Court of Justice EC, 11 July 1996, MPA Pharma v Rhône-Poulenc

TRADEMARK LAW - EXHASUTION

Conditions for repackaging pharmaceutical products

- **Article 36 of the EC Treaty must be interpreted as meaning that a trade mark owner may rely upon his rights as owner to prevent an importer from marketing a pharmaceutical 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 thereto, 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 requirement 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 from their original external packaging and their insertion into new external packaging, or the addition to the packaging of new user instructions or information; 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;
- ° 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; 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.

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Court of Justice EC, 11 July 1996
(G.C. Rodríguez Iglesias, President, C.N. Kakouris, J.-P Puissochet, G. Hirsch, G.F. Mancini, J.C. Moitinho de Almeida, C. Gulmann, P. Jann , H. Ragnemalm)
Judgment of the Court of 11 July 1996. - MPA Pharma GmbH v Rhône-Poulenc Pharma GmbH. - Reference for a preliminary ruling: Oberlandesgericht Köln - Germany. - Repackaging of trade-marked products - Article 36 of the EC Treaty. - Case C-232/94.
European Court reports 1996 Page I-03671
In Case C-232/94,
REFERENCE to the Court under Article 177 of the EC Treaty by the Oberlandesgericht Koeln (Germany) for a preliminary ruling in the proceedings pending before that court between
MPA Pharma GmbH
and
Rhône-Poulenc Pharma GmbH
on the interpretation of Article 36 of the EC Treaty in relation to trade marks,
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:
° MPA Pharma GmbH, by Wolfgang A. Rehmann, Rechtsanwalt, Munich,
° Rhône-Poulenc Pharma GmbH, by Kurt Bauer, Rechtsanwalt, Cologne,
° the French Government, by Catherine de Salins, Assistant Director in the legal directorate of the Ministry of Foreign Affairs, and Philippe Martinet, Secretary for Foreign Affairs in the same directorate, acting as Agents,
° the Commission of the European Communities, by Richard Wainwright, Principal Legal Adviser, and Angela Bardenhewer, of its Legal Service, acting as Agents,
having regard to the Report for the Hearing,
after hearing the oral observations of MPA Pharma GmbH, Rhône-Poulenc Pharma GmbH, the French Government and the Commission 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

Grounds

1 By an order of 29 July 1994, received at the Court on 11 August 1994, the Oberlandesgericht Koeln (Higher Regional Court, Cologne) referred to the Court for a preliminary ruling under Article 177 of the EC Treaty a number of questions on the interpretation of Article 36 of the EC Treaty in relation to trade marks.

2 The questions were raised in proceedings between Rhône-Poulenc Pharma GmbH (hereinafter "Rhône-Poulenc"), which manufactures pharmaceutical products, and MPA Pharma GmbH (hereinafter "Pharma"), which imports some of those products into Germany.

3 Rhône-Poulenc is a German subsidiary of the French company Rhône-Poulenc Rover SA, which owns the trade mark "Orudis" in Germany and other countries. Under licence from its parent company, it markets the pharmaceutical product "Orudis retard" in Germany as a remedy for rheumatism, in packets of 20, 50 and 100 tablets contained in blister packs, thereby complying with the standard sizes recommended by various professional and commercial groups and by the German sickness insurance institutions.

4 In Spain, Orudis retard is sold only in packets of 20 tablets, by a sister company of Rhône-Poulenc.

5 Pharma imports Orudis retard in parallel from Spain, and markets it in Germany. In order to obtain packages of 50 tablets, it repackages the product in new external packaging designed by itself, in which it places the blister packs taken from various original Spanish packets.

6 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:

"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."

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

8 Rhône-Poulenc regards the marketing of the repackaged product as an infringement of the trade mark "Orudis", and applied for an injunction against Pharma. The application was upheld by the Landgericht, whereupon Pharma appealed to the Oberlandesgericht Koeln, which decided to stay the proceedings and refer the following questions to the Court for a preliminary ruling:

"1. Is it sufficient, for the purpose of establishing a disguised restriction on trade between Member States within the meaning of the second sentence of Article 36 of the EC Treaty, that the exercise of the national right to use a trade mark in connection with the marketing system adopted by the proprietor of the trade mark leads in objective terms to a partitioning of the markets between Member States, or is it necessary for that purpose to demonstrate that the proprietor of the trade mark exercises his right to use the trade mark in connection with the marketing system which he has adopted with the aim of bringing about an artificial partitioning of the markets?

2. 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?"

9 In these questions, which it is convenient to examine together, the national court is essentially asking in what circumstances a trade mark owner may, in accordance with Article 36 of the Treaty, rely on his rights as owner in order to prevent an importer from marketing a pharmaceutical 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. In particular, the Court is asked to explain the significance and content of the concept of "artificial partitioning of the markets" and to rule whether certain further conditions must be fulfilled by the importer.

10 Before considering those questions, it should be mentioned that it has been argued before the Court that the national legislation in question should be assessed in the light not of Article 36 of the Treaty but 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"). That directive was to be transposed into national law not later than 31 December 1992, the time-limit fixed by Council Decision 92/10/EEC of 19 December 1991 postponing the date on which the national provisions applying Directive 89/104/EEC to approximate the laws of the Member States relating to trade marks are to be put into effect (OJ 1992 L 6, p. 35).

11 Since the national court has not referred any question on the interpretation of Article 7 of the directive, the two following observations will suffice in that regard.

12 First, the consistent case-law of the Court shows that a directive may not of itself impose obligations on an individual and cannot therefore be relied upon as such against an individual (see, in particular, Case 152/84 Marshall v Southampton and South-West Hampshire Area Health Authority [1986] ECR 723, paragraph 48; Case C-106/89 Marleasing v La Comercial Internacional de Alimentación [1990] ECR I-4135, paragraph 6; Case C-91/92 Faccini Dori v Recreb [1994] ECR I-3325, paragraph 20). According to that case-law, however, when applying national law, whether adopted before or after the directive, the national court that has to interpret that law must do so, as far as possible, in the light of the wording and the purpose of the directive so as to achieve the result it has in view and thereby comply with the third paragraph of Article 189 of the EC Treaty.

13 Next, as stated in the judgment of the Court today in Joined Cases C-427/93, C-429/93 **and C-436/93 Bristol-Myers Squibb and Others v Paranova, paragraph 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.

14 As for the interpretation of Article 36 of the Treaty, prohibitions or restrictions on imports justified on grounds of the protection of industrial and commercial property are authorized by that article, provided they do not constitute a means of arbitrary discrimination or a disguised restriction on trade between Member States.

15 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.

16 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 Case C-10/89 CNL-SUCAL v HAG GF [1990] ECR I-3711 ("HAG II"), paragraph 13**, and **Case C-9/93 IHT Internationale Heiztechnik v Ideal Standard [1994] ECR I-2789, paragraphs 37 and 45**).

17 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 **Case 102/77 Hoffmann-La Roche v Centrafarm [1978] ECR 1139, paragraph 7**; **Case 1/81 Pfizer v Eurim-Pharm [1981] ECR 2913, paragraph 7**; **HAG II, paragraph 14; and IHT Internationale Heiztechnik, paragraph 33**).

18 It follows that 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, **Case 16/74 Centrafarm v Winthrop [1974] ECR 1183, paragraphs 7 to 11**; **HAG II, paragraph 12; and IHT Internationale Heiztechnik, paragraphs 33 and 34**).

19 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**).

20 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 prod-

ucts 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**).

21 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**).

22 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 in order 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 reliance on 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.

23 That case-law must, however, be clarified further in the light of the arguments raised in these cases, and in **Bristol-Myers Squibb**, cited above, and Joined Cases C-71/94, C-72/94 and C-73/94 Eurim-Pharm v Beiersdorf and Others, in which the Court has also given judgment today.

Artificial partitioning of the markets between Member States

24 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.

25 The trade mark owner cannot therefore oppose the repackaging of the product in new external packaging when the packet size 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.

26 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.

27 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.

28 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.

29 Finally, contrary to Rhône-Poulenc' s argument, 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 thereunder in order 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

30 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.

31 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.

32 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.

33 It follows from that case-law that the mere removal of blister packs from their original external packaging and their insertion with one or more original packages into new external packaging or their insertion into another original package cannot affect the original condition of the product inside the packaging.

34 It has, however, been argued before the Court 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 packages and grouped together in single external packaging might have come from different production batches with different use-by dates.

35 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.

36 As for an operation consisting in the addition to the packaging of new user instructions or information in the language of the Member State of importation, there is nothing to suggest that the original condition of the product inside the packaging is directly affected thereby.

37 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.

38 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

39 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. 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.

40 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.

41 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.

42 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.

43 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.

44 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.

45 Nevertheless, 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.

46 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.

47 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.

48 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.

49 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 such as 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.

50 Accordingly, the answer to the questions referred must be that Article 36 of the Treaty must be interpreted as meaning that a trade mark owner may rely upon his rights as owner to prevent an importer from marketing a pharmaceutical 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 thereto, 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 requirement 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 from their original external packaging and their insertion into new external packaging, or the addition to the packaging of new user instructions or information; 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;

° 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; 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.

Decision on costs

Costs

51 The costs incurred by the French Government and 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 action pending before the national court, the decision on costs is a matter for that court.

Operative part

On those grounds,

THE COURT,

in answer to the questions referred to it by the Oberlandesgericht Koeln by order of 29 July 1994, hereby rules:

Article 36 of the EC Treaty must be interpreted as meaning that a trade mark owner may rely upon his rights as owner to prevent an importer from marketing a pharmaceutical 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 thereto, 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 requirement 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 from their original external

packaging and their insertion into new external packaging, or the addition to the packaging of new user instructions or information; 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;

° 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; 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.