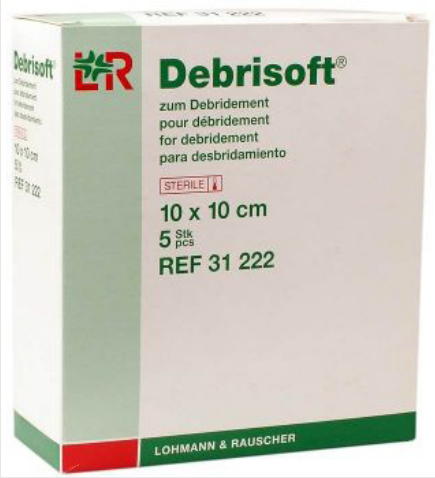
Court of Justice EU, 17 May 2018, Junek v Lohman and Rauscher



TRADEMARK LAW

Trade mark proprietor cannot oppose parallel import of a medical device in authentic inside- and outside packaging

- which, by its content, function, size, presentation and placement, does not give rise to a risk to the guarantee of origin of the medical device bearing the mark

Having regard to the foregoing considerations, the answer to the question referred is that Article 13(2) of Regulation No 207/2009 must be interpreted as meaning that the proprietor of a mark cannot oppose the further commercialisation, by a parallel importer, of a medical device in its original internal and external packaging where an additional label, such as that at issue in the case in the main proceedings, has been added by the importer, which, by its content, function, size, presentation and placement, does not give rise to a risk to the guarantee of origin of the medical device bearing the mark.

Conditions from judgements Bristol-Meyers Squibb (IPPT19960711) and Boehringer (IPPT20070426) only applicable when importer has repackaged the product

- Thus, the five conditions referred to in the previous paragraph, which, when they are satisfied, preclude the proprietor of the mark from legitimately opposing the further commercialisation of the product concerned, only apply where the importer has repackaged that product.

Repackaging implies that the original package has been opened

- It follows that, in the cases that gave rise to those judgments, at issue was an intervention by the parallel importer that involved, not only affixing an additional external label to the packaging of the pharmaceutical products concerned or its repackaging, but also, in every case, the opening of the original packaging in order to insert an information leaflet in a language different from that of the country of origin of the product which bore the mark in question.

The mere attachment of an extra label on an unprinted portion of the original packaging is not a repackaging within the meaning of these judgments

- By contrast, in the case in the main proceedings, it must be observed, first, that the parallel importer has merely affixed an additional label to the unprinted part of the original packaging of the medical device in question, which, moreover, had not been opened.

Second, the label is small in size and included, as the only information provided, the name, address and telephone number of the parallel importer, a barcode and a central pharmacological number which serves to organise the movement of the products with pharmacies.

35. Given that the packaging of the medical device concerned has not been modified and the original presentation of the packaging has not been affected other than by the attachment of a small label, which does not conceal the mark and which designates the parallel importer as responsible for placing it on the market by setting out his details, a barcode and a central pharmacological number, it cannot be held that the attachment of such a label constitutes repackaging within the meaning of the judgments of 23 April 2002, Boehringer Ingelheim and Others (C‑143/00, EU:C:2002:246), and of 26 April 2007, Boehringer Ingelheim and Others (C‑348/04, EU:C:2007:249).

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Court of Justice EU, 17 May 2018

(J.L. da Cruz Vilaça, E. Levits, A. Borg Barthet (Rapporteur), M. Berger, F. Biltgen)

JUDGMENT OF THE COURT (Fifth Chamber)

17 May 2018 (*)

(Reference for a preliminary ruling — Intellectual property — Trade-mark law — Regulation (EC) No 207/2009 — Article 13 — Exhaustion of the rights

conferred by a trade mark — Parallel imports — Repackaging of the product bearing the mark — New labelling — Conditions applicable to medical devices)
In Case C‑642/16,
REQUEST for a preliminary ruling under Article 267 TFEU from the Bundesgerichtshof (Federal Court of Justice, Germany), made by decision of 6 October 2015, and received at the Court on 14 December 2016, in the proceedings
Junek Europ-Vertrieb GmbH
v
Lohmann & Rauscher International GmbH & Co. KG
THE COURT (Fifth Chamber),
composed of J.L. da Cruz Vilaça, President of the Chamber, E. Levits, A. Borg Barthet (Rapporteur), M. Berger and F. Biltgen, Judges,
Advocate General: M. Bobek,
Registrar: K. Malacek, Administrator,
having regard to the written procedure and further to the hearing on 24 January 2018,
after considering the observations submitted on behalf of:
– Junek Europ-Vertrieb GmbH, by J. Sachs and C. Sachs, Rechtsanwälte,
– Lohmann & Rauscher International GmbH & Co. KG, by C. Rohnke and M. Stütz, Rechtsanwälte,
– the German Government, by T. Henze and M. Hellmann, acting as Agents,
– The Italian Government, by G. Palmieri, acting as Agent, assisted by M. Russo, avvocato dello Stato,
– the European Commission, by G. Braun, É. Gippini Fournier and T. Scharf, acting as Agents,
having decided, after hearing the Advocate General, to proceed to judgment without an Opinion,
gives the following

Judgment

1. This request for a preliminary ruling concerns the interpretation of Article 13(2) of Council Regulation (EC) No 207/2009 of 26 February 2009 on the European Union trade mark (OJ 2009 L 78, p. 1).
2. The request has been made in proceedings between Junek Europ-Vertrieb GmbH, parallel importer of sanitary preparations for medical purposes and dressings, and Lohmann & Rauscher International GmbH & Co. KG, manufacturer of such products, concerning dressings manufactured by the latter which were imported as parallel imports and marketed in Germany by Junek Europ-Vertrieb, after having been relabelled.

Legal context

3. Article 13 Regulation No 207/2009, entitled *'Exhaustion of the rights conferred by a trade mark'*, provides:

'1. The [European Union] trade mark shall not entitle the proprietor to prohibit its use in relation to goods which have been put on the market in the [European Union] 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 dispute in the main proceedings and the question referred for a preliminary ruling

4. Lohmann & Rauscher International is the proprietor of the EU trade mark *'Debrisoft'*, No 8852279, registered on 22 June 2010 for *'sanitary preparations for medical purposes'*, *'plasters, materials for dressings'* and *'dressings, medical'*. It manufactures and markets, inter alia, the product *'Debrisoft for debridement, STERILE, 10 x 10 cm, 5 pieces'*, which is a dressing used for the superficial treatment of wounds.
5. Junek Europ-Vertrieb is a company established in Austria and markets in Germany, by way of parallel importation, sanitary preparations for medical purposes and medical dressings manufactured and exported to Austria by the applicant.
6. On 25 May 2012, Lohmann & Rauscher International purchased in a pharmacy in Düsseldorf a pack of *'Debrisoft for debridement, STERILE, 10 x 10 cm, 5 pieces'* which Junek Europ-Vertrieb had previously imported from Austria. Before the sale to the pharmacy, that company had affixed on that box a label (*'the contested label'*) featuring the following information: the company responsible for the importation, its address and telephone number, a barcode and a central pharmaceutical number. The label was applied neatly to an unprinted part of the box and did not conceal the mark of Lohmann & Rauscher International.
7. The packaging of the product had been modified as illustrated below, with the contested label located on the bottom left.

8. The contested label, enlarged, presents as follows:

9. Junek Europ-Vertrieb had not given prior notice to Lohmann & Rauscher International of the reimportation of the product concerned and also had not supplied it with the modified packaging of the product with the contested label affixed. Lohmann & Rauscher International considered that the conduct of Junek Europ-Vertrieb was an infringement of the Debrisoft mark of which it was the proprietor.

10. It therefore lodged an action before the Landgericht Düsseldorf (Regional Court, Düsseldorf, Germany), seeking, in particular, to prohibit, under threat of a penalty, Junek Europ-Vertrieb from using in the course of trade, without its agreement, that mark for the purpose of designating dressings for debridement and to order that company to recall, withdraw from the market and destroy the products concerned.
11. The Landgericht Düsseldorf (Regional Court, Düsseldorf) upheld that claim.
12. The Oberlandesgericht Düsseldorf (Higher Regional Court, Düsseldorf, Germany), dismissed the appeal that Junek Europ-Vertrieb had lodged against the judgment given by the Landgericht Düsseldorf (Regional Court, Düsseldorf), with the reservation that the prohibition on use of the mark at issue related to Germany only. Junek Europ-Vertrieb then lodged an appeal on a point of law before the Bundesgerichtshof (Federal Court of Justice, Germany).
13. According to the referring court, the outcome of the dispute before it depends on whether the principles developed by the Court in respect of parallel imports of pharmaceutical products, according to which prior notice and the supply of a packaging specimen on demand by the trade mark proprietor are conditions for exhaustion of the rights conferred by its trade mark, also apply to the parallel importation of medical devices.
14. First, the referring court states that, according to the case-law of the Court, it is the repackaging of the trade-marked pharmaceutical products in itself which is prejudicial to the specific subject matter of the mark, which is to guarantee the origin of the product that it identifies. It refers, in particular, to the judgments of **23 April 2002, Boehringer Ingelheim and Others (C-143/00, EU:C:2002:246)**, and of **26 April 2007, Boehringer Ingelheim and Others (C-348/04, EU:C:2007:249)**, according to which the Court held that the repackaging of a pharmaceutical product by a third party without the permission of the proprietor gives rise to real risks for the guarantee of origin and that affixing a new label to the packaging also constitutes repackaging.
15. Second, it is clear from the case-law of the Court that the trade mark proprietor's opposition to commercialisation of repackaged pharmaceutical products under Article 13(2) of Regulation No 207/2009, which is a derogation from the free movement of goods, cannot, however, be accepted if the proprietor's exercise of that right constitutes a disguised restriction on trade between Member States within the meaning of Article 36 TFEU (judgments of **11 July 1996, Bristol-Myers Squibb and Others, C-427/93, C-429/93 and C-436/93, EU:C:1996:282**, and of **26 April 2007, Boehringer Ingelheim and Others, C-348/04, EU:C:2007:249)**. It follows that the proprietor of a mark may oppose a modification which involves any repackaging of a pharmaceutical product bearing its mark, which, by its very nature, creates real risks for the guarantee of origin of the pharmaceutical product, unless five conditions are met, namely:
– it is established that the use of the trade mark rights by the proprietor thereof to oppose the marketing of the relabelled products under that trade mark would contribute to the artificial partitioning of the markets between Member States;
– it is shown that the repackaging cannot affect the original condition of the product inside the packaging;
– the new packaging states clearly who repackaged the product and the name of the manufacturer;
– the presentation of the repackaged product is not such as to be liable to damage the reputation of the trade mark and of its owner; thus, the packaging must not be defective, of poor quality, or untidy; and
– the importer gives notice to the trade mark proprietor before the repackaged product is put on sale, and, on demand, supplies him with a specimen of the repackaged product.
16. Secondly, the application of those principles is not restricted to cases of the parallel importation of pharmaceutical products. Thus, in its **judgment of 11 November 1997, Loendersloot (C-349/95, EU:C:1997:530)**, the Court held that the criteria relating to the repackaging of pharmaceutical products could also, in principle, apply to parallel trade of alcoholic beverages. In addition, it notes that the conditions for the exhaustion of the rights conferred by a mark that are applicable depends on the relevant legitimate interests of the proprietor of the mark in the given case, having regard to the particular nature of the product.
17. Thirdly, the referring court considers that there was relabelling in the present case. Agreeing with the appellate court, it considers that the contested label affixed by Junek Europ-Vertrieb includes important information in the language of the importing country and that that label could give rise to the suspicion on the part of the consumer that the product which is offered to them was the object, at an earlier stage of its marketing, to interference by a third party, without the authorisation of the proprietor of the mark, which affects the original condition of the product.
18. Fourthly, as regards the question of whether the principles developed by the Court in respect of the parallel importation of pharmaceutical products apply without restriction to the parallel importation of medical devices, the referring court notes that even though medicinal devices are not, as is the case for pharmaceutical products, subject to authorisation procedures, nevertheless, the conformity assessment procedure necessary for them to be allowed onto the market makes them, from the point of view of both manufacturers and consumers, particularly sensitive products for which the guarantee of origin provided by the mark covering the product, owing to the high degree of responsibility of the manufacturer, has particular importance.
19. It adds that medical devices, just like pharmaceutical products, are products that have a direct connection with health. Since customers particularly

value and pay attention to their own health, it was not necessary, according to the referring court, to call in question the appellate court's finding that medical devices, as well as pharmaceuticals, are particularly sensitive products for which the guarantee of origin provided by the mark affixed to the product is of particular importance because of the high degree of responsibility of the manufacturer.

20. In those circumstances the Bundesgerichtshof (Federal Court of Justice) decided to stay the proceedings before it and to refer the following question to the Court for a preliminary ruling:

'Must Article 13(2) of Regulation [...] No 207/2009 be interpreted as meaning that the proprietor of the mark can oppose further commercialisation of a medical device imported from another Member State in its original internal and external packaging, to which the importer has affixed an additional external label, unless

– it is established that reliance on trade-mark rights by the proprietor in order to oppose the marketing of the overstickered product under that trade mark would contribute to an artificial partitioning of the markets between Member States;

– it is shown that the new labelling cannot adversely affect the original condition of the product inside the packaging;

– the packaging states clearly who overstickered the product and the name of the manufacturer;

– the presentation of the overstickered product is not such as to be liable to damage the reputation of the trade mark and of its proprietor; thus, the label must not be defective, of poor quality, or untidy; and

– the importer gives notice to the trade mark proprietor before the overstickered product is placed on the market, and, on demand, provides him with a specimen of that product?'

Consideration of the question referred

21. By its question, the referring court asks, in essence, whether Article 13(2) of Regulation No 207/2009 must be interpreted as meaning that the proprietor of a mark may oppose the further commercialisation, by a parallel importer, of a medical device in its original internal and external packaging when an additional label, such as that at issue in the main proceedings, has been added by the importer. More specifically, it wishes to know whether the principles developed by the Court in its judgments of **11 July 1996, Bristol-Myers Squibb and Others (C‑427/93, C‑429/93 and C‑436/93, EU:C:1996:282)** and of **26 April 2007, Boehringer Ingelheim and Others (C‑348/04, EU:C:2007:249)** apply without restriction to the parallel import of medical devices.

22. As a preliminary matter, it is necessary to recall the case-law of the Court and the principles developed by it as regards the parallel import of pharmaceutical products.

23. In that regard, it is clear from the settled case-law 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, to that effect, **judgment of 10 November 2016, Ferring Lægemidler, C‑297/15, EU:C:2016:857**, paragraph 14 and the case-law cited).

24. According to the case-law of the Court, it is the repackaging of the trade-marked pharmaceutical products in itself which is prejudicial to the specific subject matter of the mark, and it is not necessary in that context to assess the actual effects of the repackaging by the parallel importer (see, to that effect, judgment of **26 April 2007, Boehringer Ingelheim and Others, C‑348/04, EU:C:2007:249**, paragraph 15).

25. In addition, it must be observed that the Court has held, as regards Article 7(2) of the First Council Directive 89/104/EEC of 21 December 1988 to approximate the laws of the Member States relating to trade marks (OJ 1989 L 40, p. 1) the wording of which is equivalent to that of Article 13(2) of Regulation No 207/2009, that, under that provision, the trade mark proprietor's opposition to repackaging, 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 36 TFEU (judgments of **23 April 2002, Boehringer Ingelheim and Others, C‑143/00, EU:C:2002:246**, paragraph 18 and of **26 April 2007, Boehringer Ingelheim and Others, C‑348/04, EU:C:2007:249**, paragraph 16 and the case-law cited).

26. A disguised restriction within the meaning of that provision will exist where the exercise by a trade mark proprietor of its 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. This means, in particular, that the repackaging must not adversely affect the original condition of the product and must not be such as to harm the reputation of the mark (judgment of **26 April 2007, Boehringer Ingelheim and Others, C‑348/04, EU:C:2007:249**, paragraph 17 and the case-law cited).

27. The Court thus laid down the principles on the restrictions on the exhaustion of the rights conferred by a trade mark in the context of the parallel importation of pharmaceutical products (judgments of **11 July 1996, Bristol-Myers Squibb and Others, C‑427/93, C‑429/93 and C‑436/93, EU:C:1996:282**, paragraph 79, and of **26 April 2007, Boehringer Ingelheim and Others, C‑348/04, EU:C:2007:249**, paragraph 32).

28. According to that case-law, pursuant to Article 7(2) of the First Directive 89/104, the proprietor of a mark may legitimately oppose the further commercialisation of a pharmaceutical product imported from another Member State in its original internal and external packaging with an additional external label applied by the importer, unless:

– it is established that the use of the trade mark rights by the proprietor thereof to oppose the marketing of the relabelled products under that trade mark would contribute to the artificial partitioning of the markets between Member States;
– it is shown that the repackaging cannot affect the original condition of the product inside the packaging;
– the new packaging states clearly who repackaged the product and the name of the manufacturer;
– the presentation of the repackaged product is not such as to be liable to damage the reputation of the trade mark and of its owner; thus, the packaging must not be defective, of poor quality, or untidy; and
– the importer gives notice to the trade mark proprietor before the repackaged product is put on sale, and, on demand, supplies him with a specimen of the repackaged product.

29. Thus, the five conditions referred to in the previous paragraph, which, when they are satisfied, preclude the proprietor of the mark from legitimately opposing the further commercialisation of the product concerned, only apply where the importer has repackaged that product.

30. As regards the concept of *'repackaging'*, the Court has clarified that it includes the relabelling of the pharmaceutical products bearing the mark (**judgment of 26 April 2007, Boehringer Ingelheim and Others, C-348/04, EU:C:2007:249**, paragraph 28).

31. Nevertheless, it is necessary to note that the facts that gave rise to the judgments of **23 April 2002, Boehringer Ingelheim and Others (C-143/00, EU:C:2002:246)**, and of **26 April 2007, Boehringer Ingelheim and Others (C-348/04, EU:C:2007:249)**, which concerned additional labels being affixed to the packaging of the pharmaceutical products concerned, are different from the facts at issue in the main proceedings.

32. It is clear from paragraph 7 of the judgment of **23 April 2002, Boehringer Ingelheim and Others (C-143/00, EU:C:2002:246)**, and paragraph 24 of the **judgment of 26 April 2007, Boehringer Ingelheim and Others (C-348/04, EU:C:2007:249)** that, in the cases that gave rise to those judgments, in certain cases, a label including certain important information, such as the name of the parallel importer and its parallel import licence number, had been attached, in other cases, the product concerned had been repackaged in boxes which had been designed by the parallel importer and on which the mark had been reproduced and, in yet further cases, that product had been repackaged in boxes which had been designed by the parallel importer and which did not bear the mark, but only the generic name of the product. The Court added that, in all those cases of repackaging, the boxes contained a patient information leaflet in the language of the country of importation, namely English, which bore the mark at issue.

33. It follows that, in the cases that gave rise to those judgments, at issue was an intervention by the parallel importer that involved, not only affixing an additional external label to the packaging of the pharmaceutical products concerned or its repackaging, but also, in every case, the opening of the original packaging in order to insert an information leaflet in a language different from that of the country of origin of the product which bore the mark in question.

34. By contrast, in the case in the main proceedings, it must be observed, first, that the parallel importer has merely affixed an additional label to the unprinted part of the original packaging of the medical device in question, which, moreover, had not been opened. Second, the label is small in size and included, as the only information provided, the name, address and telephone number of the parallel importer, a barcode and a central pharmacological number which serves to organise the movement of the products with pharmacies.

35. Given that the packaging of the medical device concerned has not been modified and the original presentation of the packaging has not been affected other than by the attachment of a small label, which does not conceal the mark and which designates the parallel importer as responsible for placing it on the market by setting out his details, a barcode and a central pharmacological number, it cannot be held that the attachment of such a label constitutes repackaging within the meaning of the judgments of **23 April 2002, Boehringer Ingelheim and Others (C-143/00, EU:C:2002:246)**, and of **26 April 2007, Boehringer Ingelheim and Others (C-348/04, EU:C:2007:249)**.

36. Consequently, it cannot, in any event, be held that the attachment of such a label affects the specific purpose of the mark, which is to guarantee the origin of the product that it identifies.

37. In those circumstances, the attachment of an additional label, such as that at issue in the case in the main proceedings, by the parallel importer, namely by Junek Europ-Vertrieb, to the original packaging of the medical device, which has not been opened, is not a legitimate reason that justifies the proprietor of the mark, in this case Lohmann & Rauscher International, opposing the further commercialisation of the medical device concerned.

38. Therefore, the situation which gave rise to the case in the main proceedings constitutes a case of exhaustion of the rights conferred by a trade mark pursuant to Article 13(1) of Regulation No 207/2009.

39. Having regard to the foregoing considerations, the answer to the question referred is that Article 13(2) of Regulation No 207/2009 must be interpreted as meaning that the proprietor of a mark cannot oppose the further commercialisation, by a parallel importer, of a medical device in its original internal and external packaging where an additional label, such as that at issue in the case in the main proceedings, has been added by the importer, which, by its content, function, size, presentation and placement, does not give rise to a risk to the guarantee of origin of the medical device bearing the mark.

Costs

40. 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 13(2) of Council Regulation (EC) No 207/2009 of 26 February 2009 on the European Union trade mark must be interpreted as meaning that the proprietor of a mark cannot oppose the further commercialisation, by a parallel importer, of a medical device in its original internal and external packaging where an additional label, such as that at issue in the case in the main proceedings, has been added by the importer, which, by its content, function, size, presentation and placement, does not give rise to a risk to the guarantee of origin of the medical device bearing the mark.

[Signatures]

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*. Language of the case: German.