Reports of Cases

JUDGMENT OF THE COURT (Fifth Chamber)

17 November 2022 *

(Reference for a preliminary ruling – Intellectual property – EU trade mark – Regulation (EU) 2017/1001 – Article 9(2) – Rights conferred by a mark – Article 15 – Exhaustion of the rights conferred by a trade mark – Parallel import of medicinal products – Repackaging of the product bearing the mark – New outer packaging – Opposition by the proprietor of the mark – Artificial partitioning of the markets between Member States – Medicinal products for human use – Directive 2001/83/EC – Article 47a – Safety features – Replacement – Equivalent features – Delegated Regulation (EU) 2016/161 – Article 3(2) – Anti-tampering device – Unique identifier)

In Case C-147/20,

REQUEST for a preliminary ruling under Article 267 TFEU from the Landgericht Hamburg (Regional Court, Hamburg, Germany), made by decision of 27 February 2020, received at the Court on 23 March 2020, in the proceedings

Novartis Pharma GmbH

v

Abacus Medicine A/S,

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:

– Novartis Pharma GmbH, by U. H. Grundmann, Rechtsanwalt,

– Abacus Medicine A/S, by S. Hees, Rechtsanwalt,

* Language of the case: German.

– the Polish Government, by B. Majczyna, acting as Agent,

– the European Commission, by G. Braun, É. Gippini Fournier and L. Haasbeek, 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 Article 9(2) and Article 15 of 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), in conjunction with Article 47a and Article 54(o) 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 2012/26/EU of the European Parliament and of the Council of 25 October 2012 (OJ 2012 L 299, p. 1) ('Directive 2001/83') and Article 5(3) of Commission Delegated Regulation (EU) 2016/161 of 2 October 2015 supplementing Directive 2001/83 (OJ 2016 L 32, p. 1).

2 The request has been made in proceedings between Novartis Pharma GmbH, established in Germany and the exclusive proprietor, in that Member State, of rights over the word marks Novartis and Votrient, and Abacus Medicine A/S, established in Denmark, concerning the marketing in Germany by that latter undertaking of medicinal products of the Votrient mark imported in parallel from other Member States.

Legal context

European Union law

Regulation 2017/1001

3 Recital 22 of Regulation 2017/1001 states:

'It follows from the principle of free movement of goods that it is essential that the proprietor of an EU trade mark not be entitled to prohibit its use by a third party in relation to goods which have been put into circulation in the European Economic Area, under the trade mark, by him or with his consent, save where there exist legitimate reasons for the proprietor to oppose further commercialisation of the goods.'

4 Under Article 9 of that regulation, entitled 'Rights conferred by an EU trade mark':

'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 of those goods;

(b) offering the goods or 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;

…'

5 Article 15 of that regulation, entitled 'Exhaustion of the rights conferred by an EU trade mark', provides:

'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 2001/83

6 Recitals 2 to 5 and 40 of Directive 2001/83 state:

'(2) The essential aim of any rules governing the production, distribution and use of medicinal products must be to safeguard public health.

(3) However, this objective must be attained by means which will not hinder the development of the pharmaceutical industry or trade in medicinal products within the Community.

(4) Trade in medicinal products within the Community is hindered by disparities between certain national provisions, in particular between provisions relating to medicinal products (excluding substances or combinations of substances which are foods, animal feeding-stuffs or toilet preparations), and such disparities directly affect the functioning of the internal market.

(5) Such hindrances must accordingly be removed; whereas this entails approximation of the relevant provisions.

…

(40) The provisions governing the information supplied to users should provide a high degree of consumer protection, in order that medicinal products may be used correctly on the basis of full and comprehensible information.'

7 Under Article 40 of that directive:

'1. Member States shall take all appropriate measures to ensure that the manufacture of the medicinal products within their territory is subject to the holding of an authorisation. This manufacturing authorisation shall be required notwithstanding that the medicinal products manufactured are intended for export.

2. The authorisation referred to in paragraph 1 shall be required for both total and partial manufacture, and for the various processes of dividing up, packaging or presentation.

…'

8 Article 47a(1) of that directive provides:

'The safety features referred to in point (o) of Article 54 shall not be removed or covered, either fully or partially, unless the following conditions are fulfilled:

(a) the manufacturing authorisation holder verifies, prior to partly or fully removing or covering those safety features, that the medicinal product concerned is authentic and that it has not been tampered with;

(b) the manufacturing authorisation holder complies with point (o) of Article 54 by replacing those safety features with safety features which are equivalent as regards the possibility to verify the authenticity, identification and to provide evidence of tampering of the medicinal product. Such replacement shall be conducted without opening the immediate packaging as defined in point 23 of Article 1.

Safety features shall be considered equivalent if they:
(i) comply with the requirements set out in the delegated acts adopted pursuant to Article 54a(2); and
(ii) are equally effective in enabling the verification of authenticity and identification of medicinal products and in providing evidence of tampering with medicinal products;

(c) the replacement of the safety features is conducted in accordance with applicable good manufacturing practice for medicinal products; and

(d) the replacement of the safety features is subject to supervision by the competent authority.'

9 Under Article 54 of that directive:

'The following particulars shall appear on the outer packaging of medicinal products or, where there is no outer packaging, on the immediate packaging:

…

(o) for medicinal products other than radiopharmaceuticals referred to in Article 54a(1), safety features enabling wholesale distributors and persons authorised or entitled to supply medicinal products to the public to:

– verify the authenticity of the medicinal product, and

– identify individual packs,

as well as a device allowing verification of whether the outer packaging has been tampered with.'

10 Article 54a of Directive 2001/83 provides:

'1. Medicinal products subject to prescription shall bear the safety features referred to in point (o) of Article 54, unless they have been listed in accordance with the procedure pursuant to point (b) of paragraph 2 of this Article.

…

2. The [European] Commission shall adopt, by means of delegated acts in accordance with Article 121a and subject to the conditions laid down in Articles 121b and 121c, measures supplementing point (o) of Article 54 with the objective of establishing the detailed rules for the safety features referred to in point (o) of Article 54.

…'

11 Article 59 of that directive lists the information which must be included in the package leaflet accompanying the medicinal product.

12 The first subparagraph of Article 63(1) of that directive is worded as follows:

'The particulars for labelling listed in Articles 54, 59 and 62 shall appear in an official language or official languages of the Member State where the medicinal product is placed on the market, as specified, for the purposes of this Directive, by that Member State.'

Directive 2011/62/EU

13 Recitals 2, 3, 11, 12, 29 and 33 of Directive 2011/62/EU of the European Parliament and of the Council of 8 June 2011 amending Directive 2001/83 (OJ 2011 L 174, p. 74) state:

‘(2) There is an alarming increase of medicinal products detected in the Union which are falsified in relation to their identity, history or source. Those products usually contain sub-standard or falsified ingredients, or no ingredients or ingredients, including active substances, in the wrong dosage thus posing an important threat to public health.

(3) Past experience shows that such falsified medicinal products do not reach patients only through illegal means, but via the legal supply chain as well. This poses a particular threat to human health and may lead to a lack of trust of the patient also in the legal supply chain. Directive [2001/83] should be amended in order to respond to this increasing threat.

…

(11) Safety features for medicinal products should be harmonised within the Union in order to take account of new risk profiles, while ensuring the functioning of the internal market for medicinal products. Those safety features should allow verification of the authenticity and identification of individual packs, and provide evidence of tampering. …

(12) Any actor in the supply chain who packages medicinal products has to be a holder of a manufacturing authorisation. In order for the safety features to be effective, a manufacturing authorisation holder who is not himself the original manufacturer of the medicinal product should only be permitted to remove, replace or cover those safety features under strict conditions. In particular, the safety features should be replaced in the case of repackaging by equivalent safety features. To this end, the meaning of the term “equivalent” should be clearly specified. Those strict conditions should provide adequate safeguards against falsified medicinal products entering the supply chain, in order to protect patients as well as the interests of marketing authorisation holders and manufacturers.

…

(29) This Directive is without prejudice to provisions concerning intellectual property rights. It aims specifically to prevent falsified medicinal products from entering the legal supply chain.

…

(33) Since the objective of this Directive, namely to safeguard the functioning of the internal market for medicinal products, whilst ensuring a high level of protection of public health against falsified medicinal products, cannot be sufficiently achieved by the Member States, and can, by reason of the scale of the measure, be better achieved at Union level, the Union may adopt measures, in accordance with the principle of subsidiarity as set out in Article 5 [TEU]. In accordance with the principle of proportionality, as set out in that Article, this Directive does not go beyond what is necessary to achieve that objective.’

Delegated Regulation 2016/161

14 Recitals 1, 11, 12 and 15 of Delegated Regulation 2016/161 state:

‘(1) Directive [2001/83] provides for measures to prevent the entry into the legal supply chain of falsified medicinal products by requiring the placing of safety features consisting of a unique identifier and an anti-tampering device on the packaging of certain medicinal products for human use for the purposes of allowing their identification and authentication.

…

(11) To facilitate the verification of the authenticity and decommissioning of a unique identifier by wholesalers and persons authorised or entitled to supply medicinal products to the public, it is necessary to ensure that the structure and printing quality of the two-dimensional barcode encoding the unique identifier allow for high-speed reading and minimisation of reading errors.

(12) The data elements of the unique identifier should be printed on the packaging in human-readable format so to allow the verification of the authenticity of the unique identifier and its decommissioning in case the two-dimensional barcode is unreadable.

…

(15) The verification of both safety features is necessary to ensure the authenticity of a medicinal product in an end-to-end verification system. The verification of the authenticity of the unique identifier aims at ensuring that the medicinal product originates from the legitimate manufacturer. The verification of the integrity of the anti-tampering device shows whether the packaging has been opened or altered since it left the manufacturer, thereby ensuring that the content of the packaging is authentic.’

15 Under Article 3(2) of Delegated Regulation 2016/161:

‘The following definitions shall apply:

(a) “unique identifier” means the safety feature enabling the verification of the authenticity and the identification of an individual pack of a medicinal product;

(b) “anti-tampering device” means the safety feature allowing the verification of whether the packaging of a medicinal product has been tampered with;

…’

16 Article 4 of that delegated regulation, entitled ‘Composition of the unique identifier’, provides:

‘The manufacturer shall place on the packaging of a medicinal product a unique identifier which complies with the following technical specifications:

(a) The unique identifier shall be a sequence of numeric or alphanumeric characters that is unique to a given pack of a medicinal product.

…’

17 Article 5 of that delegated regulation, entitled ‘Carrier of the unique identifier’, provides, in paragraphs 1 to 3:

‘1. Manufacturers shall encode the unique identifier in a two-dimensional barcode.

2. The barcode shall be a machine-readable Data Matrix and have error detection and correction equivalent to or higher than those of the Data Matrix ECC200. …

3. Manufacturers shall print the barcode on the packaging on a smooth, uniform, low-reflecting surface.’

18 Article 6 of that delegated regulation, entitled ‘Quality of the printing of the two-dimensional barcode’, states:

‘1. Manufacturers shall evaluate the quality of the printing of the Data Matrix by assessing at least the following Data Matrix parameters:

…

2. Manufacturers shall identify the minimum quality of the printing which ensures the accurate readability of the Data Matrix throughout the supply chain until at least one year after the expiry date of the pack or five years after the pack has been released for sale or distribution in accordance with Article 51(3) of Directive [2001/83], whichever is the longer period.

…’

19 Article 10 of Delegated Regulation 2016/161, entitled ‘Verification of the safety features’, is worded as follows:

‘When verifying the safety features, manufacturers, wholesalers and persons authorised or entitled to supply medicinal products to the public shall verify the following:

(a) the authenticity of the unique identifier;

(b) the integrity of the anti-tampering device.’

20 Under Article 16(1) of that delegated regulation:

‘Before removing or covering, either fully or partially, the safety features in accordance with Article 47a of Directive [2001/83], the manufacturer shall verify the following:

(a) the integrity of the anti-tampering device;

(b) the authenticity of the unique identifier and decommission it if replaced.’

21 Article 17 of that delegated regulation, entitled 'Equivalent unique identifier', provides:

'When placing an equivalent unique identifier for the purposes of complying with Article 47a(1)(b) of Directive [2001/83], the manufacturer shall verify that the structure and composition of the unique identifier placed on the packaging complies, with regard to the product code and the national reimbursement number or other national number identifying the medicinal product, with the requirements of the Member State where the medicinal product is intended to be placed on the market, so that that unique identifier can be verified for authenticity and decommissioned.'

22 Article 24 of the delegated regulation, entitled 'Actions to be taken by wholesalers in case of tampering or suspected falsification', is worded as follows:

'A wholesaler shall not supply or export a medicinal product where he has reason to believe that its packaging has been tampered with, or where the verification of the safety features of the medicinal product indicates that the product may not be authentic. He shall immediately inform the relevant competent authorities.'

23 Article 25 of Delegated Regulation 2016/161, entitled 'Obligations of persons authorised or entitled to supply medicinal products to the public', provides, in paragraphs 1 and 3:

'1. Persons authorised or entitled to supply medicinal products to the public shall verify the safety features and decommission the unique identifier of any medicinal product bearing the safety features they supply to the public at the time of supplying it to the public.

…

3. In order to verify the authenticity of the unique identifier of a medicinal product and decommission that unique identifier, persons authorised or entitled to supply medicinal products to the public shall connect to the repositories system referred to in Article 31 through the national or supranational repository serving the territory of the Member State in which they are authorised or entitled.'

24 Under Article 30 of that delegated regulation, entitled 'Actions to be taken by persons authorised or entitled to supply medicinal products to the public in case of suspected falsification':

'Where persons authorised or entitled to supply medicinal products to the public have reason to believe that the packaging of the medicinal product has been tampered with, or the verification of the safety features of the medicinal product indicates that the product may not be authentic, those persons authorised or entitled to supply medicinal products to the public shall not supply the product and shall immediately inform the relevant competent authorities.'

25 Article 31(1) of the delegated regulation is worded as follows:

'The repositories system where the information on the safety features shall be contained, pursuant to Article 54a(2)(e) of Directive [2001/83], shall be set up and managed by a non-profit legal entity or non-profit legal entities established in the Union by manufacturers and marketing authorisation holders of medicinal products bearing the safety features.'

26 Article 34(4) of that delegated regulation states:

'When it receives the information referred to in Article 35(4), the hub shall ensure the electronic linking of the batch numbers before and after the repackaging or relabelling operations with the set of unique identifiers decommissioned and with the set of equivalent unique identifiers placed.'

27 Article 35(4) of Delegated Regulation 2016/161 provides:

'For each batch of repackaged or relabelled packs of a medicinal product on which equivalent unique identifiers were placed for the purposes of complying with Article 47a of Directive [2001/83], the person responsible for placing the medicinal product on the market shall inform the hub of the batch number or numbers of the packs which are to be repackaged or relabelled and of the unique identifiers on those packs. He shall additionally inform the hub of the batch number of the batch resulting from the repackaging or relabelling operations and the equivalent unique identifiers in that batch.'

28 Pursuant to the second paragraph of Article 50 thereof, Delegated Regulation 2016/161 became applicable from 9 February 2019.

German law

29 Pursuant to Paragraph 10(1)(c) of the Gesetz über den Verkehr mit Arzneimitteln (Law on the marketing of medicinal products), of 24 August 1976 (BGB1. 1976 I, p. 2445), in the version published on 12 December 2005 (BGBl. 2005 I, p. 3394), as amended by the Law of 19 October 2012 (BGBl. 2012 I, p. 2192) ('the Law on the marketing of medicinal products'), safety features and an anti-tampering device must be affixed to the outer packaging of medicinal products for human use where that is provided for or prescribed by Article 54a of Directive 2001/83.

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

30 Novartis Pharma has exclusive rights of use in Germany of the EU word marks Novartis and Votrient, of which Novartis AG is the proprietor. Novartis Pharma uses those marks for the medicinal products 'Votrient 400 mg film-coated tablets' and 'Votrient 200 mg film-coated tablets' ('the medicinal products at issue').

31 From 9 February 2019 at the latest, that is to say, from the date on which Delegated Regulation 2016/161 became applicable, in accordance with the second paragraph of Article 50 thereof, Novartis Pharma's outer packaging has had an anti-tampering device.

32 Abacus Medicine distributes, primarily in Germany, parallel-imported medicinal products from other EU Member States.

33 Taking the view that, in order to comply with Article 10 of the Law on the marketing of medicinal products, it was under an obligation to open the outer packaging of the medicinal products at issue, including that packaging's anti-tampering device, Abacus Medicine informed Novartis that it would no longer supply those medicinal products in their original outer packaging, but that it would replace that outer packaging with new packaging. In addition, Abacus Medicine sent Novartis sample packages of those medicinal products.

34 Before the referring court, Novartis Pharma asks, in essence, that Abacus Medicine should be prohibited from placing on the German market or promoting on that market the medicinal products at issue repackaged in that way which have been imported in parallel. In support of its application, it claims that, as the proprietor of the rights over those marks in Germany, it is entitled, on the basis of Article 9(2) of Regulation 2017/1001, to oppose the repackaging of those medicinal products envisaged by Abacus Medicine.

35 In that regard, Novartis Pharma submits that the rights conferred on it by those trade marks under that provision have not been exhausted within the meaning of Article 15(2) of Regulation 2017/1001. It maintains that the repackaging of the medicinal products at issue in new outer packaging is not necessary, since the requirements imposed by Articles 47a and 54a of Directive 2001/83 may be satisfied by affixing to the original outer packaging the barcode bearing the unique identifier, within the meaning of Article 3(2)(a) of Delegated Regulation 2016/161, by means of an adhesive label and, after having placed a package leaflet in German in the original packaging, a new anti-tampering device covering the traces of the opening of the original packaging. Finally, in order to dispel any doubts as to the integrity of the medicinal products repackaged accordingly, Abacus Medicine could indicate that it had affixed that new device in the context of lawful repackaging.

36 Abacus Medicine submits that the opening of the sealing label affixed by Novartis Pharma results in visible, irreversible alterations or changes to the outer packaging, labels or adhesive tape. Moreover, the affixing, on the original packaging of the medicinal products at issue, of an adhesive label bearing the unique identifier is not a satisfactory solution, since, on account of the silicone coating of the outer packaging of those medicinal products, that label can easily be removed. In addition, that coating also makes it impossible to print the barcode, in accordance with Article 5(3) of Delegated Regulation 2016/161.

37 Accordingly, Abacus Medicine submits that in order to be able to market the medicinal products at issue in Germany it is required to repackage them in new outer packaging, and that Novartis Pharma is therefore not entitled to oppose that repackaging.

38 According to the Landgericht Hamburg (Regional Court, Hamburg, Germany), which is the referring court, the outcome of the dispute in the main proceedings depends on the interpretation of Article 54(o) and Article 47a of Directive 2001/83 and Article 5(3) of Delegated Regulation 2016/161.

39 That court considers that, if the repackaging carried out by Abacus Medicine was contrary to the principles laid down by the Court in 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), Novartis Pharma would have a right of opposition under Article 9(2) of Regulation 2017/1001.

40 By contrast, that court considers that if Novartis Pharma's reliance on the rights conferred on it by the marks referred to in paragraph 2 above were capable of resulting in an artificial partitioning of the markets, Abacus Medicine's arguments would have to be upheld. The use of new outer packaging might also prove necessary if Article 5(3) of Delegated Regulation 2016/161 were to be interpreted as imposing an obligation to print directly the barcode on the packaging of the medicinal products.

41 In those circumstances the Landgericht Hamburg (Regional Court, Hamburg) decided to stay the proceedings and to refer the following questions to the Court of Justice for a preliminary ruling:

'(1) Can it lead to an artificial partitioning of the markets within the meaning of the case-law of the Court of Justice if the safety features of original outer wrapping/original packaging which are provided for underArticle 54(o) and Article 47a of Directive [2001/83] can, in the event that the parallel trader retains that original packaging, be replaced in compliance with Article 47a(1)(b) of that directive only in such a way that visible traces of opening remain after the originally existing safety features have been partly or fully removed and/or covered?

(2) Is it of significance for answering the first question whether the traces of opening become visible only when the medicinal product has been thoroughly inspected by wholesalers and/or persons authorised or entitled to supply medicinal products to the public, such as pharmacies, in fulfilment of their obligation under Articles 10, 24 and 30 of [Delegated Regulation 2016/161], or may be overlooked in a superficial inspection?

(3) Is it of significance for answering the first question whether the signs of opening become visible only when the packaging of a medicinal product is opened, for example by the patient?

(4) Is Article 5(3) of [Delegated Regulation 2016/161] to be interpreted as meaning that the barcode containing the unique identifier within the meaning of Article 3(2)(a) of that regulation must be printed directly on the packaging, so that Article 5(3) is not complied with if a parallel trader affixes the unique identifier to the original outer packaging using an additional external sticker?'

Consideration of the questions referred

The first to third questions

42 By its first to third questions, which it is appropriate to examine together, the referring court asks, in essence, whether Article 9(2) and Article 15 of Regulation 2017/1001 must be interpreted as meaning that the proprietor of an EU trade mark is entitled to oppose the marketing, by a parallel importer, of a medicinal product repackaged in new outer packaging to which that mark is affixed where the replacement of the anti-tampering device of the original external packaging carried out in accordance with Article 47a(1) of Directive 2001/83 would leave visible traces of opening on that packaging.

43 In that regard, it must be borne in mind that, first, under Article 9(1) of Regulation 2017/1001, the registration of a trade mark confers on its proprietor exclusive rights which, according to Article 9(2)(a), entitle that proprietor to prevent all third parties not having his or her 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 mark was registered.

44 That exclusive right of the proprietor of the mark was conferred in order to enable him or her to protect his or her specific interests as proprietor, namely to ensure that the trade mark can fulfil its function. The exercise of that right must therefore 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).

45 It is apparent from settled case-law that repackaging of the product bearing the trade mark by a third party without the authorisation of the trade mark 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).

46 Furthermore, according to Article 15(1) of Regulation 2017/1001, the rights conferred by an EU trade mark are not to 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 or her consent. That provision seeks to reconcile the fundamental interests of trade mark protection, on the one hand, with those of free movement of goods in the internal market, on the other hand (see, by analogy, as regards Article 7(1) 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), judgment of 20 December 2017, *Schweppes*, C-291/16, EU:C:2017:990, paragraph 35).

47 More specifically, it follows from Article 15(2) of Regulation 2017/1001 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 a trade mark constitutes a disguised restriction on trade between Member States within the meaning of the second sentence of Article 36 TFEU (see, by analogy, 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).

48 A disguised restriction within the meaning of the second sentence of Article 36 TFEU will exist where the exercise, by the trade mark proprietor, of his or her 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 medicinal 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).

49 However, the conclusion that the proprietor may not rely on the rights conferred by the trade mark in order to oppose the marketing under his or her trade mark of products repackaged by an importer amounts to conferring on the importer certain rights which in normal circumstances are reserved for the trade mark proprietor himself or herself. Consequently, in the interests of the proprietor as owner of the trade mark, and to protect him or her against any misuse, those rights must be recognised only in so far as the importer concerned complies with a number of other requirements (see, to that effect, judgment of 28 July 2011, *Orifarm and Others*, C-400/09 and C-207/10, EU:C:2011:519, paragraph 26 and the case-law cited).

50 Thus, according to settled case-law, the proprietor of a mark may legitimately oppose the further marketing in a Member State of a pharmaceutical product bearing his or her 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 repackaged 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; and

– the importer gives notice to the trade mark proprietor before the repackaged product is put on sale, and, on demand, supplies him or her with a specimen of the repackaged product (see, to that effect, judgment of 17 May 2018, *Junek Europ-Vertrieb*, C-642/16, EU:C:2018:322, paragraph 28 and the case-law cited).

51 As regards, in particular, the first of the conditions set out in the preceding paragraph of the present judgment, the Court has held that a trade mark proprietor's opposition to repackaging of medicinal 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).

52 That condition of necessity is satisfied, in particular, if the rules or practices in the importing Member State prevent the product in question from being marketed in that State in the same packaging as that in which the product is marketed in the exporting Member State (see, to that effect, judgment of 26 April 2007, *Boehringer Ingelheim and Others*, C-348/04, EU:C:2007:249, paragraph 36).

53 Conversely, 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).

54 According to the case-law of the Court, the condition in question that packaging be necessary concerns both the actual fact of repackaging the product and the choice between new packaging and relabelling (see, to that effect, judgment of 26 April 2007, *Boehringer Ingelheim and Others*, C-348/04, EU:C:2007:249, paragraph 38). As the Advocate General observed in point 118 of his Opinion, in so far as the recognition of the right of a parallel trader to market in new packaging a product bearing a trade mark without the authorisation of the proprietor of that trade mark amounts to giving the parallel trader a licence normally reserved to the proprietor, namely a licence to affix that trade mark to that new packaging, such repackaging in new packaging constitutes a greater interference with the prerogatives of that proprietor than the marketing of the product in its relabelled original packaging.

55 The Court has thus held that the trade mark proprietor may oppose replacement packaging where the parallel importer is able to reuse the original packaging for the purpose of marketing in the Member State of importation by affixing labels to that packaging (judgment of 23 April 2002, *Boehringer Ingelheim and Others*, C-143/00, EU:C:2002:246, paragraph 49 and the case-law cited). However, the trade mark proprietor is entitled to oppose the parallel importer's use of that replacement packaging only on condition that the relabelled medicinal product is able to have effective access to the market concerned (see, to that effect, judgment of 23 April 2002, *Boehringer Ingelheim and Others*, C-143/00, EU:C:2002:246, paragraph 50).

56 In accordance with the Court's case-law, the criterion of the necessity of the repackaging, the circumstances prevailing at the time of marketing in the importing Member State, which render repackaging objectively necessary for the medicinal product concerned to be placed on the market in that Member State by the parallel importer, must be taken into account in the assessment (judgment of 10 November 2016, *Ferring Lægemidler*, C-297/15, EU:C:2016:857, paragraph 20 and the case-law cited).

57 In that regard, it should be borne in mind that, as is apparent from recitals 2 and 3 of Directive 2011/62, in conjunction with recital 1 of Delegated Regulation 2016/161, the EU legislature adopted that directive in order to address the increasing threat to human health constituted by falsified medicinal products by introducing, in Directive 2001/83, measures to prevent the entry of falsified medicinal products in the legal supply chain.

58 Directive 2011/62 thus inserted into Article 54 of Directive 2001/83 a point (o) pursuant to which the outer packaging or, where there is no outer packaging, the immediate packaging of medicinal products other than radiopharmaceuticals referred to in Article 54a(1) of that directive must be equipped with safety features enabling wholesale distributors and persons authorised or entitled to supply medicinal products to the public to verify the authenticity of the medicinal product concerned, to identify individual packs and to verify whether the outer packaging of that medicinal product has been tampered with.

59 More specifically, Article 25(1) of Delegated Regulation 2016/161 requires persons authorised or entitled to supply medicinal products to the public to verify those safety features. In addition, Articles 24 and 30 of that delegated regulation prohibit wholesalers and persons authorised or entitled to supply medicinal products to the public from supplying medicinal products to the public where they have reason to believe that the packaging of those products has been tampered with.

60 Furthermore, Article 47a(1) of Directive 2001/83 provides that those safety features may be removed or covered only under strict conditions, intended to guarantee the authenticity of the medicinal product and the absence of any tampering.

61 In particular, it is apparent from Article 47a(1)(b) that those conditions include the condition that the safety features in question must be replaced by 'equivalent' safety features. Under that provision, in order to be regarded as such, a safety feature must, inter alia, be equally effective in enabling the verification of the authenticity of the medicinal products concerned and their identification, as well as in providing evidence of tampering with them.

62 It thus follows from that provision, read in the light of recital 12 of Directive 2011/62, that the EU legislature, which expressly provided for the possibility of 'replacing' the safety features referred to in paragraph 58 above, did not intend to prevent the reuse of the original outer packaging even

where that packaging had such features. That interpretation is borne out by Article 34(4) and Article 35(4) of Delegated Regulation 2016/161, under which an equivalent unique identifier may be affixed both to a repackaged pack, in new packaging, and to a relabelled pack.

63 That being so, it follows from Article 47a(1)(b) of Directive 2001/83 that such reuse is possible only on condition that the original safety features can be replaced by features which are equally effective in enabling the verification of the authenticity of the medicinal products concerned, their identification, and in providing evidence of tampering with them.

64 Pursuant to Article 54a(2) of Directive 2001/83, Delegated Regulation 2016/161 establishes the detailed rules for those safety features. Recital 1 of that delegated regulation identifies two types of safety features, namely (i) a unique identifier and (ii) an anti-tampering device. An anti-tampering device is defined in Article 3(2) of that delegated regulation as the safety feature enabling the verification of whether the packaging of a medicinal product has been tampered with.

65 In that regard, it should be noted that, under Article 47a(1)(a) of Directive 2001/83, the manufacturing authorisation holder – authorisation that, as is apparent from Article 40(2) of that directive, any actor in the supply chain which packages medicinal products must possess – must verify, prior to partly or fully removing or covering those safety features, that the medicinal product concerned is authentic and that it has not been tampered with.

66 Thus, in accordance with Article 47a(1)(b) of Directive 2001/83, a replacement anti-tampering device must make it possible to verify, with the same effectiveness as an original anti-tampering device, that the outer packaging of a medicinal product has not been unlawfully opened between the time at which that medicinal product is repackaged and that at which it is supplied to the public.

67 Consequently, the presence on the outer packaging of a medicinal product of possible traces of having been opened is not, in itself, sufficient for the view to be taken that the replacement anti-tampering device is not equivalent, where there is no doubt, on the part of wholesalers and persons authorised or entitled to supply medicinal products to the public, that those traces of opening are attributable to the repackaging of that medicinal product by a parallel importer.

68 It follows that the fact that the replacement of the anti-tampering device of the original packaging of a medicinal product leaves visible traces of opening on that packaging does not preclude the finding that the new device is equivalent, within the meaning of Article 47a(1)(b) of Directive 2001/83, or, therefore, that that replacement was carried out in accordance with that Article 47a(1).

69 In the light of the considerations set out in paragraphs 57 to 68 of this judgment, effective access of a relabelled medicinal product to the market of the Member State of importation must be considered to be hindered where the anti-tampering device with which the outer packaging of that medicinal product is equipped cannot objectively be replaced by an equivalent device, within the meaning of Article 47a(1)(b) of Directive 2001/83, it being recalled that, as was found in paragraph 67 of this judgment, the presence of traces of opening is, in itself, insufficient to support the inference that the condition of equivalence has not been satisfied.

70 The existence on a market or on a substantial part of it of such strong resistance from a significant proportion of consumers to relabelled medicinal products that there must be held to be a hindrance to effective market access also constitutes such an obstacle, such as to necessitate

repackaging by replacing the packaging. In those circumstances, repackaging of the medicinal products in new packaging would not be explicable solely by the attempt to secure a commercial advantage, but would be aimed at securing effective access to the market in question (see, to that effect, judgment of 23 April 2002, *Boehringer Ingelheim and Others*, C-143/00, EU:C:2002:246, paragraph 52).

71 Similarly, if a significant proportion of consumers in the importing Member State are opposed to the idea of acquiring a medicinal product whose outer packaging bears visible traces of being opened which are caused by the replacement of the existing anti-tampering device by an equivalent device carried out in accordance with Article 47a(1) of Directive 2001/83, the effective access of that medicinal product to the market of that Member State must be regarded as being hindered and, therefore, its repackaging in new outer packaging must be regarded as necessary for the purposes of its being marketed in that Member State.

72 Accordingly, in the circumstances described in the preceding paragraph, the trade mark proprietor's opposition to such repackaging contributes to artificial partitioning of the markets between the Member States.

73 However, as the Advocate General observed, in essence, in point 139 of his Opinion, a parallel importer cannot rely on a general presumption of consumer resistance to relabelled medicinal products whose anti-tampering devices have been replaced. In the light of the considerations set out in paragraphs 49 and 56 of this judgment, the possible existence of such resistance and its extent must be assessed *in concreto*, taking into account, in particular, the circumstances prevailing in the Member State of importation at the time at which the medicinal product concerned was marketed, and of the fact that traces of opening are visible or, on the contrary, can be detected only after a thorough verification by wholesalers or persons authorised or entitled to supply medicinal products to the public pursuant to their verification obligations under Articles 10, 24 and 30 of Delegated Regulation 2016/161.

74 Having regard to all the foregoing considerations, the answer to the first to third questions is that Article 9(2) and Article 15 of Regulation 2017/1001 must be interpreted as meaning that the proprietor of an EU trade mark is not entitled to oppose the marketing by a parallel importer of a repackaged medicinal product in a new outer packaging bearing that mark, where the replacement of the anti-tampering device of the original outer packaging of that medicinal product carried out in accordance with Article 47a(1) of Directive 2001/83 would leave visible traces of opening on that packaging and where those traces would cause such strong resistance on the part of a significant proportion of consumers on the market of the Member State of importation or on a substantial part of that market to medicinal products repackaged in that way that it would constitute an obstacle to effective access to that market, which must be established on a case-by-case basis.

The fourth question

75 By its fourth question, the referring court asks, in essence, whether Article 5(3) of Delegated Regulation 2016/161 must be interpreted as precluding the barcode containing the unique identifier referred to in Article 3(2)(a) of that delegated regulation from being affixed to the outer packaging of a medicinal product by means of an adhesive label.

76 As a preliminary point, it should be noted that, in accordance with Article 54(o) of Directive 2001/83, the outer packaging of the medicinal products referred to in that provision must, in addition to the device enabling it to be verified whether that packaging has been tampered with, be equipped with safety features enabling the authenticity of those medicinal products to be verified and the individual packs of medicinal products to be identified.

77 Delegated Regulation 2016/161 defines the technical characteristics and specifications of the unique identifier which, as is apparent from Article 3(2) of that delegated regulation, is specifically intended to fulfil those functions.

78 In particular, Article 5(1) of that delegated regulation provides that manufacturers are to encode the unique identifier in a two-dimensional barcode. In accordance with Article 5(3), manufacturers are to print that barcode on packaging with a smooth, uniform and low-reflecting surface.

79 Consequently, the unique identifier on the original packaging of a medicinal product must be printed on that packaging in accordance with the conditions laid down in Article 5(3) of Delegated Regulation 2016/161. Read in the light of recital 11 of that delegated regulation, that provision seeks to facilitate a high-speed reading of the barcode containing that unique identifier and minimisation of reading errors of that code, in order to facilitate verification of the authenticity and decommissioning of that unique identifier by wholesalers and persons authorised or entitled to supply medicinal products to the public.

80 Furthermore, it follows from Article 6 of Delegated Regulation 2016/161 that the printing quality of the barcode containing the unique identifier must ensure its accurate readability throughout the supply chain until at least one year after the expiry date of the pack of medicinal products, or five years after the date on which the pack was released for sale or distribution, whichever is the longer period.

81 However, as is apparent from Article 47a(1)(b) of Directive 2001/83, the EU legislature expressly envisaged the possibility of the unique identifier being replaced by an equivalent device.

82 Under Article 17 of Delegated Regulation 2016/161, when ‘placing an equivalent unique identifier’, the manufacturer is to verify that the structure and composition of the unique identifier meet the requirements of the Member State where the medicinal product is intended to be placed on the market, with regard to the product code and the national reimbursement number or other national number identifying the medicinal product, so that that unique identifier can be verified for authenticity and decommissioned.

83 The use of the verb ‘place’, rather than the use of the verb ‘print’ in Article 5(3) of that delegated regulation, can be explained by the fact that, as the Advocate General observed, in essence, in point 169 of his Opinion, replacing the unique identifier in the context of a relabelling of the outer packaging of a medicinal product can, in practice, be made only by means of a label affixed to that packaging.

84 It follows that that delegated regulation cannot be interpreted as requiring a parallel importer to print the barcode with the equivalent unique identifier directly on the outer packaging of a relabelled medicinal product.

85 It should nevertheless be pointed out that, as is apparent from recital 15 of that delegated regulation, verification of the authenticity of the unique identifier aims at ensuring that the medicinal product originates from the legitimate manufacturer.

86 Consequently, as the Advocate General noted, in essence, in point 170 of his Opinion, it is important that the label containing the unique equivalent identifier cannot be removed for the purpose of being affixed to another package. In that case, far from guaranteeing the authenticity of the medicinal product to which it has been newly affixed, that unique identifier makes it possible to bring into the legal supply chain falsified medicinal products, which Directive 2011/62 specifically seeks to avoid. Therefore, that label must not be capable of being removed without being damaged.

87 By contrast, to the extent that, as Article 16(1)(b) of Delegated Regulation 2016/161 requires, the unique identifier printed on the original packaging has been decommissioned when it is replaced in accordance with Article 47a(1) of Directive 2001/83, it is not necessary that the removal of the label containing the equivalent unique identifier leaves traces on the outer packaging of the medicinal product.

88 Indeed, the verification of the authenticity of the unique identifier which, in accordance with Article 10 and Article 25(1) and (3) of Delegated Regulation 2016/161, manufacturers, wholesalers and persons authorised or entitled to supply medicinal products to the public are required to carry out by means of the repositories system referred to in Article 31 of that delegated regulation will enable medicinal products bearing a decommissioned unique identifier to be removed from the supply chain.

89 However, it must be pointed out that, in accordance with Article 6 of that delegated regulation, the barcode containing the unique identifier, although affixed to the packaging by means of a label, must be perfectly readable throughout the supply chain and throughout the entire period referred to in Article 6.

90 In the light of all the foregoing considerations, the answer to the fourth question is that Article 5(3) of Delegated Regulation 2016/161 must be interpreted as not precluding the barcode containing the unique identifier referred to in Article 3(2)(a) of that delegated regulation from being affixed to the outer packaging of the medicinal product by means of an adhesive label, provided that that label cannot be removed without being damaged and that, in particular, the barcode remains perfectly readable throughout the supply chain and throughout the entire period referred to in Article 6 of that delegated regulation.

Costs

91 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:

1. Article 9(2) and Article 15 of Regulation (EU) 2017/1001 of the European Parliament and of the Council of 14 June 2017 on the European Union trade mark

must be interpreted as meaning that the proprietor of an EU trade mark is not entitled to oppose the marketing by a parallel importer of a repackaged medicinal product in a new outer packaging bearing that mark, where the replacement of the anti-tampering device of the original outer packaging of that medicinal product carried out in accordance with Article 47a(1) 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, as amended by Directive 2012/26/EU of the European Parliament and of the Council of 25 October 2012, would leave visible traces of opening on that packaging and where those traces would cause such strong resistance on the part of a significant proportion of consumers on the market of the Member State of importation or on a substantial part of that market to medicinal products repackaged in that way that it would constitute an obstacle to effective access to that market, which must be established on a case-by-case basis.

2. **Article 5(3) of Commission Delegated Regulation (EU) 2016/161 of 2 October 2015 supplementing Directive 2001/83**

must be interpreted as not precluding the barcode containing the unique identifier referred to in Article 3(2)(a) of that delegated regulation from being affixed to the outer packaging of the medicinal product by means of an adhesive label, provided that that label cannot be removed without being damaged and that, in particular, the barcode remains perfectly readable throughout the supply chain and throughout the entire period referred to in Article 6 of that delegated regulation.

[Signatures]