Reports of Cases

JUDGMENT OF THE COURT (Fifth Chamber)

17 November 2022 *

(Reference for a preliminary ruling – Intellectual property – Trade marks – Directive (EU) 2015/2436 – Approximation of the laws of the Member States relating to trade marks – Article 10(2) – Rights conferred by a trade 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-204/20,

REQUEST for a preliminary ruling under Article 267 TFEU from the Landgericht Hamburg (Regional Court, Hamburg, Germany), made by decision of 2 April 2020, received at the Court on 13 May 2020, in the proceedings

**Bayer Intellectual Property GmbH**

v

**kohlpharma GmbH,**

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:

– Bayer Intellectual Property GmbH, by C. Giesen and U. Reese, Rechtsanwälte,

– kohlpharma GmbH, by W. Rehmann and D. Tietjen, Rechtsanwälte,

* Language of the case: German.

– the Danish Government, by M. Jespersen, J. Nymann-Lindegren and M. Søndahl Wolff, acting as Agents,

– 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 10(2) and Article 15 of 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) and Article 47a 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').

2 The request has been made in proceedings between Bayer Intellectual Property GmbH ('Bayer'), the proprietor of the German trade mark Androcur, and kohlpharma GmbH concerning the marketing in Germany by the latter of medicinal products bearing the trade mark Androcur imported in parallel from the Netherlands.

## Legal context

### *European Union law*

*Directive 2015/2436*

3 Recital 28 of Directive 2015/2436 states:

'It follows from the principle of free movement of goods that the proprietor of a trade mark should not be entitled to prohibit its use by a third party in relation to goods which have been put into circulation in the [European] Union, under the trade mark, by him or with his consent, unless the proprietor has legitimate reasons to oppose further commercialisation of the goods.'

4 Article 10 of that directive, entitled 'Rights conferred by a trade mark', provides:

'1. The registration of a 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 registered trade mark, the proprietor of that registered 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 trade mark and is used in relation to goods or services which are identical with those for which the trade mark is registered;

(b) the sign is identical with, or similar to, the 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 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 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 trade mark is registered, where the latter has a reputation in the Member State and where use of that sign without due cause takes unfair advantage of, or is detrimental to, the distinctive character or the repute of the trade mark.

3. The following, in particular, may be prohibited under paragraph 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 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 directive, headed 'Exhaustion of the rights conferred by a trade mark', provides:

'1. A trade mark shall not entitle the proprietor to prohibit its use in relation to goods which have been put on the market in the Union under that trade mark by the proprietor or with the proprietor's 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 nothwithstanding 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 (EU) 2016/161*

14 Recitals 1, 11, 12 and 15 of Commission Delegated Regulation (EU) 2016/161 of 2 October 2015 supplementing Directive 2001/83 (OJ 2016 L 32, p. 1), 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 that 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):

'For medicinal products intended for use in humans, safety features and an anti-tampering device must be affixed to the outer packaging in order to detect possible tampering with the packaging, in so far as this is required by Article 54a of [Directive 2001/83] or laid down in accordance with Article 54a of [Directive 2001/83].'

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

30 Bayer is the proprietor of the German trade mark Androcur, which it uses for medicinal products.

31 kohlpharma distributes in Germany parallel-imported medicinal products from other Member States of the European Union.

32 In a letter of 28 January 2019, kohlpharma informed Bayer that it intended to import the medicinal product 'Androcur 50 mg' from the Netherlands in packs of 50 film-coated tablets in order to market that product in Germany in packs of 50 and 100 film-coated tablets. Subsequently, kohlpharma informed Bayer that, for the purposes of that importation, the anti-tampering device affixed to the outer packaging of that medicinal product had to be broken and that, consequently, the replacement of that packaging was necessary.

33 Bayer objected to the proposed replacement, arguing that the use of new packaging would go beyond what was necessary in order that that medicinal product could be marketed in Germany.

34 It submits that it is apparent from Directive 2011/62 and Delegated Regulation 2016/161 that the use of new labelling or new packaging constitutes alternatives available to the parallel importer which offer equivalent safeguards in terms of safety. In this instance, the need for new packaging is not made out, since new labelling would be sufficient, in objective terms, to guarantee access to the market by the product concerned.

35 kohlpharma contends that the relabelling of the original packaging would be inappropriate owing to the traces of tampering which the removal of the anti-tampering device would cause and which would still be visible after the relabelled original packaging was opened.

36 Since wholesalers and pharmacists are now required to detect any tampering with the packaging of medicinal products, only new outer packaging would make it possible to prevent them from refusing to supply the medicinal product concerned. Although new labelling is 25% less expensive than repackaging in new packaging, kohlpharma contends that it should be preferred on the ground that it would be better accepted by health professionals and consumers. In its submission, the use of original labels with traces of damage considerably reduces the possibility of access to the German market consisting of pharmacies and wholesalers.

37 The referring court asks, in the first place, whether it follows from the relevant provisions of Directive 2011/62 and Delegated Regulation 2016/161 that repackaging in new packaging is now preferable to relabelling a medicinal product.

38 That court asks, in the second place, whether the choice between relabelling and new packaging is a matter for a parallel importer.

39 In the third place, the referring court raises the question of the scope of the argument that professionals and end users could be deterred or unsettled by the presence of traces of opening on the packaging of a medicinal product.

40 In the fourth place, the referring court raises the question of the practice of the competent national authorities of certain Member States, including the Kingdom of Sweden, of interpreting the new rules on protection against falsification as meaning that, in the case of parallel imports of medicinal products, it is generally necessary to replace the packaging after breaking the anti-tampering device affixed to the original packaging.

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

‘(1) Is Article 47a of Directive [2001/83] to be interpreted as meaning that, in the case of parallel imported products, the measures for the removal and reaffixing of the safety features pursuant to point (o) of Article 54 of Directive [2001/83], which are carried out by the parallel importer either by means of “relabelling” (use of adhesive labels on the original secondary packaging) or by means of “reboxing” (production of new secondary packaging for the medicinal product), can be considered equivalent if both measures otherwise comply with all the requirements set out in Directive [2011/62] and Delegated Regulation [2016/161] and are equally effective in enabling the verification of authenticity and identification of medicinal products and in providing evidence of tampering with medicinal products?

(2) If the first question is to be answered in the affirmative: In the light of the new anti-falsification rules, can a trade mark owner oppose the repackaging of the product in new external packaging ("reboxing") by a parallel importer where the parallel importer is also able to achieve packaging which may be marketed in the Member State of importation by merely affixing new adhesive labels to the original secondary packaging ("relabelling")?

(3) If the second question is to be answered in the affirmative, is it the case that no harm is done if, in the case of "relabelling", it is apparent to the relevant public that a safety feature of the original supplier has been damaged, as long as it is ensured that the parallel importer is responsible for this and has affixed a new safety feature to the original secondary packaging? Does it make any difference whether the signs of opening become visible only when the secondary packaging of a medicinal product is opened?

(4) If Question 2 and/or 3 is to be answered in the affirmative, must repackaging by means of 'reboxing' nevertheless be deemed to be objectively necessary within the meaning of the five conditions for exhaustion in respect of the repackaging (see judgments of 11 July 1996, *Bristol-Myers Squibb and Others*, C-427/93, C-429/93 and C-436/93, EU:C:1996:282, paragraph 79, and of 26 April 2007, *Boehringer Ingelheim and Others*, C-348/04, EU:C:2007:249, paragraph 21) if the national authorities state, in their current guidelines for implementing the requirements of [Directive 2011/62] or other such announcements of the authorities, that the resealing of opened packaging is not normally accepted or, at least, is accepted only on an exceptional basis and under strict conditions?'

## Consideration of the questions referred

### *The first question*

42 By its first question, the referring court asks, in essence, whether Article 47a of Directive 2001/83 must be interpreted as meaning that, provided that all the requirements referred to in that article are satisfied, repackaging in new packaging and the relabelling of medicinal products imported in parallel constitute equivalent forms of repackaging as regards the efficacy of the safety features referred to in Article 54(o) of that directive, without one prevailing over the other.

43 As a preliminary point, it should be borne in mind that, as is apparent from recitals 2 and 3 of Directive 2011/62, read 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.

44 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.

45 Pursuant to Article 54a(2) of Directive 2001/83, Delegated Regulation 2016/161 sets out 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. It is apparent from Article 3(2)(a) and (b) of that delegated regulation, read in the light of recital 15 thereof, that the verification of the authenticity of the unique identifier is intended to ensure that the medicinal product originates from the legitimate manufacturer, whereas verification of the integrity of the anti-tampering device shows whether the packaging has been opened or altered, thereby ensuring that the content of the packaging is authentic, the verification of those two safety features being necessary in order to guarantee the authenticity of a medicinal product throughout the supply chain.

46 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.

47 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.

48 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.

49 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 44 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 and to a relabelled pack.

50 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, in accordance with the aim of Directive 2011/62, which, as is apparent from recital 29 thereof, is to prevent falsified medicinal products from entering the legal supply chain.

51 In those circumstances, in the absence, in Directive 2001/83 and Delegated Regulation 2016/161, of any provision indicating that one form of repackaging should be preferred over the other, it must be held that, provided that all the requirements referred to in Article 47a of that directive are satisfied, repackaging in new packaging and relabelling of parallel imported medicinal products are equivalent forms of repackaging as regards the effectiveness of the safety features.

52 In the light of all the foregoing considerations, the answer to the first question is that Article 47a of Directive 2001/83 must be interpreted as meaning that, provided that all the requirements referred to in that article are satisfied, repackaging in new packaging and relabelling of medicinal products imported in parallel constitute equivalent forms of repackaging as regards the efficacy of the safety features referred to in Article 54(o) of that directive, without one prevailing over the other.

***The second question***

53 By its second question, the referring court asks, in essence, whether Article 10(2) and Article 15 of Directive 2015/2436 must be interpreted as meaning that the trade mark proprietor is entitled to oppose the marketing, by a parallel importer, of a medicinal product repackaged in new outer packaging to which that trade mark is affixed where relabelling of the medicinal product concerned, in compliance with the requirements laid down in Article 47a of Directive 2001/83, would also allow the medicinal product concerned to be marketed in the Member State of importation.

54 Under Article 10(1) of Directive 2015/2436, the registration of a trade mark confers on its proprietor exclusive rights which, according to Article 10(2)(a) thereof, 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.

55 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).

56 It is apparent from settled case-law that repackaging of the product bearing the trade mark carried out 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), it being noted that the concept of 'repackaging', within the meaning of that case-law, includes relabelling (see, to that effect, judgment of 17 May 2018, *Junek Europ-Vertrieb*, C-642/16, EU:C:2018:322, paragraph 30 and the case-law cited).

57 However, according to Article 15(1) of Directive 2015/2436, 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 Union 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).

58 More specifically, it follows from Article 15(2) of Directive 2015/2436 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).

59 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 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).

60 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).

61 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).

62 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).

63 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).

64 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).

65 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.

66 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).

67 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).

68 In the light of the foregoing considerations, the answer to the second question is that Article 10(2) and Article 15 of Directive 2015/2436 must be interpreted as meaning that the trade mark proprietor is entitled to oppose the marketing, by a parallel importer, of a medicinal product

repackaged in new outer packaging to which that trade mark is affixed where it is objectively possible to relabel the medicinal product concerned in compliance with the requirements provided for in Article 47a of Directive 2001/83 and where the medicinal product thus relabelled could actually access the market of the Member State of importation.

***The third question***

69 By its third question, the referring court asks, in essence, whether Article 10(2) and Article 15 of Directive 2015/2436 must be interpreted as meaning that the trade mark proprietor is entitled to oppose the marketing, by a parallel importer, of a repackaged medicinal product in new outer packaging to which that trade mark is affixed, where the replacement of the anti-tampering device of the original outer packaging, carried out in the context of a relabelling of that medicinal product, would leave visible traces of opening on that packaging and where there is no doubt that those traces are attributable to the repackaging of that medicinal product thus carried out by that parallel importer.

70 As is apparent from paragraphs 61 to 63 of this judgment, a trade mark proprietor cannot oppose the marketing by a parallel importer of a repackaged medicinal product in new outer packaging bearing that trade mark where such repackaging is necessary in order that the product imported in parallel can be marketed in the Member State of importation.

71 As is apparent from paragraph 58 above, the exercise by the trade mark proprietor of the right conferred by the trade mark to oppose such repackaging would constitute a disguised restriction on trade between Member States, within the meaning of the second sentence of Article 36 TFEU, in that it would contribute, contrary to the purpose of trade mark law, to artificially partitioning national markets within the European Union and thus to promoting the retention of price differences which may exist between Member States.

72 In the first place, that would be the case, in particular, if the anti-tampering device with which the outer packaging of the medicinal product concerned is equipped could not objectively be replaced by an equivalent device, within the meaning of Article 47a(1)(b) of Directive 2001/83, and the marketing of that medicinal product in its relabelled packaging in the Member State of importation was thus prevented.

73 In that regard, concerning the presence of traces of opening of the outer packaging of a medicinal product caused by the replacement of an anti-tampering device, it should be noted that, under Article 47a(1)(a) of Directive 2001/83, the holder of a manufacturing authorisation – 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, before removing or covering either fully or partially the safety features referred to in paragraph 44 of this judgment, that the medicinal product concerned is authentic and that it has not been tampered with.

74 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.

75 Consequently, the presence of traces of the opening of the outer packaging of a medicinal product which are clearly attributable to the repackaging of that product cannot affect the equivalent nature of the replacement anti-tampering device, provided that all the participants in the supply chain and the final consumer can determine with certainty that those traces are not attributable to tampering with that medicinal product.

76 In that regard, it should be noted that, as is apparent from the case-law referred to in paragraph 61 of this judgment, the repackager of the product concerned must clearly appear on the packaging of that product, so that the subsequent participants in the supply chain may attribute the origin of the traces of opening of that packaging to the repackaging of that product by a parallel importer.

77 Moreover, the presence of such traces is inevitable given that the function of the anti-tampering device is specifically to highlight any opening of the packaging to which it is affixed. In those circumstances, a different interpretation from that adopted in paragraph 75 of the present judgment would make it impossible, in practice, to relabel a medicinal product, thereby rendering redundant the provisions of Directive 2001/83 and Delegated Regulation 2016/161 which, as was found in paragraph 49 of the present judgment, so permit.

78 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, within the meaning of the second paragraph of Article 47a(1)(b) of Directive 2001/83, 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.

79 Accordingly, in the light of the considerations set out in paragraphs 70 to 72 above, it must be held that, in the circumstances described in the preceding paragraph, the presence of such traces does not prevent the proprietor of a trade mark from opposing repackaging in new packaging of a medicinal product bearing that mark.

80 That interpretation is supported by the essential function of the trade mark, which is to ensure that the consumer or end user can identify the trade-marked product's origin by enabling him or her, without any possibility of confusion, to distinguish it from others which have another origin. That guarantee of origin means that the consumer or end user can be certain that a trade-marked product offered to him or her has not been subject at a previous stage of marketing to interference by a third party, without the authorisation of the trade mark proprietor, in such a way as to affect the original condition of the product (see, to that effect, 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 47).

81 Where there is no doubt, in the minds of consumers, that traces of the outer packaging of a medicinal product having been opened are attributable to the repackaging of that product by a parallel importer, the guarantee of origin of that medicinal product is ensured.

82 In the second place, the Court has held that the existence on the market of the Member State 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 an obstacle to the effective access of a relabelled medicinal product to that market, such as to necessitate repackaging by replacing the packaging (see, to that effect, judgment of 23 April 2002, *Boehringer Ingelheim and Others*, C-143/00, EU:C:2002:246, paragraph 52).

83 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 opening 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.

84 In the circumstances described in the preceding paragraph, the trade mark proprietor's opposition to such repackaging cannot be accepted in so far as it would contribute to artificial partitioning of the markets between Member States.

85 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. It follows from the case-law of the Court that 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 (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) 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.

86 Having regard to the foregoing considerations, the answer to the third question is that Article 10(2) and Article 15 of Directive 2015/2436 must be interpreted as meaning that the trade mark proprietor is entitled to oppose the marketing, by a parallel importer, of a medicinal product repackaged in new outer packaging to which that trade mark is affixed, where the visible traces of opening of the original outer packaging which, where applicable, would result from relabelling of that medicinal product would be clearly attributable to the repackaging thus carried out by that parallel importer, unless those traces give rise, on the market of the Member State of importation or on a significant part of that market, to such strong resistance on the part of a significant proportion of consumers to medicinal products repackaged in that way as to constitute a barrier to effective access to that market, which must be established on a case-by-case basis.

### *The fourth question*

87 By its fourth question, the referring court asks, in essence, whether Article 10(2) and Article 15 of Directive 2015/2436 must be interpreted as meaning that the proprietor of a trade mark is entitled to oppose the marketing, by a parallel importer, of a repackaged medicinal product in new outer packaging to which that trade mark is affixed, where national guidelines implementing the provisions of Directive 2001/83 concerning safety features provide that reuse of the original packaging is not authorised or only on an exceptional basis and under strict conditions.

88 In accordance with settled case-law, the procedure provided for in Article 267 TFEU is an instrument of cooperation between the Court of Justice and the national courts, by means of which the Court provides the national courts with the points of interpretation of EU law which they need in order to decide the disputes before them (judgment of 12 March 1998, *Djabali*, C-314/96, EU:C:1998:104, paragraph 17, and order of 3 December 2020, *Fedasil*, C-67/20 to C-69/20, not published, EU:C:2020:1024, paragraph 18).

89 In accordance with equally settled case-law, questions on the interpretation of EU law referred by a national court in the factual and legislative context which that court is responsible for defining, and the accuracy of which is not a matter for the Court to determine, enjoy a presumption of relevance. The Court may refuse to rule on a question referred for a preliminary ruling by a national court only where it is quite obvious that the interpretation of EU law that is sought bears no relation to the actual facts of the main action or its purpose, where the problem is hypothetical, or where the Court does not have before it the factual or legal material necessary to give a useful answer to the questions submitted to it (judgment of 22 February 2022, *Stichting Rookpreventie Jeugd and Others*, C-160/20, EU:C:2022:101, paragraph 82 and the case-law cited).

90 The Court's function in preliminary rulings is to assist in the administration of justice in the Member States and not to deliver advisory opinions on general or hypothetical questions (see, in particular, judgments of 12 June 2003, *Schmidberger*, C-112/00, EU:C:2003:333, paragraph 32, and of 15 September 2011, *Unió de Pagesos de Catalunya*, C-197/10, EU:C:2011:590, paragraph 18).

91 It must be held that the circumstances of the case in the main proceedings clearly do not correspond to the situation described by the referring court in its fourth question.

92 First, it has been stated in paragraph 40 above that, by that question, the referring court refers to guidelines adopted by the authorities of Member States other than the Federal Republic of Germany.

93 Second, it is in no way apparent from the order for reference that the German authorities adopted guidelines according to which the reuse of the original packaging of medicinal products imported in parallel is not authorised or only on an exceptional basis and under strict conditions.

94 In those circumstances, it must be held that the situation referred to by the referring court in its fourth question is hypothetical.

95 Accordingly, that question is inadmissible.

## Costs

96 Since these proceedings are, for the parties to the main proceedings, a step in the action pending before the referring 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:

**1. Article 47a 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,**

**must be interpreted as meaning that provided that all the requirements referred to in that article are satisfied, repackaging in new packaging and relabelling of medicinal products imported in parallel constitute equivalent forms of repackaging as regards the efficacy of the safety features referred to in Article 54(o) of that directive, as amended by Directive 2012/26, without one prevailing over the other.**

2. **Article 10(2) and Article 15 of 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**

   **must be interpreted as meaning that the trade mark proprietor is entitled to oppose the marketing, by a parallel importer, of a medicinal product repackaged in new outer packaging to which that trade mark is affixed where it is objectively possible to relabel the medicinal product concerned in compliance with the requirements provided for in Article 47a of Directive 2001/83, as amended by Directive 2012/26, and where the medicinal product thus relabelled could actually access the market of the Member State of importation.**

3. **Article 10(2) and Article 15 of Directive 2015/2436**

   **must be interpreted as meaning that the trade mark proprietor is entitled to oppose the marketing, by a parallel importer, of a medicinal product repackaged in new outer packaging to which that trade mark is affixed, where the visible traces of opening of the original outer packaging which, where applicable, would result from relabelling of that medicinal product would be clearly attributable to the repackaging thus carried out by that parallel importer, unless those traces give rise, on the market of the Member State of importation or on a significant part of that market, to such strong resistance on the part of a significant proportion of consumers to medicinal products repackaged in that way as to constitute a barrier to effective access to that market, which must be established on a case-by-case basis.**

[Signatures]