BRISTOL-MYERS SQUIBB AND OTHERS v PARANOVA

OPINION OF ADVOCATE GENERAL JACOBS delivered on 14 December 1995 *

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1. This Opinion relates to a number of cases in which Danish and German courts have requested preliminary rulings in order to determine whether and within what limits it is compatible with Community law for the owner of a trade mark to oppose the importation and sale in one Member State of pharmaceutical products bearing the trade mark which have been placed on the market in another Member State with the trade mark owner's consent and have subsequently been repackaged by other persons without his consent.

I. The factual background and the questions referred

2. The present cases reveal a surprising lack of uniformity in the common market, at least as regards trade in pharmaceutical products. Two aspects of that lack of uniformity are relevant. On the one hand, there are considerable discrepancies in the prices of pharmaceutical products. Prices are appreciably lower in some countries (Greece, Spain, Portugal and the United Kingdom, for example) than in others (Denmark and Germany, for example). The reasons for those discrepancies are in dispute, but it seems clear that they are at least to some extent due to the existence of price controls in some countries and to different rules about the maximum amounts that may be reimbursed to patients under the health insurance schemes of some Member States. ¹

3. Whatever may be the cause of the price discrepancies, their existence stimulates a phenomenon known as 'parallel imports', whereby persons outside the manufacturer's official distribution system buy products which are on the market in low-price countries and export them to high-price countries where they are able to sell the goods at a profit and yet still undercut the manufacturer's official selling price.

4. Such parallel importers encounter severe obstacles, however, as a result of the second aspect of the lack of uniformity referred to above. Owing to differences in the rules and practices regarding the packaging of pharmaceutical products — for example, rules about the number of pills per packet — parallel importers frequently have to repackage goods. In the case of trade-marked goods they then have to reaffix the trade mark to the repackaged product, or allow it to remain visible through the new packaging, in order to identify the product. When the manufacturers of the products in question invoke their trade mark rights in order to oppose such parallel imports of repackaged goods, the ensuing litigation raises an issue that has come before the Court on many occasions and in the most varied of guises: namely, whether and in what circumstances industrial property rights prevail over the free movement of goods in the common market.

5. Having described the general background, I shall now summarize the specific facts of the seven cases before the Court.

(1) Joined Cases C-427/93, C-429/93 and C-436/93 Paranova

6. These three cases have been referred to the Court by Danish courts. In the first two cases the referring court is the Sø- og Handelsret (Commercial Court), Copenhagen, while the third case has been referred by the Højesteret (Supreme Court). In all three cases the defendant (or the respondent in Case C-436/93) is a Danish company called Paranova A/S (hereafter 'Paranova') which is

The existence of national measures affecting price formation is clear from Council Directive 89/105/EEC of 21 December 1988 relating to the transparency of measures regulating the pricing of medicinal products for human use and their inclusion in the scope of national health insurance systems: OJ 1989 L 40, p. 8.

a distributor of pharmaceutical products. The plaintiffs (appellants in Case C-436/93) are manufacturers of pharmaceutical products. Squibb. Paranova printed the name 'Capoten' on the packaging without the symbol 'R' and stated that the goods were manufactured by Bristol-Myers Squibb and had been imported and repackaged by Paranova.

(a) Case C-427/93 Bristol-Myers Squibb v Paranova

9. Paranova carried out similar operations on Diclocil, which is an antibiotic for treating infections. The Diclocil repackaged by Paranova was likewise purchased in Greece.

7. The plaintiff, Bristol-Myers Squibb, is the proprietor of the Danish registrations for the trade marks 'Capoten', 'Mycostatin', 'Vepesid', 'Vumon' and 'Diclocil'. The products in question are pharmaceutical preparations which are manufactured and marketed by Bristol-Myers Squibb or an associated company in various Member States.

8. Paranova bought consignments of the five products which had been placed on the market by Bristol-Myers Squibb or an associated company in a Member State other than Denmark. Paranova repackaged the goods and marketed them in Denmark, having registered the five products as pharmaceutical specialities under the same names as those used by Bristol-Myers Squibb in the Danish register of specialities. In the case of Capoten, which is used for lowering blood pressure, Paranova bought the pills in Greece in blister packets and repackaged the blister packets in external packaging manufactured by Paranova. The packaging had yellow and green stripes corresponding to the colours of advertising material used by Bristol-Myers 10. Vepesid and Vumon are anti-cancer drugs sold in phials. Paranova bought consignments of the former in the United Kingdom and the latter in Spain. Paranova removed the phials from the surrounding padding and placed a label on each phial, Bristol-Myers Squibb's label. covering Bristol-Myers Squibb's trade mark was printed on the label without the symbol 'R'. It was further stated on the labels that the goods had been 'manufactured by Bristol-Myers Squibb' and 'imported and repackaged by Paranova'. The phials were then put back in the original padding and packed in external packaging not supplied by Bristol-Myers Squibb. The external packaging bore the trade marks and the aforesaid information as to who had manufactured the goods and who had repackaged them. Paranova chose for the external packaging colours corresponding to those used on the external packaging in which Bristol-Myers Squibb presented the goods. Paranova removed the instructions for use which Bristol-Myers Squibb had supplied with the goods (written in English or Spanish) and inserted a Danish version of the instructions on which the trade marks were printed.

11. Mycostatin is used for the treatment of mycotic infections of the mouth. It is presented in various forms. Paranova bought consignments sold in Portugal in the form of a mixture put up in flasks. Paranova removed the original outer packaging, placed its own label, with the trade mark, on the flasks and put the flasks in new external packaging which bore the trade mark 'Mycostatin' and was in the same colours as the original packaging. Paranova also inserted in the packaging a spray which was not manufactured by Bristol-Myers Squibb. hereafter 'the Directive').² Article 7 of the Directive provides:

'1. The trade mark shall not entitle the proprietor to prohibit its use in relation to goods which have been put on the market in the Community under that trade mark by the proprietor or with his consent.

12. Paranova carries out the above repackaging operations in order to be able to offer the products in question in the package sizes normally used in Denmark by Bristol-Myers Squibb. Danish pharmacists are in principle required to supply pharmaceuticals in the quantity stipulated in the prescription.

2. Paragraph 1 shall not apply where there exist legitimate reasons for the proprietor to oppose further commercialization³ of the goods, especially where the condition of the goods is changed or impaired after they have been put on the market.'

13. Bristol-Myers Squibb brought proceedings against Paranova before the Sø- og Handelsret, claiming *inter alia* an injunction restraining Paranova from infringing Bristol-Myers Squibb's trade marks by affixing them, without Bristol-Myers Squibb's consent, to goods which it had repackaged. Paranova argued in its defence that its action did not amount to a trade mark infringement in the light of Article 7 of Council Directive 89/104/EEC of 21 December 1988 (the First Council Directive to approximate the laws of the Member States relating to trade marks;

14. Article 7 of the Directive has been implemented in Denmark by Paragraph 6 of Law No 341, which reproduces the terms of Article 7 practically verbatim.

2 — OJ 1989 L 40, p. 1.

The word 'commercialization' appears to be a literal translation of the French 'commercialisation'. It would be more normal in English to speak of 'further marketing of the goods'.

15. The Sø- og Handelsret stayed the proceedings and referred the following questions to the Court for a preliminary ruling: ing use of the trade mark for which the trade mark proprietor has not given his consent.

'1. Is Article 7(1) of Council Directive 89/104/EEC of 21 December 1988 to approximate the laws of the Member States relating to trade marks to be interpreted as meaning that unless Article 7(2) applies the proprietor of a trade mark who has put goods into circulation in a Member State under a trade mark cannot prevent a third party from importing the goods into another Member State in order to market the goods there under the same trade mark even if that third party has attached to the inner packaging of the goods labels on which the trade mark is affixed and substituted for the original outer packaging a new packaging on which the trade mark is affixed?

It is stressed that the question does not seek a ruling on cases in which the second sentence of Article 36 of the Treaty might justify repackaging and reaffixing a mark in accordance with the principles set out in Case 102/77 but only on whether Article 7(1) is to be construed as meaning that apart from laying down the general principle of the exhaustion of trade mark rights within the European Community it also entails a general limitation on the rights otherwise conferred on trade mark proprietors regard2. If the answer to Question 1 is affirmative, does Article 7(2) of Directive 89/104/EEC, after implementation, entail that the case-law of the Court of Justice as set out in Case 102/77 and developed subsequently comes to be of subsidiary importance since the right to repackage will primarily fall to be determined in application of national provisions corresponding to Article 7(2) of the said directive?

3. On the premise that Article 7(1) of the said directive is intended to permit parallel importers to reaffix trade marks, must the fact that goods are repackaged be regarded as "legitimate reasons" for the purposes of Article 7(2)?

In particular, does it make any difference that it is only the outer packaging that has been repackaged and remarked but not the inner packaging? 4. With regard to the derogating provision in the second sentence of Article 36 of the Treaty and in the light of the judgment of the Court of Justice in Case 102/77, what may be described as a partitioning of the market for a specific product and, in particular, what distinguishing factors are to be taken into account in assessing whether an artificial partitioning of markets between the Member States can be said to exist for a specific product in connection with the sales system applied by the trade mark proprietor?'

(b) Case C-429/93 C. H. Boehringer Sohn, Boehringer Ingelheim KG and Boehringer Ingelheim A/S v Paranova A/S

16. C. H. Boehringer Sohn and Boehringer Ingelheim KG are associated German companies which manufacture pharmaceutical products. Boehringer Ingelheim A/S is the Danish subsidiary of Boehringer Ingelheim KG. It distributes Boehringer products in Denmark. I shall refer to the three companies collectively as 'Boehringer'.

other four are used to designate specific pharmaceutical products. Atrovent, Berodual and Berotec are used for the treatment of bronchial asthma and are sold in aerosol inhalers. Boehringer manufactures the products in Germany and markets them throughout the Community but with differing quantities of the active ingredient. Catapresan is used for the treatment of high blood pressure. It is manufactured in Germany under the supervision of Boehringer in the form of tablets packaged in blister packs. Paranova bought consignments of the four products mentioned above in a Member State other than Denmark. Paranova repackaged the goods and, in the case of Berodual and Berotec, put in new inserts drawn up in a language described in the order for reference as 'Scandinavian'. On the new packaging the producer is indicated as 'Boehringer Ingelheim'. Boehringer did not authorize Paranova to produce or wrap goods on Boehringer's behalf or to apply Boehringer's trade marks. Paranova had the four products registered in Denmark as new specialties with the same specialty names as those of Boehringer.

17. Boehringer has registered in Denmark the trade marks 'Boehringer Ingelheim', 'Atrovent', 'Berodual', 'Berotec' and 'Catapresan'. The first is used generally on pharmaceuticals manufactured by Boehringer. The 18. Boehringer applied to the Sø- og Handelsret, claiming *inter alia* an injunction to restrain Paranova from infringing its trade marks by affixing them to repackaged products. That court referred to the Court of Justice two questions with the same wording as Questions (1) and (2) in Case C-427/93. (c) Case C-436/93 Bayer AG and Bayer Danmark A/S v Paranova

19. The appellants in this case are Bayer AG and Bayer Danmark A/S. Bayer AG is a German company which manufactures pharmaceutical products. Bayer Danmark A/S (hereafter 'Bayer Danmark') is a whollyowned Danish subsidiary of Bayer AG which distributes the latter's products in Denmark. Bayer AG has registered the trade mark 'Bayer' in Germany, Denmark and other Member States. Bayer AG has also registered the name 'Adalat' in all the Member States. Adalat is a pharmaceutical product for treating circulatory and heart illnesses. Bayer Danmark used to market Adalat in Denmark in packages containing 30 or 100 tablets. The packages were made up from a number of blister packs each containing 10 tablets. Since 1990 only packages containing 100 tablets have been sold in Denmark. Bayer AG markets Adalat in other Member States but the number of tablets per package varies from country to country. In Greece the product is sold in packets of 30 (three blister packs with 10 tablets each). In Greece the price of Adalat is considerably lower than in Denmark.

20. On 19 November 1989 Paranova informed wholesalers of pharmaceutical products in Denmark that with effect from 3 December 1990 it would be able to supply Adalat in packets of 100 tablets. By letter of 3 December 1990 Paranova informed Bayer Denmark that it was henceforth marketing Adalat. The Adalat tablets marketed by Paranova in Denmark are imported from Greece (where they have been placed on the market by Bayer AG's Greek subsidiary) in packets of 30 tablets which Paranova repackages in packets of 100 tablets. Paranova affixes the name 'Adalat' on the new packaging, together with a statement that the goods have been manufactured by Bayer and imported and repackaged by Paranova. A warning on the side of the packet that the goods must be stored away from the light was, according to the appellants, added only after they had drawn Paranova's attention to the photosensitivity of the product. At the hearing, however, counsel for Paranova stated that the original product placed on the market by the appellants bore no such warning.

21. On 25 September 1991 the appellants brought proceedings against Paranova before the Sø- og Handelsret, which dismissed the action. The appellants then appealed to the Højesteret, which referred the following questions to the Court:

'1. Must the possibility for a trade mark proprietor to oppose a parallel importer's action in replacing wholly or in part the original packaging of his goods by new packaging on which the parallel importer reaffixes the trade mark be determined under national trade mark law only in conjunction with Article 7(1) and (2) of the First Council Directive (89/104/EEC of 21 December 1988) to approximate the laws of the Member States relating to trade marks or also in conjunction with the first and second sentences of Article 36 of the EC Treaty?

4. In connection with Question 3, must the parallel importer show or else establish a probability that there was intent or must the trade mark proprietor show or establish a probability that there was no intent?

2. In assessing the legal steps that may be taken by the trade mark proprietor, is it significant whether there may be said to exist an "artificial partitioning of the markets" for trade in the goods in question?

5. Is the reaffixing of the trade mark, as described in Question 1, in itself sufficient "legitimate reason" within the meaning of Article 7 of the Directive or must the trade mark proprietor in addition show further circumstances, for example that the condition of the goods is changed or impaired when they are put on the market by the parallel importer?"

If so, the Court is asked to specify what is the significance as regards such steps.

(2) Joined Cases C-71/94, C-72/94 and C-73/94 Eurim-Pharm

3. If Question 2 is answered in the affirmative, is it significant for the rights of the trade mark proprietor whether he had the intention to create or exploit such an artificial partitioning of the markets?

If so, the Court is asked to specify what is the significance as regards those rights. 22. These three cases have been referred to the Court by the Bundesgerichtshof. In all three cases the appellant (the defendant in the proceedings at first instance) is Eurim-Pharm Arzneimittel GmbH (hereafter 'Eurim-Pharm'). Eurim-Pharm is a German company which distributes pharmaceutical products. In all three cases the respondent is a German company which manufactures and distributes such products. (a) Case C-71/94 Eurim-Pharm v Beiersdorf AG

23. Beiersdorf AG (hereafter 'Beiersdorf') manufactures pills known as beta-blockers for treating high blood pressure and markets them in Germany under the name 'Kerlone'. It does so by virtue of a licence granted by Laboratoires Synthelabo France (hereafter 'Synthelabo'), which is the owner of the trade mark 'Kerlone' in Germany and other countries. Beiersdorf markets Kerlone in packets of 50 or 100 pills corresponding to standard sizes recommended by various trade and professional associations and by sickness insurance institutions in Germany. In France Synthelabo markets Kerlone in packets of 28 to comply with a statutory ruling according to which pharmaceuticals are to be supplied in sufficient quantities to cover a maximum period of one month. Each packet contains two blister strips of 14 pills. The back of the blister strip is marked with the days of the week in French in such a way that one pill is allocated for each day.

(some whole and inside their original packets, others severed and removed from their original packets) inside a box, of its own design, into which a small window has been cut; through that window the trade mark 'Kerlone' printed on one of Synthelabo's original packets is visible. The outer packaging contains information about the active ingredients and a statement that the goods have been imported, packed and distributed by Eurim-Pharm. A further point to be noted is that where blister strips have been cut the series of days of the week to which individual pills are allocated is no longer complete.

25. Beiersdorf, which has been authorized by Synthelabo to sue for infringements of the 'Kerlone' trade mark in its own name, brought proceedings in the German courts for damages and an injunction restraining Eurim-Pharm from using the 'Kerlone' trade mark in the manner described. The matter eventually came before the Bundesgerichstshof, which referred the following questions to the Court:

24. Since the end of 1988 Eurim-Pharm has marketed in Germany Kerlone pills which it imports from France, where they have been placed on the market by Synthelabo. In order to attain the standard sizes recommended in Germany Eurim-Pharm has to repackage the goods. Fourteen not being a factor of 50 or 100, that can only be achieved by cutting some of the blister strips. Eurim-Pharm places a number of blister strips

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'1. Is the proprietor of an internationally registered trade mark (IR mark) having effect in Member State A entitled under Article 36 of the EC Treaty, in reliance upon the trade mark, to prevent an importer from buying medicinal products which have been marketed under the trade mark in Member State B by the proprietor of the trade mark and which require a prescription in Member State A, from repackaging them in conformity with the prescribing practices of

medical practitioners in Member State A, which are based on a recommendation by prominent organizations (including those representing the pharmaceutical industry) on therapeutically desirable sizes and which differ from the packaging sizes prescribed by statute in Member State B, and from marketing them in Member State A in external packaging styled by the importer, if such packaging contains an original packet with original blister strips from Member State B and a number of additional blister strips which have been cut up and the new packaging has a window through which the IR mark on the original packaging is visible and displays a reference to the packaging and marketing by the importer but no reference to the manufacturer? Is it of relevance for the purposes of the answer to the question that information printed on the back of the original blister strip refers (in, for Member State A, a foreign language) to the days of the week for a 14-day period, which when the blister is cut becomes incomplete?

2. Is it sufficient, for the purpose of establishing a disguised restriction on trade between Member States within the meaning of Article 36 of the EC Treaty, that the use of the national trade mark in conjunction with the marketing system adopted by the proprietor of the I R mark objectively leads to a partitioning of the markets between Member States, or is it necessary for that purpose to show that the proprietor of the I R mark exercises his trade-mark right in conjunction with the marketing system which he employs with the object of bringing about an artificial partitioning of the markets?'

(b) Case C-72/94 Eurim-Pharm v Boehringer Ingelheim KG

26. Boehringer Ingelheim KG (hereafter 'Boehringer Ingelheim') is the proprietor of the registered trade mark 'Mexitil' in Germany and France. Mexitil is used to treat disturbances of the heart rhythm. Boehringer Ingelheim sells the drug in Germany in packets of 20, 50 or 100 so as to comply with the standard recommended sizes in Germany. In France the same preparation is manufactured under licence by Boehringer Ingelheim France SARL (hereafter 'Boehringer France'), which is a member of the same group as Boehringer Ingelheim. In France Mexitil is sold in packets of 30 capsules. Each packet contains three blister strips, each of which contains 10 capsules. Each blister strip is intended to cover the patient's requirements for 10 days and accords with French legislation under which such medicaments should cover a period of 10 days or one month.

27. Eurim-Pharm imports and distributes in Germany Mexitil which has been placed on the market in France by Boehringer France. Eurim-Pharm repackages the goods in such a

way as to be able to sell Mexitil in packets of 50 and 100, thus complying with the relevant recommendations as to standard sizes. To make up a packet of 50, Eurim-Pharm places in a box designed by it one original French packet of 30 capsules and two original French blister strips of 10 capsules, together with a leaflet in German and additional instructions. The box has a rectangular opening which is just large enough to reveal the trade mark 'Mexitil' on the original French packet of 30 capsules. To make up a packet of 100 capsules Eurim-Pharm proceeds in the same manner, except that it places in the outer container three original French packets of 30 capsules and one blister strip of 10 capsules. In both cases Eurim-Pharm places stickers on the original packets of 30 capsules. The stickers describe Eurim-Pharm as the importer and distributor and state that the active ingredient is mexiletinhydrochloride. It will be apparent from the above that Eurim-Pharm is able to attain the standard sizes of 50 and 100 without cutting up the original blister strips.

effect in Member State A entitled under Article 36 of the EC Treaty, in reliance upon the trade mark, to prevent an importer from buying medicinal products which have been marketed under the trade mark in Member State B by the proprietor of the trade mark and which require a prescription in Member State A, from repackaging them in conformity with the prescribing practices of medical practitioners in Member State A, which are based on a recommendation by prominent organizations (including those representing the pharmaceutical industry) and which differ from the packaging sizes prescribed by statute in Member State B, and from marketing them in Member State A in external packaging styled by the importer, if such packaging contains an original packet with original blister strips from Member State B and a number of additional blister strips which have been cut up and if the new packaging has a window through which the I R mark on the original packaging is visible and displays a reference to the packaging and marketing by the importer but no reference to the manufacturer?'

28. Boehringer Ingelheim considers that Eurim-Pharm's marketing of the repackaged goods constitutes a breach of its trade mark and seeks damages and an injunction. The Bundesgerichtshof, by order of 27 January 1994, referred two questions to the Court. The second is identical to Question 2 in Case C-71/94. The first question is worded as follows:

'1. Is the proprietor of an internationally registered trade mark (IR mark) having

29. That question is almost identical to Question 1 in Case C-71/94, the only differences being that the final sentence, referring to the possible relevance of the severing of blister strips, is for obvious reasons omitted and that the words 'on therapeutically desirable packaging sizes' (*über therapiegerechte* Packungsgrößen) are omitted. The latter omission may be due to a clerical error. Curiously, Question 1 in Case C-72/94 still refers to the addition of severed blister strips even though no cutting-up of blister strips occurs in this case. That too may be due to a clerical error.

(c) Case C-73/94 Eurim-Pharm v Farmitalia Carlo Erba GmbH

30. Farmitalia Carlo Erba GmbH (hereafter 'Farmitalia') is the German subsidiary of an Italian company called Farmitalia Carlo Erba SRL. The latter is the owner of the registered trade mark 'Sermion' in Germany, Spain and Portugal. Farmitalia markets in Germany under licence from its parent company the medicinal products 'Sermion' (active ingredient: nicergolin 5 mg) and 'Sermion forte' (active ingredient: nicergolin 10 mg), which are used for treating disturbances of the mental faculties. In Germany those products are sold in packets of 50 or 100 capsules in order to comply with the relevant recommendations as to standard sizes.

10 capsules. The size of the packet is calculated on the basis of a period of treatment of 20 days at the rate of one capsule three times a day. According to the order for reference. the product thus attains the upper limit of what is reimbursable under the Portuguese scheme of health insurance. In Spain an associated company of Farmitalia markets the 5 mg version of the product under the name 'Sermion' in packets of 45 capsules. The 45 capsules are contained in a single blister strip. Eurim-Pharm purchases quantities of Sermion and Sermion forte which have been placed on the market in Spain and Portugal by Farmitalia's associated companies. Eurim-Pharm imports those products into Germany and markets them in that country, after first repackaging the products in packets of 50 or 100 capsules. In the case of goods purchased in Portugal it places a sticker on the back of each blister strip bearing the word 'forte'. It covers the face and a side window of the original packet of 60 capsules with stickers. It places the otherwise unaltered original packet together with four loose blister strips of 10 capsules each in an outer packet of its own design. The outer packet has a rectangular opening which is just large enough to allow the name 'Sermion' on the original Portuguese packet to show through. The word 'forte' is printed just below that window. The outer packet also contains a statement that the goods have been imported, packed and distributed by Eurim-Pharm.

31. In Portugal an associated company of Farmitalia markets the 10 mg version of the product under the name 'Sermion' (i. e. without the addition of the word 'forte'). The product is sold in packets of 60, made up of six blister strips each containing

32. In the case of goods purchased in Spain Eurim-Pharm supplements the original packet of 45 capsules with a strip of five capsules cut from an original Spanish blister pack and adds a notice in German. Eurim-Pharm places a sticker with its name and address and additional information (batch number, use-by date, registration number, etc.) on the original Spanish packet of 45 capsules. On the back of the packet it places a sticker with the notice 'import and marketing: Eurim-Pharm Arzneimittel GmbH, 8235 Piding'. medicinal practitioners prevailing in Member State A, which are based on a recommendation by prominent organizations (including those representing the pharmaceutical industry) on therapeutically desirable sizes and which differ from the standard sizes in Member State B and

33. Farmitalia, which has been authorized by its parent company to sue for infringements of its trade marks, regards the above practices as infringements of the trade marks 'Sermion' and 'Sermion forte'. It is suing for damages and an injunction. The Bundesgerichtshof, by order of 27 January 1994, has referred two questions to the Court. The second is identical to Question 2 in Cases C-71/94 and C-72/94. The first question is worded as follows:

(a) from marketing them in Member State A in external packaging styled by the importer, if such packaging contains an original packet with original blister strips from Member State B and a number of additional original blister strips and the new packaging has a window through which the trade mark on the original packet is visible and displays a reference to the repackaging and marketing by the importer but no reference to the manufacturer, or

'1. Is the proprietor of an internationally registered trade mark (IR mark) having effect in Member State A entitled under Article 36 of the EC Treaty, in reliance upon the trade mark, to prevent an importer from buying medicinal products which have been marketed under the trade mark in Member State B by an undertaking belonging to the same group as the proprietor of the trade mark and which require a prescription in Member State A, from repackaging them in conformity with the prescribing practices of

(b) from marketing them in Member State A in the original trade-marked packaging from Member State B if it is supplemented by the importer with stickers showing his firm's name and further particulars (batch number, use-by date, registration number, etc.) and with a strip containing five capsules cut from an original blister strip?'

(3) Case C-232/94 MPA Pharma GmbH v Rhône-Poulenc Pharma GmbH

34. Rhône-Poulenc Pharma GmbH (hereafter 'Rhône-Poulenc') is a German subsidiary of the French company Rhône-Poulenc Rover SA, which is the proprietor of the registered trade mark 'Orudis' for pharmaceuticals in Germany and other countries. Operating under a licence from its French parent company, Rhône-Poulenc markets in Germany the pharmaceutical 'Orudis retard', which is available only on prescription, as an anti-rheumatic drug and analgesic in packets of 20, 50 and 100 tablets corresponding to the recommended standard sizes in Germany. Orudis retard is also marketed in Spain, where it is sold only in packets of 20 tablets (two blister strips each containing 10 tablets) by another subsidiary of Rhône-Poulenc Rover SA.

35. MPA Pharma GmbH (hereafter 'MPA') buys Orudis retard which has been placed on the Spanish market by the Spanish member of the Rhône-Poulenc group and markets the product in Germany in packets of 50 tablets. In order to do that MPA removes the blister strips from their original packaging and places five strips in a new packet of its own design. On every visible face of the packet there is a label stating in German:

'MPA Import Pharmaceutical Products

50 delayed-action tablets of the pharmaceutical

Orudis retard

To be taken internally'

A label on one face states:

'Manufacturer:

Rhône-Poulenc SAE

Spain'

and

'Importer and responsible

pharmaceutical firm:

MPA Pharma GmbH, D-22946

Trittau'.

The following note is printed on one side of the packet:

trade mark). The second question referred by the Oberlandesgericht is worded as follows:

'The contents of this packet of Orudis retard were manufactured by Rhône-Poulenc Farma SAE, Alcorcón (Madrid), Spain, and imported into the Federal Republic of Germany and there packaged by MPA Pharma GmbH, D-22946 Trittau, in conformity with the provisions of the German Law on Pharmaceutical Products.'

MPA inserts in the packet user information which it has itself drawn up.

36. Rhône-Poulenc applied to the Landgericht for an injunction restraining MPA from marketing repackaged Orudis retard on the ground that MPA's conduct amounted to an infringement of the trade mark. The application was upheld by the Landgericht and MPA appealed to the Oberlandesgericht Köln, which, by order of 11 August 1994, referred two questions to the Court. The first question is identical to Question 2 in Case C-71/94 (with the sole — immaterial difference that instead of referring to the proprietor of an internationally registered mark it refers simply to the proprietor of a 'Is there a presumption of a "disguised restriction on trade between Member States" within the meaning of the second sentence of Article 36 of the EC Treaty where the proprietor of a trade mark protected in Member States A and B relies on its national trade mark in order to prevent an importer from buying medicinal products which have been marketed under the trade mark in Member State B by an undertaking belonging to the same group as the proprietor of the trade mark and which are available only on prescription in Member State A, from repackaging them and marketing them in Member State A in external packaging which the importer designs and to which he affixes the trade mark without the consent of the proprietor of the mark, if the exercise of the trade mark right results in a partitioning of the markets between the Member States (see Question 1), if it is demonstrated that the repackaging cannot impair the original condition of the product and the proprietor of the trade mark was informed in advance of the offering of the repackaged product for sale, and also if not only the manufacturer and importer are indicated on the new packaging, but also the person responsible for the repackaging, even though

(a) the information as to who repackaged the product is not set out on the external packaging with sufficient clarity, with the result that it may be overlooked by user groups, and/or

(b) neither the information concerning the repackaging itself nor the layout of the external packaging in general indicates that the repackaging was carried out by the importer without the consent of the proprietor of the trade mark or its associated undertaking?' movement of goods (Articles 30 and 36). In other cases the questions referred postulate the applicability of the Directive.

39. I shall now summarize the relevant caselaw on Articles 30 and 36 and then examine the relevant provisions of the Directive.

II. The relevant case-law and legislation

(1) The case-law on Articles 30 and 36 of the Treaty

37. The fundamental issue raised by these cases is whether and in what circumstances the proprietor of a trade mark who has allowed goods bearing the trade mark to be placed on the market in a Member State may rely on the trade mark in order to prevent the importation and sale of those goods in another Member State after they have been repackaged by other persons without the consent of the proprietor of the trade mark. 40. Article 30 of the Treaty prohibits quantitative restrictions on imports in trade between Member States and measures equivalent in effect. According to the first sentence of Article 36 of the Treaty, Article 30 does not preclude prohibitions or restrictions which are justified on grounds of the protection of industrial or commercial property. The second sentence of Article 36 goes on to state that such prohibitions or restrictions must not constitute a means of arbitrary discrimination or a disguised restriction on trade between Member States.

38. Before that question can be considered it is first necessary to determine the relevant provisions of Community law. In some of the cases it is clear from the wording of the questions referred that the national court assumes that the matter falls to be decided under the Treaty provisions on the free

41. It is clear that if a trade mark owner is allowed to use his trade mark to prevent the importation and sale of goods that are lawfully on the market in another Member State, that will amount to a quantitative restriction or a measure having equivalent effect within the meaning of Article 30. Thus it is necessary — on the assumption that the Treaty provisions on the free movement of goods are applicable — to consider whether such action is justified on grounds of the protection of industrial and commercial property.

42. There is of course an extensive body of case-law on the application of Article 36 in relation to industrial and commercial property rights. The Court has consistently held that the owner of such a right (including a trade mark) cannot invoke it in order to prevent the importation and sale of goods which have been placed on the market with his consent in another Member State. That principle, known as the exhaustion of rights, was first laid down in Deutsche Grammophon v Metro 4 and has since been confirmed on numerous occasions, most recently in IHT Internationale Heiztechnik v Ideal Standard. 5

43. In two judgments the Court has dealt with the application of that principle to pharmaceutical products which had been repackaged without the consent of the owner of the trade mark. The facts of Hoffmann-La Roche v Centrafarm⁶ were as follows. Hoffmann-La Roche marketed a drug under the trade mark 'Valium' in Germany in

taining 100 or 250 tablets for hospitals. Its United Kingdom subsidiary marketed the same product in the United Kingdom in packages of 100 or 500 tablets at considerably lower prices. Centrafarm marketed in Germany Valium purchased in the United Kingdom in the original packages which it put up in new packages of 1000 tablets, to which it affixed the trade mark Hoffmann-La Roche together with a notice that the product had been marketed by Centrafarm. Centrafarm also gave notice of its intention to repack the tablets into smaller packages intended for sale to individuals.

packages of 20 or 50 tablets for individual

buyers and in batches of five packages con-

of

44. Hoffmann-La Roche attempted to prevent such 'parallel imports' in reliance on its trade mark. The Landgericht Freiburg considered that under German law Centrafarm's conduct amounted to an infringement of Hoffmann-La Roche's trade mark. The Landgericht sought a preliminary ruling on the question whether a trade mark owner was empowered under Article 36 of the Treaty to invoke the trade mark in order to prevent parallel imports in such circumstances. In its judgment the Court observed that, while the Treaty did not affect the existence of industrial and commercial property rights recognized by the laws of a Member State, the exercise of those rights might nevertheless, depending on the circumstances, be restricted by the prohibitions contained in the Treaty. Inasmuch as it created an exception to one of the fundamental principles of the common market, Article 36 admitted of derogations from the free movement of goods only to the extent to which such exceptions were justified for the purpose of safeguarding the rights which constituted

^{4 -} Case 78/70 [1971] ECR 487, paragraph 13 of the judgment.

^{5 -} Case C-9/93 [1994] ECR I-2789, paragraph 34 of the judg-

^{6 -} Case 102/77 [1978] ECR 1139.

the specific subject-matter of that property (paragraph 6 of the judgment). The Court then stated:

⁶⁷. In relation to trade marks, the specific subject-matter is in particular to guarantee to the proprietor of the trade mark that he has the exclusive right to use that trade mark for the purpose of putting a product into circulation for the first time and therefore to protect him against competitors wishing to take advantage of the status and reputation of the trade mark by selling products illegally bearing that trade mark.

The right attributed to the proprietor of preventing any use of the trade mark which is likely to impair the guarantee of origin so understood is therefore part of the specific subject-matter of the trade mark right.

8. It is accordingly justified under the first sentence of Article 36 to recognize that the proprietor of a trade mark is entitled to prevent an importer of a trade-marked product, following repackaging of that product, from affixing the trade mark to the new packaging without the authorization of the proprietor.

In order to answer the question whether that exclusive right involves the right to prevent the trade mark being affixed by a third person after the product has been repackaged, regard must be had to the essential function of the trade mark, which is to guarantee the identity of the origin of the trade-marked product to the consumer or ultimate user, by enabling him without any possibility of confusion to distinguish that product from products which have another origin.

This guarantee of origin means that the consumer or ultimate user can be certain that a trade-marked product which is sold to him has not been subject at a previous stage of marketing to interference by a third person, without the authorization of the proprietor of the trade mark, such as to affect the original condition of the product. 9. It is, however, necessary to consider whether the exercise of such a right may constitute a "disguised restriction on trade between Member States" within the meaning of the second sentence of Article 36.

Such a restriction might arise, *inter alia*, from the proprietor of the trade mark putting onto the market in various Member States an identical product in various packages while availing himself of the rights inherent in the trade mark to prevent repackaging by a third person even if it were done in such a way that the identity of origin of the trade-marked product and its original condition could not be affected. The question, therefore, in the present case is whether the repackaging of a trade-marked product such as that undertaken by Centrafarm is capable of affecting the original condition of the product.

10. In this respect the answer must vary according to the circumstances and in particular according to the nature of the product and the method of repackaging.

Depending on the nature of the product repackaging in many cases inevitably affects its condition, while in others repackaging involves a more or less obvious risk that the product might be interfered with or its original condition otherwise affected.

Nevertheless, it is possible to conceive of the repackaging being undertaken in such a way that the original condition of the product cannot be affected.

This may be so where, for example, the proprietor of the trade mark has marketed the product in a double packaging and the repackaging affects only the external packaging, leaving the internal packaging intact, or

where the repackaging is inspected by a public authority for the purpose of ensuring that the product is not adversely affected.

Where the essential function of the trade mark to guarantee the origin of the product is thus protected, the exercise of his rights by the proprietor of the trade mark in order to fetter the free movement of goods between Member States may constitute a disguised restriction within the meaning of the second sentence of Article 36 of the Treaty if it is established that the use of the trade mark right by the proprietor, having regard to the marketing system which he has adopted, will contribute to the artificial partitioning of the markets between Member States.

11. Although this conclusion is unavoidable in the interests of freedom of trade, it amounts to giving the trader, who sells the imported product with the trade mark affixed to the new packaging without the authorization of the proprietor, a certain licence which in normal circumstances is reserved to the proprietor himself.

In the interests of the proprietor as trade mark owner and to protect him against any abuse it is therefore right to allow such licence only where it is shown that the repackaging cannot adversely affect the original condition of the product. 12. Since it is in the proprietor's interest that the consumer should not be misled as to the origin of the product, it is moreover right to allow the trader to sell the imported product with the trade mark affixed to the new packaging only on condition that he gives the proprietor of the mark prior notice and that he states on the new packaging that the product has been repackaged by him.

13. It follows from what has been stated above that, subject to consideration of the facts of a particular case, it is irrelevant in answering the legal question raised regarding the substance of trade mark law that the question referred by the national court is exclusively concerned with medicinal products.'

Accordingly, the Court made the following ruling:

'(a) The proprietor of a trade mark right which is protected in two Member States at the same time is justified pursuant to the first sentence of Article 36 of the EEC Treaty in preventing a product to which the trade mark has lawfully been applied in one of those States from being marketed in the other Member State after it has been repacked in new packaging to which the trade mark has been affixed by a third party.

- (b) However, such prevention of marketing constitutes a disguised restriction on trade between Member States within the meaning of the second sentence of Article 36 where:
 - It is established that the use of the trade mark right by the proprietor, having regard to the marketing system which he has adopted, will contribute to the artificial partitioning of the markets between Member States;
 - It is shown that the repackaging cannot adversely affect the original condition of the product;
 - The proprietor of the mark receives prior notice of the marketing of the repackaged product; and
 - It is stated on the new packaging by whom the product has been repackaged.'

45. The second case in which the Court has dealt with the legality of using a trade mark to prevent parallel imports of repackaged

pharmaceuticals was Pfizer v Eurim-Pharm. 7 The facts of that case were as follows. Pfizer marketed an antibiotic under the trade mark 'Vibramycin' through its subsidiary companies in Germany and the United Kingdom. The packaging used by Pfizer in those two countries differed and the prices charged were considerably lower in the United Kingdom. Eurim-Pharm imported and sold in Germany Vibramycin which had been marketed in the United Kingdom by Pfizer in packets containing a number of blister strips. Each blister strip contained five capsules and the words 'Vibramycin Pfizer' appeared on a sheet incorporated in each blister strip. Eurim-Pharm removed the blister strips from the manufacturer's original external packaging and placed each strip in a new box designed by it, without altering the strip or its contents. On the front of the box there was an opening covered with transparent material through which the words 'Vibramycin Pfizer' appearing on the sheet incorporated in the blister strips were visible. The back of the box bore a statement that the goods had been manufactured by the United Kingdom subsidiary of Pfizer and had been imported and repackaged by Eurim-Pharm. A leaflet was inserted in the box containing information about the product, in accordance with German law. Pfizer sought an injunction in the German courts to prevent Eurim-Pharm from marketing the repackaged Vibramycin on the ground that such a practice amounted to an infringement of its trade mark. The Landgericht Hamburg requested a preliminary ruling from the Court of Justice.

46. In its judgment the Court of Justice repeated the observations that it had made

7 — Case 1/81 [1981] ECR 2913.

in Hoffmann-La Roche v Centrafarm about the specific subject-matter and essential function of the trade mark and about its role as a guarantee of origin. It then stated:

'10. No use of the trade mark in a manner liable to impair the guarantee of origin takes place in a case such as the one in point where, according to the findings of the national court and the terms of the question submitted by it, a parallel importer has repackaged a pharmaceutical product merely by replacing the outer wrapping without touching the internal packaging and by making the trade mark affixed by the manufacturer on the internal packaging visible through the new external wrapping.

11. In such circumstances the repackaging in fact involves no risk of exposing the product to interference or influences which might affect its original condition and the consumer or final user of the product is not liable to be misled as to the origin of the product, above all where, as in this case, the parallel importer has clearly indicated on the external wrapping that the product was manufactured by a subsidiary of the proprietor of the trade mark and has been repackaged by the importer.

12. The fact that the parallel importer inserted in the external packaging a leaflet

containing information relating to the medicinal product ... does not affect this conclusion.'

held in the latter State by the same proprietor.

47. Another case which is indirectly relevant is Centrafarm v American Home Products Corporation, 8 in which the Court's approach closely resembled that followed in Hoffmann-La Roche v Centrafarm. American Home Products Corporation sold the same pharmaceutical product under the name 'Serenid' in the United Kingdom and under the name 'Seresta' in the Netherlands. Centrafarm bought pharmaceuticals which American Home Products Corporation had marketed in the United Kingdom under the name 'Serenid' and remarked them with the name 'Seresta' before marketing them in the Netherlands. Under Dutch law that amounted to a trade mark infringement. Litigation was commenced before a Dutch court, which sought a preliminary ruling on whether reliance on a trade mark in such circumstances was compatible with the Treaty rules on the free movement of goods. The Court stated as follows:

'18. The proprietor of a trade mark which is protected in one Member State is ... justified pursuant to the first sentence of Article 36 in preventing a product from being marketed by a third party in that Member State under the mark in question even if previously that product has been lawfully marketed in another Member State under another mark 19. Nevertheless it is still necessary to consider whether the exercise of that right may constitute a "disguised restriction on trade between Member States" within the meaning of the second sentence of Article 36.

20. In this connexion it should be observed that it may be lawful for the manufacturer of a product to use in different Member States different marks for the same product.

21. Nevertheless it is possible for such a practice to be followed by the proprietor of the marks as part of a system of marketing intended to partition the markets artificially.

22. In such a case the prohibition by the proprietor of the unauthorized affixing of the mark by a third party constitutes a disguised restriction on intra-Community trade for the purposes of the above-mentioned provision.

8 — Case 3/78 [1978] ECR 1823.

23. It is for the national court to settle in each particular case whether the proprietor

has followed the practice of using different marks for the same product for the purpose of partitioning the markets.'

48. I will conclude this survey of the case-law by noting that the Court made a more emphatic statement about the role of trade marks in a developed economy in *CNL-Sucal* v HAG GF ('HAG II'). ° There the Court stated:

"Trade mark rights are, it should be noted, an essential element in the system of undistorted competition which the Treaty seeks to establish and maintain. Under such a system, an undertaking must be in a position to keep its customers by virtue of the quality of its products and services, something which is possible only if there are distinctive marks which enable customers to identify those products and services. For the trade mark to be able to fulfil this role, it must offer a guarantee that all goods bearing it have been produced under the control of a single undertaking which is accountable for their quality."

(2) Council Directive 89/104

49. The Directive was adopted on the basis of Article 100a of the Treaty. Its purpose is to eliminate disparities in the trade mark laws of the Member States 'which may impede the free movement of goods and freedom to provide services and may distort competition within the common market': see the first recital in the preamble. The use of the epithet 'first' in the title of the Directive implies that the approximation of national laws brought about by the Directive is not intended to be complete. That is confirmed by the third recital in the preamble, which states that 'it does not appear to be necessary at present to undertake full-scale approximation of the trade mark laws of the Member States and it will be sufficient if approximation is limited to those provisions of law which most directly affect the functioning of the internal market.'

50. Article 5 of the Directive defines the rights conferred by a trade mark. It provides, in material part, as follows:

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

- (a) any sign which is identical with the trade mark in relation to goods or services which are identical with those for which the trade mark is registered;
- (b) any sign where, because of its identity with, or similarity to, the trade mark and the identity or similarity of the goods or

^{9 —} Case C-10/89 [1990] ECR I-3711, paragraph 13 of the judgment.

services covered by the trade mark and the sign, there exists a likelihood of confusion on the part of the public, which includes the likelihood of association between the sign and the trade mark.

2. ...

...'

Article 6(1) provides:

'1. The trade mark shall not entitle the proprietor to prohibit a third party from using, in the course of trade,

(a) ...

- 3. The following, *inter alia*, may be prohibited under paragraphs 1 and 2:
- (a) affixing the sign to the goods or to the packaging thereof;
- (b) offering the goods, or putting them on the market or stocking them for these purposes under that sign, or offering or supplying services thereunder;
- (c) importing or exporting the goods under the sign;
- (d) using the sign on business papers and in advertising.

- (b) ...
- (c) the trade mark where it is necessary to indicate the intended purpose of a product or service, in particular as accessories or spare parts;

provided he uses them in accordance with honest practices in industrial or commercial matters.'

51. The exhaustion of rights is dealt with in Article 7, the text of which I have already quoted in paragraph 13 of this Opinion.

52. Article 16 provides:

'1. The Member States shall bring into force the laws, regulations and administrative provisions necessary to comply with this Directive not later than 28 December 1991. They shall immediately inform the Commission thereof.

2. Acting on a proposal from the Commission, the Council, acting by qualified majority, may defer the date referred to in paragraph 1 until 31 December 1992 at the latest.

53. By Decision 92/10/EEC ¹⁰ the Council made use of the power conferred on it by Article 16(2) and postponed the deadline for implementing the Directive until 31 December 1992.

(3) The relationship between the Treaty provisions and the Directive

54. The relationship between Articles 30 to 36 of the Treaty and the provisions of the

10 - OJ 1992 L 6, p. 35.

55. Two further issues must be addressed at this point, namely the direct effect of the Directive and its temporal application.

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...,

the question whether the provisions of the Directive have replaced, or merely supplemented, those of the Treaty. In my view, once the Community legislature has adopted specific provisions dealing with the effects of a trade mark and in particular with the issue of exhaustion, it is logical to seek a solution in the terms of the relevant legislation. That does not however mean that Articles 30 and 36 of the Treaty may be disregarded entirely. On the contrary, the Directive must be interpreted in the light of the Treaty provisions. If there were any conflict between them and the Directive, the conflict would have to be resolved by giving precedence to the Treaty provisions, which are a primary source of law. Clearly a directive adopted under Article 100a of the Treaty for the purpose of approximating the laws of the Member States could not derogate from the fundamental rules of the Treaty on the free movement of goods. Certainly a directive could not legitimize obstacles to trade between Member States which would otherwise be contrary to Articles 30 and 36 of the Treaty. Fortunately, as I shall seek to demonstrate, there is not in my view any conflict between the Treaty provisions and those of the Directive.

Directive has been discussed at considerable length in some of the observations submitted

to the Court. The discussion has centred on

56. As regards the first issue, it is now well established that a directive cannot produce what is known as horizontal direct effect; in other words, it can only be relied on in proceedings against the State or some public body. ¹¹ The national courts are however under a duty to interpret national legislation in the light of a directive so as to ensure, wherever possible, that the result prescribed by the directive is attained. ¹² That duty applies as regards not only national legislation specifically introduced in order to implement a directive but also other provisions of national law, including those adopted before the directive.

57. As regards the temporal application of the Directive, it is not disputed that the Directive is relevant in the cases referred by the Danish courts. Denmark adopted legislation implementing the Directive before the expiry — on 31 December 1992 — of the period prescribed for its implementation. Such legislation must obviously be interpreted in the light of the Directive, even as regards the period between its adoption and the expiry of the time-limit for implementing the Directive. ¹³

58. In Germany the Directive was not implemented within the prescribed period and according to the written observations of Boehringer it had still not been implemented when those observations were lodged in June 1994. The Commission contends that the Directive cannot be relevant in the German cases because the importations which gave rise to the litigation occurred before 31 December 1992. In so far as damages are sought for alleged trade mark infringements which took place before that date, the Commission's contention is doubtless correct, on the assumption — which I accept — that before the expiry of the time-limit for implementing a directive the national courts' duty to interpret its domestic law in the light of the directive applies only as regards legislation adopted specifically for the purpose of implementing the directive. It must however be borne in mind that in all the present cases the trade mark proprietors seek injunctions as well as damages. While damages are a remedy for wrongs done in the past, an injunction is a remedy designed to prevent a wrong from occurring or recurring in the future. Any injunction granted by the national courts after a preliminary ruling is delivered in the present cases will necessarily

^{11 —} Casc 152/84 Marshall v Southampton and South-West Hampshire Area Health Authority [1986] ECR 723, paragraph 46 of the judgment, Case C-91/92 Faccini Dori v Reereb [1994] ECR I-3325 and Case C-316/93 Vaneetveld [1994] ECR I-763.

Case 14/83 Von Colson and Kamann v Land Nordrhein-Westfalen [1984] ECR 1891, paragraph 26 of the judgment, and Case C-106/89 Marleasing [1990] ECR I-4135, paragraph 8.

^{13 —} See Prechal, Directives in European Community law: a study of directives and their enforcement in national courts, Oxford, 1995, p. 207; see also my Opinion in Case C-156/91 Hansa Fleisch Ernst Mundt [1992] ECR I-5567, paragraph 23.

relate to the period subsequent to 31 December 1992. After that date the national courts' duty to interpret domestic law in the light of the Directive applies not just to specific implementing legislation but to *all* provisions of domestic law. Thus, in deciding whether to grant the injunctions sought by the trade mark owners, the German courts should seek to interpret the relevant provisions of German law in such a way as to ensure that the result prescribed by the Directive is attained.

III. The exhaustion of rights in relation to repackaged goods

59. I shall first examine the position under Articles 30 and 36 of the Treaty and then consider whether the Directive has changed matters.

(1) Repackaging under the Treaty rules

(a) The basis of exhaustion: marketing in the Community with the consent of the trade mark owner

60. The basis of the exhaustion principle is the idea that commerce would be fettered unjustifiably if the proprietors of intellectual property rights were able to use those rights in order to control further dealing in goods when they have voluntarily transferred ownership of the goods to other persons. The exclusivity attaching to a trade mark, patent, design right, copyright etc. applies only to the first sale; the owner of the right must take his profit on that sale and relinquishes the power to prevent subsequent owners of the goods from reselling them or otherwise dealing with them as they see fit.

61. The exhaustion principle, or something analogous, exists in most legal systems and typically applies only to goods marketed within national territory. In accordance with the single-market philosophy of the Treaty the Court has consistently applied a Community-wide doctrine of exhaustion: any sale within the territory of the Community, made with the consent of the owner of an intellectual property right, exhausts the right. The justification for that approach is that if the proprietor of the right could preclude the importation and sale of products marketed in another Member State by him or with his consent, he would be able to partition the national markets and thus restrict trade between Member States, even though such a restriction is not necessary to protect the substance of the right. 14 What matters for the application of the exhaustion principle, according to the case-law of the Court, is not whether the owner of the right obtains a fair reward from the sale, but whether he consents to it. 15

^{14 —} Case 187/80 Merck v Stephar and Exler [1981] ECR 2063, paragraphs 10 and 11 of the judgment, and Case 19/84 Pharmon v Hoechst [1985] ECR 2281, paragraphs 25 and 30.

^{15 —} See, for example, Case 15/74 Centrafarm v Sterling Drug [1974] ECR 1147, paragraph 12 of the judgment.

62. In all of the present cases the trade mark proprietor opposing parallel imports is part of the same group of companies as the undertaking which manufactured the imported goods and placed them on the market in another Member State. The trade mark proprietors are therefore deemed to have consented to the marketing of the goods in question: the goods fall within the formula products put into circulation by the same undertaking, by a licensee, by a parent company, by a subsidiary of the same group, or by an exclusive distributor', which the Court used in IHT Internationale Heiztechnik v Ideal Standard 16 to define the situations in which the exhaustion principle applies. It is necessary to consider whether there are any grounds for not applying that principle in the present cases.

(b) The two types of repackaging: are they really different?

63. The previous case-law dealt with two situations which, for convenience, I shall call 'Situations A and B'. In Situation A the parallel importer removes the goods from their original external packaging and, without altering the internal packaging, places the goods in new external packaging to which he affixes the trade mark. In Situation B the parallel importer likewise replaces the external packaging but, instead of affixing the trade mark to the new external packaging, he designs that packaging in such a way that the trade mark affixed to the internal packaging by the proprietor of the mark remains visible.

64. Situation A was considered by the Court in Hoffmann-La Roche v Centrafarm. 17 Situation B was at issue in Pfizer v Eurim-Pharm. 18 In the former case the Court established the basic rule that under the first sentence of Article 36 the proprietor of a trade mark is entitled to prevent an importer of the trade-marked product, following repackaging of the product, from affixing the trade mark to the new packaging without the authorization of the proprietor (paragraph 8 of the judgment). The basis for that rule was that the guarantee of origin implied by the trade mark means that the consumer can be certain that a trade-marked product has not been subject to interference by a third party, without the authorization of the proprietor of the trade mark, such as to affect the original condition of the product (paragraph 7 of the judgment). The Court went on to hold that that basic rule ceases to apply if a disguised restriction, within the meaning of the second sentence of Article 36, exists; such a restriction may arise if the proprietor of the trade mark markets in various Member States an identical product in different packaging and invokes the trade mark in order to prevent repackaging even if it is done in such a way that the identity of origin of the trade-marked product and its original condition cannot be affected (paragraph 9 of the judgment).

17 — Cited at note 6. 18 — Cited at note 7. 65. In *Pfizer* the Court considered that the repackaging carried out in Situation B could not impair the trade mark's function as a guarantee of origin, since it could not affect the condition of the goods and could not mislead the consumer as to the origin of the goods; there was therefore no justification for allowing the proprietor of the trade mark to oppose parallel imports. The Court appears to have reached that conclusion on the basis of the first sentence of Article 36, without having to consider the issue of a disguised restriction under the second sentence.

66. In my view, it would not be appropriate to make a rigid distinction between Situation A and Situation B; nor do I think that the case-law should necessarily be read as establishing a rigid distinction. There appears to be little difference of substance between the two situations. The point will perhaps become clearer if a more mundane example, far removed from the somewhat special market in pharmaceutical products, is considered. Suppose, for example, that Company X buys a large quantity of a well-known carbonated beverage which has been placed in cardboard boxes, each containing 100 cans bearing the trade mark 'Coca Cola', by the Coca Cola Company and marketed in Member State A; Company X removes the external packaging and places 12 cans of the beverage in a cardboard box and writes on the outside of the box '12 cans of Coca Cola manufactured by the Coca Cola Company, Atlanta, USA, and repackaged by Company X'. If Company X then imports the product into Member State B, would there be any justification for allowing the proprietor of the trade mark 'Coca Cola' to block

such parallel imports? Would the justification be any greater than if Company X placed 12 cans of Coca Cola in a cardboard box with cellophane windows through which the trade mark on the cans could be seen?

67. In my view, it is difficult to see how there can be grounds for opposing parallel imports in the one case but not in the other. In neither case does Company X misappropriate goodwill belonging to the Coca Cola Company or represent its own goods as being the goods of another. In neither case does the repackaging impair the ability of the trade mark to function as a guarantee of origin. In both cases it is equally clear that the repackaging cannot affect the quality of the goods.

68. It would of course be a different matter if Company X bought Coca Cola in 100 litre barrels and then transferred the beverage to cans on which it placed the trade mark. In such a case there would be no way of ensuring that the repackaging did not affect the quality of the product. The beverage might be contaminated or adulterated and the trade mark's function as a guarantee of origin would clearly be compromised. This suggests that the crucial factor in determining whether the trade mark proprietor is justified in opposing parallel imports of repackaged goods is, not whether the parallel importer affixes the trade mark to the goods or merely allows the original mark to remain visible, but whether he interferes with the goods in such a way that it is no longer possible to be certain that their original condition has not been affected. condition of the goods. That, in my view, is a correct interpretation of Article 36, for reasons which I shall explain in the following section.

69. That is in fact confirmed by a closer examination of the Court's reasoning in Hoffmann-La Roche v Centrafarm. In the part of the judgment which established the basic rule that the trade mark proprietor may prevent the sale of repackaged goods on which the trade mark is affixed without the proprietor's consent the Court was addressing the issue of repackaging in the most general terms. There is no reference in paragraphs 7 and 8 of the judgment to the specific facts of the case, and the rule established there is clearly designed to cover the type of situation in which the repackaging is done in such a way that the original condition of the goods may be affected (for example, the situation which Ι have described in the previous paragraph).

70. It was only in the following part of the judgment (paragraphs 9 and 10) that the Court dealt with the specific situation which arose in Hoffmann-La Roche v Centrafarm: namely, a situation in which the trade mark proprietor uses different packaging in different Member States, the goods are packed in two layers and only the outer layer is changed. That part of the judgment, together with the judgment in Pfizer v Eurim-Pharm, establishes that the trade mark cannot be used to prevent the sale of repackaged goods where the use of different packages in different Member States has led to a partitioning of the market and where it is established that the repackaging cannot affect the original (c) The true basis for restricting the application of the exhaustion principle in relation to repackaged goods

71. What exactly does Article 36 mean when it authorizes trade restrictions 'justified ... on grounds of the protection of industrial and commercial property', provided that they do not constitute a means of 'arbitrary discrimination' or a 'disguised restriction' on trade between Member States? To answer that question, in relation to restrictions based on trade mark rights, it is necessary to consider the fundamental issue why trade mark protection exists at all.

72. All advanced legal systems grant traders the right to use certain distinctive signs and symbols in relation to their goods. They do so (a) in order to enable traders to protect the reputation of their goods and prevent the theft of their goodwill by unscrupulous competitors who might otherwise be tempted to pass their own goods off as those of another trader with an established reputation and (b) in order to enable consumers to make informed purchasing choices on the basis of the assumption that goods sold under the same name will emanate from the same source and will, in normal circumstances, be of uniform quality. Thus trade mark law seeks to protect the interests, not only of the trade mark proprietor, but also of the consumer. In so far as the trade mark protects the interests of its proprietor by enabling him to prevent competitors from taking unfair advantage of his commercial reputation, the exclusive rights conferred on the proprietor are said, in the language of the Court's case-law, to constitute the specific subject-matter of the trade mark. In so far as the trade mark protects the interests of consumers by acting as a guarantee that all goods bearing the mark are of the same commercial origin, that is known, in the Court's terminology, as the essential function of the trade mark. Those two aspects of trade mark protection are of course two sides of the same coin.

73. It is most emphatically not the purpose of trade marks to help traders to divide up the common market, to maintain price differentials between different Member States and to create or reinforce artificial barriers to trade between Member States. Where price differentials are caused by matters lying outside the control of the manufacturer, such as statutory price controls or rules on the reimbursement of medical expenses, it is understandable that the manufacturer will feel aggrieved if goods which he has placed on the market in one Member State at a controlled price find their way on to the market in another Member State where there is theoretically a free market but where the manufacturer's freedom will be circumscribed by having to face competition from parallel imports of his own goods.

74. In a sense the net effect of the free movement of goods in such a context is to export one country's price legislation to the rest of the common market. While manufacturers may regard that as unfair, it cannot justify the use of trade marks to exclude parallel imports of goods which the trade mark owner has placed on the market under a regime of statutory price controls. It is clearly not the function of trade marks to redress distortions caused by divergent legislation on prices.

75. It is well established that the exhaustion principle does not cease to apply simply because the goods in question were placed on the market in a Member State where price controls exist. In Centrafarm v Winthrop 19 the Court held that a trade mark cannot be invoked in order to exclude parallel imports of goods which the trade mark owner has placed on the market, under the trade mark, in another Member State where price controls were applicable. In Centrafarm v Sterling Drug 20 the Court held that the holder of parallel patents in the Netherlands and the United Kingdom could not rely on the Dutch patent in order to prevent imports into the Netherlands of pharmaceuticals which it had marketed in the United Kingdom, where statutory price controls were in force.

^{19 -} Case 16/74 [1974] ECR 1183.

^{20 -} Cited at note 15.

76. As far as patents are concerned, the application of the exhaustion principle in such a situation is open to criticism on the ground that the very purpose of a patent (or its specific subject-matter) is to enable the holder to obtain a fair reward for his contribution to scientific progress and that he may not be able to obtain a fair reward if he is not allowed to fix his own selling prices. But that criticism cannot apply in relation to trade marks, the purpose of which is entirely different. None of the interests protected by a trade mark (i. e. the specific subject-matter and essential function of the trade mark, as defined in paragraph 72 above) is affected by rules which restrict the trade mark owner's freedom to fix his own selling prices. The trade mark's ability to function as a guarantee of origin is not impaired simply because the exhaustion principle is applied to goods which have been placed on the market at a regulated price.

77. In order to determine what restrictions on trade are permitted by Article 36 on grounds of trade mark protection it is necessary to bear in mind at all times the interests defined above in paragraph 72. It is necessary to balance those interests against the fundamental concern of Article 30, which is to ensure that goods can circulate freely within the Community and that trade between Member States is not hindered any more than necessary. That is what the Court means when it emphasizes, as it has on numerous occasions, that Article 36, as an exception to a fundamental principle, must be construed narrowly and can only be invoked in favour of restrictions which are necessary in order to safeguard the specific subject-matter of an industrial property right.

78. Thus in order to determine whether the trade mark owner may oppose parallel imports of repackaged goods the following questions must be asked. Has the condition of the goods been so modified that they can no longer truthfully be described as the goods of the trade mark owner, with the result that the parallel importer would unfairly be taking advantage of the reputation of the trade mark? Has the condition of the goods been modified in such a way that their further marketing under the trade mark might unfairly damage the reputation of the trade mark? Would consumers be misled, in the sense that they would assume that the goods had been produced under the control of the trade mark owner and so possess the quality normally associated with the trade mark when in fact, as a result of the repackaging, the goods have been interfered with in such a way that their original quality may have been impaired? In other words, is the trade mark's function as a guarantee of origin compromised?

79. If any of those questions is answered in the affirmative, the trade mark owner would be justified in opposing parallel imports of repackaged goods. If, on the other hand, all those questions receive a negative answer, it is difficult to see what justification there can be for allowing the free movement of goods to be impeded in the name of trade mark protection. Certainly some of the additional factors alluded to by the trade mark owners in the present cases are irrelevant. The fact that the trade mark owners have spent large sums of money in promoting their goods in Denmark and Germany cannot justify them in attempting to exclude competition from goods which they have themselves marketed

in other Member States. Equally irrelevant, for the reasons given above, is the fact that they have had to sell their goods at lower prices in other Member States as a result of statutory price controls or rules governing the reimbursement of medical expenses. trade mark owner has deliberately used different packaging with a view to artificially partitioning the market.

82. That is not to say that the issue of a dis-

(d) The concept of a disguised restriction

80. The trade mark owners in these proceedings argue, on the basis of the Court's judgments in Hoffmann-La Roche v Centrafarm and Centrafarm v American Home Products Corporation, ²¹ that one further condition must be satisfied before they lose the right to oppose parallel imports of repackaged goods to which the trade mark has been affixed without their authorization. They contend that it must be established that by using different packaging in different Member States they have deliberately sought to partition the market artificially and thus create a disguised restriction on trade between Member States.

81. I disagree with that view. If the repackaging is done in such a way that it does not compromise the trade mark's function as a guarantee of origin and does not impair the reputation of the trade mark, there seems no valid reason for saying that the parallel importer should only be allowed to sell the repackaged goods if he can show that the

guised restriction is irrelevant, still less to pretend that the second sentence of Article 36 does not exist. The two sentences of Article 36 should in my view be read as whole. It is a mistake to construe the second sentence as an exception to a general rule laid down in the first sentence (or, as Boehringer Ingelheim and Farmitalia contend, as a counter-exception, on the assumption that Article 30 lays down the general rule and that the first sentence of Article 36 lays down an exception to that rule). Either a measure is justified on one of the grounds listed in Article 36 or it is not justified. One of the factors to be taken into account in assessing justification is whether the measure leads to a disguised restriction, in other words whether the measure, though ostensibly intended to safeguard industrial property, is really designed to achieve some other purpose unconnected with trade mark protection. If a trade mark owner uses the trade mark in order to exclude parallel imports of his own goods when the sale of those goods does not threaten the interests protected by the specific subject-matter of the trade mark and does not compromise the essential function of the trade mark by preventing it from acting as a guarantee of origin, then the presumption inevitably arises that the trade mark is being used for some other purpose, for example to cause or reinforce a partitioning of the common market and to allow the

trade mark owner to maintain price

^{21 -} Cited at note 8.

differences in the various Member States. The fact that such partitioning occurs as a result of rules governing the sizes of pharmaceutical products is not, in my view, relevant. If a trade mark owner takes advantage of a situation that has arisen as a result of circumstances outside his control and relies on his trade mark in order to exclude parallel imports even though the exclusion of such imports is not necessary on grounds of trade mark protection, his conduct must amount to an abusive exercise of the trade mark and a disguised restriction on trade.

outside their control. It would in any event be illogical and impracticable to require proof of a deliberate intention to partition the market by the use of different packaging. Such an intention might be difficult, or indeed impossible, to prove. A parallel importer who wishes to repackage goods needs to be able to determine with a reasonable degree of certainty whether he may lawfully do so. The legality of his conduct should not depend on the subjective intentions of another person.

83. Although in Hoffmann-La Roche v Centrafarm the Court spoke of an artificial partitioning of the market, it did not say that a disguised restriction on trade exists only if the trade mark owner deliberately contrives to partition the market by using different packaging. The Court said that a disguised restriction exists if it is established that 'the use of the trade mark right by the proprietor, having regard to the marketing system which he has adopted, will contribute to the artificial partitioning of the markets between Member States'. 22 Although that wording is not without ambiguity, it seems to imply an essentially objective test. In so far as a subjective element is required the mere fact of relying on a trade mark to prevent parallel imports which do not threaten the specific subject-matter or essential function of the trade mark is sufficient. Trade mark owners are mistaken if they believe that they are free to exploit, in any way that suits them, a partitioning of the market caused by factors

84. Finally, it may be noted that there is a marked contrast between the judgment in Hoffmann-La Roche v Centrafarm and the judgment delivered several months later in Centrafarm v American Home Products Corporation as regards the relevance of an intention to partition the market. In the later judgment the Court did indeed make it clear that, where the trade mark owner uses different marks in different Member States for the same product, a parallel importer is not entitled to substitute one mark for the other unless the use of different marks is deliberately intended to partition the market. 23 However, it seems to me that rather more difficult problems arise when the parallel importer changes the trade mark, as opposed to simply changing the packaging, and different solutions may be called for.

22 — Paragraph 10 of the judgment.

23 - See paragraphs 21 to 23 of the judgment.

(e) The additional conditions which the parallel importer must satisfy

85. In Hoffmann-La Roche v Centrafarm the Court held that a parallel importer who affixed the trade mark to repackaged products must give prior notice of the marketing of the repackaged product to the proprietor of the trade mark and must state on the new packaging by whom the product had been repackaged. It has been suggested in Case C-232/94 that the repackaged product should also bear a statement that the repackaging has taken place without the consent of the proprietor of the trade mark. The questions referred in Joined Cases C-71/94, C-72/94 and C-73/94 imply that the failure to mention the name of the manufacturer on the new packaging may be a ground for allowing the trade mark owner to oppose parallel imports.

86. The precise justification for a requirement that the trade mark owner must receive prior notice of the repackaging is not clear from the judgment in Hoffmann-La Roche v Centrafarm, and there may be circumstances in which such notice would be superfluous. In general it does not however seem an unreasonable requirement, at least in relation to pharmaceuticals. It can be justified on the ground that it makes it easier for the trade mark owner to verify the authenticity of repackaged goods and thus combat the activities of counterfeiters. If trade-marked goods were to appear in various parts of the Community in unfamiliar packaging, it might be difficult for the proprietor of the trade mark to determine whether the goods were genuine. That task is to some extent simplified if the new packaging and the identity of the undertaking responsible for it have been made known to the proprietor of the mark in advance. The dangers of counterfeiting, from the point of view of the public, are particularly serious in the case of pharmaceuticals.

87. I would in fact go slightly further than the Court went in Hoffmann-La Roche v Centrafarm and hold that an undertaking which repackages trade-marked pharmaceuticals must not only give prior notice to the trade mark owner but must also provide him with a specimen of the repackaged product, so that the trade mark owner may point out any deficiencies and demand that they be corrected. The original packaging may contain important information (for example, that the pharmaceuticals are sensitive to light, that they must be stored at a certain temperature and out of reach of children, etc.). The trade mark owner should be entitled to object to the marketing of repackaged goods if such information is not reproduced on the new packaging. Some of these particulars must in any case be mentioned on the outer packaging of medicinal products by virtue of Article 2 of Council Directive 92/27/EEC of 31 March 1992 on the labelling of medicinal products for human use and on package leaflets. 24

88. The requirement that the repackaged product must bear a statement identifying the undertaking responsible for the repack-

24 — OJ 1992 L 113, p. 8.
aging is obviously justified. Without such a statement the impression would be created that the owner of the trade mark was responsible for the new packaging and for any defects in it. A parallel importer who engages in repackaging must indicate what part he has played in altering the appearance of the product. On the other hand, I do not think that it is necessary to indicate that the repackaging has been carried out without the consent of the trade mark owner. Such a statement, which would inevitably be seen to imply that the repackaged product is not entirely legitimate, is not necessary for the purpose of ensuring that the trade mark functions as a guarantee of origin. Nor do I think that it is essential to mention the name of the manufacturer on the new packaging. Although the parallel importer will normally want to include such information, it is difficult to see how its omission can affect the function of the trade mark or be detrimental to the interests of the trade mark owner, at least where he is identified as the manufacturer of the goods on the original internal packaging.

them in new external packaging, to which he affixes the trade mark or through which the trade mark affixed to the internal packaging remains visible, and markets the repackaged goods in another Member State, the proprietor of the trade mark cannot invoke it in order to prevent such marketing unless the repackaging is done in such a way that it is capable of affecting the original condition of the goods or otherwise impairing the reputation of the trade mark. The person who repackages the goods must in principle inform the trade mark proprietor and provide him with a specimen of the repackaged product. He must also indicate on the repackaged product that he is responsible for the repackaging but need not mention the manufacturer of the goods or state that the proprietor of the trade mark has not authorized the repackaging.

(2) Repackaging under the Directive

(f) A general conclusion

89. On the basis of the above considerations I arrive at the following general conclusion:

Where goods bearing a trade mark are placed on the market in a Member State with the consent of the proprietor of the trade mark and another person buys those goods, places 90. Exactly the same results should be reached, in my view, under Article 7 of the Directive.

91. Article 7 was clearly modelled on the Court's case-law establishing the principle of exhaustion. That is apparent from its terms and from the heading above the text of the article, which reads 'Exhaustion of the rights conferred by a trade mark'. The purpose of Article 7 was to ensure that the principle of Community-wide exhaustion was enshrined in the domestic laws of the Member States, some of which regarded intellectual property rights as being exhausted only by marketing within their national territory.

92. Thus Article 7(1) provides that the proprietor of the trade mark may not prohibit its use in relation to goods which have been put on the market in the Community under the trade mark by the proprietor or with his consent. Those words strongly echo the language used in the Court's judgments establishing the exhaustion principle.

93. Article 7(2) of the Directive, like the Court's case-law, recognizes that the exhaustion principle is not absolute: it does not apply where there exist 'legitimate reasons' for the proprietor of the trade mark to oppose further marketing of the goods, 'especially where the condition of the goods is changed or impaired after they have been put on market'. Once again the language of the Directive echoes the Court's case-law, in particular the judgments in Hoffmann-La Roche v Centrafarm and Pfizer v Eurim-Pharm. It cannot therefore be contended that the previous case-law has become redundant. On the contrary, Article 7(2) is so vague that it needs to be supplemented by an awareness of the case-law. The imprecise reference to the condition of the goods being changed or impaired offers little guidance, by itself, as to what may constitute 'legitimate reasons' for not applying the principle of exhaustion. The

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relevance of such matters only becomes apparent through study of the case-law.

94. It would not however be appropriate to say that the Directive purports to 'codify' the case-law. The brevity of Article 7(2) suffices to show that it pursues no such aim. There are good reasons for that. It is questionable to what extent the Council is competent under Article 100a of the Treaty to codify case-law relating to Article 36 of the Treaty. Moreover, the Council doubtless realized that principles established in a handful of cases were not yet ready to be fixed in anything resembling a legislative code, but must instead be allowed to evolve in the light of whatever factual situations might be thrown up by the accidents of litigation. The use of the word 'especially' in Article 7(2) confirms the non-exhaustive nature of that provision and shows that the Council did not intend to fetter the Court's power to define, and redefine, the circumstances which justify the trade mark proprietor's opposition to further dealings in trade-marked goods after the first marketing.

95. Like Article 36 of the Treaty, Article 7 of the Directive seeks to strike a balance between the free movement of goods within the common market and the protection of trade mark rights. The appropriate balance can be found by permitting restrictions on free movement only if they are necessary in order to safeguard the specific subject-matter and essential function of the trade mark. Hence the discussion in paragraphs 71 to 89 above is equally relevant to the interpretation of the Directive. The principal effect of Article 7 of the Directive is simply that, once the Directive is properly implemented, a solution can be found in the national implementing measures. Whereas previously there might have existed a conflict between national law and the Treaty (a conflict which would have had to be resolved by disapplying the offending provisions of national law), national law should now be consistent with the Treaty: the principle of Communitywide exhaustion of trade mark rights, subject to the 'legitimate reasons' exception, should, after proper implementation of the Directive, now be built into the national law of the Member States. That, in my opinion, is all that Article 7 of the Directive was intended to achieve.

96. The German Government and the trade mark proprietors in Joined Cases C-427/93, C-429/93 and C-436/93 argue in effect that Article 7 has granted more extensive rights to trade mark proprietors and has limited the circumstances in which the exhaustion principle applies in relation to repackaged goods. According to that argument, Article 7(1) applies only to goods which are marketed in their original state, i. e. in their original packaging. Thus, the trade mark owner may oppose the marketing of repackaged goods on which the trade mark is placed without his consent, even though the condition of the goods cannot be affected by the repackaging. 97. I do not agree with that argument. In the first place, it is difficult to reconcile with the wording of Article 7(2), according to which Article 7(1) ceases to apply only where there are legitimate reasons for allowing the trade mark owner to oppose further marketing of the goods. There are clearly situations (such as those described in paragraph 66 above) in which it is by no means obvious that the trade mark owner has any legitimate reason to oppose the use of the trade mark on repackaged goods. To hold that a person who simply changes the external packaging of goods is never allowed to identify the goods by affixing the trade mark to the new packaging would be excessive.

98. Secondly, the above argument disregards the fact that Article 7 was modelled on the case-law of the Court. It is clear from *Hoffmann-La Roche* v Centrafarm that the Court did not take the view that the exhaustion principle is incapable of being applied to repackaged goods to which the trade mark is affixed by a third party. If the legislature had wished to make a radical change in the law, it would surely have done so by clear words rather than by echoing the language of the Court.

99. Thirdly, if the above argument were accepted, it would mean that the Directive had in fact amounted to a backward step in terms of market integration and the removal of barriers to trade between Member States. It would mean that the obstacles to parallel imports are greater now than they were before the adoption of the Directive. The assumption must surely be that the object of harmonizing the laws of the Member States under Articles 100 and 100a of the Treaty is to remove barriers to intra-Community trade, not to strengthen them. that the use of the trade mark contributes to the artificial partitioning of markets and *it is shown* that the repackaging cannot adversely affect the original condition of the product (see paragraph (b) of the operative part of the judgment).

(3) The burden of proof

100. The United Kingdom contends that Article 7 of the Directive has one further effect, namely to reverse the burden of proof: whereas the undertaking which affixed the trade mark to repackaged goods previously had the onus of showing that the repackaging could not affect the original condition of the goods, the onus is now on the trade mark owner to demonstrate the existence of legitimate reasons for opposing further marketing of the repackaged goods.

101. I am not persuaded by that contention. I can see no reference, either express or implied, to the burden of proof in Article 7. Article 7 is silent on that issue. Nor did the Court deal expressly with the burden of proof in Hoffmann-La Roche v Centrafarm and Pfizer v Eurim-Pharm. Admittedly, some of the language used in Hoffmann-La Roche v Centrafarm may give the impression that that issue is being addressed. The judgment appears to suggest that the trade mark owner can in principle object to the use of the trade mark on repackaged goods and that he only loses that right in exceptional circumstances, namely where it is established 102. However, I do not think that such language was intended to interfere with technical rules about the burden of proof or to establish a presumption that the trade mark owner's use of the trade mark to prevent the sale of repackaged goods is legitimate until the contrary is proved. The question of proof is a procedural matter and is thus governed, in accordance with the principle of procedural autonomy, by national law. 25 The Court has consistently held that in the absence of any specific rules of Community law it is for the domestic legal system of each Member State to determine the conditions governing the implementation of directly effective Community law in the Member States, provided that two requirements are met: namely, that the procedural rules applicable to claims founded on Community law must not be less favourable than those governing similar actions of a domestic nature and may not be arranged in such a way as to render the exercise of rights flowing from Community law practically impossible or

^{25 —} Joined Cases 205/82 to 215/82 Deutsche Milchkontor v Germany [1983] ECR 2633, paragraphs 36 and 39 of the judgment. On the principle of procedural autonomy in general, see Bridge, 'Procedural aspects of the enforcement of Community law through the legal systems of the Member States' (1984) 9 EL Rev. 28, and Mertens de Wilmars, 'L'efficacité des différentes techniques nationales de protection juridique contre les violations du droit communautaire par les autorités nationales et les particuliers', (1981) 17 CDE 379.

excessively difficult. 26 It is only in exceptional cases that Community law interferes with the power of the national court to apply its own rules on matters such as evidence or the burden of proof. 27 Sometimes Community legislation states expressly on whom the burden of proof falls or specifies what type of proof is required, for example in the field of customs law. 28 Sometimes the Court has expressly ruled that in certain types of case the burden of proving certain matters falls on a particular party. That seems to have occurred mainly in cases relating to equal pay for men and women 29 and the justification for interfering with the procedural autonomy of the Member States has been that the effective exercise of the right to equal pay might be rendered virtually impossible if the burden of proof were imposed on the worker in certain situations. 30

103. It is logical therefore to ask whether in the present cases the application of rules as to the burden of proof may have the effect of making the exercise of rights recognized in Community law virtually impossible or excessively difficult. Two such rights are in

- 26 Sec, for example, Case 33/76 Rewe v Landwirtschaftskammer Saarland [1976] ECR 1989, paragraph 5 of the judgment, Case 199/82 Amministrazione delle Finanze dello Stato v San Giorgio [1983] ECR 3595, paragraphs 12 and 14, Case C-208/90 Emmott [1991] ECR I-4269, paragraph 16, and Joined Cases C-31/91 to C-44/91 Laggeder and Others [1993] ECR I-1761, paragraphs 27 to 29.
- 27 See San Giorgio, cited in note 26, paragraph 14 of the judgment; and Joined Cases C-6/90 and C-9/90 Francovich and Others [1991] ECR I-5357, paragraph 43.
- 28 Scc, for example, the legislation at issue in Case C-83/89 Houben [1990] ECR I-1161 and Case C-301/88 Fish Producers and Grimsby Fish [1990] ECR I-3803.
- 29 Case 109/88 Danfoss [1989] ECR 3199 and Case C-127/92 Enderby [1993] ECR 1-5535.
- 30 See Danfoss, paragraphs 13 and 14 of the judgment, and Enderby, paragraph 14.

issue: namely, the right of trade mark proprietors to prevent unjustified use of their trade marks by third parties and the right of parallel importers to market trade-marked goods, provided that no harm is done to the legitimate interests of the trade mark owners. Both rights are of great importance and any conflict between them must be resolved by balancing the competing interests. None of the parties should be subjected to a probatio diabolica: that is to say, compelled to prove something which cannot be proved or can only be proved with the utmost difficulty. Arguably, that might be the case if the parallel importers were required to prove that the repackaging cannot affect the original condition of the goods. It is a truism to say that proof of a negative is extremely difficult. Clearly the national courts must avoid applying unreasonable rules as to the burden and standard of proof. It would not however be unreasonable to require the parallel importers to show that they take adequate safeguards when repackaging goods, for example that they have proper facilities and employ competent staff.

104. Thus a balanced approach is required, similar to that prescribed by the Court in the Sandoz judgment.³¹ That case concerned a Dutch provision under which food and beverages containing added vitamins could only be sold with the authorization of the competent minister. The Court ruled that 'Community law (i. e. Articles 30 and 36 of the

31 - Case 174/82 [1983] ECR 2445.

Treaty) does not permit national rules which subject authorization to market to proof by the importer that the product in question is not harmful to health, without prejudice to the right of the national authorities to ask the importer to submit all the information in his possession needed to assess the facts'. ³²

105. Sandoz is one of several judgments in which the Court has held that whenever Article 36 is invoked it must in each case be shown that the restriction on imports is necessary for the purpose of safeguarding one of the interests referred to in that provision. 33 What the Court means by such pronouncements is that a national authority --- or a proprietor of an intellectual property right - must, in order to qualify for the benefit of Article 36, do more than make a general reference to one of the interests listed in that provision; a coherent argument is required, showing precisely how the interest in question will be impaired. I do not think that the Court means to lay down technical rules about the incidence of the burden of proof or about the standard of proof.

and do not make the exercise of rights under Community law unduly difficult. Where a trade mark owner objects to the importation of goods which he has placed on the market in another Member State on the ground that they have been repackaged by another person, it would not be unreasonable to require that other person to show that he takes adequate safeguards to ensure that the repackaging is not likely to affect the original condition of the goods.

IV. The application of the above principles to the specific facts of each case

107. It is of course for the national court to determine how the above principles are to be applied to the specific facts of each case. The Court may none the less offer guidance in the light of those facts. That is what I shall now attempt to do.

(1) Case C-427/93

106. I conclude that in principle the national court must apply its own rules of domestic law on the burden of proof, the standard of proof and the admissibility of evidence, provided that such rules are non-discriminatory

32 - Paragraph 24 of the judgment.

^{33 —} Paragraph 22 of the judgment. See also Case 251/78 Denkavit Futtermittel v Minister für Ernährung, Landwirtschaft und Forsten [1979] ECR 3369, paragraph 24, and Case 227/82 van Bennekom [1983] ECR 3883, paragraph 40.

issue the inner packaging does not appear to undergo any alteration except that in some cases (Vepesid, Vumon and Mycostatin) a label is placed on it. In the case of Capoten and Diclocil the pharmaceutical preparation is in the form of pills and the inner packaging consists of blister packets. In the case of Vepesid and Vumon the pharmaceutical preparation is in liquid form and phials are used for the inner packaging. On the new outer packaging Paranova generally uses the same colour scheme as Bristol-Myers Squibb. In one case (Mycostatin) an additional product is inserted in the new packaging, namely a small syringe-like spray. The spray is wrapped in a sealed plastic bag on which the names 'Asic' and 'ONCE' appear; there is no suggestion that these names are trade marks of Bristol-Myers Squibb. It is stated on the external packaging that the box contains a spray which was manufactured by Paranova.

109. The question that arises is whether any of the above operations threatens any of the legitimate interests protected by trade mark law (interests defined above in paragraph 72). The mere fact that Paranova replaces the external packaging and places the trade mark on the new packaging does not seem to affect any of those interests. The product described as 'Capoten' is authentic Capoten produced by Bristol-Myers Squibb. Paranova does not represent its own goods as being those of Bristol-Myers Squibb. The consumer is not deceived into buying a product which appears to emanate from the owner of the trade mark 'Capoten', whereas in fact it comes from a different source. The use of the same colours as on the products marketed in

Denmark by Bristol-Myers Squibb is not misleading; it merely helps to identify the products. No theft of Bristol-Myers Squibb's goodwill takes place. Arguably, if the external packaging were shoddy or defective, it might damage the reputation of the trade mark, but that does not seem to be contended by Bristol-Myers Squibb.

110. As to the crucial question whether the repackaging is capable of affecting the original condition of the goods, the answer appears to be negative in the case of four products. In the case of Capoten and Diclocil the original blister packs are left intact and Paranova simply prints a statement on them (without obscuring the original trade marks) to the effect that the goods have been repackaged by Paranova. In the case of Vepesid and Vumon Paranova apparently removes the original label from the phials or flasks and places a new label on them which identifies the goods and describes Paranova's role. It seems difficult to see how in any of those cases the repackaging can affect the original condition of the goods.

111. Mycostatin is repackaged in the same way as Vepesid and Vumon, and again the original condition of the medicine itself should not be affected. Greater difficulties, however, are posed by the addition of a spray in the case of Mycostatin. In principle a trade mark owner is entitled to object to the insertion, in a packet bearing the trade mark, of goods emanating from a different source since the impression is created that the additional goods were produced under his control. Arguably a clear statement on the side of the packet that the goods were produced by a different undertaking should be capable of dispelling that impression. It is for the national court to determine whether the statement is sufficiently clear and whether, notwithstanding such a statement, responsibility for the additional material might still be attributed to the trade mark owner.

(2) Case C-429/93

the translation of the instructions or that there is a risk of the inhalers being contaminated in the course of repackaging. These are questions of fact to be determined by the national court. As regards the repackaging of Catapresan it is difficult to see how there can be any risk of the original condition of the goods being impaired. Paranova simply removes blister packs from their original boxes and places them in new boxes. The blister strips are not severed and the risk of contamination appears to be minimal, or non-existent. It is for the national court to determine whether the information printed on the new external packaging is accurate and sufficient.

(3) Case C-436/93

112. In principle it is difficult to see how the repackaging carried out by Paranova in this case can affect the original condition of the goods. In the case of Atrovent, Berodual and Berotec Paranova simply removes the aerosol inhalers from their original cardboard boxes and places them in new boxes. Before repackaging the inhalers Paranova places a new sticker on them with information written in Danish. The new sticker completely covers the original sticker. It contains information about the active ingredients, the use-by date and the lot number, and states that the product was imported and repackaged by Paranova. In some cases a Danish version of the instructions for use is inserted.

113. It could be argued that mistakes might be made in reproducing the use-by date or in 114. This case also concerns the repackaging of unsevered blister packs in new external packaging. The remarks made in relation to Catapresan seem to apply equally to the product (Adalat) in issue in this case.

115. It is for the national court to decide whether the failure to include a warning about the photo-sensitivity of the product might justify prohibiting the sale of the goods in question. This point illustrates the desirability of supplying a specimen of the repackaged product to the proprietor of the trade mark. It is hardly necessary to point out that if the warning was not placed on the original packaging the trade mark owner cannot complain about its omission from the repackaged product.

(4) Case C-71/94

116. Three specific features of this case raise particular difficulties. First, there is the question whether the use of severed blister packs and of external packaging with a window through which the trade mark printed on the original internal packaging is visible gives the product a shoddy appearance and whether that alone may be a ground for not applying the exhaustion principle. Secondly, there is the question whether the severing of blister packs involves a risk of contamination. Thirdly, it is necessary to consider whether the interruption — as a result of the severing - of the series of days of the week to which each pill is allocated might confuse the consumer or even endanger his health.

117. The first of these points raises an important general question about the breadth of the protection conferred by a trade mark. Can the trade mark be relied on to prevent the further marketing of repackaged goods on the ground that the repackaging has been done in such a way that, while it does not affect the technical quality of the goods, the image of the mark is capable of being damaged because of the appearance of the repackaged product? Since part of the function of the trade mark is to enable its proprietor to protect his commercial reputation, it would be wrong to say that the trade mark can never be relied on to prevent the further marketing of goods on account of their shoddy appearance. It is obvious that the reputation of the trade mark may suffer if it is used on goods which are badly presented. The importance of presentation may vary depending on the type of goods. For luxury goods such as perfume and jewellery an attractive presentation may be more important than for more functional goods such as pharmaceuticals.

118. Once again it is for the national court to decide whether, on the facts, the appearance of the repackaged goods is capable of damaging the reputation of the trade mark. In doing so it will have to consider whether the statement on the new external packaging to the effect that the goods have been repackaged by Eurim-Pharm excludes any danger of the trade mark being damaged as a result of the alleged shoddiness of the new packaging. It could be argued that in the case of prescription-only pharmaceuticals the relevant persons, for the purpose of deciding whether the reputation of the trade mark is damaged, are the pharmacists who dispense the product and that they, being aware of the existence of parallel imports, know precisely why goods are repackaged and are unlikely to hold the trade mark in less esteem simply because the original packets have been placed in a new box with an opening on the side or because some of the blister packs are incomplete.

119. It is also for the national court to decide whether there is a risk of contamination as a result of the severing of blister packs. It may be noted that in the sample supplied to the Court by Eurim-Pharm the blister pack has been cut in such a way that some of the pills are extremely close to the edge. The national court will have to consider whether that increases the risk of the pills accidentally being exposed to the air. Certainly it would be difficult to say *a priori* that there is no risk of contamination.

120. As regards the interruption of the series of days of the week, it cannot be denied that that may result in considerable confusion for the consumer. In the sample supplied to the Court the series is interrupted in such a way that two pills appear to be allocated to the same day (Thursday). The danger that some consumers may occasionally exceed the correct dose cannot be ruled out. The fact that the days of the week are indicated in French and English, but not in German, does not change matters, since it may be assumed that a significant number of German consumers of pharmaceuticals have some knowledge of English or French. ticals since Eurim-Pharm simply removes blister packs from the original external packaging and places them, unsevered, in new packets. In this case too, the 'windows' method of repackaging is used and the remarks made in relation to Case C-71/94 seem equally valid, even though the trade mark owner does not appear to be objecting specifically to the appearance of the goods.

(6) Case C-73/94

122. Two special features of this case raise difficulties, namely the use of severed blister packs in order to make up a packet of 50 capsules from the packets of 45 sold in Spain and the addition of the word 'forte' to denote that the goods imported from Portugal correspond to the stronger version of the product.

(5) Case C-72/94

121. In this case there does not appear to be any risk of contamination of the pharmaceu123. As regards the severing of blister packs, the comments made in relation to Case C-71/94 are also relevant to this case. I will merely note that in the sample supplied to the Court the blister pack has been severed in such a way that the pills are several millimetres away from the edge of the pack. If the sample is representative the risk of contamination seems slight, though I stress that the ultimate decision on that point lies with the national court.

124. The addition of the word 'forte' raises more difficult problems. In some ways there is a parallel with American Home Products Corporation v Centrafarm, 34 in so far as slightly different names (Sermion and Sermion forte) are used for the same product (the stronger version of the drug, with 10 mg of the active ingredient) in different Member States (Portugal and Germany). If the ruling in the former case were applied directly, the result might be that Farmitalia could object to the changing of the name by the parallel importer unless it were shown that Farmitalia and its associates had used different names with a view to deliberately partitioning the market.

125. I do not advocate that approach in the present case. It will be recalled that in American Home Products Corporation the two trade marks were 'Serenid' and 'Seresta'; one mark could not be turned into the other simply by adding a sticker with an extra word. The present case is therefore not identical. The starting-point in the search for a solution to the problem raised in the present case is the observation that Sermion marketed with Farmitalia's consent in Portugal may in principle be resold in Germany by a parallel importer under the name 'Sermion'; the

owner of the trade mark cannot object on the ground that the product which it sells in Portugal under the name 'Sermion' is different from the product which it sells in Germany under that name. The owner of the mark cannot contend that consumers (or pharmacists) will be misled into thinking that the product contains 5 mg of the active ingredient rather than 10 mg. In IHT Internationale Heiztechnik v Ideal Standard 35 the Court held that 'if the manufacture of products is decentralized within a group of companies and the subsidiaries in each of the Member States manufacture products whose quality is geared to the particularities of each national market, a national law which enabled one subsidiary of the group to oppose the marketing in the territory of that State of products manufactured by an affiliated company on grounds of those quality differences would ... be precluded [by Articles 30 and 36] .' 36

126. It is clear then that Eurim-Pharm may in principle sell in Germany under the mark 'Sermion' a product which the owner of that mark has placed on the market in Portugal under the mark 'Sermion'. But if that would cause confusion, since the product is twice as strong as the product known as 'Sermion' in Germany, it is clearly necessary, from everyone's point of view, that Eurim-Pharm should be allowed to remove the confusion by making it clear that the product corresponds to the product known in Germany as 'Sermion forte'.

35 - Cited at note 5.

36 — Paragraph 38 of the judgment.

(7) Case C-232/94

127. In principle this case does not appear to pose any special difficulty. MPA removes blister packs from the original external packaging and places them, intact, in new external packaging. There seems to be virtually no risk of the quality of the goods being impaired.

128. The national court's second question implies that the information as to who repackaged the product is not set out with sufficient clarity on the external packaging. The content of that information, as described in paragraph 35 of this Opinion, seems perfectly adequate, and it may be that the only issue is whether the information is printed in sufficiently large letters. That is of course a question of fact for the national court. It should however be stressed that a reasonable approach to this issue is required. If the information is written in such a way that a consumer with normal eyesight, exercising a normal degree of attentiveness, would be able to understand who is responsible for the repackaging, that is sufficient. The writing must not be abnormally small but it need not be abnormally large.

V. The replies to the questions referred

129. Rather than reply directly to each of the specific questions referred by the different national courts, it would in my view be more fruitful to enunciate a number of general propositions which will help the national courts to determine in what circumstances a trade mark owner may rely on the trade mark to oppose further marketing of repackaged goods and then to formulate a number of specific rulings which will enable the national courts to resolve particular problems that have arisen in some of the cases. In formulating the proposed rulings I have also sought to make it clear that the same results are reached regardless of whether the Treaty provisions or those of the Directive are applied.

Conclusion

130. Accordingly, I am of the opinion that the questions referred to the Court should be answered as follows:

Joined Cases C-427/93, C-429/93 and C-436/93

(1) Articles 30 and 36 of the Treaty and Article 7(1) and (2) of Council Directive 89/104/EEC of 21 December 1988 to approximate the laws of the Member

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States relating to trade marks are to be interpreted as meaning that, where goods bearing a trade mark are placed on the market in a Member State with the consent of the proprietor of the trade mark and another person buys those goods, places them in new external packaging, to which he affixes the trade mark, and markets the repackaged goods in another Member State, the proprietor of the trade mark cannot invoke it in order to prevent such marketing unless the repackaging is done in such a way that it is capable of affecting the original condition of the goods or otherwise impairing the reputation of the trade mark. In the case of pharmaceutical products, the person who carries out the repackaging of the goods must in principle inform the trade mark proprietor and provide him with a specimen of the repackaged product. He must also indicate on the repackaged product that he is responsible for the repackaging but need not mention the manufacturer of the goods or state that the proprietor of the trade mark has not authorized the repackaging.

(2) The question whether the repackaging is capable of affecting the original condition of the goods or otherwise impairing the reputation of the trade mark is essentially a question of fact to be determined by the national court in accordance with its own domestic rules regarding procedural matters such as the burden of proof, the standard of proof and the admissibility of evidence. Those rules must not treat claims founded on Community law less favourably than claims founded on national law and must not make the enforcement of rights arising from Community law unduly difficult.

(3) Where the product in question is a pharmaceutical product which was originally packaged in blister packs, phials, flasks or aerosol containers and the person responsible for the repackaging simply removes the blister packs, phials, flasks or aerosol containers from their original external packaging and places them in new external packaging without cutting or opening them, and where that person uses suitable premises, employs competent staff and takes all reasonable safeguards, there is not in principle any ground for finding that the original condition of the goods may be affected, and the national court is precluded from making such a finding in the absence of specific evidence.

- (4) The fact that the person responsible for the repackaging uses the same colour scheme for the repackaged product as the owner of the trade mark is irrelevant.
- (5) [Applies only to Case C-427/93] Where the person responsible for the repackaging inserts in the new packaging additional goods not produced under the responsibility of the owner of the trade mark, the latter may in principle object to the further marketing of the repackaged goods under the trade mark, unless the origin of the additional material is indicated in such a way as to dispel any impression that the trade mark owner is responsible for it.

Joined Cases C-71/94, C-72/94 and C-73/94

- (1) Articles 30 and 36 of the Treaty and Article 7(1) and (2) of Council Directive 89/104/EEC of 21 December 1988 to approximate the laws of the Member States relating to trade marks are to be interpreted as meaning that, where goods bearing a trade mark are placed on the market in a Member State with the consent of the proprietor of the trade mark and another person buys those goods, places them in new external packaging, through which the trade mark affixed to the internal packaging remains visible, and markets the repackaged goods in another Member State, the proprietor of the trade mark cannot invoke it in order to prevent such marketing unless the repackaging is done in such a way that it is capable of affecting the original condition of the goods or otherwise impairing the reputation of the trade mark. In the case of pharmaceutical products, the person who carries out the repackaging of the goods must in principle inform the trade mark proprietor and provide him with a specimen of the repackaged product. He must also indicate on the repackaged product that he is responsible for the repackaging but need not mention the manufacturer of the goods or state that the proprietor of the trade mark has not authorized the repackaging.
- (2) The question whether the repackaging is capable of affecting the original condition of the goods or otherwise impairing the reputation of the trade mark is essentially a question of fact to be determined by the national court in accordance with its own domestic rules regarding procedural matters such as

the burden of proof, the standard of proof and the admissibility of evidence. Those rules must not treat claims founded on Community law less favourably than claims founded on national law and must not make the enforcement of rights arising from Community law unduly difficult.

- (3) Where the product in question is a pharmaceutical product which was originally packaged in blister packs and the person responsible for the repackaging simply removes the blister packs from their original external packaging and places them in new external packaging without cutting them, and where that person uses suitable premises, employs competent staff and takes all reasonable safeguards, there is not in principle any ground for finding that the original condition of the goods may be affected, and the national court is precluded from making such a finding in the absence of specific evidence.
- (4) Where the blister packs are severed, the owner of the trade mark is entitled to object to the further marketing of the goods if the national court considers that that practice is capable of affecting the original condition of the goods in view of the risk of contamination.
- (5) The owner of the trade mark is entitled to object to the further marketing of repackaged goods under the trade mark not only where the repackaging affects the technical quality of the goods but also where it gives them a shoddy appearance capable of damaging the reputation of the trade mark.
- (6) [Applies only to Case C-71/94] Where information printed on the back of the blister packs allocates the pills to specific days of the week for a certain period and that period becomes incomplete as a result of the severing of the blister packs, the owner of the trade mark is entitled to object to the further marketing of the goods if the national court considers that the interruption of the series of days of the week causes unacceptable confusion for the consumer or endangers his health or is detrimental to the reputation of the trade mark.

(7) [Applies only to Case C-73/94] Where a trade mark owner sells two versions of a product in Member State A under the names 'Sermion' and 'Sermion forte' and sells in Member State B under the name 'Sermion' a product which corresponds to the product known as 'Sermion forte' in Member State A, he cannot invoke his trade mark rights in order to prevent the resale in Member State A of goods which he has placed on the market in Member State B under the name 'Sermion', even though the person who resells the goods describes them as 'Sermion forte'.

Case C-232/94

- (1) Articles 30 and 36 of the Treaty and Article 7(1) and (2) of Council Directive 89/104/EEC of 21 December 1988 to approximate the laws of the Member States relating to trade marks are to be interpreted as meaning that, where goods bearing a trade mark are placed on the market in a Member State with the consent of the proprietor of the trade mark and another person buys those goods, places them in new external packaging, to which he affixes the trade mark, and markets the repackaged goods in another Member State, the proprietor of the trade mark cannot invoke it in order to prevent such marketing unless the repackaging is done in such a way that it is capable of affecting the original condition of the goods or otherwise impairing the reputation of the trade mark. The person who repackages the goods must in principle inform the trade mark proprietor and provide him with a specimen of the repackaged product. He must also indicate on the repackaged product that he is responsible for the repackaging but need not mention the manufacturer of the goods or state that the proprietor of the trade mark has not authorized the repackaging. The indication as to who is responsible for the repackaging must be written in such a way that a person with normal eyesight, exercising a normal degree of attentiveness, would be able to understand it.
- (2) The question whether the repackaging is capable of affecting the original condition of the goods or otherwise impairing the reputation of the trade mark is essentially a question of fact to be determined by the national court in accordance with its own domestic rules regarding procedural matters such as

the burden of proof, the standard of proof and the admissibility of evidence. Those rules must not treat claims founded on Community law less favourably than claims founded on national law and must not make the enforcement of rights arising from Community law unduly difficult.

(3) Where the product in question is a pharmaceutical product which was originally packaged in blister packs and the person responsible for the repackaging simply removes the blister packs from their original external packaging and places them in new external packaging without cutting them, and where that person uses suitable premises, employs competent staff and takes all reasonable safeguards, there is not in principle any ground for finding that the original condition of the goods may be affected, and the national court is precluded from making such a finding in the absence of specific evidence.