a common packaging design for all the products it imports. Since the Appellant is not the only parallel importer repackaging and marketing the Respondents' products on the Norwegian market, a situation may occur where the same product under the same trade mark owned by the Respondents is marketed in various package designs, which situation has the inherent risk of degeneration of the relevant trade mark.

27 The EFTA Surveillance Authority argues that the necessity test is precluded in the present case. However, there may be "legitimate reasons," such as damage done to the reputation of the trade mark or the creation of an impression that there is a commercial connection between the Appellant and the Respondents within the meaning of Article 7(2) of the Directive. The EFTA Surveillance Authority submits further that there may also be a potential for causing confusion as to which of the undertakings is the manufacturer of the product and for suggesting that there is a special relationship between the two undertakings. In the absence of a risk that the public will be led to believe so, any additional advantage gained by a parallel trader from its graphic design would not, however, be subject to prohibition under Article 7(2) of the Directive and the difficulties faced by the Respondents would not seem sufficient to invoke this provision.

28 The Commission of the European Communities submits that the necessity test applies to the act of repackaging, not to the presentation of the repackaged product. Under the trade mark's function of origin, however, the proprietor may oppose the presentation of the products if the presentation is liable to damage the distinctive character of the trade mark or if the presentation of the repackaged goods is liable to damage the reputation of the trade mark and its owner. In circumstances where it is established that the marketing of the repackaged goods is customary in the reseller's sector of trade, the recognition of "legitimate reasons" depends upon whether the use of the trade mark seriously damages its reputation.

29 The Kingdom of Norway states that graphic elements such as different colours on the packaging minimise the risk of harm to public health, whereas packaging of similar appearance will increase the risk of confusion and of incorrect use of pharmaceuticals. While the use of graphic elements has not been prohibited in Community law by the Court of Justice of the European Communities, the need to safeguard public health must be taken into consideration when interpreting the Directive.

IV Findings of the Court

30 *Høyesterett* essentially asks whether, in a case where it has been established that repackaging of a pharmaceutical product was necessary to allow a parallel importer effective access to the market, "legitimate reasons" within the meaning of Article 7(2) of the Directive exist on the grounds that the parallel importer has equipped the new packaging with coloured stripes, and whether the use of such packaging design should be measured against a "necessity test," along the lines developed in the case law of the Court of Justice of the European Communities to assess the conditions for effective access to the market, or whether the assessment should relate solely to adverse effects on the reputation of the trade mark or of the trade mark proprietor.

Preliminary Remarks

31 Article 7(1) of the Directive is framed in terms corresponding to those used by the Court of Justice of the European Communities in judgments that, in interpreting Articles 28 (ex 30) and 30 (ex 36) EC, have recognized in Community law the principle of exhaustion of the rights conferred by a trade mark. According to that Court's case law, the owner of a trade mark protected by the legislation of a Member State cannot rely on that legislation to prevent the importation or marketing of a product that was put on the market in another Member State by it or with its consent. In other words, the specific subject-matter of trade marks consists in particular in guaranteeing to the proprietor of the trade mark that it has the right to use that mark for the purpose of putting a product into circulation for the first time (see, in particular, Cases 16/74 *Centrafarm* v *Winthrop* [1974] ECR 1183, at paragraphs 7 to 11; C-3/78 *Centrafarm* v *American Home Products* [1978] 1823, at paragraph 11; C-10/89 *CNL-SUCAL* v *HAG GF* ('*HAG II*') [1990] ECR I-3711, at paragraph 12; and C-9/93 *IHT Internationale Heiztechnik* v *Ideal Standard* [1994] ECR I-2789, at paragraphs 33 and 34).

32 The case law cited above is now reflected in Article 7 of the Directive which is worded in general terms and comprehensively regulates the issue of the exhaustion of trade mark rights for products traded in the European Economic Area (see Case E-2/97 *Mag Instrument* v *California Trading Company Norway* [1997] EFTA Ct. Rep. 127, at paragraph 17).

33 The Directive must, however, be interpreted in the light of primary law rules on the free movement of goods (see, for comparison, Court of Justice of the European Communities Case C-427/93 *Bristol-Myers Squibb and Others* v *Paranova* [1996] ECR I-3457, at paragraph 27). It follows that Article 13 EEA and Article 7 of the Directive, which pursue the same result, are to be interpreted in the same way (see, with regard to Article 30 (ex 36) EC, the Court of Justice of the European Communities in *Bristol-Myers Squibb*, at paragraph 40).

34 In codifying the principle of exhaustion, the Community legislature appears to have intended to reconcile the interest in protecting trade mark rights on the one

hand and the interest in the free movement of goods on the other. With regard to the weight to be given to these interests, the Court observes the following: Trade mark rights have to be considered essential elements of the system of undistorted competition, which the EEA Agreement is intended to establish and maintain (see, with regard to Community law, *Hag II*, at paragraph 13). Nevertheless, the free movement of goods, aiming in particular at avoiding artificial partitioning of the markets in the EEA (Case E-1/98 *Astra Norge* [1998] EFTA Ct. Rep. 140, at paragraph 16), forms a fundamental principle of that system, which confers on the parallel importer rights that have been characterized as "a certain license" by the Court of Justice of the European Communities with regard to Community law in Case 102/77 *Hoffmann-La Roche* [1978] ECR 1139, at paragraph 11.

35 As far as the balancing of interests under Article 7(2) of the Directive is concerned, derogations from the principle of free movement of goods are justifiable only to the extent necessary to enable the trade mark proprietor to safeguard rights that form part of the specific subject-matter of the mark, as understood in the light of its essential function (see, to this extent, the Court of Justice of the European Communities in Case C-143/00 *Boehringer Ingelheim and Others* [2002] ECR I-3759, at paragraph 28).

36 The essential function of the trade mark is the function of origin, *i.e.* to guarantee the identity of the origin of the marked product to the consumers or ultimate users by enabling them, without any possibility of confusion, to distinguish that product from products which have another origin and by ensuring that all the goods or services bearing the mark have been manufactured or supplied under the control of a single undertaking that is responsible for their quality.

37 As to the interest in the free movement of goods, regard must be had to the specific market situation. In this context, the Court notes that parallel importers in the pharmaceutical sector are often in a position to offer the goods at a price lower than the one asked by the original producer for the same product (see, to that extent, the Court of Justice of the European Communities in Case 104/75 *De Peijper* [1976] ECR 613, at paragraph 25) and thereby provide less expensive drugs for the benefit of both patients and the national health care systems.

38 The Court recalls that under the procedure provided for by Article 34 of the Agreement between the EFTA States on the Establishment of a Surveillance Authority and a Court of Justice, it has to give the national court guidelines for the interpretation of EEA law that are required for the decision of the matter before it. It is for the national court to examine and evaluate evidence and to make factual findings, and then apply the relevant EEA law to the facts of the case (see, for instance, Case E-8/00 *LO and NKF* v *KS and Others* [2002] EFTA Ct. Rep. 114, at paragraph 48).

The Question

39 In applying these considerations to the present case, the Court notes that it is undisputed between the parties to the main proceedings that the Appellant in

principle is entitled to repackage the Respondents' products and reaffix the latter's trade marks to the repackaging under the conditions established in Community law (see *Hoffmann-La Roche*, at paragraph 14, with regard to Article 30 EC and *Bristol-Myers Squibb*, at paragraph 50, with regard to Article 7(2) of the Directive).

40 That case law is relevant for the Court when interpreting the Directive. The criteria that determine the extent to which the trade mark proprietor may rely on its trade mark rights to prevent the use of its mark by the parallel importer, or whether the parallel importer may rely on its rights flowing from the free movement of products that have been lawfully placed on the market, with respect to repackaging or further marketing, may be summarized as follows:

- whether the upholding of the trade mark rights of the proprietor, having regard to its marketing system, will contribute to the artificial partitioning of the markets between Contracting Parties;

- whether it is shown that the repackaging cannot adversely affect the original condition of the product;

- whether the parallel importer has given prior notice of the marketing of the repackaged product to the trade mark proprietor;

- whether the new packaging clearly states the name of the manufacturer;

- whether the new packaging clearly states the name of the repackager;

- whether the parallel importer has, on demand, supplied the trade mark proprietor with a specimen of the repackaged product; and

- whether, and to what extent, the presentation of the repackaged product is such as to be liable to damage the reputation of the trade mark and of its owner.

41 On the basis of the first criterion, 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.

42 The territoriality of national trade mark rights would, as a matter of principle, lead to an artificial partitioning of the EEA market. Permitting parallel imports and repackaging are means which aim at securing the free movement of goods. Obstacles to be surmounted by the parallel importer through repackaging exist, for example, where pharmaceutical products purchased by the parallel importer cannot be placed on the market in the Member State of importation in their original packaging by reason of national rules or practices relating to packaging, or where health insurance rules make reimbursement of medical expenses dependent on a certain packaging or where well-established medical prescription

practices are based, *inter alia*, on standard sizes recommended by professional groups and health insurance institutions (see, for comparison, *Bristol-Myers Squibb*, at paragraphs 53 and 54; Case C-443/99 *Merck Sharpe & Dohme* [2002] ECR I-3703, at paragraph 26) or in cases of strong resistance from a significant proportion of consumers to relabelled pharmaceutical products (see, for comparison, *Boehringer*, at paragraph 52).

43 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 of the European Communities has in Community law established the necessity test central to the dispute in the main proceedings. That Court held that the power of the owner of the trade mark protected in a Member State to oppose the marketing of repackaged products under that 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 (*Bristol-Myers Squibb*, at paragraph 56; Case C-379/97 *Pharmacia & Upjohn* v *Paranova* [1999] I-6927, at paragraph 19). In other words, where repackaging is necessary to allow the product imported in parallel to be marketed in the importing state, opposition of the trade mark proprietor to the repackaging of the pharmaceutical products is to be regarded as constituting artificial partitioning of the markets (*Merck Sharpe & Dohme*, at paragraph 24).

44 It follows that the necessity requirement 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, as in the present case, 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.

45 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 packaging design, would constitute a disproportionate restriction on the free movement of goods.

46 As the EFTA Surveillance Authority and the Commission of the European Communities have stated, it follows from the judgment of the Court of Justice of the European Communities in the *Dior* case, that together with the exhaustion of the trade mark proprietor's right to prohibit the use of its trade mark, the right to use the trade mark for the purpose of bringing to the public's attention the further

commercialization of those goods is also exhausted (Case C-337/95 *Parfums Christian Dior* v *Evora* [1997] I-6013, at paragraphs 36 and 37).

47 In applying Article 7(2) of the Directive to the presentation of parallel imported pharmaceuticals, the national court cannot limit itself to mechanically applying the necessity test in question, but has to carry out a comprehensive factual investigation leading to a careful balancing of interests.

48 When interpreting the term "legitimate reasons" regard must be had to the need to guarantee the function of origin as the essential function of the trade mark right.

49 This function requires that the original condition of the product inside the packaging must not be affected, and that the reaffixing is not done in such a way that it may damage the reputation of the trade mark or of its owner. It is undisputed that the pharmaceutical products repackaged by the Appellant have not been subject to interference in such a way as to affect their original condition.

50 Moreover, the protection of the trade mark as a guarantee of origin also requires that the repackaging must not be done in such a way that it is liable to damage the reputation of the trade mark, and thus of its owner (see, for comparison, *Bristol-Myers Squibb*, at paragraph 75; and *Dior*, at paragraph 43). Impairment of the reputation of the trade mark, and thus of its owner, may therefore, in principle, constitute "legitimate reasons" within the meaning of Article 7(2).

51 With respect to the circumstances that may be liable to damage the trade mark's reputation, and thus constitute "legitimate reasons," the Court of Justice of the European Communities held in *Bristol-Myers Squibb*, at paragraph 76, that defective, poor quality or untidy packaging might have that effect. Such damage, and consequently "legitimate reasons," may also result from the use of the trade mark in order to bring to the public's attention the further commercialisation of the goods (see *Dior*, at paragraph 48; Case C-63/97 *BMW and BMW Nederland* v *Deenik* [1999] I-905, at paragraph 49).

52 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.

53 A further basis for "legitimate reasons," with reference to damage to the reputation of the trade mark, was established by the Court of Justice of the

European Communities in *BMW and BMW Nederland* v *Deenik*. In that case, it was held in paragraph 51 that where the trade mark is used 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 with the trade mark proprietor's distribution network or that there is a special relationship between the two undertakings, "legitimate reasons," within the meaning of Article 7(2) of the Directive, may exist. In assessing whether the use of coloured stripes would in fact give rise to such an impression, the national court must take into account the level of knowledge and consciousness of doctors and pharmacists, since the products at issue are prescription drugs. Moreover, regard must be had to common practice in the design of packaging for pharmaceutical products. The Appellant has stated that the use of colours in package design is customary in the pharmaceutical trade, and this assertion has not been contested. At first sight, the coloured stripes affixed along the edges of the product packaging would not appear to create a risk of confusion as to whether there is a connection between the parties in question.

54 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.

55 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.

56 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 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).

57 The argument put forward by the Appellant that the Respondents have lost their right to invoke their trade mark right due to passivity has not been commented upon by the latter. It is for the national court to make the necessary findings and to express itself on the relevance of this issue.

58 The answer to the question referred to the Court must be that:

- "Legitimate reasons" within the meaning of Article 7(2) of the Directive to oppose the further commercialisation of repackaged pharmaceutical products may exist where the packaging has been equipped with coloured stripes along the edges if this is liable to damage the reputation of the trade mark. Whether this is the case, is to be answered by the national court on the basis of the relevant facts.

- The question of whether "legitimate reasons" exist if coloured stripes are used in the described presentation of a product cannot mechanically be assessed on the basis of the necessity test as developed by the Court of Justice of the European Communities.

V Costs

59 The costs incurred by the EFTA Surveillance Authority, the Commission of the European Communities and the Kingdom of Norway, which have submitted observations to the Court, are not recoverable. In so far as the parties to the main proceedings are concerned, these proceedings are a step in the proceedings pending before the national court. The decision on costs is therefore a matter for that court.

On those grounds,

THE COURT,

in answer to the question referred to it by *Høyesterett* by a reference of 17 December 2002, hereby gives the following Advisory Opinion:

1 "Legitimate reasons" within the meaning of Article 7(2) of the Directive to oppose the further commercialisation of repackaged pharmaceutical products may exist where the packaging has been equipped with coloured stripes along the edges if this is liable to damage the reputation of the trade mark. Whether this is the case, is to be answered by the national court on the basis of the relevant facts.

2 The question of whether "legitimate reasons" exist if coloured stripes are used in the described presentation of a product cannot mechanically be assessed on the basis of the necessity test as developed by the Court of Justice of the European Communities.

Carl Baudenbacher Per Tresselt Thorgeir Örlygsson

Delivered in open court in Luxembourg on 8 July 2003.

Lucien Dedichen
Registrar

Carl Baudenbacher
President