Reports of Cases

JUDGMENT OF THE COURT (Fifth Chamber)

10 November 2016*

(Reference for a preliminary ruling — Trade marks — Directive 2008/95/EC — Article 7(2) — Medicinal products — Parallel import — Partitioning of the markets — Need for the repackaging of the product bearing the mark — Medicinal product placed on the exporting market and importing market by the trade mark proprietor with the same kind of packaging)

In Case C-297/15,

REQUEST for a preliminary ruling under Article 267 TFEU from the Sø- og Handelsretten (Maritime and Commercial Court, Denmark), made by decision of 10 June 2015, received at the Court on 18 June 2015, in the proceedings

Ferring Lægemidler A/S, acting on behalf of Ferring BV

v

Orifarm A/S,

THE COURT (Fifth Chamber),

composed of J.L. da Cruz Vilaça (Rapporteur), President of the Chamber, M. Berger, A. Borg Barthet, E. Levits and F. Biltgen, Judges,

Advocate General: M. Wathelet,

Registrar: A. Calot Escobar,

having regard to the written procedure,

after considering the observations submitted on behalf of:

— Ferring Lægemidler A/S, acting on behalf of Ferring BV, by T. Ryhl, advokat,

— Orifarm A/S, by K. Jensen, advokat,

— the European Commission, by H. Støvlbæk, T. Scharf and J. Samnadda, acting as Agents,

having decided, after hearing the Advocate General, to proceed to judgment without an Opinion,

gives the following

* Language of the case: Danish.

Judgment

1 This request for a preliminary ruling concerns the interpretation of Article 7(2) of 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).

2 The request has been made in proceedings between Ferring Lægemidler A/S, acting on behalf of Ferring BV ('Ferring'), and Orifarm A/S in respect of Ferring's opposition to the marketing in Denmark of one of its medicinal products, as repackaged by Orifarm, in the context of parallel imports originating in Norway carried out by that company.

Legal context

The EEA Agreement

3 Article 13 of the Agreement on the European Economic Area of 2 May 1992 (OJ 1994 L 1, p. 3, 'the EEA Agreement') reproduces the content of Article 36 TFEU.

4 Directive 2008/95 was incorporated into the EEA Agreement by Decision No 146/2009 of the EEA Joint Committee of 4 December 2009, amending Annex XVII (Intellectual Property) of the EEA Agreement (OJ 2010 L 62, p. 43).

European Union legislation

5 Article 7 of Directive 2008/95 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.'

Danish law

6 It is apparent from the request for a preliminary ruling that Article 6 of the varemærkeloven (Law on trade marks), implementing Directive 2008/95 in Denmark, is essentially identical to Article 7 of Directive 2008/95.

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

7 Ferring markets a medicinal product under the trade mark Klyx, of which it is the proprietor, in Denmark, Finland, Sweden and Norway. In all those States, Klyx is sold in identical packaging, namely containers of 120 ml or 240 ml, as well as in packets containing 1 or 10 such containers.

8 In the course of its parallel import business, Orifarm purchases Klyx in Norway in packets of 10 and sells that product on the Danish market, after having repackaged it in new packets of 1, upon which the mark Klyx is reaffixed ('the contested repackaging').

9 Before the referring court, Ferring claims that it can legitimately oppose the contested repackaging in that, in the first place, that repackaging is not necessary to market the product imported in parallel and, in the second place, that repackaging is justified only by the importer's attempt to secure a commercial advantage.

10 Orifarm, for its part, contends that the repackaging is necessary to gain access to the segment of the Danish market for Klyx packaged in packets of one.

11 The referring court observes that it follows from the case-law of the Court that the trade mark proprietor cannot oppose the repackaging if that opposition contributes to the partitioning of the markets. That would be the case where the opposition prevents a repackaging which is necessary to market the medicinal product in the importing State. In those circumstances, the referring court questions whether the contested repackaging can be considered 'necessary', given that Klyx is available in packets of 1 or packets of 10 in all the States party to the EEA Agreement in which the medicinal product is placed on the market, including in the States in question in the main proceedings.

12 In those circumstances, the Sø- og Handelsretten (Maritime and Commercial Court, Denmark) decided to stay the proceedings and refer the following questions to the Court for a preliminary ruling:

'(1) Must Article 7(2) of Directive 2008/95/EC and the related case-law be interpreted as meaning that a trade mark proprietor may lawfully object to the continued marketing of a medicinal product by a parallel importer, where the importer has repackaged the medicinal product in a new, outer packaging and reaffixed the trade mark in a situation where the trade mark proprietor has marketed the medicinal product in the same volume and packet sizes in all EEA countries where the medicinal product is sold?

(2) Will the answer to the first question be different if the trade mark proprietor in both the country of export and the country of import has marketed the medicinal product in two different packet sizes (10-piece packets and 1-piece packets) and the importer has purchased 10-piece packets in the country of export and repackaged them in 1-piece packets, on which the trade mark has been reaffixed before the products are marketed in the country of import?'

The questions referred

13 By these questions, which must be examined together, the referring court asks, in essence, whether Article 7(2) of Directive 2008/95 must be interpreted as meaning that a trade mark proprietor may oppose the continued marketing of a medicinal product by a parallel importer, where that importer has repackaged the medicinal product in a new, outer packaging and reaffixed the trade mark.

14 In this respect, it must be noted, first, that the specific purpose of a mark is to guarantee the origin of the product bearing that mark and that a repackaging of that product carried out by a third party without the authorisation of the proprietor is likely to create real risks for that guarantee of origin (see, by analogy, judgment of 26 April 2007, *Boehringer Ingelheim and Others*, C-348/04, EU:C:2007:249, paragraph 14 and the case-law cited).

15 Second, it must be noted that under Article 7(2) of Directive 2008/95, the trade mark proprietor's opposition to the repackaging, in so far as 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 States party to the EEA Agreement within the meaning of the second sentence of Article 13 of that agreement (see, by analogy, with regard to the second sentence of Article 36 TFEU, judgment of 26 April 2007, *Boehringer Ingelheim and Others*, C-348/04, EU:C:2007:249, paragraph 16 and the case-law cited).

16 A disguised restriction within the meaning of that latter 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 the States party to the EEA Agreement, where the repackaging is done in such a way that the legitimate interests of the proprietor are respected (see, by analogy, with regard to the second sentence of Article 36 TFEU, judgments of 26 April 2007, *Boehringer Ingelheim and Others*, C-348/04, EU:C:2007:249, paragraph 17, and of 28 July 2011, *Orifarm and Others*, C-400/09 and C-207/10, EU:C:2011:519, paragraph 24 and the case-law cited).

17 A trade mark proprietor's opposition to repackaging contributes to the artificial partitioning of the markets between the States party to the EEA Agreement where the repackaging is necessary to enable the product imported in parallel to be marketed in the importing State (see, by analogy, judgment of 26 April 2007, *Boehringer Ingelheim and Others*, C-348/04, EU:C:2007:249, paragraph 18 and the case law cited).

18 As is apparent from the case-law of the Court, the power of the proprietor of trade mark rights protected in a Member State to oppose the marketing of repackaged products under the trade mark should be limited only in so far as the repackaging undertaken by the importer is necessary in order to market the product in the Member State of importation (see, by analogy, judgment of 11 July 1996, *Bristol-Myers Squibb and Others*, C-427/93, C-429/93 and C-436/93, EU:C:1996:282, paragraph 56).

19 It follows from those considerations that the change brought about by any repackaging of a trade-marked medicinal product — creating by its very nature the risk of interference with the original condition of the product — may be prohibited by the trade mark proprietor unless the repackaging is necessary in order to enable the marketing of the products imported in parallel and the legitimate interests of the proprietor are also safeguarded (see, by analogy, judgments of 23 April 2002, *Boehringer Ingelheim and Others*, C-143/00, EU:C:2002:246, paragraph 34, and of 26 April 2007, *Boehringer Ingelheim and Others*, C-348/04, EU:C:2007:249, paragraph 19).

20 As regards in particular the criterion of the necessity of the repackaging, the circumstances prevailing at the time of marketing in the importing State, which render repackaging objectively necessary for the medicinal product to be placed on the market in that State by the parallel importer, must be taken into account in the assessment. A trade mark proprietor's opposition to repackaging is not justified if it hinders effective access to the importing market (see, by analogy, judgments of 12 October 1999, *Upjohn*, C-379/97, EU:C:1999:494, paragraph 43, and of 23 April 2002, *Boehringer Ingelheim and Others*, C-143/00, EU:C:2002:246, paragraph 46).

21 In particular, it should be noted, first of all, that the trade mark proprietor cannot oppose the repackaging of the product in new external packaging, when the packet size used by that proprietor in the State party to the EEA Agreement where the importer purchased the product, cannot be marketed in the importing State because of, in particular, a rule authorising packaging only of a certain size or a national practice to the same effect, sickness insurance rules making the reimbursement of medical expenses depend on the size of the packaging, or well-established medical prescription practices based, inter alia, on standard sizes recommended by professional groups and sickness insurance institutions (see, by analogy, judgment of 11 July 1996, *Bristol-Myers Squibb and Others*, C-427/93, C-429/93 and C-436/93, EU:C:1996:282, paragraph 53).

22 Then, where, in accordance with the rules and practices in force in the importing State, the proprietor uses several different sizes of packaging in that State, the finding that one of those sizes is also marketed in the exporting State party to the EEA Agreement is not enough to justify the conclusion that repackaging is unnecessary. Partitioning of the markets would exist if the importer were able to sell the product in only part of his market (see, by analogy, judgment of 11 July 1996, *Bristol-Myers Squibb and Others*, C-427/93, C-429/93 and C-436/93, EU:C:1996:282, paragraph 54).

23 Finally, it is for the parallel importer to prove the existence of the conditions preventing the trade mark proprietor from lawfully opposing further marketing of those medicinal products (see, by analogy, judgment of 26 April 2007, *Boehringer Ingelheim and Others*, C-348/04, EU:C:2007:249, paragraph 52).

24 In this case, it is apparent from the request for a preliminary ruling that, in all the States party to the EEA Agreement in which it is placed on the market, including in the States in question in the main proceedings, Klyx is marketed by Ferring in the same packaging.

25 Conversely, it is not apparent from the information available to the Court that one of the situations set out in paragraph 21 of the present judgment existed in the present case or that, because of the specific circumstances prevailing at the time of the marketing, effective access to the Danish market for Klyx was hindered.

26 It is for the referring court to determine whether one or several of the situations referred to in paragraph 21 of the present judgment are in existence in the main proceedings. If this is not the case, the trade mark proprietor can oppose the contested repackaging, as long as the product imported in parallel can be marketed in Denmark in the same packaging as that in which that product is marketed in Norway.

27 Orifarm, in its written observations, contends that the partitioning of markets is an inherent consequence of the opposition to the repackaging, in that the importer can only penetrate the Danish sub-market of packets of one container of Klyx by importing the product in the same packaging from Norway. Thus, without the contested repackaging, the imported product could only be marketed in a limited part of the Danish market.

28 In this regard, it must be stated that the documents before the Court do not contain any information making it possible to state that the market for Klyx in packets of 10 represents only a limited part of the market of the importing State, namely Denmark. It is, in any event, for the referring court to determine if such a condition is met in the main proceedings.

29 In these circumstances, the answer to the questions referred is that Article 7(2) of Directive 2008/95 must be interpreted as meaning that a trade mark proprietor may object to the continued marketing of a medicinal product by a parallel importer, where that importer has repackaged that medicinal product in a new, outer packaging and reaffixed the trade mark, where, first, the medicinal product at issue can be marketed in the importing State party to the EEA Agreement in the same packaging as that in which it is marketed in the exporting State party to the EEA Agreement and, second, the importer has not demonstrated that the imported product can only be marketed in a limited part of the importing State's market, and those are matters which it is for the referring court to determine.

Costs

30 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. Costs incurred in submitting observations to the Court, other than the costs of those parties, are not recoverable.

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

Article 7(2) of 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 must be interpreted as meaning that a trade mark proprietor may object to the continued marketing of a medicinal product by a parallel importer, where that importer has repackaged that medicinal product in a new, outer packaging and reaffixed the trade mark, where, first, the medicinal product at issue can be marketed in the importing State party to the EEA Agreement, of 2 May

1992, in the same packaging as that in which it is marketed in the exporting State party to the EEA Agreement and, second, the importer has not demonstrated that the imported product can only be marketed in a limited part of the importing State's market, and those are matters which it is for the referring court to determine.

[Signatures]