JUDGMENT OF THE COURT (First Chamber)

28 July 2011

(Trade marks – Directive 89/104/EEC – Article 7(2) – Pharmaceutical products – Parallel imports – Repackaging of the product bearing the trade mark – New packaging indicating as the repackager the holder of the marketing authorisation on whose instructions the product was repackaged – Physical repackaging carried out by a separate undertaking)

In Joined Cases C-400/09 and C-207/10,

REFERENCES for preliminary rulings under Article 234 EC and Article 267 TFEU from the Højesteret (Denmark), made by decisions of 7 October 2009 and 22 April 2010, received at the Court on 19 October 2009 and 30 April 2010, in the proceedings

Orifarm A/S,

Orifarm Supply A/S,

Handelsselskabet af 5. januar 2002 A/S, in liquidation,

Ompakningsselskabet af 1. november 2005 A/S (C-400/09),

and

Paranova Danmark A/S,

Paranova Pack A/S (C-207/10)

v

Merck Sharp & Dohme Corp., formerly Merck & Co. Inc.,

Merck Sharp & Dohme BV,

Merck Sharp & Dohme,

THE COURT (First Chamber),

composed of A. Tizzano, President of the Chamber, J.-J. Kasel, M. Ilešič (Rapporteur), E. Levits and M. Safjan, Judges,

Advocate General: Y. Bot,

Registrar: C. Strömholm, Administrator,

having regard to the written procedure and further to the hearing on 7 April 2011,

after considering the observations submitted on behalf of:

– Orifarm A/S, Orifarm Supply A/S, Handelsselskabet af 5. januar 2002 A/S, in liquidation, and Ompakningsselskabet af 1. november 2005 A/S, by J.J. Bugge and K. Jensen, advokater,

– Paranova Danmark A/S and Paranova Pack A/S, by E.B. Pfeiffer, advokat,

– Merck Sharp & Dohme Corp., formerly Merck & Co. Inc., Merck Sharp & Dohme BV and Merck Sharp & Dohme, by R. Subiotto QC and T. Weincke, advokat,

– the Czech Government, by M. Smolek and K. Havlíčková, acting as Agents,

– the Italian Government, by G. Palmieri, acting as Agent, and S. Fiorentino, avvocato dello Stato,

– the Portuguese Government, by L. Inez Fernandes and P.A. Antunes, acting as Agents,

– the European Commission, by H. Krämer, H. Støvlbæk and F.W. Bulst, acting as Agents,

after hearing the Opinion of the Advocate General at the sitting on 12 May 2011,

gives the following

Judgment

1 These references for preliminary rulings concern 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) and the associated case-law of the Court, in particular Case 102/77 *Hoffmann-La Roche* [1978] ECR 1139, Case 1/81 *Pfizer* [1981] ECR 2913, Joined Cases C-427/93, C-429/93 and C-436/93 *Bristol-Myers Squibb and Others* [1996] ECR I-3457, and Case C-232/94 *MPA Pharma* [1996] ECR I-3671. In those judgments the Court specified the conditions under which a parallel importer may market repackaged medicinal products bearing a trade mark, without the proprietor of the trade mark being able to object.

2 The references have been made in proceedings between – in Case C-400/09 – Orifarm A/S ('Orifarm'), Orifarm Supply A/S ('Orifarm Supply'), Handelsselskabet af 5. januar 2002 A/S, in liquidation, ('Handelsselskabet') and Ompakningsselskabet af 1.

november 2005 A/S ('Ompakningsselskabet') and – in Case C-207/10 – Paranova Danmark A/S ('Paranova Danmark') and Paranova Pack A/S ('Paranova Pack') and Merck Sharp & Dohme Corp., formerly Merck & Co. Inc., Merck Sharp & Dohme BV and Merck Sharp & Dohme (referred to together as 'Merck') concerning the lack of an indication of the actual repackager on the new packaging of medicinal products imported in parallel.

Legal context

3 Directive 89/104 was repealed by Directive 2008/95/EC of the European Parliament and of the Council of 22 October 2008 to approximate the laws of the Member States relating to trade marks (OJ 2008 L 299, p. 25), which entered into force on 28 November 2008. However, having regard to the time at which the facts occurred, the disputes in the main proceedings remain governed by Directive 89/104.

4 Article 5 of Directive 89/104, 'Rights conferred by a trade mark', provided:

'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. Any Member State may also provide that the proprietor shall be entitled to prevent all third parties not having his consent from using in the course of trade any sign which is identical with, or similar to, the trade mark in relation to goods or services which are not similar to those for which the trade mark is registered, where the latter has a reputation in the Member State and where use of that sign without due cause takes unfair advantage of, or is detrimental to, the distinctive character or the repute of the trade mark.

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 Under Article 7 of that directive, 'Exhaustion of the rights conferred by a trade mark':

'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.'

The actions in the main proceedings and the questions referred for a preliminary ruling

Case C-400/09

6 Orifarm, Orifarm Supply, Handelsselskabet and Ompakningsselskabet are companies in the Orifarm group. That group is the largest parallel importer of medicinal products in the Nordic countries, and was in 2008 the largest supplier of medicinal products to Danish pharmacies. The head office of the group is in Odense (Denmark).

7 Merck, which is one of the world's largest groups producing medicinal products, manufactured the medicinal products at issue in the main proceedings, which were imported in parallel onto the Danish market by the Orifarm group. Merck is also the proprietor of trade mark rights relating to those medicinal products, or is entitled to bring judicial proceedings under licence agreements concluded with proprietors of trade mark rights.

8 Orifarm and Handelsselskabet are or were the holders of authorisations to market and sell those medicinal products, while Orifarm Supply and Ompakningsselskabet, which carried out the repackaging, are or were holders of authorisations to do so.

9 All decisions concerning the purchase, repackaging and sale of the medicinal products at issue in the main proceedings, including those relating to the design of the new packagings and to the labelling, were taken by Orifarm or Handelsselskabet. Ompakningsselskabet and Orifarm Supply purchased and repackaged the medicinal products, assuming liability for compliance with the requirements for repackagers laid down by the Lægemiddelstyrelsen (the Danish Medicinal Products Agency).

10 The packaging of the medicinal products indicated that they had been repackaged by Orifarm or Handelsselskabet as the case may be.

11 Merck brought two actions before the Sø- og Handelsret (Maritime and Commercial Court) (Denmark), one against Orifarm and Orifarm Supply and the other against Handelsselskabet and Ompakningsselskabet, on the ground that the name of the actual repackager did not appear on the packaging of the medicinal products in question. In judgments delivered on 21 February and 20 June 2008 respectively, the Sø- og Handelsret found that the defendants had infringed Merck's trade mark rights by failing to indicate on the packaging the name of the undertaking which had actually performed the repackaging, and consequently ordered them to pay monetary compensation to Merck.

12 The Højesteret (Supreme Court) (Denmark), hearing the appeals on a point of law brought by Orifarm, Orifarm Supply, Handelsselskabet and Ompakningsselskabet against the judgments of the Sø- og Handelsret, decided to stay the proceedings and refer the following questions to the Court for a preliminary ruling:

'(1) The Court of Justice is requested to clarify whether [*Bristol-Myers Squibb and Others* and *MPA Pharma*] are to be interpreted as meaning that a parallel importer which is the holder of the marketing authorisation for, and possesses information on, a medicinal product imported in parallel, and which issues instructions to a separate undertaking for the purchase and repackaging of a medicinal product, for the detailed design of the product's packaging and for arrangements in relation to the product, infringes the rights of the trade mark proprietor by indicating itself – and not the separate undertaking which holds the repackaging authorisation, has imported the product and has carried out the physical repackaging, including (re)affixing of the trade mark proprietor's trade mark – as the repackager on the outer packaging of the medicinal product imported in parallel.

(2) The Court of Justice is requested to clarify whether it is of significance in answering Question 1 that an assumption might be made that, where the marketing authorisation holder indicates itself as the repackager instead of the undertaking which physically carried out the repackaging to order, there is no risk that the consumer/end user might be misled into assuming that the trade mark proprietor is responsible for the repackaging.

(3) The Court of Justice is requested to clarify whether it is of significance in answering Question 1 that an assumption might be made that the risk of misleading the consumer/end user into assuming that the trade mark proprietor is responsible for the repackaging is excluded if the undertaking which physically carried out the repackaging is indicated as being the repackager.

(4) The Court of Justice is requested to clarify whether it is only the risk that the consumer/end user might be misled into assuming that the trade mark proprietor is responsible for the repackaging which is of significance in answering Question 1, or whether other considerations regarding the trade mark proprietor are also relevant, for example

(a) that the entity which undertakes the importation and physical repackaging and (re)affixes the trade mark proprietor's trade mark on the product's outer packaging potentially on its own account infringes the trade mark proprietor's trade mark by so doing, and

(b) that it may be due to factors for which the entity that physically carried out the repackaging is responsible that the repackaging affects the original condition of the product or that the presentation of the repackaging is of such a kind that it must be assumed to harm the trade mark proprietor's reputation (see, inter alia, … *Bristol-Myers Squibb and Others* …).

(5) The Court of Justice is requested to clarify whether it is of significance in answering Question 1 that the holder of the marketing authorisation, which has indicated itself as being the repackager, at the time of the notification of the trade mark proprietor prior to the intended sale of the parallel imported medicinal product once repackaged, belongs to the same group as the actual repackager (sister company).'

Case C-207/10

13 Paranova Danmark and Paranova Pack are subsidiaries of Paranova Group A/S ('Paranova Group'), which carries out parallel imports of medicinal products into Denmark, Sweden and Finland. The group has its head office in Ballerup (Denmark), where the two subsidiaries are also located.

14 In the same way as was done in Case C-400/09, Paranova Group imported in parallel into Denmark the medicinal products at issue in the main proceedings, which were manufactured by Merck, which is the proprietor of trade mark rights relating to those medicinal products, or is entitled to bring judicial proceedings under licence agreements concluded with the proprietors of the trade marks.

15 Paranova Danmark is the holder of a marketing authorisation for those medicinal products, while Paranova Pack, which carried out the repackaging, is the holder of an authorisation to do so.

16 All decisions concerning the purchase, repackaging and sale of the medicinal products at issue in the main proceedings, including those relating to the design of the new packagings and to the labelling, were taken by Paranova Danmark. Paranova Pack purchased and actually repackaged the medicinal products, in compliance with the requirements laid down for repackagers by the Lægemiddelstyrelsen, and released them for sale in accordance with the legislation on pharmaceutical products, assuming liability for those operations.

17 The packaging of the medicinal products indicated that they had been repackaged by Paranova Danmark.

18 Merck brought two actions against Paranova Danmark and Paranova Pack on the ground that the name of the actual repackager did not appear on the packaging of the medicinal products in question. As a result of those actions, Paranova Danmark and Paranova Pack were prohibited – the former by order of the Fogedret i Ballerup (Bailiff's Court, Ballerup) of 26 October 2004, confirmed on appeal by the Sø- og Handelsret on 15 August 2007, the latter by judgment of the Sø- og Handelsret of 31 March 2008 – from selling those medicinal products, on the ground that their packaging did not indicate the name of the undertaking which had actually carried out the repackaging.

19 The Højesteret, hearing the appeals on a point of law brought by Paranova Danmark and Paranova Pack against the judgments of the Sø- og Handelsret, decided to stay the proceedings and refer the following questions to the Court for a preliminary ruling:

'(1) Are Article 7(2) of [Directive 89/104] and the associated case-law, in particular the judgments of the Court of Justice in … *Hoffmann-La Roche* … and … *Pfizer* … and … *Bristol-Myers Squibb and Others* … to be interpreted as meaning that a trade mark proprietor may rely on these provisions in order to prevent a parallel importer's marketing company, which is the holder of a marketing authorisation for a medicinal product in a Member State, from selling that product with an indication that the product is repackaged by the marketing company, although the marketing company has the physical repackaging carried out by another company, the repackaging company, to which the marketing company gives instructions for the purchasing and repackaging of the product, for the detailed design of the product's packaging and for other arrangements in relation to the product, and which holds the repackaging authorisation and reaffixes the trade mark on the new package in the course of repackaging?

(2) Is it of significance in answering Question 1 that an assumption might be made that the consumer or end-user is not misled with regard to the origin of the product and will not be led to believe that the trade mark proprietor is responsible for the repackaging through the indication by the parallel importer of the manufacturer's name on the packaging along with the indication as described of the undertaking responsible for the repackaging?

(3) Is it only the risk that the consumer or end-user might be misled into assuming that the trade mark proprietor is responsible for the repackaging which is of significance in answering Question 1, or are other considerations regarding the trade mark proprietor also relevant, for example

(a) that the entity which in fact undertakes the purchasing and repackaging and reaffixes the trade mark proprietor's trade mark on the product's packaging thereby potentially infringes independently the trade mark proprietor's trade mark rights, and that that may be due to factors for which the entity that physically carried out the repackaging is responsible,

(b) that the repackaging affects the original condition of the product, or

(c) that the presentation of the repackaged product is of such a kind that it may be assumed to harm the trade mark or its proprietor's reputation?

(4) If, in answering Question 3, the Court finds that it is also relevant to take account of the fact that the repackaging company potentially infringes independently the trade mark rights of the trade mark proprietor, the Court is asked to indicate whether it is of significance to this answer that the marketing company and repackaging company of the parallel importer are jointly and severally liable under national law for the infringement of the trade mark proprietor's trade mark rights.

(5) Is it of significance in answering Question 1 that the parallel importer which holds the marketing authorisation and has indicated itself as being responsible for repackaging, at the time of the notification of the trade mark proprietor prior to the intended sale of the repackaged medicinal product, belongs to the same group as the company which undertook the repackaging (sister company)?

(6) Is it of significance in answering Question 1 that the repackaging company is indicated as the manufacturer in the package leaflet?'

20 By order of the President of the First Chamber of the Court of 31 January 2011, Cases C-400/09 and C-207/10 were joined for the purposes of the oral procedure and the judgment.

Consideration of the questions referred

21 By its questions, which should be taken together, the referring court asks essentially whether Article 7(2) of Directive 89/104 must be interpreted as allowing the proprietor of a trade mark relating to a pharmaceutical product which is the subject of parallel imports to oppose the further marketing of that product in repackaged form on the ground that the new packaging indicates as the repackager not the undertaking which, on instructions, actually repackaged the product and holds an authorisation to do so, but the undertaking which holds the marketing authorisation for the product, on whose instructions the repackaging was carried out, and which assumes liability for the repackaging.

22 Orifarm, Paranova Danmark, the Czech and Portuguese Governments and the European Commission take the view that those questions, as reformulated, should be answered in the negative, while Merck and the Italian Government take the opposite view.

23 It should be recalled, as a preliminary point, that under Article 7(2) of Directive 89/104 the trade mark proprietor's opposition to the repackaging of products bearing the mark, in that it constitutes a derogation from free movement of goods, cannot be

accepted if the proprietor's exercise of that right constitutes a disguised restriction on trade between Member States within the meaning of the second sentence of Article 30 EC (now the second sentence of Article 36 TFEU) (see Case C-348/04 *Boehringer Ingelheim and Others* [2007] ECR I-3391, paragraph 16 and the case-law cited).

24 A disguised restriction within the meaning of that provision will exist where the exercise by the trade mark proprietor of his right to oppose repackaging contributes to artificial partitioning of the markets between Member States and where, in addition, the repackaging is done in such a way that the legitimate interests of the proprietor are respected (see *Boehringer Ingelheim and Others*, paragraph 17 and the case-law cited).

25 On the latter point, the Court has held that, 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 proprietor (see *Bristol-Myers Squibb and Others*, paragraph 67, and *MPA Pharma*, paragraph 39).

26 However, it has also held that the conclusion that the proprietor may not rely on the rights conferred by the trade mark in order to oppose the marketing under his trade mark of products repackaged by an importer amounts to conferring on the importer certain rights which in normal circumstances are reserved for the trade mark proprietor himself. Consequently, in the interests of the proprietor as owner of the trade mark, and to protect him against any misuse, those rights must be recognised only in so far as the importer also complies with a number of other requirements (see, to that effect, *Bristol-Myers Squibb and Others*, paragraphs 68 and 69, and *MPA Pharma*, paragraphs 40 and 41).

27 It thus follows from settled case-law, in particular the judgments which the referring court asks the Court to interpret, that the proprietor of a trade mark may not legitimately oppose the further marketing of a pharmaceutical product bearing his trade mark which has been repackaged by an importer who has reaffixed the mark if

– it is shown that such opposition would contribute to artificial partitioning of the markets between Member States, in particular because the repackaging is necessary for marketing the product in the Member State of import;

– it is shown that the repackaging cannot affect the original condition of the product inside the packaging;

– the new packaging clearly indicates the repackager of the product and the name of the manufacturer;

– the presentation of the repackaged product is not liable to damage the reputation of the trade mark and its proprietor, which implies in particular that the packaging must not be defective, of poor quality, or untidy; and

– the importer gives notice to the proprietor of the trade mark before putting the repackaged product on sale, and supplies him, on request, with a specimen of the repackaged product (see, inter alia, *Hoffmann-La Roche*, paragraph 14; *Bristol-Myers Squibb and Others*, paragraph 79; *MPA Pharma*, paragraph 50; *Boehringer Ingelheim and Others*, paragraph 21; and Case C-276/05 *The Wellcome Foundation* [2008] ECR I-10479, paragraph 23).

28 As regards the condition at issue in the main proceedings that the new packaging must indicate clearly the repackager of the product, that requirement is justified by the trade mark proprietor's interest in the consumer or end user not being led to believe that the proprietor is responsible for the repackaging (see *Bristol-Myers Squibb and Others*, paragraph 70, and *MPA Pharma*, paragraph 42).

29 As the Advocate General observes in points 34 and 35 of his Opinion, that interest of the proprietor is fully safeguarded where the name of the undertaking at whose order and on whose instructions the repackaging has been carried out, and which assumes responsibility for the repackaging, appears clearly on the packaging of the repackaged product. Such an indication, as long as it is printed so as to be comprehensible to a normally attentive person, is such as to avoid the consumer or end user being given the incorrect impression that the product has been repackaged by the proprietor.

30 Moreover, because that undertaking assumes full responsibility for the repackaging operations, the proprietor can enforce his rights and, where appropriate, obtain compensation if the original condition of the product within the packaging has been affected by the repackaging or the presentation of the repackaged product is liable to damage the reputation of the trade mark. It should be stated that, in such a case, an undertaking which is mentioned as the repackager on the new packaging of a repackaged product will have to answer for any damage caused by the undertaking which actually carried out the repackaging, and cannot avoid liability by arguing, in particular, that that undertaking acted contrary to its instructions.

31 In those circumstances, the proprietor of the trade mark has no legitimate interest in requiring that the name of the undertaking which actually repackaged the product should appear on the packaging merely because the repackaging is liable to affect the original condition of the product and might therefore cause harm to his trade mark rights.

32 The interest of the trade mark proprietor in the preservation of the original condition of the product inside the packaging is sufficiently protected by the requirement, noted in paragraph 27 above, that it must be shown that the repackaging

cannot affect the original condition of the product. In circumstances such as those of the main proceedings, it is for the holder of the marketing authorisation, on whose instructions the repackaging has been carried out and who assumes liability for it, to show that that is the case.

33 Merck submits, however, that it is necessary in order to protect consumers to indicate on the packaging of the repackaged product the name of the undertaking which actually carried out the repackaging. Consumers have an interest in knowing the name of that undertaking, in particular where they are able under their national law to bring proceedings not only against the holder of the marketing authorisation but also against the repackager if they have suffered damage as a result of the repackaging.

34 That argument cannot be accepted, however. It suffices to state in this respect that it is clear from the wording of Article 7(2) of Directive 89/104 that the exception in that provision to the principle of the exhaustion of the rights conferred by the trade mark is limited to the protection of the legitimate interests of the trade mark proprietor, the specific protection of the legitimate interests of consumers being ensured by other legal instruments.

35 In any event, even it were supposed that the interests of the trade mark proprietor coincide, if only partly, with those of the consumer, the fact remains that, as the Advocate General observes in points 42 and 43 of his Opinion, the indication on the packaging of the product of the undertaking responsible for its repackaging enables the consumer to be sufficiently informed, from the point of view of trade mark law.

36 It follows from all the foregoing that Article 7(2) of Directive 89/104 must be interpreted as not allowing the proprietor of a trade mark relating to a pharmaceutical product which is the subject of parallel imports to oppose the further marketing of that product in repackaged form on the sole ground that the new packaging indicates as the repackager not the undertaking which, on instructions, actually repackaged the product and holds an authorisation to do so, but the undertaking which holds the marketing authorisation for the product, on whose instructions the repackaging was carried out, and which assumes liability for the repackaging.

Costs

37 Since these proceedings are, for the parties to the main proceedings, a step in the actions pending before the national court, the decisions on costs are a matter for that court. Costs incurred in submitting observations to the Court, other than the costs of those parties, are not recoverable.

On those grounds, the Court (First Chamber) hereby rules:

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 must be

interpreted as not allowing the proprietor of a trade mark relating to a pharmaceutical product which is the subject of parallel imports to oppose the further marketing of that product in repackaged form on the sole ground that the new packaging indicates as the repackager not the undertaking which, on instructions, actually repackaged the product and holds an authorisation to do so, but the undertaking which holds the marketing authorisation for the product, on whose instructions the repackaging was carried out, and which assumes liability for the repackaging.

[Signatures]

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* Language of the case: Danish.