REPORT FOR THE HEARING
in Case E-3/02

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

Paranova AS

and

Merck & Co Inc. and others

concerning 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,[1] as referred to in Annex XVII, point 4 to the EEA Agreement.

I. Introduction

1. By a reference dated 17 December 2002, registered at the Court on 24 December 2002, the *Høyesterett* made a request for an advisory opinion in a case pending before it between Paranova AS (hereinafter the "Appellant") and Merck & Co Inc. and others (hereinafter the "Respondents").

II. Facts and procedure

2. The case 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 in designing the repackaging, where the pharmaceutical producer's trade mark is reaffixed.

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[1] OJ No L 40, 11.2.1989, p. 1.

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 occurs in Denmark.

4. The Respondents belong to the Merck group, which is a worldwide group of companies in the pharmaceutical industry. In these proceedings, the Merck group is represented by the following companies: 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, which is 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. Parallel import of pharmaceutical products to Norway from other EEA States has been permitted since the EEA Agreement entered into force 1 January 1994. For patented pharmaceutical products, which are generally more expensive, parallel import has been permitted since 1 January 1995. The parallel imported pharmaceutical products are sold in Norway in direct competition with the producer's/direct importer's own sales in the Norwegian market.

6. 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. The parallel imported pharmaceutical products at issue are produced by the Respondents and are identical in medicinal effect to those pharmaceutical products that the Respondents themselves sell in the Norwegian market (direct import), but may vary in form, colour and additives. The Appellant's sales in Norway are only to wholesalers, who in turn sell to pharmacies and hospitals.

7. The packaging the Respondents utilise 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 volume (number of tablets). 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 packaging (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 the *Høyesterett*, it is established that the condition of the goods has not been changed or impaired, and also that the pharmaceutical

market is nationally partitioned, *inter alia*, as a result of the fact that varying package volumes are utilised in the different countries.

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

9. Since it first started marketing in Norway in 1995, the Appellant has affixed vertical or horizontal coloured stripes to the edges of the repackaging. The colour of the stripes varies depending on the producer – the Respondents or others – as the Appellant employs colours reminiscent of those used by the producer itself in the Scandinavian market. Whether the stripes are vertical or horizontal will depend on the shape of the packaging.

10. 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 marketed in Norway. The case was brought on grounds of both patent and trade mark infringement, but the claim of patent infringement was later dropped. However, the case was expanded to include all those Merck-produced pharmaceutical products that the Appellant marketed in Norway on which the Respondents have registered the product name as a trade mark.

11. By agreement between the parties, the main case before Asker and Bærum *herredsrett* was suspended pending a decision by the Court of Justice of the European Communities in the *Bristol-Myers Squibb* case.[2] The judgment in *Bristol-Myers Squibb* was rendered on 11 July 1996. The case before Asker and Bærum *herredsrett* was resumed in the fall of 1997, and the *herredsrett* rendered judgment on 21 January 1999 in favour of the Respondents. In paragraph 1.1 of this judgment, the Appellant "*is prohibited from using the trade marks "Aldomet," "Blocadren," "Clinoril," "Indocid," "Mevacor," "Renitec," "Sinemet" or "Zocor" for products that are imported, offered or put on the market by Paranova AS, when the packaging is also labelled with a trade mark and/or a logo for Paranova AS or a related company, and/or a symbol depicting the Norwegian flag.*"

12. The Appellant appealed the judgment to Borgarting *lagmannsrett* on 23 March 1999. Thereafter, the Appellant changed its packaging by removing the trade mark and the logo. It also has changed the colours of the vertical or horizontal stripes along the edges on its packaging of the Respondents' products, as dark green and light green were replaced by dark green and charcoal grey, so that it became more similar to the Respondents' own colour usage (dark green

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[2] Joined Cases C-427/93 et al. *Bristol-Myers Squibb and others* v *Paranova* [1996] ECR I-3457.

and grey). In preparatory appellate procedure, by a pleading dated 7 February 2000, the Respondents opposed that packaging. The Appellant's use of the coloured stripes on the packaging thus became a separate issue for the *lagmannsrett*, and the application of "graphic elements that make up a part of the packaging's design" was formulated as a separate demand in the Respondents' complaint. At what point in time the Respondents first lodged an objection to the Appellant's use of coloured stripes is disputed.

13. The case before the *lagmannsrett* concerned *inter alia* the conditions for repackaging/re-labelling, as well as the design of various categories of packaging utilised by the Appellant. 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*." The *lagmannsrett*'s assessment and findings of fact on this point are disputed.

14. 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."* Paragraph 2 of the *lagmannsrett*'s judgment, regarding the design of the packaging, thus implies a broadening of paragraph 1.1 of the *herredsrett*'s judgment.

15. Even though the Appellant disputed the correctness of the *lagmannsrett*'s prohibition, it chose to comply with the prohibition pending a legally binding decision. It therefore notified both the Respondents and the market that it would shift to white packaging with black writing. *Statens Legemiddelverk* (the Norwegian Medicines Control Authority, hereinafter "SLV") was also notified by letter dated 12 February 2002; the reason being that all pharmaceutical special preparations must, in order to be legally marketed in Norway, have a marketing license from SLV.[3] In connection with the granting of marketing licenses, SLV also approves the packaging.

16. In a decision of 26 February 2002, SLV refused to accept the Appellant's use of white packaging with black lettering. The grounds were that extensive use

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[3] Cf. § 8(3) of the Pharmaceuticals Act, with appurtenant regulation No. 951 of 22 October 1993, regarding pharmaceutical special preparations.

of such packaging could lead to increased confusion and incorrect usage. That decision was appealed to the superior administrative body, i.e. the Ministry of Health. On 10 September 2002, SLV decided to maintain its decision, and the matter has been forwarded as a complaint to be dealt with by the Ministry of Health.

17. The case before the *Høyesterett* does not concern the parallel importer's repackaging and re-labelling 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. The Respondents' objections to the type of packaging used by the Appellant since 1999 are solely related to the use of the vertical or horizontal stripes. The Respondents allege that this results in a consistent use of uniform design that mainly leads to recognition of the Appellant itself. The Appellant disputes this.

18. The legal question on which the *Høyesterett* must decide is whether packaging onto which have been affixed vertical or horizontal coloured stripes along the edges, or other "*graphic elements that make up a part of the packaging's design and that are affixed by or for Paranova AS,*"[4] can be prohibited on those grounds by virtue of the exclusive right of the trade mark proprietor. The *Høyesterett* thus faces the question of whether the Appellant's use of coloured stripes on the repackaging on which the Respondents' trade mark was also reaffixed was an infringement of the Respondents' trade mark, *i.e.* that in accordance with Article 7(2) of the Trade Marks Directive (hereinafter "the Directive"),[5] the Respondents had "legitimate reasons" for opposing the Appellant's use of coloured stripes. According to the *Høyesterett*, central to the dispute between the parties is the question of whether the criterion of necessity, which has been developed through the case law of the Court of Justice of the European Communities in interpreting Article 7(2) of the Directive, only applies to the issue of the parallel importer's repackaging and reaffixing of the trade mark, or whether it also applies to the issue of the trade mark proprietor's objections to the design of the parallel importer's packaging.

III. Questions

19. The following questions were referred to the EFTA 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**

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4 cf. paragraph 2 of the operative part of the *lagmannsrett*'s judgment

5 OJ No L 40, 11.2.1989, p.1.

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.

IV. Legal background

20. § 4 of the Norwegian Trade Marks Act reads as follows:

"The right to a sign in accordance with sections 1 to 3 has the effect that no one other than the holder may in the course of trade use the same sign for his goods, cf. the third period. This applies whether the sign is used on the goods or their packaging, in advertising, in business documents or in any other way, including the use thereof in the spoken word, and regardless of whether the goods are intended to be sold or offered in any other way in this country or abroad, or imported into this country. In the context of the present Act, "the same sign" shall be understood to mean a sign that is so similar to another sign, that it is liable to be confused with this sign in the ordinary course of trade, cf. section 6.

It shall also be regarded as unlawful use if anyone in selling or offering spare parts, accessories, or the like, refers to a sign which is the property of someone else in such a way as to give the wrongful impression that the goods offered originate from the holder of that sign or that he has consented to the use of that sign.

Where a sign as referred to in sections 1 to 3 has been in legitimate use for a product and the product afterwards has been substantially altered by processing, repairs, or the like by someone other than the holder of the sign, the sign must not, without the consent of the holder, be kept or used for the product if the product is subsequently imported, sold or offered in the course of trade, unless the alteration is clearly indicated or is otherwise apparent from the circumstances."

21. According to the *Høyesterett*, that provision must, in light of EEA law, be interpreted in a manner so as to limit the scope of its language. In connection with parallel import, the trade mark proprietor's exclusive right to control the trade mark must be construed as implying an exception thereto. The salient point

is how far this exception reaches, i.e. to what extent an exception must be implied in § 4 of the Trade Marks Act in light of what must be deemed to be "legitimate reasons" within the meaning of Article 7(2) of the Directive.

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."*
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> Pursuant to Article 65(2) of the EEA Agreement and Annex XVII, point 4(c) 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."

23. Article 11 of the EEA Agreement reads:

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

24. 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."*

V. Written Observations

25. Pursuant to Article 20 of the Statute of the EFTA Court and Article 97 of the Rules of Procedure, written observations have been received from:

- the Appellant, represented by Jonas W. Myhre, Supreme Court Advocate, Wikborg Rein & Co., Oslo

- the Respondents, represented by Aase Gundersen, Advocate, Bugge, Arentz-Hansen & Rasmussen, Oslo

- the EFTA Surveillance Authority, represented by Elisabethann Wright, Senior Legal Officer, and Dóra Sif Tynes, Legal Officer, 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, Legal Advisor, Ministry of Foreign Affairs, and Thomas Nordby, Advocate, Office of the Attorney General (Civil Affairs), acting as Agents.

Paranova AS

26. With regard to the interpretation of Article 7(2) of the Directive and the term "legitimate reasons," the Appellant suggests that the Court first determine the applicability of the criteria proposed by the *Høyesterett* and whether additional criteria should be taken into account. The proposed criteria are both based on the case law of the Court of Justice of the European Communities starting with *Bristol-Myers Squibb*. The first is the criterion of necessity ("*necessary in order to market the product in the Member State of importation*"), used as a test to determine whether there exists artificial market partitioning. The second criterion is that the repackaging/reaffixing must not be considered an *"inappropriate presentation of the repackaged product," i.e.* that it must not be "*liable to damage the reputation of the trade mark"* (the "reputation" criterion).

27. The Appellant questions the suitability of the necessity criterion, arguing that it only applies to the assessment of the legality of repackaging/re-labelling of pharmaceuticals and reaffixing of the trade mark on the new packaging, and does not apply to the assessment of coloured stripes and/or other graphic elements used on the new packaging. Instead, the Appellant is of the opinion that the assessment of graphic elements used on the new packaging should be solely based on the reputation criterion. When judging the parallel importer's behaviour, the fact that repackaging is considered a *per se* infringement of the essential function of trade mark right is of no significance when it comes to the use of graphic elements, which in itself does not constitute an infringement.

28. As for the irrelevance of the necessity criterion to the present case, the Appellant refers to the Court of Justice of the European Communities, which makes a distinction between the applicability of the necessity criterion and other criteria, i.e. the legitimate interests. The necessity criterion cannot be understood as obliterating all other criteria. The criteria of "necessity" and "reputation" are equal and cumulative and they apply to different elements in the parallel import process leading up to marketing of the repackaged product. The particularities of marketing of pharmaceuticals must be taken into account when assessing the case at hand.

29. According to the Appellant, it must further be taken into account that the application of the necessity criterion would result in a situation where the direct importer/producer has unrestricted control over whatever design the parallel importer might choose for the new packaging. No matter how "neutral" the packaging may be, the trade mark proprietor can always claim that the design is not "objectively necessary" and consequently that it represents an infringement of its trade mark rights. The content of the trade mark rights would be construed in a way that in effect gives the trade mark owner the possibility of hindering all marketing of parallel imported pharmaceuticals. Market access, initially being granted through the demonstration of objective necessity with regard to repackaging and reaffixing of the trade name, would be denied or seriously impaired in the second round because of the assumed right of the producer/direct importer to use its trade mark rights to defeat any design which the parallel importer might employ on the packaging. The application of the necessity test on the designing of the packaging tips the balance grossly in favour of the trade mark proprietor and does not accord with the principle of proportionality. The Respondents' main reservation, that any design used in a systematic, consistent or uniform manner is illegal, would not only have serious practical consequences for the Appellant's production process, but would also amount to inconsistency and lead to confusion. The Appellant therefore seeks clarification from the Court in order to avoid parallel importers being left with uncertainty as to the design of their new packaging.

30. In addition, the Appellant stresses the relevance of interests other than commercial for the assessment of "legitimate reasons" and the overall assessment of whether the free movement of goods may be prevented. It is argued that the interest of public health is more important than the trade mark owner's right to protect its commercial interest. The main purpose of the Appellant's use of coloured stripes is to avoid confusion and misuse on the part of the end user, *i.e.* the consumer/patient using the medicine. This is achieved by varying the colour of the stripes on the pharmaceutical packaging in accordance with the colour of the packaging of the producers.

31. In this regard, the Appellant maintains it is in compliance with the rules laid down in Directive 2001/83/EC on the Community code relating to medicinal products for human use. These rules set out a balancing of the trade mark owner's interests with the interests of free movement and the public's interests in protecting health. Protecting public health by avoiding confusion/misuse of pharmaceuticals is also enshrined in Article 13 EEA and must constitute the overriding element in assessing "legitimate reasons." It was wrongly considered to be of no relevance in the judgment of Borgarting *lagmannsrett* in the present matter and in the Danish Supreme Court's two judgments of 4 January 2002[6] and

[6] In Case II 51/2000 *Orifarm* v *AstraZeneca.*

22 April 2002,[7] where the use of colours/graphic elements on the pharmaceutical packaging was considered a trade mark infringement.

32. With regard to the Norwegian Medicines Control Authority's ("SLV's") decision of 26 February 2002, the Applicant points to the decision of 22 October 2002 of the Ministry of Health.[8] According to the Appellant, the Ministry would have preferred the use of colours and/or other graphic elements to distinguish pharmaceutical packaging as a requirement for granting marketing authorisation. However, the Ministry clearly expressed the need for an explicit national rule formally allowing the SLV in Norway to require such elements as a condition for granting marketing authorisation. The SLV proposed amendments to the existing regulation on the marking of pharmaceutical products on 19 March 2003.[9] A similar rule entered into force in Denmark on 18 January 2003.[10] Similar developments can be observed in Sweden and in the UK.[11] In the view of the Appellant, these developments demonstrate the importance of public health interests. The Appellant assumes that the authorities require it to use coloured stripes and/or other graphic elements. Given the judgments of the national courts, parallel importers are left unable to comply with both the regulatory demand for clear differences between a parallel importer's packaging, and the trade mark owner's demand for white packaging with black writing.

33. The Appellant finds support for the opinion that the use of coloured stripes on its packaging has a legitimate function in the opinions of Advocate General *Jacobs* in *Bristol-Myers Squibb,*[12] *Boehringer*[13] and *Merck.*[14] In those cases the

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7 In Case II 146/2000 *Orifarm* v *Hoechst Marion Roussel.*

8 In this decision, the Ministry of Health expressed the opinion that "*weighty arguments are against an allowance of use of white packaging with black writing, and that there is no hindrance in EEA law for such a result.*"

9 The proposed change of 4-21 reads as follows: "*The packaging of pharmaceutical products is to be made in such a manner that the danger of confusion or erroneous use is reduced. The final packaging is to be authorised by the Statens Legemiddelverk. Statens legemiddelverk may demand that the packaging of pharmaceuticals is to be "equipped" with graphic elements including the use of colours*".

10 It reads: "*Marking and package leaflet must not be misleading and must not be qualified to cause confusion with other pharmaceuticals, forms of pharmaceuticals or strengths. In order to clarify the distinctions between different pharmaceutical packaging, different sizes of writing, colours, different designing of packaging or similar is to be used"*.

11 The Applicant refers to a Memo of 13 June 2002 by the Swedish Health Authority (Läkemedelsverket) concerning use of colours on packaging and the UK Medicines Control Agency's "Best practice guidance on the labelling and packaging of medicines" as implemented on 1 March 2003. In the introduction in section 1 of the Best Practice Guidance it is stated: "*Problems with labelling have also been associated with a high percentage of errors (3). Within the current regulatory framework there is the potential for improving the layout of medicines labelling to aid clarity. This would assist health professionals and patients/carers to select the correct medicine and use it safely, thereby helping to minimise medication errors."* It follows from section 4.4 of the Best Practice Guidance that: "*Innovative pack design that may incorporate the judicious use of colour is to be encouraged to ensure accurate identification of the medicine."*

12 At paragraph 109.

Advocate General expressed the view that there was nothing illegal with Paranova's use of coloured stripes. He believed that with regard to the product's origin, the coloured stripes were not confusing for the consumers. On the contrary, he wrote that the use of coloured stripes made it possible to identify the products. The Appellant also refers to the Court's judgment in *Astra Norge*,[15] where it ruled with reference to the medicinal rules now codified in the Medicinal Directive, that public health interests must prevail over attainment of industrial property rights if there is a conflict between the two.

34. Instead of applying the necessity criterion, the Appellant invites the Court to deem the reputation criterion, to which the requirements to clearly mark who had performed the repackaging and the name of the producer are closely related, alone applicable to an assessment of "legitimate reasons." It is submitted that the Court of Justice of the European Communities in stipulating these conditions in *Bristol-Myers Squibb*, stated the extent to which the goodwill and reputation of the trade mark and the trade mark proprietor was to be recognised. If the Court of Justice of the European Communities were of the opinion that the criterion of necessity applied to the design of new packaging, then there would be no reason to add the reputation criterion. Furthermore, the reputation criterion, contrary to the necessity criterion, opens up for attainment of interests other than the commercial interest of the trade mark owner, in particular public health interests. The use of the coloured stripes and/or other graphic elements cannot be considered an inappropriate presentation damaging the reputation of the Respondents' trade mark.

35. If the Court does not deem the reputation criterion applicable as the sole criterion in the assessment of "legitimate reasons," the Appellant argues that it is necessary for the Court to decide upon the applicability of supplemental criteria. If the first question were answered in the negative, the *Høyesterett* would not be given guidance on whether or not the two criteria mentioned are exhaustive in the assessment of "legitimate reasons."

36. In this regard, the Appellant suggests that the characteristics of the coloured stripes and/or other graphic elements used in the design of the packaging are relevant elements, to the extent that their use is perceived as having identifiable features that have distinctive character and which are used for the sole purpose of promoting the parallel importer. However, by establishing the condition that the packaging clearly identify the repackager/importer and producer, the Court of Justice of the European Communities has indirectly set out what is sufficient information in order to secure the protection of origin.

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13 Case C-143/00 *Boehringer Ingelheim and others* [2002] ECR, I-3759.

14 Case C-443/99 *Merck Sharpe & Dome* [2002] ECR, I-3703.

15 Case E-1/98 *Astra Norge* [1998] Ct. Rep., 140, at paragraphs 17 to 20.

37. Another important element will be whether the parallel importer has acted in accordance with accepted trade practice in the relevant product market - in the present case the sale of pharmaceutical products. It has not been alleged by the Respondents that the packaging design applied by the Appellant is not in accordance with accepted practice for repackaging of pharmaceutical products. On the contrary, the Appellant complies with the condition that the repackaging should not interfere with the original product, *i.e.* the individual tablet or capsule, not including the packaging. Furthermore, there is a clear indication on the new packaging of who performed the repackaging of the product and the name of the producer. Also, the packaging of the repackaged product cannot be considered "inappropriate," and the Appellant has complied with the requirement to clearly mark that the Respondents are the producers of the pharmaceutical products in question and that the Appellant has repackaged and imported the products to Norway. The origin of the products is thus duly brought to the knowledge of prescribing doctors, pharmacies delivering the product, and end users, *i.e.* customers/patients. The fact that the pharmaceutical products originate from the Respondents is further strengthened by the use of coloured stripes with colours similar to the colours used by the Respondents on the Norwegian market.

38. In order to support its approach towards the criteria to be applied in interpreting the "legitimate reasons," the Appellant makes particular reference to the judgments of the Court of Justice of the European Communities in *Dior*[16] and *BMW*.[17] According to the former, the trade mark proprietor cannot use its trade mark rights to decide the manner and in what context the trade mark is to be used. Unlike in *Dior*, there is no question of the parallel importer's marketing being susceptible to seriously affecting or damaging the reputation of the Respondents' trade marks in the case at hand. Using coloured stripes for the identification of the product constitutes the only legal means by which the parallel importer can communicate to the customer its own function and that of the producer. This necessary use of the trade mark for the Appellant's further commercialisation cannot be used as grounds for denying the right to use graphic elements even if it were for promoting the Appellant. In the present case the use of coloured stripes corresponding to the colours used by the Respondents on the Norwegian market helps to identify the product as a Merck product and to emphasise the lack of commercial connection between the Appellant as the reseller and the Respondents as the trade mark proprietors. It must be considered within accepted trade practise and in accordance with the proportionality test.

39. Meant as a general supplemental criterion for the Court's assessment, the Appellant submits that the Respondents presently do not have the right to invoke their trade mark right due to passive behaviour. The fact that the Respondents did not oppose or take any action to inform the Appellant of their view or to stop its

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16 Case C-337/95 *Parfums Christian Dior* v *Evora* [1997] ECR, I-6013, in particular at paragraph 54.

17 Case C-63/97 *BMW and BMW Nederland* v *Deenik* [1999] ECR, I-905, in particular at paragraph 53.

use in good faith of coloured stripes until 7 February 2000, must be a central element in the assessment of whether the Respondents may exercise their trade mark rights today.[18] There is an obligation on the part of the trade mark proprietor to take into consideration the legitimate interest of the parallel importer to market the products as soon as the marketing authorisation has been obtained. Consequently, the trade mark proprietor must act within reasonable time if it wants to protest against the marketing by the parallel importer. Passive behaviour on the part of the trade mark proprietor should, under the circumstances, be considered in itself as lack of "legitimate reason" for the trade mark proprietor to invoke its trade mark rights. If the trade mark proprietor waits until the parallel importer has performed the repackaging of a considerable stock and put the repackaged products on the market before protesting, this could result in great economic losses for the parallel importer. As to the "reasonable time," a time-limit of not more than six months is suggested.

40. The Appellant suggests to answer the questions as follows:

> *"The trade mark proprietor does not have "legitimate reasons" according to the Trade Marks Directive Article 7(2) to oppose a parallel importer's marketing of a repackaged product in a packaging, where the conditions for the repackaging with the trade mark reaffixed have been met, and which is equipped with coloured stripes and/or other graphic elements that make part of the design of the packaging, provided such use of coloured stripes and/or other graphic elements does not adversely affect the reputation of the trade mark or the trade mark proprietor."*

41. Alternatively, i.e. based on supplementary criteria, the Appellant suggests to answer the questions as follows:

> *The trade mark proprietor does not have "legitimate reasons" according to the Trade Marks Directive Article 7(2) to oppose a parallel importer's marketing of a repackaged product in a packaging, where the conditions for the repackaging with the trade mark reaffixed have been met, and which is equipped with coloured stripes and/or other graphic elements that make part of the design of the packaging, provided either:*
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> *- that the coloured stripes and/or other graphic elements do not have some identifiable features with distinctive characteristics, which serve the purpose to promote the parallel importer, or*
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> *- that, in case the coloured stripes and/or other graphic elements do have some identifiable features with distinctive characteristics, which*

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[18] With regard to the determination of what constitutes "reasonable time", the Appellant refers to the judgment of the Court of Justice of the European Communities in *Boehringer*, at paragraph 66 and 67.

serve the purpose to promote the parallel importer, such use of the coloured stripes and/or other graphic elements are:

- *either in accordance with accepted trade practice for the marketing of pharmaceutical products*

- *and/or in accordance with recognised public health interests."*

42. As a separate alternative of general application, the Appellant suggests the following answer:

"Without regard to the above answers, the trade mark proprietor does not have "legitimate reasons" according to the Trade Marks Directive Article 7(2) to oppose a parallel importer's marketing of a repackaged product, provided the trade mark proprietor has not reacted against the repackaging of the pharmaceutical product, the reaffixing of the trade mark or the designing of the packaging within reasonable time after the parallel importer has put the repackaged pharmaceutical product on the market."

The Respondents

43. The Respondents argue that the answer to the first question referred to the Court follows unequivocally from the case law of the Court of Justice of the European Communities in repackaging cases, and is most recently confirmed in *Boehringer*.[19] Further reference is made to the judgments in *Hoffmann La Roche*,[20] *Bristol-Myers Squibb*, *Upjohn*[21] and *Ballantine*[22] as well as to the judgments of the national supreme courts of Denmark and the United Kingdom.[23]

44. Taking into account the guarantee of origin as the essential function of the trade mark,[24] the trade mark proprietor may always, subject only to the second sentence of Article 30 EC, assert its trade mark rights to prevent the use of its trade mark by the parallel importer after the repackaging of the product. In terms of the Directive, this means that there exist "legitimate reasons." When the proprietor chooses to exercise its trade mark rights to oppose the further marketing of the product in a particular package because of the appearance of

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19 In particular at paragraphs 30-35.

20 Case 102/77 *Hoffman-La Roche* [1978] ECR, 1139.

21 Case C-379/97 *Pharmacia & Upjohn* v Paranova [1999] ECR, I-6927.

22 Case C-349/95 *Loendersloot* v *Ballantine* [1997] ECR, I-6227, in particular at paragraph 46.

23 Cf. the Danish Supreme Court's rulings of 4 January 2002 and 22 April 2002, cited above, and of 19 December 2002, Case 214/2001 *Handelsselskabet af 5. januar 2002* v *Løvens Kemiske Fabrik*; High Court of Justice, Chancery Division, [2003] EWHC 110 (Ch), of 6 February 2002, at paragraphs 19 and 20.

24 As defined in Case C-10/89 *Hag GF* [1990] ECR, I-3711, at paragraph 13.

that package, then it is this action that must be scrutinised to see if it amounts to a restriction of trade. The trade mark owner may not pursue objections that will lead to a denial of market access for the parallel imported product, but is free, for the purpose of safe-guarding the essential function of the trade mark, to pursue objections that do not restrict the effective access to the market. The tool for determining in what situations the objections of the trade mark proprietor, to further commercialisation of the goods under its trade mark, amounts to a disguised restriction of trade, is the necessity test.[25] At the heart of the necessity test lies the question of whether a repackaging that implies a less intrusive use of the proprietor's trade marks is possible and sufficient to enable access to the market for the product in question, *i.e.* the proportionality principle. The significance of the necessity test as a result of a careful balancing of the conflicting considerations of free movement of goods and protection of trade mark rights is expressed by Advocate General *Jacobs* in his opinion in *Boehringer*.[26]

45. The Respondents accept that the exclusive trade mark may not be relied on to oppose such alterations to the product packaging that are necessary to make parallel trade feasible. Therefore, they have not objected to the re-boxing as such where this is objectively necessary to obtain a package size that has access to the market. However, they do oppose the marketing of their products under their trade marks in the Appellant's packaging by reference to the design used on the new packaging.

46. The Respondents further note that the Court of Justice of the European Communities does not distinguish between the different forms of repackaging when it comes to the application of Article 7(2) of the Directive. Re-boxing, *i.e.* repackaging in a new external packaging and re-labelling, *i.e.* sticking labels onto the original packaging are thus treated as equal. Both forms entail the use of the proprietor's trade mark. Beyond the mere use of the trade mark on the altered packaging there are various ways in which this repackaging may interfere with the proprietor's trade mark rights. The Respondents draw further distinctions between *re-branding*, *i.e.* replacing the original trade mark of the product and affixing on the new packaging (whether in the form of a new box or one or more labels) another trade mark of the proprietor, enabling trading under the same trade mark as used by the proprietor in the import state;[27] *de-branding*, *i.e.* the marketing of the product in new packaging without reference to the trade mark of the proprietor;[28] *co-branding*, *i.e.* the use of the trade mark on packaging that is also branded by the parallel importer by the use of its own trade mark and/or its house style get-up (or trade dress).[29] The repackaging by the Appellant in its

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25 As established in *Bristol-Myers Squibb*, at paragraph 56.

26 In particular at paragraphs 111 and 113.

27 As was the case in *Upjohn*.

28 As was one of the objections in *Boehringer*.

29 An underlying issue in *Boehringer*.

uniform style of trade dress amounts to a co-branding between the Respondents' trade marks and the Appellant's trade dress. In all these situations, the issue the national court needs to determine is whether the reliance on trade mark rights to oppose the changes brought about by the repackaging in issue amounts to a denial of access to the relevant market.[30] The necessary test is thus applicable.

47. Certain features of the packaging's trade dress are obviously necessary, such as any writing of information that is required by law and the regulatory authorities. If a packaging design is not capable of obtaining approval without additional features, then any such features will also be deemed necessary. However, in the present case, it is clear that the Appellant will have access to the market by the use of a neutral packaging without any graphic design elements in the form of colour, stripes or otherwise. Thus, it is not necessary for the Appellant to market the Respondents' products in packaging featuring the Appellant's own trade dress.

48. Even if the Court should disagree and conclude that the objections to the package design are not to be determined on the basis of the necessity requirement, the same result will follow from the general principles set out in the jurisprudence of the Court of Justice of the European Communities. Co-branding constitutes an interference with the essential function of the trade mark, the guarantee of origin.[31] That the goodwill generated by the marketing and use of the goods should be associated with the proprietor's trade mark and with any other indicia distinctive of the proprietor, e.g. the trade dress of the packaging, is one of the key benefits of a trade mark. This association occurs because of the way in which products and the trade marks are presented to the public. The various marks on the pack are presented in a manner which the proprietor thinks will be of most benefit to the proprietor. That includes the use of a particular get-up for the packaging. If another trader, such as an importer, is allowed to have its trade dress design put on the packs of the proprietor's goods together with the trade marks, the trade marks and the goods become associated with that trader. The parallel importer is then in a position to exploit the public's appreciation of the goods to generate goodwill in its trade dress and use that goodwill to its own commercial advantage. The valuable goodwill of the product is therefore re-directed to the importer.

49. The impact of this on the trade mark proprietor is particularly clear where the importer packages a range of goods from different manufacturers into packaging having a common design style. The Appellant's use of its own trade dress across the range of pharmaceutical products it repackages, creates the impression of a "Paranova product range" that comprises all these products. Products from different manufacturers will appear to be from a common source, or to have some other connection. Such co-branding serves only the purpose to

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30 *Upjohn*, at paragraph 43; *Boehringer*, at paragraphs 34 and 35.

31 Advocate General *Jacobs*' Opinion in *Boehringer*, at paragraph 95.

secure a commercial advantage for the Appellant who in fact uses the parallel colour stripes as a branding device in advertisements together with its registered trade mark. If a trade mark proprietor has to accept the use of its trade mark by different importers in a variety of packaging there is a real risk of the trade mark turning generic. As to the Appellant's submission that only package design meeting certain qualifications (that "there must exist some identifiable feature that has the distinctive characteristic of a trade mark, or at least can be perceived as an individual design") can be opposed by the trade mark owner, the Respondents maintain that virtually any graphic element has the inherent ability of becoming distinctive through use. Therefore, even if a particular package design is not regarded as meeting these criteria at the outset, this may change over time. By then, the harm will have been caused to the trade marks used with this package design as a result of the co-branding.

50. The Respondents suggest to answer the questions as follows:

> *"(1) Article 7(2) of the Directive should be interpreted as meaning that a trade mark proprietor may rely on his trade mark rights in order to prevent a parallel importer from marketing repackaged pharmaceutical products under the trade mark in a particular package design, unless the exercise of those rights contributes to artificial partitioning of the market within the European Economic Area.*
>
> *(2) The trade mark proprietor's objection to the use of his trade mark on the grounds of the design of the packaging used by the parallel importer contributes to artificial partitioning of the market, if such package design is objectively necessary to secure the parallel imported product effective access to the market concerned.*
>
> *It will not be objectively necessary to utilise a particular package design if the use of another package design, which is less intrusive to the specific subject matter of the trade mark rights, will ensure the parallel imported product effective access to the market concerned."*

The EFTA Surveillance Authority

51. According to the EFTA Surveillance Authority, the question of whether or not the Respondents can oppose the use of their trade mark on their goods that have been repackaged by the Appellant with various graphic elements does not belong to the discussion of repackaging and reaffixing of a trade mark by a parallel trader as a matter of "necessity." The determination of what is necessary repackaging goes to the restriction on the free movement of goods and difficulties faced by parallel traders in placing a product on the market in the importing EEA State. It is acknowledged that in the present case repackaging was necessary in order for the Appellant to market the products in Norway. This precludes the necessity argument. If one were to apply the necessity test to the

design of the packaging of parallel traded products, the question must arise of how one could establish the criteria by which to determine the "necessity" of variable elements such as colour or typeface. In support, the EFTA Surveillance Authority refers to the case law of the Court of Justice of the European Communities that suggests that a distinction is to be made between the repackaging of a product and its subsequent presentation to the consumer.[32]

52. In the opinion of the EFTA Surveillance Authority, the matter should be addressed in the context of the extent to which the Appellant is entitled pursuant to Article 7(2) of the Directive, to create its own trade dress on the packaging of another undertaking's trade marked products. With regard to *Boehringer,*[33] this means that the trade mark proprietor must demonstrate that the use of its trade mark on packaging that includes the Appellant's graphic design would constitute "legitimate reasons" for safeguarding the rights in the Respondents' trade mark even if the free movement of goods is thereby compromised.

53. Damage done to the reputation of a trade mark may, in principle, be a "legitimate reason." However, the proprietor of a trade mark may not rely on Article 7(2) to oppose the use of the trade mark, in ways customary in the reseller's sector of trade, for the purpose of bringing to the public's attention the further commercialisation of the trade-marked goods, unless it is established that such use seriously damages the reputation of the trade mark.[34] The EFTA Surveillance Authority submits that it is common practice in the pharmaceutical sector that both the trade mark of the original manufacturer and that of the parallel trader appear on repackaged products. Moreover, it is not unknown for a parallel trader to add, for example, a distinctive colour to the packaging.

54. 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 with the trade mark proprietor's distribution network or that there is a special relationship between the two undertakings, may constitute a legitimate reason for the trade mark holder to rely on the provisions of Article 7(2) of the Directive.[35] The same may be argued with respect to the use by a parallel trader of the original trade mark on repacking that is designed in such a manner that it gives rise to the impression that there is a commercial connection between the reseller and the trade mark proprietor. The extent to which a parallel trader may legitimately use selected distinctive colours in a particular manner may fall to be considered under this aspect.

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32 Cf. *Ballantine*, at paragraph 33, *Bristol-Myers Squibb*, and *Boehringer*, at paragraph 75.

33 At paragraph 28.

34 *BMW*, at paragraph 49.

35 *BMW*, at paragraph 51.

55. If, on the other hand, there is no risk that the public will be led to believe that there is a commercial connection between the reseller and the trade mark proprietor, the mere fact that the reseller derives an advantage from using the trade mark in advertisements for the sale of goods protected by the mark, which are in other respects honest and fair and lend an aura of quality to its own business, does not constitute a legitimate reason within the meaning of Article 7(2) of the Directive.[36] It might be argued that, given the nature of the products at issue, in marketing of the kind occurring in the present case, there is no risk that the public will be led to believe that there is a commercial connection between the reseller and the trade mark proprietor. If such were the case, any additional advantage gained by a parallel trader from a particular type of graphic design would not be subject to prohibition due to the provisions of Article 7(2) of the Directive. Potential arguments to be made concerning unfair trade practices have not been introduced by the referring court.

56. The situation which arises in the present case, in which a parallel trader is effectively permitted to create its own trade dress on medicinal products manufactured by another undertaking, has arguably some potential for causing confusion as to which of the undertakings is the manufacturer of the product. There also exists the potential for suggesting that there is a special relationship between the two undertakings closer than is, in fact, the case. Nevertheless, in the environment of parallel trade in pharmaceutical products, and given the implication for the free movement of goods in circumstances such as those in the present case, the EFTA Surveillance Authority submits that the difficulties faced by the Respondents do not seem sufficient to permit it to rely on the provisions of Article 7(2) of the Directive.

57. The EFTA Surveillance Authority suggests to answer the questions as follows:

> *"In a case, such as that current pending before the referring court, the circumstances for reliance by a trade mark proprietor on the provisions of Article 7(2) of the First Council Directive of 21 December 1988 to approximate the laws of the Member States relating to trade marks cannot be held to have been fulfilled 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 package that the parallel importer has equipped with graphic elements that make up a part of the design of the packaging unless it can be demonstrated by the trade mark proprietor that its trade mark needs to be protected against the damage that such use by a parallel trader could cause even if the free movement of goods is thereby compromised."*

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36 *BMW*, at paragraph 53.

The Commission of the European Communities

58. The Commission refers to *Bristol-Myers Squibb*,[37] according to which the trade mark proprietor may oppose the further commercialisation of repackaged goods unless, *inter alia*, the "necessity requirement" and the "reputation requirement" are met. The questions in the present case concern in particular whether it is a requirement that the inclusion of additional elements is "necessary." First, it appears clear to the Commission that the conditions have not been met if the presentation of the repackaged products is liable to damage the reputation of the trade mark and of its owner. Secondly, it appears equally clear that the requirement of "necessity" relates to the act of repackaging, not to the presentation of the repackaged product.

59. With regard to exemptions to the exhaustion of trade mark rights, the Commission submits that if it is established that the trade mark proprietor may oppose a particular use of the trade mark pursuant to Article 7(2) of the Directive, it does not automatically follow that the trade mark proprietor may oppose any use of the trade mark in relation to the goods. Even if the trade mark proprietor cannot oppose the further marketing of the goods it follows from the case law that the trade mark proprietor may still be able to oppose the use of the trade mark in advertising of the goods, as was held in *Dior*. It is necessary to assess whether the prerogative to oppose the repackaging of goods ultimately concerns the same prerogative which would allow the trade mark proprietor to oppose the marketing of the goods with additional elements such as the parallel importer's own logo and/or coloured stripes and/or other graphic elements that make up part of the design of the packaging. If this is not the case, it is necessary to consider whether there are any other circumstances in which a trade mark proprietor may have "legitimate reasons" to oppose the marketing of repackaged products with additional elements.

60. With regard to the "necessity" argument in the case law of the Court of Justice of the European Communities on repackaging of trade marked goods, the Commission points to the two different aspects of the essential function of the trade mark as outlined by the Court of Justice of the European Communities in *Hoffmann La Roche* (to guarantee the identity of the origin of the trade marked product): first, the interest of the trade mark proprietor to maintain the distinct character of the trade mark which enables the consumer to distinguish between products of different commercial origin; and secondly, the interest of the trade mark proprietor to maintain the integrity of the product.

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[37] At paragraph 79.

61. Based on analysis of *Bristol-Myers Squibb*[38] and *Boehringer*,[39] the Commission submits that it is not only permitted to include elements other than the trade mark on the repackaged product, but that it is a requirement with regard to the indication of the person responsible for the repackaging. The *rationale* appears to remain the protection of the essential function of the trade mark, namely identification of the origin. However, it is not intended to safeguard the integrity of the product but, rather, to maintain the distinct character of the trade mark, which again enables customers to identify the commercial origin of the products as well as the "repackaging" of the products. The *rationale* behind the requirement to indicate the origin of the "repackaging" is, therefore, different from the *rationale* behind the requirement of "necessity" for accessing the market. 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 appears unthinkable that such presentation could ever "*interfere or create by its very nature the risk of interference with the original condition of the product.*"

62. Consequently, it is not justified to expand the requirement of "necessity" to the presentation of the repackaged product and/or the 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 reasons" to oppose such inclusion on the mere basis that those elements cannot be considered "necessary" for the marketing of the goods. However, it follows from this reasoning that the trade mark proprietor has a "legitimate reason" to oppose the presentation of the products if the presentation is liable to damage the distinctive character of the trade mark, which would ultimately make it impossible for consumers to distinguish the trade marked goods from products which have another origin.

63. It is a general principle as regards the use of the trade mark in the commercialisation of goods, that the trade mark proprietor has "legitimate reasons" to oppose use of its trade mark which affects the distinctive character of the trade mark. In circumstances where there is no risk that the public will be led to believe that there is a commercial connection between the reseller and the trade mark proprietor, where the use of the trade mark is honest and fair, the trade mark proprietor may still oppose use of the trade mark provided the use of the trade mark seriously damages the reputation of the trade mark. "Legitimate reasons" may be invoked to oppose the further commercialisation of the repackaged goods if the inclusion of additional elements is likely to damage the distinct character of the trade mark or if the presentation of the repackaged goods is liable to damage the reputation of the trade mark and of its owner. In circumstances where it is established that the marketing of the repackaged goods can be said to be "customary in the reseller's sector of trade," the trade mark

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38 At paragraph 67.

39 At paragraph 34.

proprietor may still invoke “legitimate reasons” to oppose use of the trade mark whether in advertising or in relation to the presentation of the product if it is established that the use of the trade mark for this purpose “seriously damages the reputation of the trade mark.”

64. Whether, however, the inclusion of the logo and/or of coloured stripes and/or other elements damages the reputation of the trade mark is an assessment of fact that is a matter for the national court. It is not entirely clear from the facts whether the inclusion of the coloured stripes is customary in the sector in general to identify a certain category of pharmaceuticals or whether it is the practice of the trade mark proprietor, ultimately contributing to the possible confusion between the origin of the goods.

65. The Commission of the European Communities suggests to answer the questions as follows:

> *“Legitimate reasons” may be invoked to oppose the further commercialisation of repackaged goods if the inclusion of additional elements is likely to damage the distinct character of the trade mark or if the presentation of the repackaged goods is liable to damage the reputation of the trade mark and of its owner. In circumstances where it is established that the marketing of the repackaged goods can be said to be “customary in the reseller's sector of trade”, the trade mark proprietor may still invoke “legitimate reasons” to oppose use of the trade mark, whether in advertising or in relation to the presentation of the product, if it is established that the use of the trade mark for this purpose seriously damages the reputation of the trade mark.*
>
> *However, “legitimate reasons” may not be invoked solely on the ground that the inclusion of additional elements cannot be said to be “necessary.”*

The Kingdom of Norway

66. In the view of the Kingdom of Norway, graphic elements, such as different colours, on pharmaceutical packaging minimise the risk of harm to public health. Unnecessary restrictions on packaging design will unavoidably result in many packaging of similar appearance and thus increase the risk of confusion and incorrect use of medicines, which could have serious and even fatal consequences. This would be contrary to EEA law.

67. The Kingdom of Norway submits, that if the specific graphic elements, such as colours, used on the new packaging are objectively necessary for the parallel imported products to gain effective market access, the trade mark proprietor may not oppose such repackaging provided that the criteria established by the Court of Justice of the European Communities relating to the packaging are respected. It is for the national court to decide whether the graphic elements

affixed to the package by the Appellant in the case at hand are in conformity with the requirements established by relevant case law. As repackaging must be carried out in such a way that the legitimate interests of the proprietor are respected,[40] the question for the Court to decide is whether there are legitimate reasons within the meaning of Article 7(2) for the trade mark proprietor to oppose the addition of new graphic elements to the new packaging.

68. The Court of Justice of the European Communities, while having established a set of conditions that the new packaging must meet in order to safeguard the legitimate interests of the trade mark proprietor,[41] has not prohibited the use of (new) graphic elements, such as different colours. Furthermore, a general prohibition against adding graphic elements would result in a situation where a larger number of packages would lack distinctive graphic elements. This would in turn make it difficult to distinguish between different products. In the Norwegian Government's opinion, colours or other graphic elements on the packaging will generally not increase the risk that the reputation of the product will be negatively affected. However, the choice of graphic elements must not create the impression of a commercial link between the parallel importer and the trade mark proprietor and the repackaging can not be done solely in an attempt to secure a commercial advantage.[42]

69. On the other hand, such elements do make it easier to distinguish between products. This is particularly important as regards pharmaceutical products, since incorrect use must be avoided. The Norwegian Government considers that this public health concern must be taken into consideration when interpreting the Directive. This is in conformity with relevant case law and with the wording of the relevant EEA rules, provided that there is no infringement of the legitimate rights of the trade mark proprietor.[43] The need to safeguard public health must be taken into consideration and given proper weight when answering the questions referred to the Court.

70. As shown by the increase in the number of applications for black and white (neutral) packages, unnecessary restrictions on packaging design will

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40 Cf. *Boehringer*, at paragraph 32.

41 Cf. *Bristol-Myers Squibb*; *Merck, Sharp & Dohme* and *Boehringer*.

42 *Merck, Sharp & Dohme*, at paragraph 27.

43 Reference is made to the judgment of the Court in Case 3/00 [2000-2001] EFTA Ct. Rep., 73, at paragraph 27 and the decision from the Norwegian Ministry of Health, stating: "*As stated in the Norwegian Medicines Agency's decision, the conclusion is supported by the paramount importance of consideration for the safety of the consumer. One aspect of this involves avoiding confusion and mistaken use of medicinal products. The above-mentioned consideration has a very central place in both Norwegian and EU/EEA law. Pursuant to Article 13 of the EEA Agreement, on specified conditions, exceptions may be made from the basic principle of free trade if the exception is "justified on grounds of […] protection of health and life of humans, animals or plants". The importance of the safety of the users is emphasized in a number of judgments passed by the EU and EFTA courts (for example case 104/75 "De Peijper" premise 15, case E-3/00 "Kellogg's" premise 27 and case 172/00 "Ferring" premise 34)."*

unavoidably result in many packages of similar appearance and thus increase the risk of confusion. This will lead to more instances of incorrect use, which may have serious and even fatal consequences. If the packages are very different, for example in different colours, the risk of incorrect use is clearly reduced. There is no legitimate reason why the proprietor of a trade mark should, as a general rule, be allowed to enforce a prohibition that will result in such danger to the public health. A higher level of safety can be achieved by ensuring that packaging used by different preparations does not become too similar.[44]

71. The Kingdom of Norway suggests to answer the questions as follows:

"The proprietor does not have "legitimate reasons" to oppose the use of graphic elements in a situation where the addition of graphic elements, such as colours, safeguards public health provided that the graphic elements do not infringe the specific subject-matter of the mark, as understood in the light of its essential function."

Carl Baudenbacher
Judge-Rapporteur

[44] Norway also refers to the International Pharmaceutical Federation, acknowledging that both the incidence and the severity of errors can be reduced dramatically through the adaptation of systematic approaches to error prevention. The Federation therefore encourages regular and systematic review of product labelling and packaging by regulatory authorities and manufacturers with the specific aim of minimising medication errors. It recommends that the packaging and labelling on prescribed medicines should be designed with a view to minimising errors in selection and use, and recommends the use of innovative design to help practitioners distinguish between products that are already on the market. With a view to the requirements that may be made regarding documentation that a measure will have positive effects on health, Norway also refers to the precautionary principle, see *inter alia* Case E-3/00, *Kellogg's*, Report of the EFTA Court [2000-2001] 73.