Court of Justice EU, 17 November 2022, Impexeco and PI Pharma v Novartis

TRADE MARK LAW

Trademark infringement and repackaging of generic drug in outer packaging with branded reference drug by parallel importer?

- **The proprietor of the trade mark of a reference medicinal product and the trade mark of a generic medicinal product may oppose the placing on the market of a Member State, by a parallel importer, of that generic medicinal product imported from another Member State, where that medicinal product has been repackaged in new outer packaging to which the trade mark of the corresponding reference medicinal product has been affixed, unless,**
- first, the two medicinal products are identical in all respects and,
- second, the replacement of the trade mark satisfies the conditions laid down in **paragraph 79 of the judgment of 11 July 1996, Bristol-Myers Squibb and Others (C-427/93, C-429/93 and C-436/93, EU:C:1996:282)**; in **paragraph 32 of the judgment of 26 April 2007, Boehringer Ingelheim and Others (C-348/04, EU:C:2007:249)**; and in **paragraph 28 of the judgment of 17 May 2018, Junek Europ-Vertrieb (C-642/16, EU:C:2018:322)**.

Source: **ECLI:EU:C:2022:894**

Court of Justice EU, 31 March 2010
(E. Regan, D. Gratsias, M. Ilešič, I. Jarukaitis en Z. Csehi)
JUDGMENT OF THE COURT (Fifth Chamber)
17 November 2022
(References for a preliminary ruling – Articles 34 and 36 TFEU – Free movement of goods – Intellectual property – Trade marks – Regulation (EC) No 207/2009 – Article 9(2) – Article 13 – Directive 2008/95 – Article 5(1) – Article 7 – Rights conferred by a trade mark – Exhaustion of the rights conferred by a trade mark – Parallel imports of medicinal products – Reference medicinal product and generic medicinal product – Economically linked undertakings – Repackaging of the generic medicinal product – New outer packaging – Affixing the trade mark of the reference medicinal product – Opposition by the proprietor of the trade mark – Artificial partitioning of the markets between the Member States)
In Joined Cases C-253/20 and C-254/20,
REQUESTS for a preliminary ruling under Article 267 TFEU from the hof van beroep te Brussel (Court of Appeal, Brussels, Belgium), made by decisions of 25 May 2020, received at the Court on 9 June 2020, in the proceedings
Impexeco NV
v
Novartis AG (C-253/20),
and
PI Pharma NV
v
Novartis AG,
Novartis Pharma NV (C-254/20),
THE COURT (Fifth Chamber),
composed of E. Regan, President of the Chamber, D. Gratsias, M. Ilešič (Rapporteur), I. Jarukaitis and Z. Csehi, Judges,
Advocate General: M. Szpunar,
Registrar: A. Calot Escobar,
having regard to the written procedure,
after considering the observations submitted on behalf of:
– Impexeco NV and PI Pharma NV, by F. Cornette, L. Coucke, V. Pede and T. Poels-Ryckeboer, advocaten,
– Novartis AG and Novartis Pharma NV, by J. Figys, P. Maeyaert, J. Muyldermans, K. Roox, L. van Kruijsdijk and M. Van Nieuwenborgh, advocaten,
– the European Commission, by É. Gippini Fournier, P.-J. Loewenthal and F. Thiran, acting as Agents,
after hearing the Opinion of the Advocate General at the sitting on 13 January 2022,
gives the following
Judgment
1 This request for a preliminary ruling concerns the interpretation of Articles 34 and 36 TFEU.
2 The requests have been made in two sets of proceedings brought, first, by Impexeco NV against Novartis AG and, second, by PI Pharma NV against Novartis and Novartis Pharma NV concerning the marketing in Belgium of generic medicinal products imported in parallel from the Netherlands and repackaged in new outer packaging on which the mark for the generic medicinal product of which Novartis is the proprietor was replaced by the mark for the reference medicinal product of which that company is also the proprietor.
Legal context
European Union law
Regulation No 207/2009
3 Article 9 of Council Regulation (EC) No 207/2009 of 26 February 2009 on the European Union trade mark (OJ 2009 L 78, p. 1), as amended by Regulation (EU) 2015/2424 of the European Parliament and of the Council of 16 December 2015 (OJ 2015 L 341, p. 21) (‘Regulation No 207/2009’), entitled ‘Rights conferred by an EU trade mark’, provided:
‘1. The registration of an EU trade mark shall confer on the proprietor exclusive rights therein.
2. Without prejudice to the rights of proprietors acquired before the filing date or the priority date of the EU trade mark, the proprietor of that EU trade mark shall be entitled to prevent all third parties not having

his consent from using in the course of trade, in relation to goods or services, any sign where:
(a)
the sign is identical with the EU trade mark and is used in relation to goods or services which are identical with those for which the EU trade mark is registered;
(b) the sign is identical with, or similar to, the EU trade mark and is used in relation to goods or services which are identical with, or similar to, the goods or services for which the EU trade mark is registered, if there exists a likelihood of confusion on the part of the public; the likelihood of confusion includes the likelihood of association between the sign and the trade mark;
(c) the sign is identical with, or similar to, the EU trade mark irrespective of whether it is used in relation to goods or services which are identical with, similar to or not similar to those for which the EU trade mark is registered, where the latter has a reputation in the [European] Union 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 EU trade mark.
3. The following, in particular, may be prohibited under paragraph 2:
(a) affixing the sign to the goods or to the packaging thereof;
(b) offering the goods, putting them on the market, or stocking them for those purposes under the sign, or offering or supplying services thereunder;
(c) importing or exporting the goods under that sign;
…'

4 Article 13 of Regulation No 207/2009, entitled 'Exhaustion of the rights conferred by [an EU] trade mark', provided:

'1. An EU 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 Economic Area 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.'

Directive 2008/95/EC

5 Under Article 5 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), entitled 'Rights conferred by a trade mark':

'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; the likelihood of confusion includes the likelihood of association between the sign and 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 that sign;
…'

6 Article 7 of the directive, entitled 'Exhaustion of the rights conferred by a trade mark', provided as follows:

'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.'

Directive 2001/83/EC

7 Under Article 10 of Directive 2001/83/EC of the European Parliament and of the Council of 6 November 2001 on the Community code relating to medicinal products for human use (OJ 2001 L 311, p. 67), as amended by Directive 2004/27/EC of the European Parliament and of the Council of 31 March 2004 (OJ 2004 L 136, p. 34):

'1. By way of derogation from Article 8(3)(i), and without prejudice to the law relating to the protection of industrial and commercial property, the applicant shall not be required to provide the results of pre-clinical tests and of clinical trials if he can demonstrate that the medicinal product is a generic of a reference medicinal product which is or has been authorised under Article 6 for not less than eight years in a Member State or in the Community.
…
2. For the purposes of this Article:
(a) "reference medicinal product" shall mean a medicinal product authorised under Article 6, in accordance with the provisions of Article 8;
(b) "generic medicinal product" shall mean a medicinal product which has the same qualitative and quantitative composition in active substances and the same pharmaceutical form as the reference medicinal product, and whose bioequivalence with the reference medicinal product has been demonstrated by appropriate bioavailability studies. The different salts, esters, ethers, isomers, mixtures of isomers, complexes or derivatives of an active substance shall be considered to be the same active substance, unless they differ significantly in properties with regard to safety and/or efficacy. In such cases, additional information providing proof of the safety and/or efficacy of the various salts, esters or derivatives of an authorised active substance must be supplied by the applicant. The various

immediate-release oral pharmaceutical forms shall be considered to be one and the same pharmaceutical form. Bioavailability studies need not be required of the applicant if he can demonstrate that the generic medicinal product meets the relevant criteria as defined in the appropriate detailed guidelines.

…'

The Benelux Convention

8 Article 2.20 of the Benelux Convention on Intellectual Property (trademarks and designs) of 25 February 2005, signed at The Hague by the Kingdom of Belgium, the Grand Duchy of Luxembourg and the Kingdom of the Netherlands, in the version applicable to the disputes in the main proceedings ('the Benelux Convention'), entitled 'Scope of protection', provided:

'1. A registered trade mark shall confer on the proprietor exclusive rights therein. Without prejudice to the possible application of ordinary law in matters of civil liability, the exclusive right to a trade mark shall permit the owner to prevent any third party, without its consent, from:

(a) using in the course of trade 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) using in the course of trade 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. For the purposes of paragraph 1, use of a trademark or a similar sign shall mean in particular:

(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, or offering or supplying services under the sign;

(c) importing or exporting goods under the sign;

…'

9 Under Article 2.23(3) of that convention:

'The exclusive right shall not imply the right to prohibit use of the trademark for goods which have been put on the market in the European Community or [European Economic Area (EEA)] under that trademark by the holder or with his consent, unless there are legitimate reasons for the holder 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.'

Belgian law

10 Under Article 3(2) of the arrêté royal du 19 avril 2001 relatif à l'importation parallèle des médicaments à usage humain et à la distribution parallèle des médicaments à usage humain et à usage vétérinaire (Royal Decree of 19 April 2001 on parallel imports of medicinal products for human use and the parallel distribution of medicinal products for human and veterinary use) (Moniteur belge of 30 May 2001, p. 17954), as amended by the Royal Decree of 21 January 2011 (Moniteur belge of 9 February 2011, p. 9864):

'By way of derogation from the provisions of Article 4(1)(1) of the Royal Decree of 14 December 2006 on medicinal products for human and veterinary use, a person wishing to import a medicinal product in parallel may obtain authorisation for that purpose, provided that the parallel import concerns a medicinal product:

1 that is covered by a marketing authorisation in the Member State of origin which has been issued by the competent authorities of that Member State;

2 for which there is a reference medicinal product;

3 which, although not identical in all respects to the reference medicinal product:

(a) has at least the same qualitative and quantitative composition in active substances;

(b) has at least the same therapeutic indications;

(c) is at least therapeutically equivalent;

(d) has at least the same pharmaceutical form.

If it is shown that the medicinal product in respect of which a parallel import authorisation has been applied for and which satisfies subparagraphs 1(3)(a) and (d), has the same qualitative and quantitative composition in excipients and that it is manufactured following the same process, that medicinal product shall be deemed to satisfy subparagraph 1(3)(c).

If the Federal Agency finds that it has not been demonstrated that the criterion in subparagraph 1(3)(c) has been satisfied, it shall request the competent authorities of the Member State of origin to provide the necessary information to enable it to decide whether that criterion has been satisfied.

It can be demonstrated, by at least one of the following studies or tests, that the criterion in subparagraph 1(3)(c) has been met:

1 bioequivalence studies;

2 clinical trials;

3 human pharmacodynamic studies;

4 studies on local availability of the medicinal product;

5 in vitro dissolution studies.

The studies or experiments used, as referred to in subparagraph 4, shall be adapted to the specific characteristics of the medicinal product.'

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

11 Novartis, a company incorporated under Swiss law, is the parent company of the Novartis group which is active in the production of medicinal products. That group includes, inter alia, the Pharmaceuticals and Sandoz divisions which are responsible, respectively, for the development of originator medicinal products (reference medicinal products) and for the production of generic medicinal products.

12 Impexeco and PI Pharma are two companies incorporated under Belgian law which are active in the parallel trade in medicinal products.

Case C-253/20

13 Novartis developed a medicinal product with the active substance letrozole, marketed in Belgium and the

Netherlands under the EU trade mark 'Femara', of which Novartis is the proprietor.
14 That medicinal product is sold on the market in packages of 30 and 100 film-coated tablets of 2.5 mg in Belgium, and in packages of 30 film-coated tablets of 2.5 mg in the Netherlands.
15 Sandoz BV and Sandoz NV, respectively in the Netherlands and in Belgium, market the generic medicinal product 'Letrozol Sandoz 2.5 mg', in packages of 30 film-coated tablets in the Netherlands, and 30 and 100 film-coated tablets in Belgium.
16 According to the referring court, the medicinal products marketed under the names 'Femara' and 'Letrozol Sandoz' are identical.
17 By letter of 28 October 2014, Impexeco informed Novartis of its intention to import from the Netherlands and to place on the Belgian market, from 1 December 2014, the medicinal product 'Femara 2.5 mg x 100 tablets (letrozol)'. It is apparent from the order for reference that that medicinal product was, in actual fact, the medicinal product 'Letrozol Sandoz 2.5 mg', repackaged in new outer packaging to which Impexeco intended to affix the trade mark 'Femara'.
18 By letter of 17 November 2014, Novartis opposed the parallel import planned by Impexeco, claiming that a new marking of that product with the trade mark of the reference medicinal product produced by Novartis, that is to say, the trade mark 'Femara', constituted a manifest infringement of its rights in that mark and was likely to mislead the public.
19 In July 2016, Impexeco marketed in Belgium the medicinal product 'Letrozol Sandoz 2.5 mg', repackaged in new packaging bearing the trade mark 'Femara'.
20 According to the referring court, the public price of the medicinal products 'Femara (Novartis) 2.5 mg', 'Letrozol Sandoz 2.5 mg' and 'Femara (Impexeco) 2.5 mg' are identical in Belgium. By contrast, the public price of 'Letrozol Sandoz 2.5 mg' is significantly lower in the Netherlands.
21 Claiming that the marketing referred to in paragraph 19 above infringed its trade mark rights, on 16 November 2016, Novartis brought an action against Impexeco before the stakingsrechter te Brussel (Court of Cessations, Brussels, Belgium).
22 By letter of 10 April 2017, Impexeco also informed Novartis of its intention to market in Belgium the medicinal product 'Femara 2.5 mg' in packaging of 30 film-coated tablets imported from the Netherlands and re-labelled. It is apparent from the order for reference that that medicinal product was the medicinal product 'Letrozol Sandoz 2.5 mg' and that Impexeco intended to re-label that product and to affix the trade mark 'Femara' to it.

Case C-254/20

23 Novartis developed a medicinal product with the active substance methylphenidate. Novartis Pharma NV markets that medicinal product in Belgium under the Benelux word mark 'Rilatine', of which it is the proprietor, inter alia in packs of 20 tablets of 10 mg. In the Netherlands, that medicinal product is marketed by Novartis Pharma BV under the trade mark 'Ritalin', inter alia in packs of 30 tablets of 10 mg.
24 Sandoz BV places on the market in the Netherlands the generic medicinal product 'Methylphenidate HC1 Sandoz 10 mg' in packaging of 30 tablets.
25 According to the referring court, the medicinal products marketed under the names 'Methylphenidate HC1 Sandoz 10 mg tablet' and 'Ritalin 10 mg tablet' are identical.
26 By letter of 30 June 2015, PI Pharma informed Novartis Pharma NV of its intention to import from the Netherlands and to place on the Belgian market the medicinal product 'Rilatine 10 mg x 20 tablets'. It is apparent from the order for reference that that medicinal product was, in actual fact, the medicinal product 'Methylphenidate HC1 Sandoz 10 mg', in new outer packaging on which PI Pharma intended to affix the trade mark 'Rilatine'.
27 In a letter of 22 July 2015, Novartis stated its opposition to the parallel import planned by PI Pharma, claiming that a new marking of the medicinal product 'Methylphenidate HC1 Sandoz 10 mg' with the trade mark of the reference medicinal product of Novartis, that is to say, the trade mark 'Rilatine', manifestly infringed its rights in that trade mark and was likely to mislead the public.
28 In October 2016, PI Pharma marketed that repackaged medicinal product in Belgium in new packaging bearing the trade mark 'Rilatine'.
29 The referring court states that, in Belgium, the public price of the medicinal product 'Rilatine 10 mg x 20 tablets Novartis' is EUR 8.10 (EUR 0.405 per tablet) and the price of the medicinal product 'Rilatine 10 mg x 20 tablets PI Pharma' is EUR 7.95 (EUR 0.398 per tablet), while in the Netherlands the public price of the medicinal product 'Methylphenidate HC1 Sandoz 10 mg' is EUR 0.055 per tablet.
30 Claiming that the marketing referred to in paragraph 28 above infringed its trade mark rights, on 28 July 2017, Novartis brought an action against PI Pharma before the stakingsrechter te Brussel (Court of Cessations, Brussels).

Factors common to the disputes in the main proceedings

31 By two judgments of 12 April 2018, the stakingsrechter te Brussel (Court of Cessations, Brussels) held that the two actions referred to in paragraphs 21 and 30 above were well founded on the ground, inter alia, that the practice of affixing the trade marks 'Femara' and 'Rilatine' respectively to the repackaged generic medicinal products 'Letrozol Sandoz 2.5 mg' and 'Methylphenidate HC1 Sandoz 10 mg', imported from the Netherlands, infringed the trade mark rights of Novartis, for the purposes, respectively, of Article 9(2)(a) of Regulation No 207/2009 and of Article 2.20(1)(a) of the Benelux Convention. Consequently, the stakingsrechter te Brussel (Court of Cessations, Brussels) ordered that that practice be discontinued.
32 Impexeco and PI Pharma, respectively, appealed against those two judgments before the referring court.

33 Before that court, they argue that the practices of using different packaging and different trade marks for the same product both contribute to the partitioning of Member States' markets and, therefore, have the same adverse effect on trade within the European Union.

34 Relying on **paragraphs 38 to 40 of the judgment of 12 October 1999, Upjohn (C-379/97, EU:C:1999:494)**, Impexeco and PI Pharma submit that the opposition of the proprietor of a trade mark to the reaffixing of a trade mark by a parallel importer constitutes an obstacle to intra-Community trade creating artificial partitioning of the markets between Member States, where such reaffixing is necessary in order for the products concerned to be marketed by that importer in the importing Member State. That case-law can be applied to a situation in which a generic medicinal product is given a new marking by affixing the trade mark of the reference medicinal product, where those medicinal products have been placed on the market in the EEA by economically linked undertakings.

35 Novartis submits that, under Article 13(1) of Regulation No 207/2009 and Article 2.23(3) of the Benelux Convention, the rights conferred by a trade mark may be exhausted only in respect of goods which have been placed on the market in the EEA 'under that trade mark' by the proprietor or with its consent, and not where a parallel importer gives the goods concerned a new marking.

36 Taking the view, in those circumstances, that the disputes pending before it raise questions of interpretation of EU law, the hof van beroep te Brussel (Court of Appeal, Brussels, Belgium) decided to stay the proceedings and to refer the following questions, which are worded identically in Cases C-253/20 and C-254/20, to the Court of Justice for a preliminary ruling:

'(1) Must Articles 34 to 36 TFEU be interpreted as meaning that, where a branded medicine (reference medicine) and a generic medicine have been put on the market in the EEA by economically linked undertakings, a trade mark proprietor's opposition to the further commercialisation of the generic medicine by a parallel importer after the repackaging of that generic medicine by the affixing to it of the trade mark of the branded medicine (reference medicine) in the country of importation may lead to an artificial partitioning of the markets of the Member States?

*(2) If the answer to that question is in the affirmative, must the trade mark proprietor's opposition to that [new marking] be assessed by reference to the ... conditions **[set out in paragraph 79 of the judgment of 11 July 1996, Bristol-Myers Squibb and Others (C-427/93, C-429/93 and C-436/93, EU:C:1996:282)]**?*

(3) Is it relevant to the answer to those questions that the generic medicine and the branded medicine (reference medicine) are identical or have the same therapeutic effect as referred to in Article 3(2) of the ... Royal Decree of 19 April 2001 on parallel imports [of medicinal products for human use and the parallel distribution of medicinal products for human and veterinary use, as amended by the Royal Decree of 21 January 2011]?'

Procedure before the Court

37 By decision of the President of the Court of 14 July 2020, Cases C-253/20 and C-254/20 were joined for the purposes of the written and oral parts of the procedure and of the judgment.

Consideration of the questions referred

Preliminary observations

38 Regulation No 207/2009 was repealed and replaced, with effect from 1 October 2017, by Regulation (EU) 2017/1001 of the European Parliament and of the Council of 14 June 2017 on the European Union trade mark (OJ 2017 L 154, p. 1), while Directive 2008/95 was repealed and replaced, with effect from 15 January 2019, by Directive (EU) 2015/2436 of the European Parliament and of the Council of 16 December 2015 to approximate the laws of the Member States relating to trade marks (OJ 2015 L 336, p. 1).

39 However, given the dates of the facts of the disputes in the main proceedings, Regulation No 207/2009 and Directive 2008/95 remain applicable ratione temporis to those facts.

Substance

40 According to the settled case-law of the Court, in the procedure laid down by Article 267 TFEU providing for cooperation between national courts and the Court of Justice, it is for the latter to provide the national court with an answer which will be of use to it and enable it to decide the case before it. To that end, the Court should, where necessary, reformulate the questions referred to it (judgment of 26 April 2022, Landespolizeidirektion Steiermark (Maximum duration of internal border control), C-368/20 and C-369/20, EU:C:2022:298, paragraph 50 and the case-law cited). Furthermore, the Court may decide to take into consideration rules of EU law to which the national court has made no reference in the wording of its question (**judgment of 8 September 2022, RTL Television, C-716/20, EU:C:2022:643, paragraph 55 and the case-law cited**).

41 In the present case, in order to answer the questions referred, it is necessary to take into account the provisions of secondary EU law laid down in Article 9(2) and Article 13 of Regulation No 207/2009, and Article 5(1) and Article 7 of Directive 2008/95, since they concern the rights of proprietors of a trade mark and the question of the exhaustion of the rights conferred by that trade mark.

42 Thus, by its questions, which it is appropriate to examine together, the referring court asks, in essence, whether Article 9(2) and Article 13 of Regulation No 207/2009, and Article 5(1) and Article 7 of Directive 2008/95, read in the light of Articles 34 and 36 TFEU, must be interpreted as meaning that the proprietor of the trade mark of a reference medicinal product and of the trade mark of a generic medicinal product may oppose the placing on the market of a Member State, by a parallel importer, of that generic medicinal product, imported from another Member State, where that medicinal product has been repackaged in new outer packaging to which the trade mark of the corresponding reference medicinal product has been affixed.

43 As a preliminary point, it should be borne in mind that, under Article 9(1) of Regulation No 207/2009 and Article 5(1) of Directive 2008/95, the registration of a trade mark confers on its proprietor exclusive rights which, under Article 9(2)(a) of that regulation and Article 5(1)(a) of that directive, entitle that proprietor to prevent any third party without its consent from using in the course of trade any sign which is identical with that trade mark in relation to goods or services which are identical with those for which the trade mark was registered.
44 Article 9(3) of Regulation No 207/2009 and Article 5(3) of Directive 2008/95 list, non-exhaustively, several types of use which the trade mark proprietor may prohibit (**judgment of 25 July 2018, Mitsubishi Shoji Kaisha and Mitsubishi Caterpillar Forklift Europe, C-129/17, EU:C:2018:594, paragraph 38 and the case-law cited**).
45 In particular, it is apparent from Article 9(3) of that regulation and from Article 5(3) of that directive that the proprietor may, inter alia, prevent all third parties from affixing the sign in question to goods or to their packaging and from importing and marketing the goods under that sign.
46 The exclusive right of the proprietor of the trade mark was conferred in order to enable it to protect its specific interests as proprietor of that trade mark, that is to say, to ensure that the trade mark can fulfil its functions. Therefore, the exercise of that right must be reserved to cases in which a third party's use of the sign affects or is liable to affect the functions of the trade mark. Amongst those functions is not only the essential function of the mark which is to guarantee to consumers the origin of the product or service, but also the other functions of the mark, such as, in particular, that of guaranteeing the quality of the product or service, or those of communication, investment or advertising (see, to that effect, **judgment of 25 July 2018, Mitsubishi Shoji Kaisha and Mitsubishi Caterpillar Forklift Europe, C-129/17, EU:C:2018:594, paragraph 34 and the case-law cited**).
47 According to settled case-law, the repackaging of a product bearing a mark carried out by a third party without the authorisation of the proprietor is likely to create real risks for the guarantee of origin of that product (see, to that effect, **judgment of 17 May 2018, Junek Europ-Vertrieb, C-642/16, EU:C:2018:322, paragraph 23 and the case-law cited**).
48 That being so, under Article 13(1) of Regulation No 207/2009 and Article 7(1) of Directive 2008/95, a trade mark is not to 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 its consent. These provisions are intended to reconcile the fundamental interest in protecting trade mark rights, on the one hand, with the fundamental interest in the free movement of goods within the internal market, on the other (see, to that effect, **judgment of 20 December 2017, Schweppes, C-291/16, EU:C:2017:990, paragraph 35**).
49 In that context, it must be borne in mind that, although Article 13 of Regulation No 207/2009 and Article 7 of Directive 2008/95, worded in general terms, comprehensively regulate the question of the exhaustion of the rights conferred by a trade mark and although, where provision is made for the harmonisation of measures necessary to protect the interests referred to in Article 36 TFEU, any national measure relating thereto must be assessed in relation to the provisions of that regulation or that directive and not Articles 34 to 36 TFEU, that regulation and that directive, like any secondary EU legislation, must be interpreted in the light of the TFEU rules on the free movement of goods and of Article 36 TFEU in particular (see, to that effect, **judgment of 20 December 2017, Schweppes, C-291/16, EU:C:2017:990, paragraph 30 and the case-law cited**).
50 More particularly, it follows from Article 13(2) of Regulation No 207/2009 and Article 7(2) of Directive 2008/95 that 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 the rights conferred by the mark constitutes a disguised restriction on trade between Member States within the meaning of the second sentence of Article 36 TFEU (see, to that effect, **judgment of 17 May 2018, Junek Europ-Vertrieb, C-642/16, EU:C:2018:322, paragraph 25 and the case-law cited**). Trade mark rights are not intended to allow their owners to partition national markets and thus promote the retention of price differences which may exist between Member States (**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 46**).
51 A disguised restriction within the meaning of the second sentence of Article 36 TFEU 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 (see, to that effect, **judgments of 10 November 2016, Ferring Lægemidler, C-297/15, EU:C:2016:857, paragraph 16 and the case-law cited**, and of **17 May 2018, Junek Europ-Vertrieb, C-642/16, EU:C:2018:322, paragraph 26 and the case-law cited**).
52 Furthermore, the Court has held that, since the conclusion that the proprietor may not rely on the rights conferred by the trade mark in order to oppose the marketing under its 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 itself, it is necessary, in the interest of the proprietor as owner of the trade mark and in order to protect it against any abuse, to allow that option only in so far as the importer complies with certain other requirements (see, to that

effect, **judgment of 28 July 2011, Orifarm and Others, C-400/09 et C-207/10, EU:C:2011:519, paragraph 26 and the case-law cited**).

53 Thus, according to settled case-law, the proprietor of a trade mark may legitimately oppose the further commercialisation in one Member State of a pharmaceutical product bearing its trade mark and imported from another Member State, where the importer of that product has repackaged it and reaffixed that trade mark to it, 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 proprietor; and

– the importer gives notice to the trade mark proprietor before the repackaged product is put on sale, and, on demand, supplies it with a specimen of the repackaged product (see, to that effect, **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**; of **26 April 2007, Boehringer Ingelheim and Others, C-348/04, EU:C:2007:249, paragraph 32**, and of **17 May 2018, Junek Europ-Vertrieb, C-642/16, EU:C:2018:322, paragraph 28, and the case-law cited**).

54 As regards, in particular, the first of the conditions set out in the preceding paragraph, the Court has held that a trade mark proprietor's opposition to repackaging of pharmaceutical products contributes to artificial partitioning of the markets between Member States where the repackaging is necessary in order to enable the product imported in parallel to be marketed in the importing Member State **(judgment of 26 April 2007, Boehringer Ingelheim and Others, C-348/04, EU:C:2007:249, paragraph 18**).

55 That condition of necessity is satisfied, in particular, where the circumstances prevailing at the time of marketing in the importing Member State preclude the medicinal product from being placed on the market in the same packaging as that in which it is marketed in the exporting Member State, thereby making repackaging objectively necessary in order for the medicinal product concerned to be marketed in that Member State by the parallel importer (see, to that effect, **judgment of 10 November 2016, Ferring Lægemidler, C-297/15, EU:C:2016:857, paragraph 20 and the case-law cited**).

56 By contrast, that condition is not fulfilled if repackaging of the product is explicable solely by the parallel importer's attempt to secure a commercial advantage (**judgment of 26 April 2007, Boehringer Ingelheim and Others, C-348/04, EU:C:2007:249, paragraph 37**).

57 In accordance with the case-law of the Court, a trade mark owner which markets in different Member States an identical medicinal product under different trade marks according to the Member State in which the product is marketed also contributes to artificial partitioning of the markets between Member States if it opposes the replacement of the trade mark used in the exporting Member State with that used by that proprietor in the importing Member State, where that replacement is objectively necessary in order for that medicinal product to be marketed in the importing Member State by the parallel importer (see, to that effect, **judgment of 12 October 1999, Upjohn, C-379/97, EU:C:1999:494, paragraphs 19 and 38 to 40**).

58 In the present case, however, the disputes in the main proceedings are characterised by the fact that the medicinal products being traded in parallel are generic medicinal products, whereas the trade marks affixed to the new outer packaging of those medicinal products by the parallel importers concerned are the trade marks of the corresponding reference medicinal products.

59 In those circumstances, it is necessary, in the first place, to examine whether those medicinal products may be regarded as being identical, for the purposes of the case-law relating to the exhaustion of the trade mark rights, referred to in paragraph 57 above.

60 In that regard, it should be noted, first of all, that Article 10(2)(b) of Directive 2001/83, as amended by Directive 2004/27, defines a generic medicinal product as 'a medicinal product which has the same qualitative and quantitative composition in active substances and the same pharmaceutical form as the reference medicinal product, and whose bioequivalence with the reference medicinal product has been demonstrated by appropriate bioavailability studies'.

61 Next, as the Advocate General observed in point 65 of his Opinion, as is clear from the wording of the second and third sentences of Article 10(2)(b), the composition of the generic medicinal product may differ from that of the reference medicinal product as regards the pharmaceutical form, the chemical form of the active substance and its excipients.

62 Finally, as observed by the Advocate General in point 66 of his Opinion, it must be stated that, for medical reasons, it may be countraindicated to replace, during treatment, a medicinal product with an equivalent medicinal product, whether it is a reference medicinal product or a generic medicinal product. That is the case, in particular, with regard to medicinal products with a 'narrow therapeutic margin'.

63 In those circumstances, to consider that, where they are therapeutically equivalent, a reference medicinal product and its generic counterpart are identical products for the purposes of the case-law referred to in paragraph 57 above could mislead health professionals and patients as regards the exact composition of the medicinal product concerned, with potentially serious consequences for the health of those patients.

64 Therefore, only a medicinal product which is identical in all respects to another medicinal product can

be repackaged in new outer packaging bearing the trade mark of the other medicinal product.

65 That may be the case, in particular, for a reference medicinal product and a generic medicinal product manufactured by the same entity or by economically linked entities and which, in actual fact, constitute one and the same product marketed under two different sets of rules.

66 In such a case, neither the difference in the legal rules applicable to those medicinal products nor the different way in which they are perceived by health professionals or patients can justify the proprietor of the trade marks concerned being able to oppose the replacement of the trade mark which it uses in the exporting Member State by that which it affixes to the medicinal products which it markets in the importing Member State if it is established that that replacement is objectively necessary in order for those medicinal products to be marketed in the latter Member State. Otherwise, the proprietor would be able to contribute to an artificial partitioning of the markets between Member States by marketing an identical medicinal product sometimes as a reference medicinal product and sometimes as a generic medicinal product.

67 In the present case, as has been stated in paragraphs 16 and 25 above, the referring court considers that the generic medicinal product at issue in each of the cases in the main proceedings is identical to the corresponding reference medicinal product.

68 Accordingly, it is necessary, in the second place, to examine whether, in circumstances such as those in the main proceedings, the opposition of the trade mark proprietor to the replacement of the trade mark of a generic medicinal product placed on the market in the exporting Member State by that of the corresponding reference medicinal product marketed in the importing Member State constitutes an obstacle to the effective access of the medicinal product concerned to the market of the latter Member State.

69 As is apparent from paragraphs 55 and 57 above, that would be the case if the medicinal product concerned could not be marketed in the importing Member State under its trade mark of origin, thereby making the replacement of that trade mark objectively necessary in order to ensure the free movement of that medicinal product in the internal market.

70 In such a situation, the proprietor of a trade mark cannot oppose the replacement of that trade mark by a parallel importer if the latter is able to establish that the circumstances prevailing at the time of marketing the product concerned make it objectively necessary to replace the trade mark of origin by that of the importing Member State for the purpose of placing that product on the market in that Member State (see, to that effect, **judgment of 12 October 1999, Upjohn, C-379/97, EU:C:1999:494, paragraphs 42 and 43**) and if, moreover, that replacement is carried out in such a way that the legitimate interests of the proprietor are respected (see, to that effect, **judgment 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**), that is to say, under the conditions set out in the **judgments of 11 July 1996, Bristol-Myers Squibb and Others (C-427/93, C-429/93 and C-436/93, EU:C:1996:282)**; of **26 April 2007, Boehringer Ingelheim and Others (C-348/04, EU:C:2007:249)**; and of **17 May 2018, Junek Europ-Vertrieb (C-642/16, EU:C:2018:322)**.

71 Conversely, where the parallel importer is able to market that product under its trade mark of origin by adapting, where appropriate, the packaging in order to satisfy the market requirements of the importing Member State, the condition of necessity referred to in paragraph 55 above is not satisfied. In such a case, the free movement of goods, which, as is apparent from paragraphs 48 and 50 above, underpins the rule on the exhaustion of trade mark rights in trade between Member States, is not, in essence, threatened and cannot therefore take precedence over the legitimate interests of the trade mark proprietor.

72 Furthermore, it should be noted, as the Advocate General observed in point 73 of his Opinion, that a Member State cannot, in principle, refuse to grant a parallel import licence for a generic medicinal product where the corresponding reference medicinal product has marketing authorisation in that Member State, unless such a refusal is justified by considerations relating to the protection of health and life of humans (see, to that effect, judgment of 3 July 2019, Delfarma, C-387/18, EU:C:2019:556, paragraphs 26, 29 and 41). Consequently, the condition of necessity referred to in paragraph 55 above cannot be satisfied where a generic medicinal product corresponds in every respect to the reference medicinal product covered by that authorisation, given that, in such a situation, the parallel importer must be regarded as being able to market the generic medicinal product under its mark of origin.

73 Finally, as is apparent from paragraph 56 above, the right of a trade mark proprietor to oppose the marketing, under that trade mark, of products repackaged by a parallel importer cannot be limited where the replacement of the trade mark of origin by another trade mark of the proprietor is exclusively motivated by the pursuit of an economic advantage, as is the case, in particular, where an economic operator seeks to take advantage of the reputation of the trade mark of a reference medicinal product or to place a product in a more profitable category.

74 In the light of all the foregoing considerations, the answer to the questions referred is that Article 9(2) and Article 13 of Regulation No 207/2009, and Article 5(1) and Article 7 of Directive 2008/95, read in the light of Articles 34 and 36 TFEU, must be interpreted as meaning that the proprietor of the trade mark of a reference medicinal product and the trade mark of a generic medicinal product may oppose the placing on the market of a Member State, by a parallel importer, of that generic medicinal product imported from another Member State, where that medicinal product has been repackaged in new outer packaging to which the trade mark of the corresponding reference medicinal product has been affixed, unless, first, the two medicinal

products are identical in all respects and, second, the replacement of the trade mark satisfies the conditions laid down in **paragraph 79 of the judgment of 11 July 1996, Bristol-Myers Squibb and Others (C-427/93, C-429/93 and C-436/93, EU:C:1996:282**), in **paragraph 32 of the judgment of 26 April 2007, Boehringer Ingelheim and Others (C-348/04, EU:C:2007:249**), and in **paragraph 28 of the judgment of 17 May 2018, Junek Europ-Vertrieb (C-642/16, EU:C:2018:322**).

Costs

75 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 cost of those parties, are not recoverable.

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

Article 9(2) and Article 13 of Council Regulation (EC) No 207/2009 of 26 February 2009 on the European Union trade mark, as amended by Regulation (EU) 2015/2424 of the European Parliament and of the Council of 16 December 2015, and Article 5(1) and Article 7 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, read in the light of Articles 34 and 36 TFEU,

must be interpreted as meaning that the proprietor of the trade mark of a reference medicinal product and the trade mark of a generic medicinal product may oppose the placing on the market of a Member State, by a parallel importer, of that generic medicinal product imported from another Member State, where that medicinal product has been repackaged in new outer packaging to which the trade mark of the corresponding reference medicinal product has been affixed, unless, first, the two medicinal products are identical in all respects and, second, the replacement of the trade mark satisfies the conditions laid down in **paragraph 79 of the judgment of 11 July 1996, Bristol-Myers Squibb and Others (C-427/93, C-429/93 and C-436/93, EU:C:1996:282**); in **paragraph 32 of the judgment of 26 April 2007, Boehringer Ingelheim and Others (C-348/04, EU:C:2007:249**); and in **paragraph 28 of the judgment of 17 May 2018, Junek Europ-Vertrieb (C-642/16, EU:C:2018:322**).