JUDGMENT OF THE COURT

23 April 2002 *

In Case C-443/99,

REFERENCE to the Court under Article 234 EC by the Oberlandesgericht Wien (Austria) for a preliminary ruling in the proceedings pending before that court between

Merck, Sharp & Dohme GmbH

and

Paranova Pharmazeutika Handels GmbH,

on the interpretation of Article 7(2) of First Council Directive 89/104/EEC of 21 December 1988 to approximate the laws of the Member States relating to trade marks (OJ 1989 L 40, p. 1), as amended by the Agreement on the European Economic Area of 2 May 1992 (OJ 1994 L 1, p. 3),

* Language of the case: German.

THE COURT,

composed of: G.C. Rodríguez Iglesias, President, P. Jann (President of Chamber), C. Gulmann (Rapporteur), D.A.O. Edward, A. La Pergola, M. Wathelet, R. Schintgen, V. Skouris and J.N. Cunha Rodrigues, Judges,

Advocate General: F.G. Jacobs,
Registrar: D. Louterman-Hubeau, Head of Division,

after considering the written observations submitted on behalf of:

— Merck, Sharp & Dohme GmbH, by R. Subiotto, solicitor, and C. Annacker, Rechtsanwältin,

— Paranova Pharmazeutika Handels GmbH, by R. Schneider, Rechtsanwalt,

— the Belgian Government, by A. Snoecx, acting as Agent,

— the Norwegian Government, by B. Ekeberg, acting as Agent,

— the Commission of the European Communities, by K. Banks and by S. Rating and M. Desantes Real, acting as Agents,

having regard to the Report for the Hearing,

after hearing the oral observations of Merck, Sharp & Dohme GmbH, represented by R. Subiotto and C. Annacker, of Paranova Pharmazeutika Handels GmbH, represented by R. Schneider and by E.B. Pfeiffer, Geschäftsführer, of the Norwegian Government, represented by B. Ekeberg, and of the Commission, represented by K. Banks and S. Rating, at the hearing on 3 April 2001,

after hearing the Opinion of the Advocate General at the sitting on 12 July 2001,

gives the following

Judgment

1 By order of 5 November 1999, received at the Court on 22 November 1999, the Oberlandesgericht Wien (Higher Regional Court, Vienna) referred to the Court for a preliminary ruling under Article 234 EC a question on the interpretation of Article 7(2) of First Council Directive 89/104/EEC of 21 December 1988 to approximate the laws of the Member States relating to trade marks (OJ 1989 L 40, p. 1), as amended by the Agreement on the European Economic Area of 2 May 1992 (OJ 1994 L 1, p. 3; 'the Directive').

2 That question was raised in the context of proceedings between Merck, Sharp & Dohme GmbH ('Merck'), an Austrian company belonging to the pharmaceutical group Merck & Co. Inc. ('the Merck group'), established in the United States, and Paranova Pharmazeutika Handels GmbH ('Paranova') concerning the marketing in Austria of pharmaceutical products which were manufactured by the Merck group and were the subject of parallel importation by Paranova.

Community law

3 Under Article 28 EC, quantitative restrictions on imports and measures having equivalent effect are to be prohibited between Member States. Article 30 EC, however, authorises prohibitions and restrictions on imports between Member States which are justified on grounds of the protection of industrial and commercial property, on condition that they do not constitute a means of arbitrary discrimination or a disguised restriction on intra-Community trade.

4 Article 7 of Directive 89/104, entitled 'Exhaustion of the rights conferred by a trade mark', 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.

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

5 In accordance with Article 65(2) of the Agreement on the European Economic Area, in conjunction with Annex XVII, point 4, thereto, Article 7(1) of Directive 89/104 has been amended for the purposes of that agreement, the expression 'in the Community' having been replaced by 'in a Contracting Party'.

The main proceedings and the question referred for preliminary ruling

6 Merck markets in Austria, in particular, pharmaceutical products which are intended for the treatment of benign prostatic hyperplasia and are sold under the trade mark Proscar, a mark registered by the Merck group.

7 Paranova, whose sole shareholder is the Danish group Paranova A/S ('the Paranova group'), trades, like its parent company, in original pharmaceutical products and specialises in parallel importation. It purchases pharmaceutical products in Member States where prices are comparatively low in order to sell them in other Member States where prices are higher, thus exploiting the price differences within the Community.

8 On 23 November 1997, Paranova was authorised by the Austrian authorities to place on the Austrian market the pharmaceutical product Proscar imported in parallel from Spain. Following that authorisation, it purchased the pharmaceutical product in Spain and had it repackaged in Denmark by Paranova-Pack A/S, a company also belonging to the Paranova group. The repackaging involved giving the product new outer packaging, namely a new box, and attaching to it new annexes translated into German, setting out the information and precautions for use. The particulars required for marketing in Austria were also attached. The packaging used in Austria contained, as in Spain, two blister strips of 14 tablets each.

9 On 15 July 1998, Paranova notified Merck of its intention to put on the market parallel imports of Proscar. At its request, Merck received a sample of the repackaged product, enclosed with a letter of 22 July 1998 in which it was requested to make known any objections it might have.

10 By letter of 9 October 1997 to Paranova, the Austrian authorities, referring to Community case-law, drew attention to the decisive importance of the appearance of pharmaceutical products for compliance by patients with their treatment, which might be jeopardised if the packaging were over-stickered.

11 Merck opposed use of the trade mark Proscar by placing it on the packaging where the product is presented and sold in the Member State of origin in the same arrangement (number of tablets) as in Austria. It claimed that that repackaging constituted unlawful interference with its trade mark rights.

12 Paranova contended that the pharmaceutical product could be marketed only if a number of particulars in German were shown on its outer packaging, in accordance with Paragraph 7(1) of the Arzneimittelgesetz (Austrian Law on pharmaceutical products). It also relied on the fact that the Austrian authorities had recommended replacement packaging and not mere over-stickering. According to Paranova, attaching labels would have had an appreciable influence on the sale of the pharmaceutical products, because relabelled foreign packs engender reactions of mistrust and rejection from both pharmacists and consumers.

13 The Handelsgericht Wien (Commercial Court, Vienna), to which Merck had applied on 22 July 1999 for an order to desist, granted such an order by decision of 16 August 1999. It held that it was possible for the packs of the pharmaceutical product Proscar to be provided with labels on all six sides without this impeding the marketing of that product.

14 On 7 September 1999, Paranova appealed against that decision to the referring court.

15 Since it took the view that the resolution of the dispute depended on the interpretation of Community law, the Oberlandesgericht Wien decided to stay proceedings and to refer the following question to the Court for a preliminary ruling:

'Must Article 7(2) of the First Council Directive of 21 December 1988 to approximate the laws of the Member States relating to trade marks (89/104/EEC) be interpreted as meaning that a trade mark owner may oppose the marketing of a pharmaceutical product put on the market under his trade mark where the importer has repackaged it and reaffixed the trade mark and has complied with the other requirements set forth in the Court of Justice judgment in Joined Cases C-427/93, C-429/93 and C-436/93 [*Bristol-Myers Squibb and Others* [1996] ECR I-3457] (the product inside the packaging must not be affected, the manufacturer and origin must be clearly indicated, the reputation of the trade mark or its owner must not be damaged as a consequence of poor packaging, and the trade mark owner must be given notice before the repackaged pharmaceutical product is put on sale), but the marketability of the product would be jeopardised without such repackaging solely because a significant proportion of the consumers of pharmaceutical products in the State of importation is suspicious of pharmaceutical products which have clearly been produced for the market of another State (in which a different language is spoken) and are inside packagings which have been adapted merely by means of self-stick labels to the domestic provisions governing the sale of pharmaceutical products?'

The question referred for preliminary ruling

16 By its question, the national court seeks essentially to ascertain whether a trade mark proprietor may oppose the repackaging, by a parallel importer and without its authorisation, of a pharmaceutical product bearing that trade mark on the ground that the repackaging is not necessary for the product to be able to be marketed in the importing State even if, without such repackaging, the marketability of the product would be jeopardised solely because a significant proportion of the consumers in that State is suspicious of pharmaceutical products clearly intended for the market of another State.

17 The national court states that Austrian consumers are not accustomed to being offered pharmaceutical products which have clearly been put on the market in another State, where a different language is used. It states that it is perfectly conceivable that a significant number of consumers would regard such a product with the same suspicion as products with untidy or poor-quality packaging. Even attaching labels, in particular in the case before it, would scarcely mitigate that suspicion. If it were to emerge that a significant proportion of consumers would in fact be suspicious in that way, it would be entirely possible, in the view of the national court, to consider that prohibition of the repackaging would contribute to artificial partitioning of the markets.

Observations submitted to the Court

18 Merck submits that the Court has already answered the question referred and that it did so most recently in Case C-379/97 *Upjohn* [1999] ECR I-6927. Inconvenience, consisting for example in having to overcome the resistance of consumers to relabelled pharmaceutical products, cannot justify a parallel importer in repackaging an imported product. In the alternative, Merck claims that a trade mark proprietor's prohibition of the replacement of packaging is justified where it is possible for the importer merely to adapt the original packaging, even if consumers prefer products whose packaging has been replaced. In a market economy it is for the parallel importer to overcome that consumer tendency. The importer's commercial interests are subjective and cannot be used as a basis for the assessment of the validity of its conduct without offending the principle of legal certainty. Moreover, the principle of proportionality requires that a restriction on a fundamental right must not go beyond what is sufficient and necessary to achieve the objective pursued.

19 According to Paranova, the obligation to attach labels constitutes an obstacle to sale and leads to an unacceptable partitioning of markets. Replacement of the

packaging of medicinal products from other Member States is in principle lawful, provided that the importer complies with the conditions imposed by the Court in its case-law. The Court stated in *Bristol-Myers Squibb and Others* that medicinal products fall within a sensitive area where the presentation of the product may be capable of inspiring or destroying public confidence. On a market where the national authorities prefer replacement packaging of medicinal products to over-stickering, to require over-stickering amounts to an obstacle to trade which is much more significant than that arising from different sizes of packaging, as in *Bristol-Myers Squibb and Others*. The requirement of the 'necessity' of repackaging is unclear and does not constitute the decisive criterion. If, however, it were held to be applicable, that requirement should be broadly understood so as to enable effective access to the market, which precludes solely matters subjective to the parallel importer itself.

20 The Norwegian Government submits that the requirement of necessity is satisfied where a significant proportion of consumers has a tendency not to purchase products which are not repackaged because it is suspicious of medicinal products manifestly intended for the market of another State, where another language is used.

21 The Commission submits that the 'necessity' which objectively justifies repackaging by a parallel importer may be the result of circumstances of law or of fact. Since it is the basis for a derogation from the principle prohibiting trade mark infringement which is enshrined in Community law, that concept must be strictly interpreted. The parallel importer should cause as little damage as possible to the specific subject-matter of the mark. It cannot, for example, replace the packaging where it is possible to attach labels. According to the Court's case-law, a prohibition on repackaging contributes unjustifiably to an artificial partitioning of the markets only if the suspicion of the products imported is such that the parallel importer is thereby refused effective access to the market of the importing State. It therefore seems that even considerable suspicion on the part of consumers is not sufficient in that regard. There is nothing to suggest that, in the main proceedings, the replacement of the packaging satisfies in law or in fact a 'necessity' thus defined.

Findings of the Court

22 It should be noted as a preliminary point that the question referred relates to a situation in which a trade mark proprietor has opposed repackaging consisting in replacement of the original packaging by new packaging designed by the importer and required that the importer restrict itself to relabelling by means of self-adhesive stickers.

23 It is clear from paragraph 14 of the judgment in Case 102/77 *Hoffmann-La Roche* [1978] ECR 1139 that the proprietor of a trade mark right which is protected in two Member States at the same time is justified, for the purposes of the first sentence of Article 30 EC, in preventing a product to which the trade mark has lawfully been applied in one of those States from being put on the market 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. That paragraph also states, however, that such prevention of marketing will constitute a disguised restriction on trade between Member States, within the meaning of the second sentence of Article 30 EC, where it is established, in particular, 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.

24 In cases subsequent to *Hoffmann-La Roche*, in particular in *Bristol-Myers Squibb and Others* and *Upjohn*, the Court clarified what may constitute artificial partitioning of the markets between Member States. In certain circumstances, where repackaging is necessary to allow the product imported in parallel to be marketed in the importing State, opposition of the trade mark proprietor to the repackaging of pharmaceutical products is to be regarded as constituting artificial partitioning of markets.

25 The Court has found in that respect that it is necessary to take account of the circumstances prevailing at the time of marketing in the importing Member State which make repackaging objectively necessary in order that the pharmaceutical

product can be placed on the market in that State by the parallel importer. The trade mark proprietor's opposition to the repackaging is not justified if it hinders effective access of the imported product to the market of that State (see, to that effect, *Upjohn*, paragraph 43).

26 Such an impediment exists, for example, where pharmaceutical products purchased by the parallel importer cannot be placed on the market in the Member State of importation in their original packaging by reason of national rules or practices relating to packaging, or where sickness insurance rules make reimbursement of medical expenses depend on a certain packaging or where well-established medical prescription practices are based, *inter alia*, on standard sizes recommended by professional groups and sickness insurance institutions. In that regard, it is sufficient for there to be an impediment in respect of one type of packaging used by the trade mark proprietor in the Member State of importation (see *Bristol-Myers Squibb and Others*, paragraphs 53 and 54).

27 In contrast, the trade mark proprietor may oppose the repackaging if it is based solely on the parallel importer's attempt to secure a commercial advantage (see, to that effect, *Upjohn*, paragraph 44).

28 In that context, it has also been held that the trade mark proprietor may oppose replacement packaging where the parallel importer is able to reuse the original packaging for the purpose of marketing in the Member State of importation by affixing labels to that packaging (see *Bristol-Myers Squibb and Others*, paragraph 55).

29 Thus, while the trade mark proprietor may oppose the parallel importer's use of replacement packaging, that is conditional on the relabelled pharmaceutical product being able to have effective access to the market concerned.

30 Resistance to relabelled pharmaceutical products does not always constitute an impediment to effective market access such as to make replacement packaging necessary, within the meaning of the Court's case-law.

31 However, there may exist on a market, or on a substantial part of it, such strong resistance from a significant proportion of consumers to relabelled pharmaceutical products that there must be held to be a hindrance to effective market access. In those circumstances, repackaging of the pharmaceutical products would not be explicable solely by the attempt to secure a commercial advantage. The purpose would be to achieve effective market access.

32 It is for the national court to determine whether that is the case.

33 The answer to the question referred must therefore be that replacement packaging of pharmaceutical products is objectively necessary within the meaning of the Court's case-law if, without such repackaging, effective access to the market concerned, or to a substantial part of that market, must be considered to be hindered as the result of strong resistance from a significant proportion of consumers to relabelled pharmaceutical products.

Costs

34 The costs incurred by the Belgian and Norwegian Governments and by the Commission, 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.

On those grounds,

THE COURT,

in answer to the question referred to it by the Oberlandesgericht Wien by order of 5 November 1999, hereby rules:

Replacement packaging of pharmaceutical products is objectively necessary within the meaning of the Court's case-law if, without such repackaging, effective access to the market concerned, or to a substantial part of that market, must be considered to be hindered as the result of strong resistance from a significant proportion of consumers to relabelled pharmaceutical products.

Rodríguez Iglesias	Jann	Gulmann
Edward	La Pergola	Wathelet
Schintgen	Skouris	Cunha Rodrigues

Delivered in open court in Luxembourg on 23 April 2002.

R. Grass — Registrar

G.C. Rodríguez Iglesias — President