JUDGMENT OF THE COURT
11 July 1996 *

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

REFERENCES to the Court under Article 177 of the EC Treaty by the Sø-og Handelsretten i København (C-427/93 and C-429/93) and by the Højesteret (C-436/93) for a preliminary ruling in the proceedings pending before those courts between

Bristol-Myers Squibb

and

Paranova A/S (C-427/93)

and between

C. H. Boehringer Sohn,

Boehringer Ingelheim KG,

Boehringer Ingelheim A/S

* Language of the case: Danish.

and

Paranova A/S (C-429/93),

and between

Bayer Aktiengesellschaft,

Bayer Danmark A/S

and

Paranova A/S (C-436/93),

on the interpretation of Article 7 of the First Council Directive (89/104/EEC) of 21 December 1988 to approximate the laws of the Member States relating to trade marks (OJ 1989 L 40, p. 1), and of Article 36 of the EC Treaty,

THE COURT,

composed of: G. C. Rodríguez Iglesias, President, C. N. Kakouris, J.-P Puissochet and G. Hirsch (Presidents of Chambers), G. F. Mancini, J. C. Moitinho de Almeida, C. Gulmann (Rapporteur), P. Jann and H. Ragnemalm, Judges,

Advocate General: F. G. Jacobs,
Registrars: H. von Holstein, Deputy Registrar,
L. Hewlett, Administrator,

after considering the written observations submitted on behalf of:

— Bristol-Myers Squibb, by Kirsten Levinsen, Advokat, Copenhagen,

— C. H. Boehringer Sohn, Boehringer Ingelheim KG and Boehringer Ingelheim A/S, by Karen Dyekjær-Hansen, Advokat, Copenhagen,

— Bayer Aktiengesellschaft and Bayer Danmark A/S, by Dietrich C. Ohlgart, Rechtsanwalt, Hamburg, and Henrik Nebelong, Advokat, Copenhagen,

— Paranova A/S, by Erik B. Pfeiffer, Advokat, Copenhagen,

— the German Government, by Alexander von Mühlendahl, Ministerialrat at the Federal Ministry of Justice, Alfred Dittrich, Regierungsdirektor at the same ministry, and Ernst Röder, Ministerialrat at the Federal Ministry of the Economy, acting as Agents,

— the French Government, by Hélène Duchêne, Secretary for Foreign Affairs in the legal directorate of the Ministry of Foreign Affairs, and Edwige Belliard, Deputy Director in the same directorate, acting as Agents,

— the Government of the United Kingdom, by Lucinda Hudson of the Treasury Solicitor's Department, acting as Agent, assisted by Michael Silverleaf, Barrister,

— the Commission of the European Communities, by Pieter van Nuffel and Anders Christian Jessen, of the Legal Service, acting as Agents,

having regard to the Report for the Hearing,

after hearing the oral observations of Bristol Myers-Squibb, represented by Peter-Ulrik Plesner Advokat, Copenhagen, C. H. Boehringer Sohn, Boehringer Ingelheim KG and Boehringer Ingelheim A/S, represented by Karen Dyekjær-Hansen, Bayer Aktiengesellschaft and Bayer Danmark A/S, represented by Henrik Nebelong and Dietrich C. Ohlgart, Paranova A/S, represented by Erik B. Pfeiffer, the French Government, represented by Philippe Martinet, Secretary for Foreign Affairs in the legal directorate of the Ministry of Foreign Affairs, acting as Agent, of the Government of the United Kingdom, represented by Lindsey Nicoll of the Treasury Solicitor's Department, acting as Agent, and by Michael Silverleaf, and of the Commission, represented by Richard Wainwright, Hans Peter Hartvig and Angela Bardenhewer, acting as Agents, at the hearing on 4 October 1995,

after hearing the Opinion of the Advocate General at the sitting on 14 December 1995,

gives the following

Judgment

1 By orders of 22 October (C-427/93), 21 October (C-429/93) and 1 November 1993 (C-436/93), received at the Court respectively on 25 and 26 October and 4 November 1993, the Sø-og Handelsretten i København (Maritime and Commercial Court of Copenhagen) (in Cases C-427/93 and C-429/93) and the Højesteret (Supreme Court) (in Case C-436/93) referred to the Court for a preliminary ruling under Article 177 of the EC Treaty a number of questions on the interpretation of Article 7 of the First Council Directive (89/104/EEC) of 21 December 1988 to approximate the laws of the Member States relating to trade marks (OJ 1989 L 40, p. 1; hereinafter 'the directive') and Article 36 of the EC Treaty.

2 Those questions were raised in three disputes between, on the one hand, Bristol-Myers Squibb, C. H. Boehringer Sohn, Boehringer Ingelheim KG and Boehringer Ingelheim A/S (hereinafter 'Boehringer'), and Bayer Aktiengesellschaft and Bayer

Danmark A/S (hereinafter 'Bayer'), which are pharmaceutical manufacturers, and, on the other hand, Paranova A/S (hereinafter 'Paranova'), which imports into Denmark certain products manufactured by those companies.

Legal background

3 Under Article 36 of the Treaty, prohibitions or restrictions on imports between Member States which are justified on grounds of the protection of industrial and commercial property are permissible, provided they do not constitute a means of arbitrary discrimination or a disguised restriction on trade between Member States.

4 Article 5 of the directive, concerning 'Rights conferred by a trade mark', is worded 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 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. ...

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.

...'.

5 Article 7 of the directive establishes the principle of 'exhaustion of the rights conferred by a trade mark' by providing as follows:

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

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

6 Those provisions were transposed into Danish law by Articles 4 and 6 respectively of Law No 341 of 6 June 1991 on manufacturing, commercial and collective trade marks.

The facts and the questions referred

7 Bristol-Myers Squibb markets in various Member States pharmaceutical products manufactured by itself or an associated company, and holds the rights in relation to the registration in Denmark of the trade marks 'Capoten', 'Mycostatin', 'Vepesid', 'Vumon' and 'Diclocil'. Capoten is used for lowering blood pressure and is marketed as tablets in blister packs. Mycostatin is a mixture for the treatment of mycotic infections of the mouth marketed in flasks. Vepesid is an anti-cancer drug sold in phials or as tablets in blister packs. Vumon is also an anti-cancer drug packaged in ampoules. Diclocil is an antibiotic for treating infections, marketed as capsules in blister packs.

8 Boehringer manufactures pharmaceutical products in Germany and markets them throughout the Community. It registered in Denmark the trade mark 'Boehringer Ingelheim', which is used generally on its pharmaceuticals, and the trade marks 'Atrovent', 'Berodual', 'Berotec' and 'Catapresan', which are used to designate specific pharmaceutical products. Atrovent, Berodual and Berotec are used for the treatment of bronchial asthma and sold in aerosols. They are marketed throughout

all Member States in aerosol inhalers, but with differing quantities of the active ingredient. Catapresan is used to treat high blood pressure and marketed as tablets in blister packs.

9 Bayer manufactures and markets in various Member States a pharmaceutical product under the name 'Adalat', which it had registered as a trade mark in Denmark along with its company name Bayer. Adalat is used to treat heart and circulatory diseases. For a number of years, it was marketed in Denmark in packages of 30 or 100 tablets, in blister packs containing 10 tablets each. Since 1990, only packages of 100 tablets have been sold in Denmark. In other Member States, Adalat is sold in packages of varying sizes, containing 20, 30, 50, 60 or 100 tablets.

10 Paranova is a company which distributes pharmaceutical products imported in parallel. It has purchased the abovementioned products in batches in Member States where prices are relatively low (Greece, the United Kingdom, Spain and Portugal) and imported them into Denmark, where it sells them below the manufacturers' official sale prices while still making a profit.

11 For the purposes of sale in Denmark, Paranova repackaged all the medicines in new external packaging with a uniform appearance and its own style, namely white with coloured stripes corresponding to the colours of the manufacturers' original packaging. That packaging displayed, *inter alia*, the respective trade marks of the manufacturers and the statement that the product had been manufactured respectively by 'Bristol-Myers Squibb', 'Boehringer Ingelheim' and 'Bayer', together with the indication 'imported and repackaged by Paranova'.

12 In the case of Capoten, Diclocil, Catapresan and Adalat, the repackaging by Paranova involved a change in packet size.

13 Regarding Adalat in particular, the Danish packaging used by Bayer bore the words 'Adalat 20mg'. Paranova imported Adalat from Greece, where the product was sold in a packet of three blister packs of 10 tablets each, and repackaged it in packets with the description 'Adalat retard' containing 10 blister packs of 10 tablets.

14 In addition to replacing the external packaging, Paranova carried out the following operations.

15 In the case of Vepesid and Vumon, it removed the phials and ampoules from their surrounding padding and attached to each phial or ampoule a new self-stick label covering that of the manufacturer. The new label bore the trade mark of Bristol-Myers Squibb together with the indications 'manufactured by Bristol-Myers Squibb' and 'imported and repackaged by Paranova'. The phials and ampoules were then replaced in the original padding and put in the new external packaging. In the case of Mycostatin, Atrovent, Berodual and Berotec, Paranova also covered the original labels of the flasks or inhalers with its own label showing, *inter alia*, the manufacturers' trade marks.

16 In the case of Vepesid, Vumon, Berodual and Berotec, Paranova included with the new packaging user information in Danish.

17 In the packaging of Mycostatin, Paranova replaced the spray in the original packaging with a spray from a source other than Bristol-Myers Squibb.

18 In addition, and in accordance with the relevant Danish rules, Paranova registered the products as pharmaceutical specialities in the Danish register of such specialities, using the same names as the manufacturers.

19 Bristol-Myers Squibb and Boehringer brought proceedings against Paranova before the Sø- og Handelsretten, claiming, *inter alia*, that the defendant should be obliged to recognize that it had infringed the plaintiffs' trade marks by affixing them without the plaintiffs' consent to products it offered for sale, and that the defendant should be ordered to desist from affixing those trade marks to the products it repackaged and marketed.

20 The national court decided to stay the proceedings and refer the following questions to the Court for a preliminary ruling:

'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 regarding use of the trade mark for which the trade mark proprietor has not given his consent.

2. 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?'

21 In Case C-427/93, the Sø- og Handelsretten also referred the two following questions:

'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?'

22 Bayer brought proceedings against Paranova before the Sø- og Handelsretten, which dismissed the action. It 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?

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?

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

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.

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?

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?'

23 By order of the President of the Court of 18 November 1993, those cases were joined for the purposes of the written procedure, the oral procedure and the judgment.

The application of Article 7 of the directive

24 In the first question in Case C-436/93, the Højesteret is essentially asking whether the reliance by a trade mark owner on his rights as owner in order to prevent an importer from marketing a product which was put on the market in another Member State by the owner or with his consent, in circumstances where that importer has repackaged the product and reaffixed the trade mark without the owner's

authorization, is to be assessed on the basis of the combined provisions of national trade mark law and Article 7 of the directive only, or whether account must also be taken of Article 36 of the Treaty.

25 Where Community directives provide for the harmonization of measures necessary to ensure the protection of the interests referred to in Article 36 of the Treaty, any national measure relating thereto must be assessed in relation to the provisions of that directive and not Articles 30 to 36 of the Treaty (see Case 5/77 *Tedeschi* v *Denkavit* [1977] ECR 1555, paragraph 35; Case 227/82 *Van Bennekom* [1983] ECR 3883, paragraph 35; Case C-37/92 *Vanacker and Lesage* [1993] ECR I-4947, paragraph 9; and Case C-323/93 *Centre d'Insémination de la Crespelle* v *Coopérative de la Mayenne* [1994] ECR I-5077, paragraph 31).

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

27 Like any secondary legislation, however, the directive must be interpreted in the light of the Treaty rules on the free movement of goods and in particular Article 36 (see Case C-47/90 *Delhaize* v *Promalvin* [1992] ECR I-3669, paragraph 26; and Case C-315/92 *Verband Sozialer Wettbewerb* v *Clinique Laboratoires and Estée Lauder* [1994] ECR I-317, paragraph 12).

28 The answer to the first question in Case C-436/93 must therefore be that the reliance by a trade mark owner on his rights as owner in order to prevent an importer from marketing a product which was put on the market in another Member State by the owner or with his consent where that importer has repackaged the product and reaffixed the trade mark without the owner's authorization, is to be assessed on

the basis of the combined provisions of national trade mark law and Article 7 of the directive, interpreted in the light of Article 36 of the Treaty.

The interpretation of Article 7(1) of the directive

29 In the first question in Cases C-427/93 and C-429/93, the Sø-og Handelsretten is essentially asking whether, save in the circumstances specified in Article 7(2), Article 7(1) of the directive precludes a trade mark owner from relying on his rights as owner to prevent an importer from marketing a product which was put on the market in another Member State by the owner or with his consent, even if that importer has repackaged the product and reaffixed the trade mark without the owner's authorization.

30 Article 7(1) of the directive provides that the rights conferred by a trade mark do 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.

31 That provision is framed in terms corresponding to those used by the Court in judgments which, in interpreting Articles 30 and 36 of the Treaty, have recognized in Community law the principle of the exhaustion of the rights conferred by a trade mark. It reiterates the case-law of the Court to the effect that the owner of a trade mark protected by the legislation of a Member State cannot rely on that legislation to prevent the importation or marketing of a product which was put on the market in another Member State by him or with his consent (see, in particular, Case 16/74 *Centrafarm* v *Winthrop* [1974] ECR 1183, paragraphs 7 to 11; Case C-10/89 *CNL-SUCAL* v *HAG GF* [1990] ECR I-3711, paragraph 12 ('*HAG II*'); and Case C-9/93 *IHT Internationale Heiztechnik* v *Ideal Standard* [1994] ECR I-2789, paragraphs 33 and 34).

32 It has nevertheless been argued by the plaintiffs in the main actions and by the German Government that Article 7(1) of the directive does not confer on the parallel importer any right other than to resell the products in the form in which the trade mark owner put them on the market in another Member State. In their view, the owner's exclusive right under Article 5 of the directive to affix the trade mark to a product is not exhausted, so that, even apart from the exceptions set out in Article 7(2), the owner may prohibit the affixing of the trade mark to repackaged products.

33 That argument cannot be accepted.

34 The Court's case-law on Article 36 of the Treaty shows that the owner's exclusive right to affix a trade mark to a product must in certain circumstances be regarded as exhausted in order to allow an importer to market under that trade mark products which were put on the market in another Member State by the owner or with his consent (see Case 102/77 *Hoffmann-La Roche* v *Centrafarm* [1978] ECR 1139; Case 3/78 *Centrafarm* v *American Home Products Corporation* [1978] ECR 1823; and the judgments given today in Joined Cases C-71/94, C-72/94 and C-73/94 *Eurim-Pharm* v *Beiersdorf* [1996] ECR I-3603 and in Case C-232/94 *MPA Pharma* v *Rhône-Poulenc Pharma* [1996] ECR I-3671).

35 To accept the argument that the principle of exhaustion under Article 7(1) cannot apply if the importer has repackaged the product and reaffixed the trade mark would therefore imply a major alteration to the principles flowing from Articles 30 and 36 of the Treaty.

36 There is nothing to suggest that Article 7 of the directive is intended to restrict the scope of that case-law. Nor would such an effect be permissible, since a directive cannot justify obstacles to intra-Community trade save within the bounds set by the Treaty rules. The Court's case-law shows that the prohibition on quantitative restrictions and measures having equivalent effect applies not only to national

measures but also to those emanating from Community institutions (see, most recently, Case C-51/93 *Meyhui* v *Schott Zwiesel Glaswerke* [1994] ECR I-3879, paragraph 11).

37 The answer to the first question in Cases C-427/93 and C-429/93 must therefore be that, save in the circumstances defined in Article 7(2), Article 7(1) of the directive precludes the owner of a trade mark from relying on his rights as owner to prevent an importer from marketing a product which was put on the market in another Member State by the owner or with his consent, even if that importer repackaged the product and reaffixed the trade mark to it without the owner's authorization.

The interpretation of Article 7(2) of the directive

38 In the second question in Cases C-427/93 and C-429/93, the third and fourth questions in Case C-427/93 and the second, third, fourth and fifth questions in Case C-436/93, the national courts are essentially asking for a definition of the circumstances in which a trade mark owner may, under Article 7(2) of the directive, oppose the further marketing of a pharmaceutical product which has been repackaged by the importer and to which the owner's trade mark has been reaffixed. In particular, they ask whether the case-law under Article 36 of the Treaty is relevant when applying Article 7(2) of the directive, and, if it is, what is the significance and content of the concepts established by that case-law regarding the 'artificial partitioning of the markets' and adverse effect on 'the original condition of the product'.

39 Article 7(2) of the directive provides that the owner of a trade mark may oppose the further commercialization of products where there is a legitimate reason for doing so, especially where the condition of the products has been changed or

impaired since they were put on the market. The use of the word 'especially' shows that the case envisaged is given only as an example.

40 Article 7 of the directive, like Article 36 of the Treaty, is intended to reconcile the fundamental interest in protecting trade mark rights with the fundamental interest in the free movement of goods within the common market, so that those two provisions, which pursue the same result, must be interpreted in the same way.

41 The Court's case-law under Article 36 must therefore be taken as the basis for determining whether, under Article 7(2) of the directive, a trade mark owner may oppose the marketing of repackaged products to which the trade mark has been reaffixed.

42 The Court's case-law shows that Article 36 allows derogations from the fundamental principle of the free movement of goods within the common market only in so far as such derogations are justified in order to safeguard the rights which constitute the specific subject-matter of the industrial and commercial property in question.

43 Trade mark rights, the Court has held, constitute an essential element in the system of undistorted competition which the Treaty is intended to establish. In such a system, undertakings must be able to attract and retain customers by the quality of their products or services, which is possible only thanks to the existence of distinctive signs allowing them to be identified. For the trade mark to be able to fulfil that function, it must constitute a guarantee that all products which bear it have been manufactured under the control of a single undertaking to which responsibility for their quality may be attributed (see *HAG II*, paragraph 13, and *IHT Internationale Heiztechnik,* paragraphs 37 and 45).

14 Thus, as the Court has recognized on many occasions, the specific subject-matter of a trade mark is in particular to guarantee to the owner that he has the exclusive right to use that trade mark for the purpose of putting a product on the market 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 bearing it illegally (see *Hoffmann-La Roche* v *Centrafarm*, paragraph 7; Case 1/81 *Pfizer* v *Eurim-Pharm* [1981] ECR 2913, paragraph 7; *HAG II*, paragraph 14; and *IHT Internationale Heiztechnik*, paragraph 33).

45 It follows that, as mentioned above, the owner of a trade mark protected by the legislation of a Member State cannot rely on that legislation in order to oppose the importation or marketing of a product which was put on the market in another Member State by him or with his consent (see, in particular, *Winthrop*, paragraphs 7 to 11; *HAG II*, paragraph 12; and *IHT Internationale Heiztechnik*, paragraphs 33 and 34).

46 Trade mark rights are not intended to allow their owners to partition national markets and thus promote the retention of price differences which may exist between Member States. Whilst, in the pharmaceutical market especially, such price differences may result from factors over which trade mark owners have no control, such as divergent rules between the Member States on the fixing of maximum prices, the profit margins of pharmaceutical wholesalers and pharmacies, or the maximum amount of medical expenses which may be reimbursed under sickness insurance schemes, distortions caused by divergent pricing rules in one Member State must be remedied by measures of the Community authorities and not by another Member State introducing measures which are incompatible with the rules on the free movement of goods (see, in particular, *Winthrop*, paragraphs 16 and 17).

47 In answering the question whether a trade mark owner's exclusive rights include the power to oppose the use of the trade mark by a third party after the product has been repackaged, account must be taken of the essential function of the trade

mark, which is to guarantee to the consumer or end user the identity of the trade-marked product's origin by enabling him to distinguish it without any risk of confusion from products of different origin. That guarantee of origin means that the consumer or end user can be certain that a trade-marked product offered to him has not been subject at a previous stage of marketing to interference by a third person, without the authorization of the trade mark owner, in such a way as to affect the original condition of the product (*Hoffmann-La Roche*, paragraph 7; *Pfizer*, paragraph 8).

48 Therefore, the right conferred upon the trade mark owner to oppose any use of the trade mark which is liable to impair the guarantee of origin so understood forms part of the specific subject-matter of the trade mark right, the protection of which may justify derogation from the fundamental principle of the free movement of goods (*Hoffmann-La Roche*, paragraph 7; *Pfizer*, paragraph 9).

49 In *Hoffmann-La Roche*, the Court held, applying those principles, that Article 36 of the Treaty must be interpreted as meaning that a trade mark owner may rely on his rights as owner to prevent an importer from marketing a product put on the market in another Member State by the owner or with his consent, where that importer has repackaged the product in new packaging to which the trade mark has been reaffixed, unless:

— it is established that the use of the trade-mark right by the owner, 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 owner of the mark receives prior notice before the repackaged product is put on sale; and

— it is stated on the new packaging by whom the product has been repackaged.

50 In accordance with that case-law, Article 7(2) of the directive must therefore be interpreted as meaning that a trade mark owner may legitimately oppose the further marketing of a pharmaceutical product where the importer has repackaged it and reaffixed the trade mark, unless the four conditions set out in the *Hoffmann-La Roche* judgment, cited above, have been met.

51 That case-law must, however, be clarified further in the light of the arguments raised in these cases, and in the cases of *Eurim-Pharm* v *Beiersdorf* (C-71/94, C-72/94 and C-73/94) and *MPA Pharma* v *Rhône-Poulenc* (C-232/94), in which the Court has also given judgment today.

Artificial partitioning of the markets between Member States

52 Reliance on trade mark rights by their owner in order to oppose marketing under that trade mark of products repackaged by a third party would contribute to the partitioning of markets between Member States in particular where the owner has placed an identical pharmaceutical product on the market in several Member States in various forms of packaging, and the product may not, in the condition in which it has been marketed by the trade mark owner in one Member State, be imported and put on the market in another Member State by a parallel importer.

53 The trade mark owner cannot therefore oppose the repackaging of the product in new external packaging when the size of packet used by the owner in the Member State where the importer purchased the product cannot be marketed in the

Member State of importation by reason, in particular, of a rule authorizing packaging only of a certain size or a national practice to the same effect, sickness insurance rules making the reimbursement of medical expenses depend on the size of the packaging, or well-established medical prescription practices based, *inter alia*, on standard sizes recommended by professional groups and sickness insurance institutions.

54 Where, in accordance with the rules and practices in force in the Member State of importation, the trade mark owner uses many different sizes of packaging in that State, the finding that one of those sizes is also marketed in the Member State of exportation is not enough to justify the conclusion that repackaging is unnecessary. Partitioning of the markets would exist if the importer were able to sell the product in only part of his market.

55 The owner may, on the other hand, oppose the repackaging of the product in new external packaging where the importer is able to achieve packaging which may be marketed in the Member State of importation by, for example, affixing to the original external or inner packaging new labels in the language of the Member State of importation, or by adding new user instructions or information in the language of the Member State of importation, or by replacing an additional article not capable of gaining approval in the Member State of importation with a similar article that has obtained such approval.

56 The power of the owner of trade mark rights protected in a Member State to oppose the marketing of repackaged products under the trade mark should be limited only in so far as the repackaging undertaken by the importer is necessary in order to market the product in the Member State of importation.

57 Finally, contrary to the argument of the plaintiffs in the main actions, the Court's use of the words 'artificial partitioning of the markets' does not imply that the importer must demonstrate that, by putting an identical product on the market in varying forms of packaging in different Member States, the trade mark owner deliberately sought to partition the markets between Member States. By stating that the partitioning in question must be artificial, the Court's intention was to stress that the owner of a trade mark may always rely on his rights as owner to oppose the marketing of repackaged products when such action is justified by the need to safeguard the essential function of the trade mark, in which case the resultant partitioning could not be regarded as artificial.

Whether the original condition of the product is adversely affected

58 In the light of the arguments of the plaintiffs in the main actions, it should be clarified at the outset that the concept of adverse effects on the original condition of the product refers to the condition of the product inside the packaging.

59 The trade mark owner may therefore oppose any repackaging involving a risk of the product inside the package being exposed to tampering or to influences affecting its original condition. To determine whether that applies, account must be taken, as the Court held in paragraph 10 of the *Hoffmann-La Roche* judgment, of the nature of the product and the method of repackaging.

60 As regards pharmaceutical products, it follows from the same paragraph in *Hoffmann-La Roche* that repackaging must be regarded as having been carried out in circumstances not capable of affecting the original condition of the product where, for example, the trade mark owner has placed the product on the market in double packaging and the repackaging affects only the external layer, leaving the

inner packaging intact, or where the repackaging is carried out under the supervision of a public authority in order to ensure that the product remains intact.

61 It follows from that case-law that the mere removal of blister packs, flasks, phials, ampoules or inhalers from their original external packaging and their replacement in new external packaging cannot affect the original condition of the product inside the packaging.

62 The plaintiffs in the main actions have argued nevertheless that even operations of that kind entail the risk of adversely affecting the original condition of the product. Thus, blister packs coming originally from different packets and grouped together in single external packaging might have come from different production batches with different use-by dates, products might have been stored for too long, and light-sensitive products might have been damaged by light during repackaging.

63 Those arguments cannot be accepted. It is not possible for each hypothetical risk of isolated error to suffice to confer on the trade mark owner the right to oppose any repackaging of pharmaceutical products in new external packaging.

64 As for operations consisting in the fixing of self-stick labels to flasks, phials, ampoules or inhalers, the addition to the packaging of new user instructions or information in the language of the Member State of importation, or the insertion of an extra article, such as a spray, from a source other than the trade mark owner, there is nothing to suggest that the original condition of the product inside the packaging is directly affected thereby.

65 It should be recognized, however, that the original condition of the product inside the packaging might be indirectly affected where, for example:

— the external or inner packaging of the repackaged product, or a new set of user instructions or information, omits certain important information or gives inaccurate information concerning the nature, composition, effect, use or storage of the product, or

— an extra article inserted into the packaging by the importer and designed for the ingestion and dosage of the product does not comply with the method of use and the doses envisaged by the manufacturer.

66 It is for the national court to assess whether that is so, in particular by making a comparison with the product marketed by the trade mark owner in the Member State of importation. The possibility of the importer providing certain additional information should not be excluded, however, provided that information does not contradict the information provided by the trade mark owner in the Member State of importation, that condition being met in particular in the case of different information resulting from the packaging used by the owner in the Member State of exportation.

The other requirements to be met by the parallel importer

67 If the repackaging is carried out in conditions which cannot affect the original condition of the product inside the packaging, the essential function of the trade mark as a guarantee of origin is safeguarded. Thus, the consumer or end user is not misled as to the origin of the products, and does in fact receive products manufactured under the sole supervision of the trade mark owner.

68 Whilst, in these circumstances, the conclusion that the trade mark owner may not rely on his rights as owner in order to oppose the marketing under his trade mark of products repackaged by an importer is essential in order to ensure the free movement of goods, it does nevertheless confer on the importer certain rights which, in normal circumstances, are reserved for the trade mark owner himself.

69 In the interests of the owner as proprietor of the trade mark, and to protect him against any misuse, those rights must therefore, as the Court held in *Hoffmann-La Roche*, be recognized only in so far as the importer complies with a number of other requirements.

70 Since it is in the trade mark owner's interest that the consumer or end user should not be led to believe that the owner is responsible for the repackaging, an indication must be given on the packaging of who repackaged the product.

71 As the Court has already stated, that indication must be clearly shown on the external packaging of the repackaged product (*Hoffmann-La Roche*, paragraph 12, and *Pfizer*, paragraph 11). That implies, as the Advocate General pointed out in paragraph 128 of his Opinion, that the national court must assess whether it is printed in such a way as to be understood by a person with normal eyesight, exercising a normal degree of attentiveness.

72 It is, however, not necessary to require that the further express statement be made on the packaging that the repackaging was carried out without the authorization of the trade mark owner, since such a statement could be taken to imply, as the Advocate General pointed out in paragraph 88 of his Opinion, that the repackaged product is not entirely legitimate.

73 However, where the parallel importer has added to the packaging an extra article from a source other than the trade mark owner, he must ensure that the origin of the extra article is indicated in such a way as to dispel any impression that the trade mark owner is responsible for it.

74 Similarly, as paragraph 11 of the *Pfizer* judgment shows, a clear indication may be required on the external packaging as to who manufactured the product, since it may indeed be in the manufacturer's interest that the consumer or end user should not be led to believe that the importer is the owner of the trade mark, and that the product was manufactured under his supervision.

75 Even if the person who carried out the repackaging is indicated on the packaging of the product, there remains the possibility that the reputation of the trade mark, and thus of its owner, may nevertheless suffer from an inappropriate presentation of the repackaged product. In such a case, the trade mark owner has a legitimate interest, related to the specific subject-matter of the trade mark right, in being able to oppose the marketing of the product. In assessing whether the presentation of the repackaged product is liable to damage the reputation of the trade mark, account must be taken of the nature of the product and the market for which it is intended.

76 In the case of pharmaceutical products, that is certainly a sensitive area in which the public is particularly demanding as to the quality and integrity of the product, and the presentation of the product may indeed be capable of inspiring public confidence in that regard. It follows that defective, poor quality or untidy packaging could damage the trade mark's reputation.

77 However, the requirements to be met by the presentation of a repackaged pharmaceutical product vary according to whether the product is sold to hospitals or, through pharmacies, to consumers. In the former case, the products are administered to patients by professionals, for whom the presentation of the product is of little importance. In the latter case, the presentation of the product is of greater

importance for the consumer, even if the fact that the products in question are subject to prescription by a doctor may in itself give consumers some degree of confidence in the quality of the product.

78 Finally, as the Court pointed out in *Hoffmann-La Roche*, the trade mark owner must be given advance notice of the repackaged product being put on sale. The owner may also require the importer to supply him with a specimen of the repackaged product before it goes on sale, to enable him to check that the repackaging is not carried out in such a way as directly or indirectly to affect the original condition of the product and that the presentation after repackaging is not likely to damage the reputation of the trade mark. Similarly, such a requirement affords the trade mark owner a better possibility of protecting himself against counterfeiting.

79 Accordingly, the answer to the second question in Cases C-427/93 and C-429/93, the third and fourth questions in Case C-427/93, and the second, third, fourth and fifth questions in Case C-436/93, should be that Article 7(2) of the directive is to be interpreted as meaning that the trade mark owner may legitimately oppose the further marketing of a pharmaceutical product where the importer has repackaged the product and reaffixed the trade mark unless:

— it is established that reliance on trade mark rights by the owner in order to oppose the marketing of repackaged products under that trade mark would contribute to the artificial partitioning of the markets between Member States; such is the case, in particular, where the owner has put an identical pharmaceutical product on the market in several Member States in various forms of packaging, and the repackaging carried out by the importer is necessary in order to market the product in the Member State of importation, and also carried out in such conditions that the original condition of the product cannot be affected

by it; that condition does not, however, imply that it must be established that the trade mark owner deliberately sought to partition the markets between Member States;

— it is shown that the repackaging cannot affect the original condition of the product inside the packaging; such is the case, in particular, where the importer has merely carried out operations involving no risk of the product being affected, such as, for example, the removal of blister packs, flasks, phials, ampoules or inhalers from their original external packaging and their replacement in new external packaging, the fixing of self-stick labels on the inner packaging of the product, the addition to the packaging of new user instructions or information, or the insertion of an extra article; it is for the national court to verify that the original condition of the product inside the packaging is not indirectly affected, for example, by the fact that the external or inner packaging of the repackaged product or new user instructions or information omits certain important information or gives inaccurate information, or the fact that an extra article inserted in the packaging by the importer and designed for the ingestion and dosage of the product does not comply with the method of use and the doses envisaged by the manufacturer;

— the new packaging clearly states who repackaged the product and the name of the manufacturer in print such that a person with normal eyesight, exercising a normal degree of attentiveness, would be in a position to understand; similarly, the origin of an extra article from a source other than the trade mark owner must be indicated in such a way as to dispel any impression that the trade mark owner is responsible for it; however, it is not necessary to indicate that the repackaging was carried out without the authorization of the trade mark owner;

— the presentation of the repackaged product is not such as to be liable to damage the reputation of the trade mark and of its owner; thus, the packaging must not be defective, of poor quality, or untidy; and

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

Costs

80 The costs incurred by the German, French and United Kingdom Governments and by the Commission of the European Communities, which have submitted observations to the Court, are not recoverable. Since these proceedings are, for the parties to the main proceedings, a step in the actions pending before the national courts, the decision on costs is a matter for those courts.

On those grounds,

THE COURT

in answer to the questions referred to it by the Sø- og Handelsretten i København by orders of 22 October (C-427/93) and 21 October 1993 (C-429/93) and by the Højesteret by order of 1 November 1993 (C-436/93), hereby rules:

1. **The reliance by a trade mark owner on his rights as owner in order to prevent an importer from marketing a product which was put on the market in another Member State by the owner or with his consent where that importer has repackaged the product and reaffixed the trade mark without the owner's authorization, is to be assessed on the basis of the combined provisions of national trade mark law and Article 7 of the First Council Directive (89/104/EEC) of 21 December 1988 to approximate the laws of the Member States relating to trade marks, interpreted in the light of Article 36 of the EC Treaty.**

2. **Save in the circumstances defined in Article 7(2), Article 7(1) of Directive 89/104 precludes the owner of a trade mark from relying on his rights as owner to prevent an importer from marketing a product which was put on the market in another Member State by the owner or with his consent, even**

if that importer repackaged the product and reaffixed the trade mark to it without the owner's authorization.

3. Article 7(2) of Directive 89/104 must be interpreted as meaning that the trade mark owner may legitimately oppose the further marketing of a pharmaceutical product where the importer has repackaged the product and reaffixed the trade mark unless:

— it is established that reliance on trade mark rights by the owner in order to oppose the marketing of repackaged products under that trade mark would contribute to the artificial partitioning of the markets between Member States; such is the case, in particular, where the owner has put an identical pharmaceutical product on the market in several Member States in various forms of packaging, and the repackaging carried out by the importer is necessary in order to market the product in the Member State of importation, and is carried out in such conditions that the original condition of the product cannot be affected by it; that condition does not, however, imply that it must be established that the trade mark owner deliberately sought to partition the markets between Member States;

— it is shown that the repackaging cannot affect the original condition of the product inside the packaging; such is the case, in particular, where the importer has merely carried out operations involving no risk of the product being affected, such as, for example, the removal of blister packs, flasks, phials, ampoules or inhalers from their original external packaging and their replacement in new external packaging, the fixing of self-stick labels on the inner packaging of the product, the addition to the packaging of new user instructions or information, or the insertion of an extra article; it is for the national court to verify that the original condition of the product inside the packaging is not indirectly affected, for example, by the fact that the external or inner packaging of the repackaged product or new user instructions or information omits certain important information or gives inaccurate information, or the fact that

an extra article inserted in the packaging by the importer and designed for the ingestion and dosage of the product does not comply with the method of use and the doses envisaged by the manufacturer;

— **the new packaging clearly states who repackaged the product and the name of the manufacturer in print such that a person with normal eyesight, exercising a normal degree of attentiveness, would be in a position to understand; similarly, the origin of an extra article from a source other than the trade mark owner must be indicated in such a way as to dispel any impression that the trade mark owner is responsible for it; however, it is not necessary to indicate that the repackaging was carried out without the authorization of the trade mark owner;**

— **the presentation of the repackaged product is not such as to be liable to damage the reputation of the trade mark and of its owner; thus, the packaging must not be defective, of poor quality, or untidy; and**

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

Rodríguez Iglesias Kakouris Puissochet

Hirsch Mancini Moitinho de Almeida

Gulmann Jann Ragnemalm

Delivered in open court in Luxembourg on 11 July 1996.

R. Grass

Registrar

G. C. Rodríguez Iglesias

President