

Court of Justice EU, 28 July 2011, Orifarm v Merck



TRADEMARK LAW – EXHAUSTION – FREE MOVEMENT OF GOODS

Indication market authorisation holder responsible for repackaging in stead of actual repackager allowed

• [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.](#)

Source: curia.europa.eu

Court of Justice EU, 28 July 2011

(A. Tizzano, J.-J. Kasel, M. Ilešič, E. Levits en M. Safjan)

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 if 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]

OPINION OF ADVOCATE GENERAL
BOT

delivered on 12 May 2011 (1)

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

Orifarm A/S,

Orifarm Supply A/S,

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

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

v

Merck & Co. Inc.,

Merck Sharp & Dohme BV,

Merck Sharp & Dohme

and

Paranova Danmark A/S,

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

v

Merck Sharp & Dohme Corp.,

Merck Sharp & Dohme,

Merck Sharp & Dohme BV

(Reference for a preliminary ruling from the Højesteret (Denmark))

(Trade marks – Directive 89/104/EEC – Article 7(2) – Repackaging of a pharmaceutical product imported in parallel – Relevant criteria for assessing damage to trade mark rights)

1. In these cases the Court has received references for preliminary rulings 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 (2) and on the case-law relating thereto, particularly the judgments in Hoffmann-La Roche, (3)Pfizer, (4)MPA Pharma, (5) and Bristol-Myers Squibb and Others. (6)

2. In those judgments, the Court clarified the conditions under which a parallel importer may market repackaged medicinal products under a trade mark, without the trade mark proprietor being able to oppose its doing so. The questions that the Højesteret (Supreme Court, Denmark) submits to the Court relate to one of those conditions, namely that the new packaging must identify the repackager. These questions essentially seek to ascertain whether that condition requires the name of the company which actually carried out the repackag-

ing to be indicated, or whether it is sufficient to state the name of the holder of the marketing authorisation for the medicinal product imported in parallel who instructs the actual repackager to purchase and repack-age.

3. In this Opinion I shall opt for the latter alternative. I shall therefore be proposing that the Court should declare that Article 7(2) of Directive 89/104 must be interpreted as meaning that the fact that the packaging of a repackaged product does not state the name of the undertaking which actually carried out the repackaging does not entitle a trade mark proprietor to oppose the marketing of that product where the name of the undertaking in charge of the repackaging and taking responsibility for it appears alongside the name of the manufacturer.

I – Legal background

4. Article 5 of Directive 89/104, entitled ‘Rights conferred by a trade mark’, provides 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. 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 the 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 com-

mercialisation of the goods, especially where the condition of the goods is changed or impaired after they have been put on the market.’

6. 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), (7) which came into force on 28 November 2008. However, given the time when the facts occurred, the disputes in the main proceedings are governed by Directive 89/104.

7. Articles 5 and 7 of Directive 89/104 were transposed into Danish law by Articles 4 and 6 respectively of the Law on trade marks (Varemærkeloven). (8)

II – Main proceedings and questions referred

A – Case C-400/09

8. 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’) are part of the Orifarm group, which 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 group has its head office in Odense (Denmark).

9. Orifarm and Handelsselskabet are or were holders of authorisations for the marketing and sale of the relevant medicinal products, while Orifarm Supply and Ompakningsselskabet, known as Medipack A/S (‘Medipack’) at the time of the repackaging and sale of the products at issue, actually carried out the repackaging and are or were holders of the repackaging authorisation.

10. All questions regarding procurement, presentation, handling and sale are dealt with by Orifarm, while Ompakningsselskabet purchases and repackages the products and is responsible for complying with the requirements for repackagers laid down by the Lægemiddelstyrelsen (Danish agency for medicinal products). Ompakningsselskabet (Medipack) has a staff of 210 dealing with logistics, storage, and repackaging, while Orifarm employs 15 to 20 people, in particular for the marketing of medicinal products.

11. Merck & Co. Inc., Merck Sharp & Dohme BV and Merck Sharp & Dohme (together referred to as ‘Merck’) all form part of the Merck group. The Merck group is one of the world’s largest manufacturers of original medicinal products.

12. The Merck group is the manufacturer of the medicinal products at issue, which the Orifarm group imported in parallel into Denmark. The Merck group is also the proprietor of the trade mark rights relating to those products, or is entitled to bring legal proceedings under licensing agreements entered into with trade mark proprietors.

13. From the time when the medicinal products began to be imported in parallel and marketed, Orifarm and Handelsselskabet presented themselves as the repackagers on the packaging of the medicinal products for which they held marketing authorisations, although the physical repackaging was carried out on a case-by-case basis on instructions from Orifarm and/or Handels-

selskabet, by Ompakningsselskabet (Medipack), Orifarm Supply or external repackagers. However, external repackagers were not involved in the present cases.

14. Although, from 2006, the Orifarm group started to display the words ‘repackaged by Medipack A/S for Orifarm A/S’ on Merck group products, the dispute in the main proceedings concerns medicinal products which did not state the actual repackager on the packaging, only the marketing authorisation holder and the manufacturer, in the following terms:

‘Imported and repackaged by Orifarm A/S ...
Manufacturer: Merck Sharp & Dohme’.

15. Merck brought two actions before the Sø- og Handelsret (Maritime and Commercial Court) (Denmark), one against Orifarm and Orifarm Supply and one against Handelsselskabet and Ompakningsselskabet, challenging the fact that the actual repackager was not mentioned on the packaging of the medicinal products at issue. In judgments delivered on 21 February 2008 and 20 June 2008 respectively, the Sø- og Handelsret found that the defendants had infringed Merck’s trade mark rights by failing to state the actual repackager, and ordered them to pay pecuniary compensation to Merck.

16. Since appeals on a point of law had been brought before it by Orifarm, Orifarm Supply, Handelsselskabet and Ompakningsselskabet against these judgments of the Sø- og Handelsret, the Højesteret decided to stay the proceedings and to submit the following questions to the Court:

‘(1) [Are the judgments in] ... MPA Pharma ... and ... Bristol-Myers Squibb and Others ... 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 as the repackager on the outer packaging of the imported medicinal product, instead of indicating the name of the independent undertaking which is the holder of the repackaging authorisation, and imported the product and carried out the actual repackaging, including (re)affixing the trade mark concerned?’

(2) [Is it] 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) [Is it] 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) [Is it] 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 are other considerations regarding the trade mark proprietor 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) [Is it] 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)?

B – Case C-207/10

17. Paranova Danmark A/S ('Paranova Danmark') and Paranova Pack A/S ('Paranova Pack') are subsidiaries of Paranova Group A/S which carries on business as a parallel importer of medicinal products to Denmark, Finland and Sweden. The group has its head office in Ballerup (Denmark), where the two subsidiaries are also established.

18. Paranova Danmark is the holder of a marketing authorisation for the medicinal products at issue.

19. Paranova Pack carries out repackaging for the entire group and therefore physically repackaged the medicinal products at issue. It is the holder of the authorisation for the repackaging of the medicinal products.

20. All questions concerning the selection of products for sale and purchase and applications for marketing authorisations, including types of packaging, are decided by Paranova Danmark. Paranova Pack makes the actual purchases and physically packages the medicinal products in compliance with the conditions imposed on repackagers by the Lægemiddelstyrelsen and resells them in accordance with pharmaceutical legislation, assuming responsibility therefor. The specialist who took charge of the final release of the batch was originally employed by Paranova, Denmark but was later transferred to Paranova Pack. In 2003, Paranova Denmark employed 11 staff and Paranova Pack 164. This proportion also applied during the other years relevant to the present case.

21. Paranova Denmark presented itself as the repackager on the packaging of the medicinal products at issue for which it held marketing authorisations, although the physical repackaging was carried out variously by Paranova Pack or repackagers outside the Paranova group. However, repackagers outside the group were not involved in this case.

22. Merck manufactured the medicinal products at issue, which the Paranova group imported in parallel into Denmark. Merck is also the proprietor of the trade mark rights relating to the products at issue which were imported in parallel, or is entitled to bring legal proceedings under licensing agreements with trade mark proprietors.

23. Merck brought two actions against Paranova Denmark and Paranova Pack, challenging the fact that the actual repackager was not stated on the packaging of the medicinal products at issue. As a result of these actions, Paranova Denmark and Paranova Pack were prohibited, the former by order of 26 October 2004 made by the Fogedret (Bailiff's Court) i Ballerup, confirmed on appeal on 15 August 2007 by the Sø- og Handelsret, and the latter by judgment of the Sø- og Handelsret of 31 March 2008, from selling those medicinal products, on the ground that the packaging did not indicate the real repackager.

24. Since appeals on a point of law had been brought before it by Paranova Denmark and Paranova Pack against those judgments of the Sø- og Handelsret, the Højesteret decided to stay the proceedings and to submit the following questions to the Court:

'(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 ..., 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 inde-

pendently 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?

III – Analysis

25. The questions submitted to the Court by the Højesteret, which must be considered together, (9) seek essentially to ascertain whether Article 7(2) of Directive 89/104 must be interpreted as meaning that where the packaging of a repackaged product does not state the name of the company which actually carried out the repackaging, the trade mark proprietor is entitled to oppose the marketing of that product if the name of the company in charge of the repackaging operation and taking responsibility for it appears alongside the name of the manufacturer.

26. The case-law of the Court relating to the repackaging of trade-marked medicinal products by parallel importers without the trade mark proprietor's consent originated in *Hoffmann-La Roche*, which laid down the guiding principles on the subject. In that judgment, the Court addressed the issue from the standpoint of the prohibition on measures restricting imports laid down in Article 30 of the EEC Treaty, and the justification of such measures on grounds of the protection of industrial and commercial property laid down in Article 36 of the EEC Treaty.

27. The Court held in that judgment that Article 36 of the EEC Treaty allows derogations from the fundamental principle of the free movement of goods only to the extent to which such derogations are justified in order to safeguard the rights which constitute the specific subject-matter of the industrial and commercial property concerned. In that context, 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 party, without the authorisation of the trade mark proprietor, in such a way as to affect the original condition of the product.

28. Therefore, according to the Court, the right conferred on the trade mark owner to oppose any use of the mark that could distort the guarantee of origin comes within the specific subject-matter of the trade mark rights; it is accordingly justifiable under the first sentence of Article 36 of the EEC Treaty to recognise that the proprietor of a trade mark is entitled to prevent an importer of a trade-marked product, following repackaging of that product, from affixing the trade mark to the new packaging without the authorisation of the proprietor. (10)

29. It is clear from paragraph 14 of *Hoffmann-La Roche* that the proprietor of a trade mark right which is protected in two Member States at the same time is justified, pursuant to the first sentence of Article 36 of the EEC Treaty, in preventing a product to which the trade mark has lawfully been applied in one of those States from being marketed in the other Member State after it has been repacked in new packaging to which the trade mark has been affixed by a third party. Likewise it is clear from that paragraph that such prevention constitutes a disguised restriction on trade between the Member States within the meaning of the second sentence of Article 36 of the EEC Treaty where the following conditions are satisfied:

- it is established that the use of the trade-mark right by the proprietor, having regard to the marketing system which he has adopted, will contribute to the artificial partitioning of the markets between Member States;
- it is shown that the repackaging cannot adversely affect the original condition of the product;
- the proprietor of the mark receives prior notice of the marketing of the repackaged product; and
- it is stated on the new packaging by whom the product has been repackaged. (11)

30. It is the interpretation of this latter condition which is central to the present cases. At paragraph 12 of *Hoffmann-La Roche*, the Court justified the existence of the condition, as well as that of prior notification of the proprietor of the mark, by reference to his interest in ensuring that consumers are not misled as to the origin of the product.

31. In its subsequent case-law, the Court elaborated on and clarified the requirements which the parallel importer must meet in order to be able to repackage trade-marked medicinal products. It did so in the light of Article 7 of Directive 89/104, which was adopted to regulate comprehensively the issue of exhaustion of trade-mark rights as regards products put into circulation within the European Union. The Court stated in this connection that Article 7 of the directive, like Article 36 of the EC 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 objective, must be interpreted in the same way. (12)

32. In refining the principles laid down in its judgment in *Hoffmann-La Roche*, the Court thus ruled in *Bristol-Myers Squibb and Others* that Article 7(2) of Directive 89/104 must be interpreted as meaning that the trade mark proprietor may legitimately oppose the subsequent marketing of a pharmaceutical product when the importer has repackaged the product and re-affixed the trade mark to it, unless several conditions are met, including, as regards the issues in the present cases, the condition that ‘the new packaging clearly states who repackaged the product and the name of the manufacturer [(13)] 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 authorisation of the trade mark owner’. (14)

33. The justification for this condition appears clearly in paragraph 70 of *Bristol-Myers Squibb and Others*. 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.

34. However, I am of the opinion that this interest is safeguarded where the name of the undertaking responsible for the repackaging (15) as well as that of the manufacturer appear clearly on the packaging of the medicinal product. This differentiation is likely to dispel any doubt in the consumer’s mind as to the respective roles of these two entities in the manufacture and repackaging of the product. What is important is, on the one hand, that the consumer knows who is responsible for the repackaging and to whom any product defects caused by this operation may be imputed and, on the other hand, that he is aware that the repackaging has not been carried out under the trade mark proprietor’s control.

35. It is sufficient, in this regard, for mention to be made of the name of the undertaking in charge of the repackaging which instructs the company engaged and assumes responsibility for the operation. If this is the parallel importer, then an indication that the product has been repackaged by the latter is enough to avoid any confusion in consumers’ minds and to make clear to them, as well as to the trade mark owner, who was in charge of the repackaging operation. On the other hand, if it appears that this operation was carried out entirely independently by a repackaging undertaking which assumes responsibility for it, it is that undertaking’s name which should appear on the packaging alongside that of the manufacturer.

36. Since the ‘person who carried out the repackaging’, as defined in *Bristol-Myers Squibb and Others*, means the company which controls the repackaging operation and takes responsibility for it, it is for that company to

ensure that the repackaging does not affect the original condition of the product contained in the packaging and to ensure that the repackaged product is not presented in such a way as to damage the reputation of the trade mark.

37. The question whether, in the main proceedings, the undertaking indicated on the packaging of the medicinal products as the repackager had control of the repackaging operation and carries responsibility for it is a question of fact which it is for the referring court to determine. In order to determine the relations between the parallel importer and the repackaging company, it is important to ascertain who determines the specific repackaging arrangements. The fact that the two companies belong to the same group does not seem to me, in this regard, decisive, but can have only evidential value in regard to the nature of relations between these companies.

38. To require that, when the company that controls the repackaging operation and assumes responsibility for it and the undertaking actually carrying out the repackaging are two separate entities, the latter’s name must be stated would, in my view, exceed what is necessary to prevent the consumer from being led to believe that the proprietor of the trade mark is responsible for the repackaging.

39. Conversely, Merck maintains that consumer information should be as comprehensive as possible and that, consequently, consumer protection demands that the packaging of a medicinal product should mention the name of the actual repackager.

40. In the face of this attempt to establish an additional reason for a trade mark proprietor to oppose parallel imports of medicinal products, it must be pointed out, as Advocates General Jacobs (16) and Sharpston (17) have done before me, that, in the context of the law of trade marks, any exception to the principle of free movement of goods must be interpreted strictly and can only be relied on to justify restrictions required to safeguard the specific subject-matter of an industrial property right. As an exception to the principle of free movement of goods, Article 7(2) of Directive 89/104 must, therefore, be interpreted strictly.

41. As the Court clearly stated in *Boehringer Ingelheim and Others*, (18) ‘although it is possible to derogate from the fundamental principle of free movement of goods where the proprietor of a mark relies on the mark to oppose the repackaging of pharmaceutical products imported in parallel, that is only to the extent necessary to enable the proprietor to safeguard rights which form part of the specific subject-matter of the mark, as understood in the light of its essential function’. (19) Where a trade mark proprietor, in opposing the repackaging of medicinal products imported in parallel, cites reasons that are no longer strictly to do with protection of the specific subject-matter and essential function of the trade mark, such reasons may not be used to justify a derogation from the fundamental principle of the free movement of goods.

42. Therefore, as neither the specific subject-matter of the trade mark nor its essential function as a guarantee

of origin is compromised by stating the names of the undertaking responsible for repackaging and the manufacturer in conjunction, I believe that a trade mark proprietor may not rely on Article 7(2) of Directive 89/104 to claim compensation from a parallel importer on the ground of the omission to state on the repackaged product the name of the actual repackager, where the importer controls and assumes responsibility for the repackaging operation.

43. This solution, it seems to me, maintains a balance between the protection of trade mark rights and the free movement of goods, while allowing adequate information for consumers. The trade mark proprietor sees the trade mark's essential function as a guarantee of origin safeguarded and the reputation of the mark cannot be damaged by defective repackaging. At the same time, the trade mark proprietor and consumers know who may be held responsible for the repackaging if it is defective.

44. In light of all of these elements, I believe that Article 7(2) of Directive 89/104 should be interpreted as meaning that the fact that the packaging of a repackaged product does not state the name of the undertaking which actually carried out the repackaging does not entitle a trade mark proprietor to oppose the marketing of that product where the name of the undertaking in charge of the repackaging operation and taking responsibility for it appears alongside the name of the manufacturer.

IV – Conclusion

45. In the light of the foregoing I propose that the Court should reply as follows to the questions raised by the Højesteret:

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 meaning that the fact that the packaging of a repackaged product does not state the name of the undertaking which actually carried out the repackaging does not entitle a trade mark proprietor to oppose the marketing of that product where the name of the undertaking in charge of the repackaging operation and taking responsibility for it appears alongside the name of the manufacturer.

1 – Original language: French.

2 – OJ 1989 L 40, p. 1.

3 – Case 102/77 [1978] ECR 1139.

4 – Case 1/81 [1981] ECR 2913.

5 – Case C-232/94 [1996] ECR I-3671.

6 – Joined Cases C-427/93, C-429/93 and C-436/93 [1996] ECR I-3457.

7 – OJ 2008 L 299, p. 25.

8 – Codified Law No 782 of 30 August 2001, as amended.

9 – With the exception of the sixth question in Case C-207/10 which, as was confirmed at the hearing, is of a hypothetical nature and therefore inadmissible.

10 – Hoffmann-La Roche, paragraphs 7 and 8.

11 – My italics.

12 – See Bristol-Myers Squibb and Others, paragraph 40.

13 – My italics.

14 – Bristol-Myers Squibb and Others, paragraph 79.

15 – Moreover I note that in the judgment in Case C-349/95 Loendersloot [1997] ECR I-6227 it is ‘the person responsible for the repackaging’ who is referred to by the Court (paragraph 30).

16 – Point 77 of his Opinion in Bristol-Myers Squibb and Others, and his Opinions in Joined Cases C-71/94 to C-73/94 Eurim-Pharm [1996] ECR I-3603 and MPA Pharma.

17 – Point 13 of her Opinion in Case C-348/04 Boehringer Ingelheim and Others [2007] ECR I-3391.

18 – Case C-143/00 [2002] ECR I-3759.

19 – Paragraph 28.