Reports of Cases

OPINION OF ADVOCATE GENERAL
SZPUNAR
delivered on 13 January 2022 [1]

Cases C-147/20, C-204/20 and C-224/20

Novartis Pharma GmbH
v
Abacus Medicine A/S (C-147/20)
and
Bayer Intellectual Property GmbH
v
kohlpharma GmbH (C-204/20)
(Requests for a preliminary ruling
from the Landgericht Hamburg (Regional Court, Hamburg, Germany))
and
Merck Sharp & Dohme BV,
Merck Sharp & Dohme Corp.,
MSD DANMARK ApS,
MSD Sharp & Dohme GmbH,
Novartis AG,
FERRING LÆGEMIDLER A/S,
H. Lundbeck A/S
v
Abacus Medicine A/S,
Paranova Danmark A/S,
2CARE4 ApS (C-224/20)

(Request for a preliminary ruling
from the Sø – og Handelsretten (Maritime and Commercial Court, Denmark)]

(Reference for a preliminary ruling – Articles 34 and 36 TFEU – Free movement of goods – Intellectual property – Trade marks – Regulation (EU) 2017/1001 – Article 15 – Directive (EU) 2015/2436 – Article 15 – Exhaustion of the right conferred by the mark – Parallel import of medicinal products – Repackaging of the product bearing the mark – New external labelling – Opposition brought by the proprietor of the mark – Artificial partitioning of the markets between Member States – Medicinal products for human use – Directive

[1] Original language: French.

2001/83/EC – Article 47a – Safety arrangements – Replacement – Equivalent devices – Delegated Regulation (EU) 2016/161 – Article 3(2) – Anti-tampering device– Unique identifier)

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Introduction

1. There is no need whatsoever, in January 2022, for any reminder of the importance of medicinal products, not only for human health but also for the well-being of entire societies and the functioning of the economy worldwide. The fight against the COVID-19 pandemic has highlighted the need to reconcile, and also the difficulty in reconciling, three – potentially contradictory – objectives of public action in the field of the regulation of medicinal products: maintaining the economic profitability of the development and placing on the market of innovative medicinal products, ensuring their safety and effectiveness for patients and containing their costs for patients and public funds. [2]

2. Although medicinal products are indeed goods, they are nonetheless distinguished, in more than one respect, from the majority of goods that are traded.

3. First, the research and development required in order to place new medicinal products on the market require substantial financial investment, owing to the very advanced technological nature of modern therapies. Furthermore, these efforts involve a particularly high level of risk and provide results only after several years. [3] For that reason, manufacturers of medicinal products are often unable to count on the financial markets to fund their development activities and must rely on their own resources; [4] and those resources can come only from the revenue generated by the sale of the medicinal products already on the market.

[2] Caro de Sousa, P., 'Free movement and competition in the European market for pharmaceuticals', in Figueroa, P., Guerrero, A. (eds.), *EU Law of Competition and Trade in the Pharmaceutical Sector*, Edward Elgar Publishing Limited, Cheltenham, 2019, p. 431; Pilgerstorfer, M., 'EU law and policy on pharmaceuticals marketing and post-market control including product liability', in Hervey, T.K., Young, C.A., and Bishop, L.E. (eds.), *Research Handbook on EU Health Law and Policy*, Edward Elgar Publishing Limited, Cheltenham, 2017, p. 156.

[3] It is estimated that, out of 10 000 new active substances synthesised in laboratories, only one or two will reach the stage of being placed on the market and that the process takes 12 to 13 years. See Navarro Varona, E., Caballero Candelario, C., 'The pharmaceutical sector and parallel trade', in Figueroa, P., Guerrero, A. (eds.), *op. cit.*, p. 428.

[4] Durand, B., 'Competition law and pharma: an economic perspective', in Figueroa, P., Guerrero, A. (eds.), *op. cit.*, p. 3.

4. Second, the public authorities use different mechanisms to control the prices of medicinal products for their populations, whether the products in question are financed by the patients themselves or by public funds, in particular by means of health insurance. Thus, the prices of medicinal products are rarely governed solely by market mechanisms.

5. The need to obtain a return on investment, on the one hand, and the regulatory constraints on prices, on the other, result in manufacturers of medicinal products charging, for the same products, prices which differ considerably, even on closely connected markets, as is the case of the Member States of the European Union. [5] Such a situation makes it economically profitable to buy medicinal products on markets where prices are low and resell them on markets where prices are higher. That is why that process, called 'parallel trade', is followed by players who are independent of the manufacturers of medicinal products. The manufacturers do not look kindly on that practice, as it is liable to undermine their pricing policies.

6. The rights conferred by trade marks are the manufacturers' defence weapon against parallel trade. Any proprietor of a trade mark covering a product may oppose the use of that mark and therefore the marketing of the product by a third party.

7. However, such opposition runs counter to the fundamental principle of a single market within the European Union. In fact, it amounts to partitioning the single market created by the European Union into separate national markets.

8. Thus, the Court, in its case-law, has developed the principle of the exhaustion of the rights conferred by the trade mark as regards goods placed on the market in the European Union with the consent of the proprietor of the trade mark. [6] That principle was subsequently entrenched in the EU legislation on trade marks. [7] That case-law and that legislation form the legal basis of parallel trade in medicinal products in the EU.

9. The freedom of parallel trade seems to be obvious from the viewpoint of the logic of the single market: trade between Member States, even in a sector as regulated as the medicinal products sector, cannot be impeded solely by the existence of differences in prices between those Member States. However, from the viewpoint of the protection of public health, the benefits of parallel trade in medicinal products are far from obvious. In the literature, it is observed, rather, that the benefit comes above all to the parallel traders themselves and only to a much lesser extent to patients or sickness insurance schemes. In fact, owing to the rigidity not only of demand but also of the price level of medicinal products, parallel trade makes only a very small contribution to price reduction. On the other hand, harmful effects of parallel trade have been observed, both for the research and development activities of manufacturers of medicinal products, owing to the reduction of their revenues, and on supply in low-price markets, either because of the large-scale purchases made on those markets for export to markets with higher prices, or because manufacturers refuse to supply those markets, in fear of parallel trade. [8]

[5] As health remains within the remit of the Member States, the pricing policies of medicinal products are defined at national level (see, in particular, judgment of 16 September 2008, *Sot. Lélos kai Sia and Others*, C-468/06 to C-478/06, EU:C:2008:504, paragraph 59).

[6] For the details of that case-law, see points 98 to 107 of this Opinion.

[7] See points 14 and 16 of this Opinion.

[8] Caro de Sousa, P., *op. cit.*, p. 436; Durand, B., *op. cit.*, p. 5; Navarro Varona, E., Caballero Candelario, C., *op. cit.*, p. 409 and pp. 423 to 429. The questions linked with such a refusal were central to the case that gave rise to the judgment of 16 September 2008, *Sot. Lélos kai Sia and Others* (C-468/06 to C-478/06, EU:C:2008:504).

10. Another risk associated with, albeit not inherent in, parallel trade is the risk that falsified medicinal products will be introduced to the market, in particular when they are repackaged, which is often necessary in order for them to be placed on the market in Member States other than the State in which they were initially marketed. [9]

11. In order to counter that risk, the EU legislature amended the legislation and introduced mechanisms that allow the authenticity of medicinal products to be verified. [10] That amendment lays down new requirements as regards the packaging of medicinal products, by imposing new constraints, in particular, on parallel traders. The main legal issue to arise in the present cases is whether these new requirements alter the current status quo as regards the respective rights of parallel traders of medicinal products and their manufacturers in their capacity as proprietors of the trade marks under which those medicinal products are marketed.

12. Because of that main issue which the present cases share, I shall deliver a common Opinion for the three cases in question, even though they have not been formally joined.

Legal context

Trade mark law

13. Article 9(1) to (3) of Regulation (EU) 2017/1001 of the European Parliament and of the Council of 14 June 2017 on the European Union trade mark [11] provides:

'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;

…

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;

[9] That risk is a real one. See, in particular, *OECD/EUIPO, Illicit Trade. Trade in Counterfeit Pharmaceutical Products*, OECD Publishing, Paris, 2020.

[10] See point 18 et seq. of this Opinion.

[11] OJ 2017 L 154, p. 1.

(b) offering the goods, putting them on the market, or stocking them for those purposes under the sign, or offering or supplying services thereunder;

(c) importing or exporting the goods under the sign;

…'

14. Under Article 15 of that regulation:

'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.'

15. Article 10(1) to (3) 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 [12] 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;

…

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 the sign;

…'

[12] OJ 2015 L 336, p. 1.

16. According to Article 15 of that directive:

‘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.’

Pharmaceutical law

17. Under Article 40(1) and (2) 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, [13] as amended by Directive 2011/62/EU [14] (‘Directive 2001/83’):

‘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.

…’

18. Article 47a(1) of Directive 2001/83 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

[13] OJ 2001 L 311, p. 67.

[14] Directive of the European Parliament and of the Council of 8 June 2011 amending Directive 2001/83/EC on the Community code relating to medicinal products for human use, as regards the prevention of the entry into the legal supply chain of falsified medicinal products (OJ 2011 L 174, p. 74).

(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.'

19. In the words of point (o) of 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.'

20. The first subparagraph of Article 54a(2) of that directive contains a delegation to the European Commission, worded thus:

'The 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.'

21. Article 3(2)(a) and (b) of Commission Delegated Regulation (EU) 2016/161 of 2 October 2015 supplementing Directive 2001/83/EC of the European Parliament and of the Council by laying down detailed rules for the safety features appearing on the packaging of medicinal products for human use [15] provides:

'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;

…'

[15] OJ 2016 L 32, p. 1.

22. Under Article 5(1) to (3) of that delegated regulation:

‘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.’

23. In the words of Article 10 of that delegated regulation:

‘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.’

24. Article 24 of that delegated regulation provides:

‘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.’

25. Last, in the words of Article 30 of Delegated Regulation 2016/161:

‘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.’

The facts, the proceedings and the questions referred for a preliminary ruling

Case C-147/20

26. Novartis Pharma GmbH, a company governed by German law, holds the exclusive rights of use, in Germany, over the word marks Novartis and Votrient, which it uses in relation to the medicinal products Votrient 400 mg film-coated tablets and Votrient 200 mg film-coated tablets (‘the medicinal products at issue’).

27. Abacus Medicine A/S, a company governed by Danish law, primarily distributes in Germany parallel imported medicinal products from other Member States.

28. Being of the view that, in order to comply with the legal requirements, it was required to open the original external packaging of the medicinal products at issue, including removing the anti-tampering device affixed to that packaging, Abacus Medicine informed Novartis Pharma

that in future it would no longer supply those medicinal products in their original external packaging and that it would replace that packaging with a new packaging containing the same quantities.

29. 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 repackaged medicinal products at issue which have been imported in parallel.

30. Novartis Pharma claims, in particular, that the rights conferred on it by the trade marks in question are not exhausted for the purposes of Article 15(2) of Regulation 2017/1001. It maintains that the repackaging of the medicinal products at issue in new external 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 label, first, the barcode serving as a unique identifier, within the meaning of Article 3(2)(a) of Delegated Regulation 2016/161, by means of an adhesive label, and, second, after having placed a package leaflet in German in the original packaging, a new anti-tampering device covering the traces of previous opening. Furthermore, in order to dispel any doubts as to the integrity of the medicinal products, Abacus Medicine could indicate that it had affixed a new seal as part of the authorised repackaging process.

31. Abacus Medicine contends that the opening of the sealing label affixed by Novartis Pharma entails visible, irreversible alterations or changes to the external packaging, the label or the adhesive tape, and that affixing the unique identifier to the original packaging by means of an adhesive label is not a realistic solution since, owing to the silicone with which the external packaging of the medicinal products is coated, that label may be easily removed. That coating also makes it impossible to print the barcode, in accordance with Article 5(3) of Delegated Regulation 2016/161.

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

33. It was in those circumstances that 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) 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 under Article 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 [delegated] 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?'

34. The request for a preliminary ruling was received at the Court on 23 March 2020. Written observations were lodged by the parties to the main proceedings and by the Polish Government and the Commission. There was no hearing. The parties answered in writing the questions put by the Court.

Case C-204/20

35. Bayer Intellectual Property GmbH, a company governed by German law ('Bayer'), is the proprietor of the German mark Androcur, which it uses in relation to medicinal products.

36. kohlpharma GmbH, also a company governed by German law, distributes in Germany parallel imported medicinal products from other Member States.

37. 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 sell that product in Germany in packs of 50 and 100 film-coated tablets. kohlpharma subsequently informed Bayer that the anti-tampering device affixed to the external packaging of the imported medicinal product would have to be broken for the purposes of parallel importation, thus making it necessary to replace that packaging.

38. Bayer objected to the proposed replacement, claiming that the use of new packaging went further than was necessary in order for a parallel imported product to be able to be marketed in Germany.

39. It maintains that it follows from Directive 2011/62 and from Delegated Regulation 2016/161 that relabelling and reboxing are alternatives that could reasonably be contemplated by the parallel importer and that they provide equivalent guarantees 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 resulting from the parallel importation.

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

41. Furthermore, kohlpharma maintains that the rule/exception relationship between relabelling and reboxing has been reversed since the entry into force of the new regulatory framework applicable to medicinal products, consisting in Directive 2001/83 and Delegated Regulation 2016/161.

42. It was in those circumstances that 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) 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 [2001/83] 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 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 [16] and of 26 April 2007, *Boehringer Ingelheim and Others*, C-348/04, EU:C:2007:249, paragraph 21 [17]) if the national authorities state, in their current guidelines for implementing the requirements of the Falsified Medicines Directive 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?'

43. The request for a preliminary ruling was received at the Court on 13 May 2020. Written observations were lodged by the parties to the main proceedings, the Danish and Polish Governments and the Commission. There was no hearing. The parties answered in writing the questions put by the Court.

16 'Judgment in *Bristol-Myers Squibb and Others*'.

17 'The judgment of 2007 in *Boehringer Ingelheim and Others*'.

Case C-224/20

44. Merck Sharp & Dohme BV, Merck Sharp & Dohme Corp., MSD DANMARK ApS, MSD Sharp & Dohme GmbH, Novartis AG, FERRING LÆGEMIDLER A/S, and H. Lundbeck A/S (together 'the plaintiffs in the main proceedings') are manufacturers of medicinal products and proprietors of the trade marks under which the medicinal products which they produce are sold.

45. Abacus Medicine A/S, Paranova Danmark A/S and 2CARE4 ApS (together 'the defendants in the main proceedings') import into Denmark medicinal products placed on the market in other Member States by the plaintiffs in the main proceedings.

46. Before being placed on the market in Denmark, the parallel imported medicinal products are repackaged in new external packaging; in some cases the trade marks of the plaintiffs in the main proceedings (the product names) are reaffixed, while in other cases those trade marks are not reaffixed but are replaced by new product names, the user information or other information nonetheless stating that the medicinal products concerned correspond with those sold by the plaintiffs in the main proceedings under their respective marks.

47. The plaintiffs in the main proceedings claim that, in circumstances such as those of the disputes in the main proceedings, trade mark law confers on them the right to oppose the repackaging of the medicinal products in new external packaging.

48. The defendants in the main proceedings contend that repackaging in new external packaging is necessary and therefore lawful.

49. The referring court states that, on 18 December 2018, the Lægemiddelstyrelsen (Danish Medicines Agency) published a document containing questions and answers about safety features on the packaging of medicinal products, which, in the version updated on 20 January 2020, states, in particular, the following:

'The Danish Medicines Agency considers that it is a general rule that parallel importers must repackage the products in new packaging according to the new rules of the regulation. That also follows from the purpose of the new rules of the regulation, including the requirement for an anti-tampering device to be designed in such a way that any opening of, or tampering with, the package can be identified. Parallel importers which open the packaging of medicinal products and break the anti-tampering device for the purpose of placing a Danish package leaflet and so forth in the packaging must therefore, in principle and in accordance with the new rules of the regulation, repackage the products in new packaging and attach a new unique identifier and anti-tampering device to the packaging, as well as upload information and so forth.

The [Commission document "Safety features for medicinal products for human use – Questions and answers – version 18" ("the Commission Q&A document")] stated that, under certain specific conditions, it is possible for parallel importers "lawfully" to open the packaging of medicinal products with a view, inter alia, to placing a new package leaflet in the packaging and then replace the original anti-tampering device with a new anti-tampering device, provided it is carried out under the supervision of the competent authorities and provided the new anti-tampering device seals the packaging completely and covers all visible signs of the lawful opening. In addition, the replacement of the anti-tampering device must be carried out in accordance with the Good Manufacturing Practice (GMP) for medicinal products and a parallel importer who lawfully opens the packaging of medicinal products and attaches a new

anti-tampering device must verify beforehand the authenticity of the unique identifier and the integrity of the anti-tampering device on the original packaging in accordance with Article 47a(1)(a) of Directive 2001/83.

Since it is, as mentioned above, a general rule that parallel importers must, under the new rules of the regulation, repackage the products in new packaging, the Danish Medicines Agency considers that the exemption described by the Commission can be applied only in exceptional situations, including, for example, where there is a risk to the supply of medicinal products.

In Denmark, the exemption cannot in principle be used in connection with a new application for marketing authorisation for parallel imports. Those applications will have to satisfy the general requirements, including the general rule that medicinal products must be repackaged in new packaging.

The exemption, as described by the Commission, will mean that, where a marketing authorisation for parallel import for the specific product has been issued, where the medicinal product is marketed and where a parallel importer, in a specific and limited situation, wishes to make use of the exemption from the general rule on repackaging, parallel importers may apply for an exemption by submitting an application for an exemption from the order on labelling … In addition to following that guidance, parallel importers must adequately describe how they intend to replace the anti-tampering device, submitting pictures of both the original anti-tampering device and the new anti-tampering device. In addition, it must be demonstrated that the replacement of the anti-tampering device will be carried out in accordance with the GMP rules and in such a way that the new anti-tampering device completely seals the packaging and covers all visible signs of the lawful opening. Furthermore, an exemption should cover all the products concerned, including the form and strength and the related countries of export.'

50. It was in those circumstances that the Sø – og Handelsretten (Maritime and Commercial Court, Denmark) decided to stay the proceedings and to refer the following questions to the Court of Justice for a preliminary ruling:

'(1) Must Article 15(2) of [Directive 2015/2436] and Article 15(2) of [Regulation 2017/1001] be interpreted as meaning that a trade mark proprietor may oppose further commercialisation of a medicinal product which a parallel importer has repackaged in new external packaging to which the trade mark has been reaffixed, where:

(i) the importer is able to achieve packaging which may be marketed and gain effective access to the market of the Member State of importation by breaking the original external packaging in order to affix new labels to the inner packaging and/or replace the package leaflet and then reseal the original external packaging with a new device to verify whether the packaging has been tampered with, in accordance with Article 47a of [Directive 2001/83] and Article 16 of [Delegated Regulation 2016/161]?

(ii) the importer is not able to achieve packaging which may be marketed and gain effective access to the market of the Member State of importation by breaking the original external packaging in order to affix new labels to the inner packaging and/or replace the package leaflet and then reseal the original external packaging with a new device to verify whether the packaging has been tampered with, in accordance with Article 47a of [Directive 2001/83] and Article 16 of Delegated Regulation 2016/161?

(2) Must [Directive 2001/83], including, in particular, Article 47a and point (o) of Article 54, be interpreted as meaning that a new device to verify whether the packaging has been tampered with ("anti-tampering device"), affixed to the original packaging of the medicinal products (in connection with additional labelling after the packaging has been opened in such a way that the original anti-tampering device has been fully or partially covered and/or removed), within the meaning of Article 47a(1)(b), "is equivalent as regards the possibility to verify the authenticity, identification and to provide evidence of tampering [with] the medicinal product" and, within the meaning of Article 47a(1)(b)(ii), "is equally effective in enabling the verification of authenticity and identification of medicinal products and in providing evidence of tampering with medicinal products", where the packaging of the medicinal products displays visible signs that the original anti-tampering device has been tampered with, or that can be established by touching the product, including:

(i) through mandatory verification of the integrity of the anti-tampering device carried out by the manufacturers, wholesalers, pharmacists and persons authorised or entitled to supply medicinal products to the public (see Article 54a(2)(d) of [Directive 2001/83] and Article 10(b) and Articles 25 and 30 of Delegated Regulation 2016/161), or

(ii) after the packaging of the medicinal products has been opened, for example by a patient?

(3) If the answer to Question 2 is in the negative:

Must Article 15 of Directive 2015/2436, Article 15 of Regulation 2017/1001 and Articles 36 and 34 TFEU, then be interpreted as meaning that repackaging in new external packaging is objectively necessary for effective access to the market of the State of importation, where it is not possible for the parallel importer to affix additional labelling and reseal the original packaging in accordance with Article 47a of [Directive 2001/83], that is to say without the packaging of the medicinal products displaying visible signs that the original anti-tampering device has been tampered with, or that can be established by touching the product, as described in Question 2, in a manner which is not in accordance with Article 47a?

(4) Must [Directive 2001/83] and Delegated Regulation 2016/161 in conjunction with Articles 34 and 36 TFEU and Article 15(2) of Directive 2015/2436 and Article 15(2) of Regulation 2017/1001, be interpreted as meaning that a Member State (in Denmark: the Lægemiddelstyrelsen (Danish Medicines Agency)) is entitled to lay down guidelines, in accordance with which, in general, repackaging in new external packaging is to be carried out and it is only on application, in exceptional cases (for example where there is a risk to the supply of the medicinal product), that additional labelling and resealing may be permitted to be carried out by attaching new security features to the original external packaging, or is the Member State's issuing and observance of such guidelines incompatible with Articles 34 and 36 TFEU and/or Article 47a of Directive 2001/83 and Article 16 of Delegated Regulation 2016/161?

(5) Must Article 15(2) of Directive 2015/2436 and Article 15(2) of Regulation 2017/1001, in conjunction with Articles 34 and 36 TFEU, be interpreted as meaning that repackaging in new external packaging carried out by a parallel importer in accordance with the guidelines laid down by a Member State, as referred to in Question 4, must be regarded as necessary for the purposes of the case-law of the Court of Justice:

(i) where such guidelines are compatible with Articles 34 and 36 TFEU and the case-law of the Court of Justice of the European Union on parallel imports of medicinal products; or

(ii) where such guidelines are incompatible with Articles 34 and 36 TFEU and the case-law of the Court of Justice of the European Union on parallel imports of medicinal products?

(6) Must Articles 34 and 36 TFEU be interpreted as meaning that the repackaging of a medicinal product in new external packaging must be objectively necessary for effective access to the market of the importing State, even if the parallel importer has not reaffixed the original trade mark (product name), but instead given the new external packaging a product name which does not contain the trade mark proprietor's product trade mark (de-branding)?

(7) Must Article 15(2) of Directive 2015/2436 and Article 15(2) of Regulation 2017/1001 be interpreted as meaning that a trade mark proprietor may oppose further commercialisation of a medicinal product which a parallel importer has repackaged in a new external packaging, in so far as the parallel importer has reaffixed only the trade mark proprietor's product-specific trade mark, but has not reaffixed the other trade marks and/or commercial indications which the trade mark proprietor had affixed to the original external packaging?'

51. The request for a preliminary ruling was received at the Court on 29 May 2020. Written observations were lodged by the plaintiffs and the defendants in the main proceedings, by the Danish and Polish Governments and by the Commission. There was no hearing. The parties answered in writing the questions put by the Court.

Analysis

52. The questions referred for a preliminary ruling in the present cases raise a whole series of legal problems, relating to:

– first, whether the new rules on protection against the falsification of medicinal products, introduced by Directive 2011/62 and Delegated Regulation 2016/161, require parallel traders, de facto or *de jure*, to favour repackaging parallel imported medicinal products in new packaging rather than using the original packaging, relabelled (first question in Case C-204/20 and second question in Case C-224/20);

– second, whether and, if so, to what extent those new rules alter the scope of the right of the proprietors of the trade marks on medicinal products to oppose the repackaging in new packaging of parallel imported medicinal products by comparison with the legal situation resulting from the Court's current case-law (first to third questions in Case C-147/20, second and third questions in Case C-204/20 and first and third questions in Case C-224/20);

– third, whether the authorities of the Member States are entitled to lay down stricter rules with respect to the mode of repackaging parallel imported medicinal products and, if so, with what consequences for the right of the manufacturers of those medicinal products resulting from trade mark law (fourth question in Case C-204/20 and fourth and fifth questions in Case C-224/20);

– fourth, the technical problem relating to the affixing of the new unique identifier on the original packaging of a parallel imported medicinal product (fourth question in Case C-147/20); and,

– fifth, the extent of the right of the proprietor of the trade mark on a parallel imported medicinal product to oppose the repackaging of that medicinal product where the parallel trader does not

reproduce, or reproduces only some of, the trade marks used by the proprietor for the medicinal product (sixth and seventh questions in Case C-224/20). [18]

53. In this Opinion, I shall address those problems in the order indicated above, before inferring the answers to the various questions referred.

The interpretation of Article 47a of Directive 2001/83, in conjunction with Delegated Regulation 2016/161

The subject matter of the disputes in the main proceedings

54. The disputes in the main proceedings in the present cases are between the proprietors of the trade marks on medicinal products and the parallel importers of those medicinal products and relate to the authorised methods of repackaging those medicinal products when they are the subject of parallel importation.

55. In fact, in so far as the applicable legislation requires that medicinal products display certain information, both on the packaging and in a packet leaflet normally contained inside the packaging, which must be in the official language or languages of the Member State in which they are put on the market, [19] parallel traders are normally required to open the original packaging in order to replace the packet leaflet with a leaflet in the language of the Member State in which the medicinal product is to be marketed. The question then arises whether, in the light of the new rules designed to combat the falsification of medicinal products introduced by Directive 2011/62 and Delegated Regulation 2016/161, parallel importers may reclose the original packaging and affix the requisite elements to it, in particular a new anti-tampering device, or whether they are required, *de jure* or de facto, to make new packaging.

56. The discussion surrounding that question is fuelled, it seems, in particular by the Commission's Q&A document and also by the guidelines issued by the medicines agencies of certain Member States, in particular the Danish agency. According to those documents, the new safety rules for medicinal products entail, in principle, a requirement for parallel traders to repackage the medicinal products in new packaging after the original packaging has been opened.

57. Thus, the parallel traders – the defendants in the main proceedings – and the Danish Government maintain that repackaging in new packages is now the rule and that the reclosing of the original packaging is allowed only exceptionally. Conversely, the proprietors of the trade marks on the medicinal products – the plaintiffs in the main proceedings – and the Polish Government and, in spite of the guidance set out in its document, the Commission, maintain in essence that the new safety rules applicable to medicinal products have not fundamentally altered the existing rules, that to say, that both the reuse of the original packaging and repackaging in new packaging are possible in principle, and that the legislation relating to medicinal products does not introduce any priority for either method. [20]

[18] Although this division of the legal problems raised by the present cases and the questions referred for a preliminary ruling departs to some extent from the wording of the questions referred, it seemed useful to me in order to clarify the complex matter of the present case and to structure the reasoning followed.

[19] See Articles 54, 59, 62 and 63 of Directive 2001/83.

[20] The question whether such priority follows from the provisions of trade mark law is central to the second legal problem raised by the present cases (see points 98 to 140 of this Opinion).

58. In order to settle that controversy, it is necessary to analyse the provisions of Article 47a of Directive 2001/83 and those of Delegated Regulation 2016/161.

59. It will be recalled that, under Article 47a of Directive 2001/83, the safety features referred to in point (o) of Article 54 of that directive, namely the unique identifier and the anti-tampering device,[21] can be removed or covered only by a manufacturing authorisation holder,[22] on certain conditions, including the replacement of the safety feature, under the supervision of the competent authority, with an equivalent feature.

60. Furthermore, under Articles 24 and 30 of Delegated Regulation 2016/161, wholesalers and persons authorised or entitled to supply medicinal products to the public are required not to supply medicinal products and to inform the competent authorities immediately where they have reason to believe that the packaging of the medicinal product has been tampered with or where it is apparent from the verification of the safety features of the medicinal product that the product may not be authentic.

The positions of the parties

61. Relying on those provisions, the parallel traders and the Danish Government maintain, in essence, that it is particularly difficult in practice for the parallel traders to replace an anti-tampering device after the packaging has been opened in such a way as to satisfy the criteria of the inspection that must be carried out by wholesalers and persons authorised to supply medicinal products to the public.[23] They claim, in particular, that it is virtually impossible to replace that device in a way that leaves no trace of the original device having been opened. However, such a trace will give rise to suspicion of tampering and therefore to the obligation for wholesalers and persons authorised to supply medicinal products to the public to remove the medicinal product from the supply chain and alert the authorities.

62. For that reason, those parties maintain that the new safety features of medicinal products require that the parallel traders repackage the medicinal products in new packaging rather than use the original packaging, replacing only the safety features. In fact, only the intact anti-tampering device of a new package is in their view capable of meeting the regulatory requirements and inspiring confidence in the various participants in the supply chain, enabling them to be satisfied as to the identify and the authenticity of the parallel imported medicinal products. On the other hand, the use of the original packaging and the replacement of an anti-tampering device should be reserved for only quite exceptional cases. It is on that reasoning that, in their submission, the guidelines issued by the Danish Medicines Agency are based.

63. That viewpoint is not shared by the proprietors of the trade marks on the medicinal products, or by the Polish Government or the Commission.

64. Those parties maintain, in essence, that neither the relevant provisions of Directive 2001/83 nor those of Delegated Regulation 2016/161 preclude the repackaging of parallel imported medicinal products in the original packaging with the replacement of the anti-tampering device or favour the use of new packaging.

[21] As defined in Article 3(2)(a) and (b) of Delegated Regulation 2016/161.

[22] Under Article 40(2) of Directive 2001/83, parallel traders who repackage medicinal products are required to obtain that authorisation.

[23] Unlike the anti-tampering device, the process for the replacement of the unique identifier, which is regulated in detail in Delegated Regulation 2016/161, does not seem to cause any problems. The discussion in the present cases relates mainly to the replacement of the anti-tampering device (see, however, points 162 to 169 of this Opinion).

65. In the parties' submissions, that is already clear merely from the wording of those provisions, which explicitly mention both techniques, without favouring either of them. Furthermore, the proprietors of the trade marks observe that the purpose of the anti-tampering device is not to prevent any opening of the packaging, but only to provide evidence of tampering, namely unlawful opening. As the parallel traders are required, before the packaging is opened, to be satisfied that the anti-tampering device is intact, the new device which they then affix to reclose the packaging serves only to prove that the packaging was not opened while the medicinal product was in transit between the parallel trader and the end user (a patient or a health establishment). Thus, any traces of the opening of the original anti-tampering device does not give rise to suspicions on the part of the participants in the supply chain, since they are able to be satisfied that the opening of that device is attributable to a parallel trader and was done in accordance with the rules.

66. According to those parties, the new rules designed to combat falsified medicinal products are ineffective as regards the possibility for parallel traders to use the original packaging for the purpose of the repackaging of medicinal products.

My analysis

67. In principle, I share the viewpoint of the proprietors of the trade marks on the medicinal products, the Polish Government and the Commission when they assert that the relevant provisions do not preclude or favour, as a matter of principle, either of the repackaging methods.

68. In particular, the expression 'replacement of the safety features' used in Article 47a of Directive 2001/83 does not in any way imply the need for new packaging. Quite the contrary, where the medicinal product is repackaged in new packaging, that packaging is to be provided with a safety feature in accordance with point (o) of Article 54 of that directive. In fact, there is a reason why a parallel trader who repackages medicinal products must hold a manufacturing authorisation. Accordingly, where the repackaging involves new packaging, I doubt it is possible to speak of a 'replacement' of the safety feature, within the meaning of Article 47a(1)(b) of that directive. The replacement of the safety feature applies only where the original packaging is retained.

69. Furthermore, recital 12 of Directive 2011/62 suggests that, according to the EU legislature, a manufacturing authorisation holder, such as a parallel trader, should be authorised, inter alia, to 'replace' the safety feature, that is to say, in all logic, to replace it on the original packaging.

70. It is therefore permissible, in my view, to consider that if the EU legislature had wished to require manufacturing authorisation holders who repackage medicinal products, like parallel traders, to use new packaging, it would have made express provision to that effect, by removing from the supply chain packages which have been opened.

71. On the other hand, the trade mark proprietors, and the Commission, seem to me to underestimate the question, to which the Polish Government has rightly drawn attention, of the equivalence of the new safety feature that replaces the original safety feature.

72. In fact, under Article 47a(1)(b) of Directive 2001/83, manufacturing authorisation holders who repackage medicinal products are required to replace any safety features which are removed by safety features 'which are equivalent as regards the possibility to verify the authenticity, identification and to provide evidence of tampering of the medicinal product'.

73. The option for parallel traders to use the original packaging for the purpose of repackaging the medicinal products therefore depends on the possibility of replacing the original safety feature with a safety feature that is equivalent for the purpose of that provision. It is therefore necessary to determine the conditions in which a safety feature may be considered to be equivalent to the original safety feature.

74. In that regard, recital 12 of Directive 2011/62 expresses the EU legislature's belief that 'the meaning of the term "equivalent" should be clearly specified'. So far as the unique identifier is concerned, Delegated Regulation 2016/161 defines in detail the criteria which a new unique identifier must meet in order to be considered to be equivalent. As regards the anti-tampering device, on the other hand, the relevant provisions do not seem to me to match that ambition.

75. Article 47a(1)(b) of Directive 2001/83 merely gives a somewhat tautological definition, according to which, apart from satisfying the requirements laid down in the delegated acts adopted pursuant to Article 54a(2) of that directive – such requirements being virtually non-existent in the case of the anti-tampering device, in the absence of an appropriate delegation given to the Commission in the latter provision – a safety feature 'equivalent as regards the possibility to verify the authenticity, identification and to provide evidence of tampering of the medicinal product … is to be 'equally effective in enabling the verification of authenticity and identification of medicinal products and providing evidence of tampering with medicinal products'. All that can be inferred from the above is that a safety feature is equivalent where it is equally effective as the original safety feature. We remain in the realms of the abstract. It is therefore appropriate to arrive at an interpretation which enables the objectives of the provision referred to above to be achieved in practice.

76. The number of safety features that can be used for the external packaging of medicinal products is limited. ISO Standard ISO 21976:2018 'Packaging – Tamper verification features for medicinal product packaging',[24] referred to in the Commission's Q&A document[25] as making it possible to comply with the requirements of Article 47a and point (o) of Article 54 of Directive 2001/83, lists several categories of 'tamper verification features' that may be used in the medicinal product packaging. Those categories include, inter alia, folding boxes closed with glue, sealing labels and tapes, sleeves or breakable or tear-away closures. I would add that several tamper verification features, from different categories, may be used in the same packaging, for example a closure affixed with glue on one side of the box and a breakable closure on the other side.

77. Without wishing to stray too far into the terrain of factual assessments, it seems clear to me that the effectiveness of these different categories of tamper verification features in demonstrating that the packaging has been opened varies, that is to say, that it may be easier or less easy, after packaging has been opened, to reclose it by applying an anti-tampering device as effective as the original device.

78. To give an example, it may readily be imagined that it is easier to remove and then replace an adhesive tape than to re-glue a box, not to mention repairing a tear-away closure.

[24] The table of contents and the informative part of the standard are available free of charge at the following internet address: https://www.iso.org/obp/ui/#iso:std:iso:21976:ed-1:v1:en.

[25] In Version 18B. Previous versions mentioned ISO Standard 16679:2014, which was replaced by Standard 21976:2018.

79. In order to be equivalent for the purposes of Article 47a(1)(b) of Directive 2001/83, the replacement anti-tampering device must in my view have the same technical characteristics as the original device. I therefore endorse the Commission's view that the replacement anti-tampering device must have the same resistance, reliability and quality as those of the original device. In practice – but without laying down an absolute rule, as such a rule does not follow from the legislation – the replacement anti-tampering device will in most cases have to be of the same type as the original device. In my view, it is therefore not sufficient, for example, for a box that was closed with glue, or a box with a tear-away closure, which has been opened to be closed with adhesive tape, even though sealing labels and tapes are among the categories of tamper verification features that are compatible with ISO Standard 21976:2018.

80. Thus, a parallel trader who repackages medicinal products will meet the requirements of Article 47a(1)(b) of Directive 2001/83 by using the original packaging if, after it has been opened, he or she is able to replace the original anti-tampering device with a device that satisfies the criteria described above. If that is impossible, on the other hand, notably because the anti-tampering device is designed in such a way that opening the package means that the device is destroyed, the parallel trader will find it objectively necessary to use new packaging.

81. The Commission maintains, both in its Q&A document and, in a more nuanced fashion, in its observations in the present cases, that parallel traders are required to cover with the replacement anti-tampering device all visible traces of the packaging having been opened, including traces of the original device. I am of the view, however, that such a requirement does not follow from either Article 47a(1)(b) of Directive 2001/83 or the provisions of Delegated Regulation 2016/161.

82. As regards Article 47a(1)(b) of Directive 2001/83, such a requirement is not a condition of the replacement anti-tampering device's capability to provide evidence of tampering with the medicinal product, as required by that provision. As the trade mark proprietors rightly submit in their observations, the replacement anti-tampering device serves to guarantee that the packaging has not been opened between the repackager's establishment and sale to the end user. That fact that traces of *lawful* opening for the purposes of repackaging remain does not affect the objective of the anti-tampering device, provided that it is clear that the tampering was lawful. That, moreover, is recognised by the Commission in its observations. From that aspect, it seems more effective to me to use a replacement device that meets the requirements set out in point 79 above than to cover in any way any trace of the packaging having been opened.

83. Nor, to my mind, do Articles 24 and 30 of Delegated Regulation 2016/161 require that when the medicinal products are repackaged the replacement anti-tampering device entirely covers all traces of the packaging having been opened. Those provisions place an obligation on wholesalers and persons authorised to supply medicinal products to the public not to supply those products where they 'have reason to believe that the packaging of the medicinal product has been tampered with'. The lawful opening of the packaging when the medicinal products are repackaged is not 'tampering' (*manipulation illicite*) within the meaning of Article 47a of Directive 2001/83. Thus, where the anti-tampering device has been replaced by a device which meets the requirements set out in point 79 of this Opinion, the persons referred to in Articles 24 and 30 of Delegated Regulation 2016/161 should not have reason to believe that the packaging has been tampered with.

84. I therefore consider that parallel traders who repackage medicinal products may use the original packaging when doing so, provided that they are in a position to replace the anti-tampering device with a device which has the same technical characteristics as the original device and which makes it possible to ensure that the opening of the package was due to the lawful repackaging of the medicinal products concerned.

Final remarks

85. Leaving aside the interpretation of the rules in force in the strict sense, the various parties, in particular the trade mark proprietors and the parallel traders, put forward opposing arguments based on the greater or lesser ability of the different methods of repackaging medicinal products to ensure their safety. Thus, according to the trade mark proprietors, retaining the original packaging, and affixing a new anti-tampering device, which clearly shows that the opening of the packaging was lawful and was done by an authorised person, is a measure of the authenticity of the product contained in the packaging. According to the parallel traders, on the other hand, only new packaging with an intact anti-tampering device will guarantee that the medicinal product has not been tampered with and possibly falsified.

86. Those arguments, according to those parties, have implications for the interpretation of the applicable legislative provisions.

87. I do not think that such conclusions can be drawn, whether in one sense or in the other.

88. It is clear that the best guarantee of authenticity is provided by a medicinal product which goes from the manufacturer to the end user in intact packaging. Conversely, in a situation where the packaging must be opened at one stage in the supply chain, in particular in order to replace the original packet leaflet with one in a different language, the guarantee of authenticity of the medicinal product is necessarily reduced. The integrity and the correct performance of the procedures put in place by the parallel trader or by his or her subcontractors will then be crucial for ensuring that the medicinal product, repackaged and then sent down the supply chain, is the same as the one that arrived at the parallel trader. Here, it is the unique identifier that plays the key role.

89. Conversely, it does not seem possible to be able to state at the outset that one or the other repackaging method is better. Although, in a specific case, one of those methods may have advantages, that cannot in my view be stated as the general rule. To put it more bluntly, manufacturing packaging for medicinal products or replacing an anti-tampering device is not witchcraft. It involves neither more nor less than closing a simple cardboard box. If criminals are capable of falsifying the medicinal product, they will also be able to falsify the packaging.

90. I therefore consider that the arguments based on the alleged superiority of one packaging method over the other do not alter the conclusions that may be drawn from the interpretation of the applicable provisions.

The answers to the questions referred

91. It is now appropriate to formulate the answers to the first question in Case C-204/20 and the second question in Case C-224/20.

92. By its first question, the referring court in Case C-204/20 asks, in essence, whether the safety feature, within the meaning of point (o) of Article 54 of Directive 2001/83, reaffixed by a manufacturing authorisation holder when the medicinal products are repackaged, is equivalent to the original safety feature, within the meaning of Article 47a(1)(b) of that directive, when it makes it possible to verify the authenticity, identification and to provide evidence of tampering in accordance with the requirements arising from that directive and from Delegated Regulation 2016/161.

93. That question is somewhat circular, since Article 47a(1)(b) of Directive 2001/83 defines, precisely, a safety feature equivalent to the original feature as being a safety feature that permits verification of the aspects mentioned by the referring court in its question.[26] The answer can therefore only be in the affirmative. In light of the above developments, I consider it useful to clarify that answer.

94. I therefore propose that the answer to the first question referred in Case C-204/20 should be that Article 47a(1)(b) of Directive 2001/83 must be interpreted as meaning that a safety device, within the meaning of point (o) of Article 54 of that directive, reaffixed by a manufacturing authorisation holder when the medicinal products are repackaged, is equivalent to the original safety feature, within the meaning of the first of those provisions, when it enables the verification of authenticity and identification of the medicinal products and provides evidence of tampering, in accordance with the requirements arising from that directive and Delegated Regulation 2016/161. That is the case, in particular, where the replacement anti-tampering device, within the meaning of Article 3(2)(b) of that delegated regulation, has the same technical characteristics as the original safety feature.

95. By its second question, the referring court in Case C-224/20 asks, in essence, whether the anti-tampering device, within the meaning of Article 3(2)(b) of Delegated Regulation 2016/161, reaffixed by a manufacturing authorisation holder when the medicinal products are repackaged, is equivalent to the original safety feature, within the meaning of Article 47a(1)(b) of Directive 2001/83, where the packaging in question shows, during a verification under Articles 16, 20 or 25 of that delegated regulation or after it has been opened by the end user, perceptible signs that the original anti-tampering device has been tampered with.[27]

96. I propose that the answer to this question should be that Article 47a(1)(b) of Directive 2001/83 must be interpreted as meaning that the anti-tampering device, within the meaning of Article 3(2)(b) of Delegated Regulation 2016/161, reaffixed by a manufacturing authorisation holder when the medicinal products are repackaged, is equivalent to the original safety feature, within the meaning of Article 47a(1)(b) of that directive, even if the packaging in question shows, during a verification under Articles 16, 20 or 25 of that delegated regulation or after the packaging has been opened by the end user, perceptible signs that the original anti-tampering device has been tampered with, provided that it is clear that that tampering was done lawfully.

[26] See point 75 of this Opinion.

[27] Concerning this question, as formulated by the referring court, it should be observed that the anti-tampering device referred to in this question serves only to provide evidence of tampering with the medicinal product. Verification of the identity and the authenticity of the medicinal product is done with the help of the unique identifier, which is not the subject of the question.

The trade mark proprietors' right to oppose the repackaging of the medicinal products in the context of parallel trade

97. The second series of questions referred in the present cases concerns whether and, if so, to what extent the new rules on protection against the falsification of medicinal products, introduced by Directive 2011/62 and Delegated Regulation 2016/161, alter the scope of the right of the proprietors of the trade marks to oppose the repackaging in new packaging of parallel imported medicinal products by comparison with the legal situation arising from Article 15 of Regulation 2017/1001 and Article 15 of Directive 2015/2436 and from the Court's present case-law in the matter.[28] I consider that a brief reminder of that case-law is necessary before I embark on my analysis.

The evolution of the Court's case-law

98. In its judgment in *Centrafarm and de Peijper*,[29] which already concerned parallel imports of medicinal products, the Court established, by reference to the free movement of goods, the principle of the exhaustion of the right of a trade mark proprietor to oppose the marketing by a third party, without the authorisation of that proprietor, of a product bearing that mark which has previously been placed on the market in another Member States with the proprietor's consent.[30]

99. As regards the right of the proprietor of a trade mark to oppose the marketing under that trade mark of a product which has been repackaged in new packaging, the Court ruled, in its judgment in *Hoffmann-La Roche*,[31] that, in such a situation, the opposition of the proprietor of the trade mark is, in principle, justified. According to the Court, accepting the marketing of the product bearing a trade mark after it has been repackaged in new packaging amounts to giving the parallel trader a certain licence which in normal circumstances is reserved for the trade mark proprietor,[32] namely the licence to affix the trade mark to new packaging.

100. However, the use by the proprietor of the trade mark of his power of opposition may constitute a disguised barrier to trade between Member States. That would be the case, in particular, if the repackaging were done in such a way that neither the identity of the origin of the product nor its original state was affected. The original state of the product is not affected, inter alia, where the product is packaged in double packaging and the repackaging affects only the external packaging, or where the repackaging is inspected by a public authority. In such circumstances, the fact that the proprietor of the trade mark uses different packaging for the same product in various Member States and then prevents repackaging in new packaging for the purpose of the parallel import of the product would contribute to the artificial partitioning of the markets between Member States.[33]

[28] Although these two legal instruments establish distinct systems of protection (EU trade marks and national trade marks), the provisions that are relevant for the present cases, which are worded in identical terms, must be given a similar interpretation. I shall therefore examine them together.

[29] Judgment of 31 October 1974 (16/74, EU:C:1974:115). In the Court's previous case-law, that judgment is referred to as 'the judgment in *Winthrop*'.

[30] See point 1 of the operative part.

[31] Judgment of 23 May 1978 (102/77, EU:C:1978:108; 'the judgment in *Hoffmann-La Roche*'; point 1(a) of the operative part).

[32] Judgment in *Hoffmann-La Roche* (paragraph 11).

[33] Judgment in *Hoffmann-La Roche* (paragraphs 9 and 10).

101. The Court therefore ruled that the prevention by the proprietor of a trade mark of the marketing under his or her mark of a product which has been repackaged in new packaging constitutes a disguised restriction on trade between Member States where:

– it is established that the use of the trade mark right by the proprietor, having regard to the marketing system which he or she has adopted, would contribute to the artificial partitioning of the markets between Member States;

– it is shown that the repackaging cannot adversely affect the original condition of the product;

– the proprietor of the mark receives prior notice of the marketing of the repackaged product; and

– it is stated on the new packaging by whom the product has been repackaged. [34]

102. The principle of the exhaustion of the right of the proprietor of a trade mark to oppose the marketing without his or her authorisation of a product bearing that mark, which has already been put on the market with his or her consent in another Member State, was then entrenched by the EU legislature in Article 7 of Directive 89/104/EEC. [35] That provision was reproduced, in essentially identical terms, in Article 15 of Regulation 2017/1001 and Article 15, also, of Directive 2015/2436.

103. The Court nonetheless continues to interpret those provisions in the light of the free movement of goods, being of the view that they pursue the same objective as the present Article 36 TFEU, so that its case-law based on the latter provision [36] continues to apply. [37]

104. That case-law has however been clarified and supplemented on a number of points by subsequent judgments of the Court.

105. Thus, it has been held, in particular, that the proprietor's opposition to the marketing under a trade mark belonging to him or her of products which have been repackaged in new packaging contributes to the partitioning of markets if that repackaging is necessary in order to market the product in the Member State of importation. Such necessity arises where the product cannot be marketed in its original packaging because of the rules or practices in that Member State. [38]

106. Furthermore, an additional condition was added in order for the proprietor of a trade mark to be prohibited from opposing the marketing of the product under his or her mark after it has been repackaged in new packaging, namely that the presentation of the repackaged product cannot be such that it might damage the reputation of the mark or that of its proprietor, which would be the case if the new packaging were defective, of poor quality or untidy. [39]

[34] Judgment in *Hoffmann-La Roche* (point 1(b) of the operative part).

[35] First Council Directive of 21 December 1988 to approximate the laws of the Member States relating to trade marks (OJ 1989 L 40, p. 1).

[36] More precisely, of Article 36 of the EEC Treaty.

[37] See judgment in *Bristol-Myers Squibb and Others* (paragraphs 40, 41 and 50).

[38] Judgment in *Bristol-Myers Squibb and Others* (paragraphs 52 to 56 and first indent of point 3 of the operative part).

[39] Judgment in *Bristol-Myers Squibb and Others* (paragraphs 75 to 77 and fourth indent of point 3 of the operative part).

107. Last, the Court has ruled that the conditions that must be satisfied in order for the proprietor of a trade mark not to be able to oppose the marketing under that mark of a repackaged product, in particular the requirement of necessity, apply not only in cases of repackaging in new packaging, but also in cases of repackaging consisting in a new label affixed to the original packaging. [40]

108. In the present cases, the question is whether and, if so, to what extent the new rules on protection against the falsification of medicinal products, introduced by Directive 2011/62 and Delegated Regulation 2016/161, alter what we can learn from the preceding points of this Opinion. The parties which have submitted observations in these cases hold different views on that point.

The positions of the parties

109. The parallel trader parties to the disputes in the main proceedings maintain that the new rules on protection against the falsification of medicinal products require, de facto if not *de jure*, that the medicinal products covered by those rules which are parallel traded be repackaged in new packaging and that the proprietors of the trade marks cannot therefore oppose that form of repackaging. That viewpoint is also argued by the Danish Government. According to those parties, only new packaging is capable of fully satisfying the requirements relating to the anti-tampering device referred to in point (o) of Article 54 and Article 47a of Directive 2001/83. In their submission, any replacement safety feature would allow doubts to remain as to whether the opening and reclosing of the original packaging were lawful.

110. On the other hand, the trade mark proprietors who are parties to the disputes in the main proceedings dispute that viewpoint and maintain that the new rules on protection against the falsification of medicinal products do not affect the assessment of the criterion of the necessity of the repackaging of parallel traded medicinal products, including the need to use new packaging. Quite the contrary, they submit that it is specifically the retention of the original packaging that best contributes to the objectives of the new legislation, because it allows the medicinal products to be preserved in the condition that is closest to their original condition.

111. While the Polish Government's position closely resembles that of the proprietors of the trade marks, it observes, however, that the reluctance of wholesalers, health professionals and patients to accept replacement anti-tampering devices affixed to the original packaging of medicinal products after they have been repackaged may argue in favour of new packaging.

112. Last, the Commission maintains that, although the Court's earlier case-law allowed the trade mark proprietors to oppose the marketing of medicinal products in new packaging when the original packaging could be used, the more recent judgments seem, however, to apply that criterion of necessity only to repackaging in the strict sense, leaving it to parallel traders to choose between new packaging and using the original packaging. Thus, in the Commission's submission, a trade mark proprietor cannot oppose the use of new packaging on the sole ground that the use of the original packaging would also permit access to the market of the Member State of importation.

113. Those different positions lead me to make the following remarks.

[40] Judgment of 2007 in *Boehringer Ingelheim and Others* (paragraphs 28 to 31 and point 1 of the operative part).

The condition of the necessity of the use of new packaging in the Court's case-law

114. I shall begin by analysing the Commission's arguments, which seem to be based on an innovative reading of the Court's case-law.

115. As I have said, according to the Commission, the Court has abandoned in its recent judgments the conditions of necessity as regards the parallel trader's choice between new packaging and the original packaging, by applying that condition only to repackaging as such. The Commission relies, in that regard, on a number of judgments in which the Court has considered that the condition of necessity relates only to the fact of the repackaging and not to the manner or style in which the products in question have been repackaged. [41] The Commission further submits that the application of the condition of necessity to the use of new packaging in place of the relabelled original packaging is not justified, since it does not derive expressly from the legislation. Accordingly, the application of that condition entails the application of a double criterion of necessity and constitutes a disproportionate restriction on the free movement of goods. Furthermore, the Commission maintains that the use of new packaging does not always constitute a more serious breach of the trade mark proprietor's rights than the relabelling of the original packaging.

116. I do not support that position or those arguments.

117. In the Court's case-law, which I have summarised in points 98 to 107 of this Opinion, the conditions which had to be satisfied in order for a trade mark proprietor not to be able to rely on that mark in order to oppose the marketing of a product under the mark without his or her authorisation related only to products which had been repackaged in new packaging. That is the case, in particular, of the condition of necessity. The Court made it clear that the proprietor of a trade mark could oppose the repackaging of the product in new packaging if the parallel trader was able to market the product in the Member State of importation using the original packaging and adapting it to the requirements of that Member State. [42]

118. That solution was based on the finding that recognition of the right of a parallel trader to use new packaging in order to market a product bearing a trade mark without the authorisation of the proprietor of that trade mark amounted to giving the parallel trader a licence normally reserved to the proprietor, namely a licence to affix that trade mark to the new packaging. [43] Thus, repackaging a product in new packaging necessarily results in a greater interference with the prerogatives of the proprietor of a trade mark than merely marketing the product in its original packaging, even when it is relabelled.

119. The Commission's argument is therefore unfounded. It is true that, in specific factual circumstances, the relabelling of the original packaging may be carried out in such a way that it is more damaging to the *image* of the trade mark than new packaging would have been. However, that question is different from the question of the extent of the interference in the realm of the *exclusive rights* of the proprietor of that mark.

41 Judgment of 2007 in *Boehringer Ingelheim and Others* and judgment of 22 December 2008, *The Wellcome Foundation* (C-276/05, EU:C:2008:756, paragraph 25).

42 Judgment in *Bristol-Myers Squibb and Others* (paragraph 55).

43 Judgment in *Hoffmann-La Roche* (paragraph 11).

120. It is true that, in its judgment of 23 April 2002, *Boehringer Ingelheim and Others* (C-143/00, EU:C:2002:246; 'the judgment of 2002 in *Boehringer Ingelheim and Others*'), and in the judgment of 2007 in *Boehringer Ingelheim and Others*, the Court extended to repackaging by relabelling the application of the conditions which must be satisfied in order for the proprietor of a trade mark not to be able to oppose the marketing of a repackaged product under that trade mark, taking the view that that form of repackaging, just like reboxing, creates risks for the guarantee of origin of the product which the mark seeks to protect. [44]

121. However, the Court has not by any means abandoned the application of the criterion of necessity to repackaging in new packaging by comparison with the relabelling of the original packaging. Quite the contrary, it expressly applied that criterion in its judgment of 2002 in *Boehringer Ingelheim and Others* (point 2 of the operative part), where it ruled that replacement packaging of pharmaceutical products is objectively necessary within the meaning of the Court's case-law if, without such packaging, effective access to the market concerned, or to a substantial part of that market, must be considered to be hindered as the result of strong resistance from a significant proportion of consumers to relabelled pharmaceutical products.

122. That was confirmed in the judgment of 2007 in *Boehringer Ingelheim and Others*, where the Court held that 'the condition that packaging be necessary is directed only at the fact of repackaging the product – *and the choice between a new carton and oversticking* – for the purposes of allowing that product to be marketed in the importing State, and not at the manner or style in which it has been repackaged'. [45] Unlike the Commission, I do not find that passage ambiguous. To my mind, it may be readily inferred that, in the Court's view, the condition of necessity is (also) directed against the choice between new packaging and new labelling and that that choice does not relate to 'the manner or style in which [the product] has been repackaged'. Subsequent judgments do not invalidate that finding. Quite the contrary, the case that gave rise to the judgment of 10 November 2016, *Ferring Lægemidler* (C-297/15, EU:C:2016:857), concerned the precise question whether repackaging in a new packaging was necessary.

123. Nor am I convinced by the Commission's other arguments.

124. It is true that the application of the criterion of necessity, first of all to repackaging in general, then to new packaging, may seem to constitute duplication. However, if that condition is satisfied so far as new packaging is concerned, it is automatically also satisfied for repackaging in general. There is no need for a separate verification. Furthermore, on a market as heavily regulated as the market for medicinal products, the condition that repackaging be necessary is virtually always satisfied, if only in order to provide patients with the information required by law in the official language or languages of the Member State of importation. While there may be exceptional situations, such as that of parallel trade between two Member States that use the same language, as in the case that gave rise to the judgment of 17 May 2018, *Junek Europ-Vertrieb* (C-642/16, EU:C:2018:322), they are, however, very rare. Applying that condition not to the choice between new packaging and relabelling, but only to repackaging in general, would therefore largely deprive it of its essence.

125. As regards the argument that the application of the condition of necessity to repackaging in new packaging does not follow from the EU legislation, it is sufficient to recall that all the conditions that allow the exhaustion of the rights conferred by the trade mark to be relied on in the context of parallel trade, whether they are applied to the simple repackaging of the products

44 See, in particular, judgment of 2007 in *Boehringer Ingelheim and Others* (paragraphs 28 to 31).

45 Emphasis added.

or to the use of a new label, have their origin solely in the case-law and are not expressly set out in the legislation. Last, since the relabelling of the product concerned permits effective access to the market of the importing Member State, the application of the condition of necessity to repackaging in new packaging cannot constitute a disproportionate restriction on the free movement of goods.

The arguments relating to protection against falsified medicinal products

126. The parallel trader parties to the disputes in the main proceedings maintain that only the repackaging of medicinal products in new packaging allows the objectives of the new rules on protection against the falsification of medicinal products, introduced by Directive 2011/62 and Delegated Regulation 2016/161, to be achieved in full. In their submission, only new packaging, with an intact anti-tampering device and showing no traces of having been opened, allows health professionals and patients to be satisfied that the medicinal product has not been tampered with. The proprietors of the trade marks, on the other hand, take the opposite view.

127. It should be borne in mind that the Court had already declared, in its judgment in the leading case relating to trade mark law, in the context of parallel trade in medicinal products, that although the protection of the public against risks arising from defective pharmaceutical products was a matter of legitimate concern, the measures necessary to achieve that objective must be such as may properly be adopted in the field of health control and must not constitute a misuse of the rules concerning industrial and commercial property, and that the specific considerations underlying the protection of such property were distinct from the considerations underlying the protection of the public and any responsibilities which that might imply.[46] It therefore ruled that the owner of a trade mark relating to a pharmaceutical product cannot avoid the incidence of Community rules concerning the free movement of goods for the purpose of controlling the distribution of the product with a view to protecting the public against defects in those goods.[47] That approach was subsequently confirmed with respect to the adequate information provided to consumers on the packaging of medicinal products.[48]

128. Likewise, the objectives of the fight against falsified medicinal products must be achieved by means of specific provisions adopted for that purpose and those provisions must be complied with throughout the supply chain. Trade mark proprietors cannot therefore oppose the repackaging of medicinal products in new packaging on the sole ground that, in their view, the relabelling of the original packaging makes a greater contribution to achieving the objectives of those provisions. As the Court has already observed, although it is possible to derogate from the fundamental principle of free movement of goods where the proprietor of a mark relies on the mark to oppose the repackaging of parallel imported pharmaceutical products, such derogation is possible only to the extent necessary to enable the proprietor to safeguard rights which form part of the specific subject matter of the mark, as understood in the light of its essential function.[49]

129. Admittedly, the Court has observed that the conditions in which the proprietors of the trade marks cannot oppose parallel trade in their goods, in particular the condition that prior notice must be given to the trade mark proprietor, are deemed to enable, inter alia, those proprietors to

[46] Judgment of 31 October 1974, *Centrafarm and de Peijper* (16/74, EU:C:1974:115, paragraphs 20 to 22).

[47] Judgment of 31 October 1974, *Centrafarm and de Peijper* (16/74, EU:C:1974:115, point 3 of the operative part).

[48] Judgment of 28 July 2011, *Orifarm and Others* (C-400/09 and C-207/10, EU:C:2011:519, paragraph 34).

[49] Judgment of 2002 in *Boehringer Ingelheim and Others* (paragraph 28). See also recitals 5 and 29 of Directive 2011/62, which establish a clear distinction between the provisions of that directive and intellectual property rights.

protect themselves against counterfeiting,[50] but that remark was made from the aspect of the protection of the industrial property, in this instance trade marks, and not of the fight against falsified medicinal products.[51] It is not apparent from those passages that the problem to which Directive 2011/62 relates comes within the scope of trade mark law.

130. However, what applies to trade mark proprietors also applies to parallel traders. The possibility for parallel traders to interfere with the rights of the proprietors of the trade marks is justified by the desire to maintain the free movement of goods. The extent to which they are able to do so must therefore be assessed by reference to the criterion specific to that freedom, namely effective access to the market. Other factors, such as the alleged advantages from the viewpoint of the protection of patients against falsified medicinal products, do not have to be considered.

131. Thus, the balance between the rights of the trade mark proprietors and the interests of the parallel traders must be defined with the help of the only relevant criteria, namely (i) the essential function of the mark, which is to guarantee the origin of the goods, and (ii) the maintenance of effective access to the market of the Member State of importation. The arguments relating to the effectiveness of the fight against falsified medicinal products, on the other hand, play no part in this discussion.

The effect of the rules against the falsification of medicinal products on the balance between the interests of the trade mark proprietors and those of the parallel traders

132. As is clear from the foregoing, following the entry into force of the new rules on protection against the falsification of medicinal products, introduced by Directive 2011/62 and Delegated Regulation 2016/161, the Court's case-law relating to the right of the proprietors of the trade marks to oppose the marketing, under their trade marks, of goods which have been repackaged remains fully applicable.

133. Under that case-law, notwithstanding that their right to prohibit the use of the trade marks for goods which have been put on the market in the EU with their consent has been exhausted, the proprietors of the trade marks retain, in principle, the right to oppose the tampering represented by any repackaging of such a product. However, that opposition is contrary to the freedom of movement of those goods where the set of conditions defined by the Court in its judgment in *Bristol-Myers Squibb and Others* are satisfied. Those conditions include the requirement, first, that the repackaging, including the replacement of the original repackaging with new packaging, is necessary in order to permit effective access to the market of the Member State of importation and, second, that the presentation of the repackaged product does not damage the reputation of the mark or the reputation of its owner.

134. The new rules on protection against the falsification of medicinal products, introduced by Directive 2011/62 and Delegated Regulation 2016/161, have no consequence, in law, for the application of those conditions. In fact, however, new factors may come into play when specific situations fall to be assessed.

[50] Judgment in *Bristol-Myers Squibb and Others* (paragraph 78) and judgment of 2002 in *Boehringer Ingelheim and Others* (paragraph 61).

[51] See judgment in *Hoffmann-La Roche* (paragraph 12), where the Court established the condition that prior notice must be given 'since it is in the proprietor's interest that the consumer should not be misled as to the origin of the product'.

135. First, as I mentioned in the first part of the analysis in this Opinion, [52] the parallel trader may, in certain situations, not be able, after opening the packaging, to replace the anti-tampering device with a device that satisfies the equivalence test in Article 47a(1)(b) of Directive 2001/83. The inability to do so would therefore constitute a legitimate reason for the parallel trader to repackage the products in new packaging, which the trade mark proprietor cannot oppose.

136. Second, the condition that the presentation of the repackaged product must not damage the reputation of the mark or that of its proprietor applies to all aspects of the packaging of the repackaged product, including the replacement anti-tampering device. That device must satisfy not only the requirements of Article 47a(1)(b) of Directive 2001/83, but also the condition that no reputational damage is caused.

137. Third, and last, as the Court has already had occasion to state, there may exist on a market, or on a substantial part of it, such strong resistance from a significant proportion of consumers to relabelled pharmaceutical products that there must be held to be a hindrance to effective market access. In those circumstances, repackaging of the medicinal products in new packaging would be necessary in order to have effective access to the market of the Member State of importation. [53]

138. Such resistance may exist, in particular, to the packaging of medicinal products whose anti-tampering devices have been replaced. That is particularly so since Articles 10, 24 and 30 of Delegated Regulation 2016/161 place on wholesalers and health professionals an enhanced duty of vigilance as regards the integrity of the anti-tampering devices on the packaging of the medicinal products which they sell or supply. Such resistance, if it is proved to exist, might therefore justify the use of new packaging, which would enable the problem of the replaced anti-tampering devices to be circumvented.

139. However, that resistance must be genuinely proved, on the basis of supporting evidence, in a specific case. It is not sufficient for it to be potential or presumed. In fact, as a general rule, a replacement anti-tampering device should provide sufficient guarantee that the medicinal product has not been tampered with. Parallel traders cannot therefore rely on a presumption of generalised resistance to medicinal products whose anti-tampering devices have been replaced in order to justify repackaging those products in new packaging.

140. Nor is it sufficient, in itself, that the replacement of the anti-tampering device leaves traces of the opening of the packaging which are visible after a more or less detailed inspection of that packaging where there are no reasonable doubts as to the person responsible for opening the packaging.

The answers to the questions referred

141. On the basis of the arguments set out above, I am able to propose the following answers to the first, second and third questions in Case C-147/20, to the second and third questions in Case C-204/20 and to the first and third questions in Case C-224/20.

[52] See points 79 and 80 of this Opinion.

[53] Judgment of 23 April 2002, *Merck, Sharp & Dohme* (C-443/99, EU:C:2002:245, paragraph 31), and judgment of 2002 in *Boehringer Ingelheim and Others* (paragraph 52).

142. I infer from the first three questions in Case C-147/20, which I propose to answer together, that the referring court is asking, in essence, whether Article 15 of Regulation 2017/1001 and Article 15 of Directive 2015/2436 must be interpreted as meaning that the fact that the replacement by a parallel trader of the anti-tampering device on a medicinal product, referred to in point (o) of Article 54 of Directive 2001/83, leaves traces which are visible or can be detected following inspection of that device or after the packaging has been opened by the patient is sufficient to support the conclusion that the trade mark proprietor's opposition to any repackaging of that medicinal product in new packaging would contribute to the artificial partitioning of the markets between Member States and would therefore be contrary to the principle of the free movement of goods. [54]

143. I propose that the answer to that question should be that those provisions should not be interpreted in that way, unless the visibility of the traces of the opening of the packaging provokes a resistance to the medicinal products thus repackaged that is so strong as to constitute a real barrier to effective access to the market of the Member State of importation, which must be verified on a case-by-case basis.

144. By its second and third questions, which I propose to answer together, the referring court in Case C-204/20 is asking, in essence, whether Article 15 of Directive 2015/2436 must be interpreted as meaning that the proprietor of a trade mark on a medicinal product may oppose the repackaging of that medicinal product in new packaging in the context of parallel trade when the parallel trader is capable of using the original packaging and replacing the safety features in accordance with the provisions of Directive 2001/83 and of Delegated Regulation 2016/161, including where that replacement leaves traces which are visible and can be detected following inspection or after the packaging has been opened by the patient.

145. I propose that the answer to that question should be that Article 15 of Directive 2015/2436 must be interpreted as indicated, unless the visibility of the traces of the opening of the packaging provokes a resistance towards the medicinal products thus repackaged that is so strong as to constitute a real barrier to effective access to the market of the Member State of importation, which it is for the referring court to verify.

146. By its first and third questions, which I propose to answer together, the referring court in Case C-224/20 is asking, in essence, whether Article 15 of Regulation 2017/1001 and Article 15 of Directive 2015/2436 must be interpreted as meaning that the proprietor of a trade mark on a medicinal product may oppose the repackaging of that product in new packaging in the course of parallel trade where the parallel trader is able to use the original packaging and replace the safety features in accordance with the provisions of Directive 2001/83 and of Delegated Regulation 2016/161.

147. I propose that the answer to that question should be analogous to the answer given in Case C-204/20.

[54] In simple terms, the question is whether the parallel trader may rely on the fact that the traces of the opening of the original packaging are visible after it has been relabelled, in order to repackage the products in new packaging, without the trade mark proprietor being able to oppose such repackaging.

The possibility for the national authorities to require parallel traders to repackage the medicinal products in new packaging

148. By the fourth question in Case C-204/20 and the fourth question in Case C-224/20, the respective referring courts are asking, in essence, whether the national authorities responsible for supervising the pharmaceutical market are entitled to lay down rules requiring that medicinal products bearing the safety features referred to in point (o) of Article 54 of Directive 2001/83 which are parallel imported from other Member States be, as a general rule, repackaged in new packaging, with relabelling being possible only in exceptional cases. By its fifth question, the referring court in Case C-224/20 also asks whether such rules are sufficient to justify the conclusion that the condition of necessity as regards repackaging in new packaging is satisfied.

149. As regards the fourth question in Case C-204/20, I share the Commission's view that it is inadmissible. In fact, it is clear from the case file in that case that that question originates in the rules issued by the Swedish authorities. There is no indication that those or similar rules would be applicable in the main proceedings in that case. The question therefore seems to be purely hypothetical.

150. The fourth and fifth questions in Case C-224/20, on the other hand, relate to the guidelines issued by the Danish Medicines Agency, which are applicable in the dispute in the main proceedings, and are therefore admissible.

The fourth question in Case C-224/20

151. According to the guidelines issued by the Danish Medicines Agency,[55] parallel traders who wish to introduce to the Danish market medicinal products from other Member States displaying the safety features referred to in point (o) of Article 54 of Directive 2001/83 must, as a general rule, repackage those medicinal products in new packaging. Relabelling the original packaging and replacing the safety features are authorised only in exceptional situations, such as where there is a risk to the supply of medicinal products.

152. Under Article 47a(1)(d) of Directive 2001/83, the replacement of the safety features referred to in point (o) of Article 54 of that directive is to be subject to supervision by the competent authority. It is clear that, in the context of that supervision, a competent authority of a Member State may issue guidelines providing information about the conditions and procedures whereby that supervision is carried out. However, those guidelines cannot alter the EU legislation in force.

153. Both the provisions of Directive 2001/83 introduced by Directive 2011/62 and the provisions of Delegated Regulation 2016/161 expressly provide that a manufacturing authorisation holder may replace the safety features referred to in point (o) of Article 54 of Directive 2001/83. In addition, EU law does not refer to national law for the purpose of clarifying those provisions, nor does it authorise the Member States to adopt stricter rules.

154. Quite the contrary, Directive 2001/83 expressly prohibits the adoption of such rules. In fact, point (o) of Article 54 of Directive 2001/83, which lays down the obligation to provide safety features on certain medicinal products, appears under Title V of that directive, entitled 'Labelling and package leaflet'. It follows that the safety features referred to in that provision form part of the

[55] See point 49 of this Opinion.

labelling of medicinal products, within the meaning of Directive 2001/83;[56] and Article 60 of that directive, which also appears under Title V, provides that Member States may not prohibit or impede the placing on the market of medicinal products within their territory on grounds connected with labelling where the labelling complies with the requirements of that title. Member States are therefore not entitled to require the repackaging of medicinal products in new packaging if parallel traders are able to replace, on the original packaging, the safety features with safety features which comply with those requirements.[57]

155. The argument that Member States would be entitled, on the basis of the protection of patients against falsified medicinal products, to determine the level at which they wish to provide that protection is, in my view, ineffective here. In so far as the EU legislature has exercised competence in the sphere of the fight against falsified medicinal products, in particular by means of the safety features affixed to medicinal products, that question has been removed from the competence of the Member States. There is therefore no longer any scope for them to be able to decide on the level of that protection.

156. Furthermore, although, in the main proceedings in the present cases the parallel traders claim the right to repackage medicinal products in new packaging, that might not be the case in other situations, in which such repackaging would be perceived as an additional burden. The national rules requiring repackaging in new packaging would constitute a barrier to the free movement of goods which would have to be justified on the basis of Article 36 TFEU. Such justification is not self-evident, however, having regard to the fact that EU secondary legislation expressly allows repackaging by relabelling.

157. I therefore propose that the answer to the fourth question in Case C-224/20 should be that Article 47a(1) of Directive 2001/83 must be interpreted as meaning that the national authorities responsible for supervising the pharmaceutical market are not entitled to lay down rules requiring that medicinal products provided with the safety features referred to in point (o) of Article 54 of that directive, coming from other Member States in the course of parallel trade, be, as a general rule, repackaged in new packaging, and limiting relabelling to exceptional cases.

The fifth question in Case C-224/20

158. By its fifth question, the referring court in Case C-224/20 is asking, in essence, whether rules issued by a medicinal products supervisory authority which prohibit, as a general rule, the relabelling of medicinal products provided with safety features, imported from other Member States in the context of parallel trade, are sufficient to support the conclusion that, as regards repackaging in new packaging, the condition of necessity, as defined in the Court's case-law relating to the right of trade mark proprietors to oppose the use of their marks, is satisfied.

159. Clearly, that question is meaningless unless the rules in question are lawful. In fact, if, as I propose the Court should rule, those rules are incompatible with EU law, they have no reason to exist and cannot determine the action of market operators such as parallel traders in medicinal products. I shall therefore address that question solely in the interest of completeness, in case the Court should not share my analysis concerning the preceding question.

[56] Clearly, this does not apply to the package leaflet, which is inside the packaging.

[57] Which to my mind encompasses the provisions of Delegated Regulation 2016/161, as the delegation to adopt that regulation also appears under Title V of Directive 2001/83.

160. Rules such as those laid down and applied by the Danish Medicines Agency prevent parallel traders, in practice, from placing on the national market concerned medicinal products in their relabelled original packaging. Only medicinal products which have been repackaged in new packaging may have access to that market. In other words, such repackaging becomes necessary in order to have effective access to the market of the Member State of importation. Therefore, any opposition by the proprietors of the trade marks on those medicinal products to their being repackaged in new packaging would create a barrier to that effective access. The condition of necessity, as defined in the Court's case-law established in its judgment in *Bristol-Myers Squibb and Others*, must therefore be considered to be satisfied.

161. That to my mind is the only solution that would permit the conclusion that rules such as those laid down by the Danish Medicines Agency are compatible with EU law. If the existence of such rules were not sufficient to overcome the trade mark proprietors' opposition to repackaging in new packaging, the consequence would be the creation of a barrier to trade that would not be justified either from the aspect of the protection of the legitimate interests of the proprietors of the trade marks or from the aspect of the protection of patients against falsified medicinal products. There is therefore no solution other than to consider that the condition of necessity is satisfied or to declare rules such as those at issue to be contrary to Articles 34 and 36 TFEU.

162. Should the Court not follow my proposed answer to the fourth question in Case C-224/20, it would thus be necessary to consider that rules issued by a medicinal products supervisory authority prohibiting, as a matter of principle, the relabelling of medicinal products bearing safety features which are imported from other Member States in the context of parallel trade are sufficient to support the conclusion that, as regards repackaging in new packaging, the condition of necessity as defined in the Court's case-law relating to proprietors' right to oppose the use of their marks is satisfied.

The affixing of the unique identifier to the packaging of the medicinal product

163. By its fourth question, the referring court in Case C-147/20 asks whether Article 5(3) of Delegated Regulation 2016/161 must be interpreted as meaning that the barcode containing the unique identifier, referred to in Article 3(2)(a) of that delegated regulation, must be printed directly on the packaging, so that affixing that barcode by means of an adhesive label on that package would not comply with that provision.

164. The safety features referred to in point (o) of Article 54 of Directive 2001/83 contain, in addition to the anti-tampering device, a unique identifier.[58] According to Article 4 of Delegated Regulation 2016/161, the unique identifier is to be a sequence of numeric or alphanumeric characters for each pack of a medicinal product, and is to contain certain information. The extent of that information may to a certain degree be determined by the Member State in which the medicinal product is to be placed on the market.[59] Furthermore, in accordance with Article 54a(5) of Directive 2001/83, Member States may extend the obligation to affix safety features to medicinal products intended to be placed on the market of their territories to categories of medicinal products which are not covered by that obligation under that directive.

[58] Article 3(2)(a) of Delegated Regulation 2016/161.

[59] Article 4(b)(iii) of Delegated Regulation 2016/161.

165. It may therefore be the case that the parallel trader is required to replace the unique identifier of a medicinal product [60] or to add a unique identifier in order to comply with the requirements of the Member State of importation. Thus, if the answer to the present question were that the unique identifier must be printed directly on the packaging, that would have the consequence that in each of those situations the parallel trader would in practice always be required to repackage the medicinal product in new packaging, while, if the answer were to the contrary, the parallel trader would be able to relabel the original packaging. Unsurprisingly, Abacus Medicine, a parallel trader, opts for the first answer and Novartis Pharma, a holder of trade marks in relation to medicinal products, for the second.

166. Articles 5 and 6 of Delegated Regulation 2016/161 contain the provisions relating to the technical aspects of the affixing of the unique identifier, in the form of a barcode, on the packaging of medicinal products. According to Article 5(3) of that delegated regulation, that barcode must be printed on the packaging, on a smooth, uniform, low-reflecting surface. Taken in isolation, and literally, that provision seems to argue in favour of the obligation to print the barcode directly on the packaging. [61]

167. I do not think that that is the only possible interpretation, however. To my mind, Article 5 of Delegated Regulation 2016/161 is drafted from the perspective of the original manufacturer of the medicinal product, for whom it is natural to print the unique identifier, as well as the other necessary information, directly on the packaging.

168. On the other hand, both Article 47a of Directive 2001/83 and Articles 16 and 17 of Delegated Regulation 2016/161 expressly provide for the possibility of removing or covering the safety features, in particular the unique identifier, and replacing them with equivalent devices. Furthermore, Article 35 of Delegated Regulation 2016/161, which relates to the repositories of the unique identifiers of medicinal products, describes, in paragraph 4, the procedure to be followed in the case of 'repackaged *or relabelled* packs of a medicinal product on which equivalent unique identifiers [have been] placed'. [62] The replacement of the unique identifier when the product is repackaged is therefore provided for in the relevant provisions.

169. In fact, the replacement of the unique identifier following the relabelling of a pack of medicinal products can, logically, be envisaged only by means of an additional label placed on that packaging. Article 5(3) of Delegated Regulation 2016/161 must therefore be interpreted, in the light of the provisions of Directive 2001/83 and of that delegated regulation referred to in the preceding points, as allowing the barcode containing the unique identifier to be printed not directly on the packaging but on a label affixed to that packaging.

170. On the other hand, as the Commission emphasises in its observations, and also in its Q&A document, [63] such a label, as well as having to comply with the requirements of Articles 5, 6 and 17 of Regulation 2016/161, must be affixed to the packaging in such a way that it is impossible to remove it without destroying it and without damaging the packaging or leaving traces of its removal. The aim is to prevent the label containing the unique identifier and the

60 In accordance with Article 47a of Directive 2001/83 and Articles 16 and 17 of Delegated Regulation 2016/161.

61 Although the wording of that provision in French seems to place the emphasis mainly on the nature of the surface on which the barcode must be printed, the other language versions, in particular the Spanish, German, English or Polish versions, state clearly that it must be printed 'on the packaging'.

62 Emphasis added.

63 Question 2.21.

packaging from being separated and possibly then used separately. Thus, the unique identifier on a label will be an integral part of the packaging and can be regarded as being printed 'on the packaging', as required by Article 5(3) of that regulation.

171. I therefore propose that the answer to the fourth question in Case C-147/20 should be that Article 5(3) of Delegated Regulation 2016/161 must be interpreted as meaning that the barcode containing the unique identifier, referred to in Article 3(2)(a) of that delegated regulation, may be affixed by means of a label glued to the packaging, provided that that label, in addition to complying with the requirements of Articles 5, 6 and 17 of that delegated regulation, is affixed to the packaging in such a way that it is impossible to remove it without destroying it and without damaging the packaging or leaving traces of its removal.

The non-reproduction of the original trade marks on the packaging of parallel traded medicinal products

172. The sixth and seventh questions in Case C-224/20 relate to situations in which parallel traders do not reproduce, or reproduce only in part, the medicinal product manufacturers' trade marks after repackaging the medicinal products in new packaging, and the extent of the trade mark proprietors' right to oppose such a practice. Unlike the questions analysed above, those questions are not based on the rules on protection against the falsification of medicinal products, introduced by Directive 2011/62 and Delegated Regulation 2016/161.

Preliminary remarks

173. By its sixth question, the referring court in Case C-224/20 asks whether Articles 34 and 36 TFEU must be interpreted as meaning that the condition that a parallel traded medicinal product must be repackaged in new packaging, required in order for the proprietor of the trade marks on that medicinal product not to be able to oppose its being marketed, must be satisfied in a situation where the parallel trader does not reaffix those marks on the new packaging (this process is known as 'de-branding'). As for the seventh question, it concerns whether Article 15(2) of Regulation 2017/1001 and Article 15(2) of Directive 2015/2436 must be interpreted as meaning that the trade mark proprietor may oppose the marketing of a medicinal product which has been repackaged by a parallel trader in new packaging on which the parallel trader has reaffixed the proprietor's trade mark that is specific to that product without reproducing the other trade marks which the trade mark proprietor had affixed to the original external packaging.

174. The referring court does not explain the reason that led it to submit the same question from the aspect of the provisions of the FEU Treaty and the Court's case-law, and also from the aspect of secondary legislation. It should be borne in mind that, according to settled case-law, those questions are to be assessed on the basis of EU trade mark law, interpreted in the light of Article 36 TFEU.[64] According to that interpretation, the proprietor of a trade mark is, in principle, entitled to oppose the marketing of a product which has been repackaged and on which the trade mark proprietor's mark has been affixed, unless it satisfies a set of conditions defined in the Court's case-law.[65]

[64] Judgment in *Bristol-Myers Squibb and Others* (point 1 of the operative part).

[65] Judgment in *Bristol-Myers Squibb and Others* (point 3 of the operative part) and judgment of 2007 in *Boehringer Ingelheim and Others* (point 1 of the operative part).

175. It must then be observed that, in the case of the specific products that medicinal products constitute, it is practically impossible for a parallel trader to be able to put a product on the market and wholly avoid using the trade marks of the original manufacturer of that product.

176. First, as Ferring Lægemidler rightly states in its observations, the marketing authorisation for a medicinal product in the context of parallel trade is issued by reference to the marketing authorisation (in the Member State of importation) of the original medicinal product, that is to say, of the same product marketed by its manufacturer, the proprietor of the trade marks on that medicinal product, or with the latter's consent.[66] The parallel trader therefore makes use of that proprietor's trade marks (the product name and the manufacturer's company name), within the meaning of Article 9 of Regulation 2017/1001 and Article 10 of Directive 2015/2436, where he or she refers to that original medicinal product in order to obtain that authorisation and, subsequently, in the information for patients contained in the packaging or in the package leaflet of the parallel traded medicinal product.

177. Second, if the parallel trader is entitled to repackage a medicinal product without the opposition of the trade mark proprietor, that is conditional on the immediate packaging being left intact.[67] That immediate packaging must state, in particular, the name of the medicinal product and the name of the holder of authorisation for placing the product on the market,[68] which are normally signs protected by trade marks belonging to the original manufacturer of the medicinal product. Thus, the parallel trader places the products on the market under signs identical with those trade marks, within the meaning of the provisions referred to above.

178. It follows, in my view, that, where medicinal products are concerned, the original trade marks are always used, in the form of references to the name of the original product and of its manufacturer, and also on the immediate packaging, even if the parallel trader repackages the medicinal product in new external packaging, on which he replaces the original marks with other signs. The proprietor of the original marks thus retains his or her right to oppose such use of those marks, and the conditions defined in the Court's case-law, which must be satisfied in order for that proprietor not to be able to rely on his or her right, continue to apply.

179. I wish to add that the trade mark proprietors who are the plaintiffs in the main proceedings in Case C-224/20, and also the Commission, refer to the judgment of 25 July 2018, *Mitsubishi Shoji Kaisha and Mitsubishi Caterpillar Forklift Europe* (C-129/17, EU:C:2018:594), in which the Court held that the operation consisting, on the part of the third party, in removing signs identical with the trade mark in order to affix its own signs to the product may be regarded as a use of that mark in the course of trade.[69] However, that case concerned the parallel import of goods which had not yet been placed on the market in the EU and the solution arrived at by the Court was essentially based on the fact that it was impossible for the proprietor of the trade marks on those goods to decide on that initial placing of those goods on the market in the EU. For that reason, too, that judgment does not take account of the (current) Article 15 of Regulation 2017/1001 and Article 15 of Directive 2015/2436. I therefore consider that that judgment offers little assistance for the purpose of resolving the present case.

66 Judgment of 10 September 2002, *Ferring* (C-172/00, EU:C:2002:474, paragraphs 21 and 22).

67 Judgment in *Hoffmann-La Roche* (paragraph 10).

68 Article 55 of Directive 2001/83.

69 Paragraph 48.

180. That notwithstanding, for the reasons set out in points 175 to 178 of this Opinion, I am of the view that, from the aspect of the trade mark proprietor's right of opposition, the situation envisaged in the seventh question in Case C-224/20 (partial 'de-branding') is not fundamentally different from that envisaged in the sixth question ('total' de-branding). I therefore propose to analyse them together, reformulating them in order to take account of the foregoing observations.

Analysis and answer to the questions referred

181. Thus, the sixth and seventh questions should be reformulated as meaning that, by those questions, the referring court is asking, in essence, whether Article 15 of Regulation 2017/1001 and Article 15 of Directive 2015/2436 must be interpreted as allowing the trade mark proprietor to oppose the marketing of a product, in a situation where the parallel trader has repackaged the product in new packaging, to which he has affixed only some of the trade marks belonging to that proprietor which appeared on the original packaging or has replaced them with other signs, using those trade marks only as a reference to the name of the product and of its manufacturer.

182. As I have already stated, according to the Court's case-law, in such a situation, the proprietor of the trade marks in question is not entitled to oppose the marketing of the product if a set of conditions is satisfied, in particular the condition that the presentation of the repackaged product is not such that it might damage the reputation of the mark and that of its proprietor. [70]

183. As regards that condition, the Court has had occasion to rule that the question whether the parallel importer

– does not affix the trade mark to the new exterior packaging of the product (de-branding), or

– affixes to the packaging his or her own logo or a 'house style' or a get-up used for a number of different products (co-branding), or

– affixes an additional label to the packaging in such a way as wholly or partially to obscure the proprietor's trade mark, or

– fails to state on the additional label that the trade mark in question belongs to the proprietor, or

– prints the name of the parallel importer in capital letters,

is liable to damage the trade mark's reputation was a question of fact which it is for the national court to decide in the light of the circumstances of each case. [71]

184. In a more recent judgment, [72] however, the Court also ruled that, where the reseller, without the consent of a trade mark proprietor, removes that trade mark from the goods ('de-branding') and replaces it with a label bearing the reseller's name, with the result that the trade mark of the manufacturer of the goods in question is entirely concealed, the trade mark proprietor is entitled to prevent the reseller from using that mark to advertise that resale. The Court considered that, in such a case, damage was caused to the essential function of the trade mark, which is to indicate and guarantee the origin of the goods, and that the consumer was prevented from distinguishing

[70] Judgment in *Bristol-Myers Squibb and Others* (point 3 of the operative part).

[71] Judgment of 2007 in *Boehringer Ingelheim and Others* (point 4 of the operative part).

[72] Judgment of 8 July 2010, *Portakabin* (C-558/08, EU:C:2010:416).

the goods originating from the proprietor of the trade mark and those originating from the reseller or other third parties.[73] The Court concluded that, in such a situation, the proprietor of the trade mark in question was entitled, on the basis of Article 7(2) of Directive 89/104, to oppose the use of that mark.[74]

185. Likewise, where a parallel trader replaces the original marks on the external packaging of a product with other signs, in such a way that those marks appear either as references to the original name of the product and of its manufacturer, or on the immediate packaging, there is a risk of damage to the essential function of the trade mark, which is to indicate and guarantee the origin of the product. That is the case in particular where, as in the dispute in the main proceedings in Case C-224/20, the signs contain the company name of the parallel trader. In fact, consumers, who are not necessarily aware of the rules on parallel trade in medicinal products, will not be in a position to correctly attribute the products to their actual manufacturer or indeed will tend to associate that manufacturer with the parallel trader.

186. In such a case, in my view, the conditions on which the proprietor of the trade marks cannot oppose the use of those marks will not apply. Those conditions assume that the trade marks belonging to the original manufacturer of the medicinal product are affixed on the new packaging after the product has been repackaged. There is then no risk of damage to the specific function of the trade mark, namely to guarantee the origin of the product. Conversely, the existence of such a risk would justify derogations from the fundamental principle of the free movement of goods,[75] that is to say the application, in the context of parallel trade between Member States, of Article 15(2) of Regulation 2017/1001 and Article 15(2) of Directive 2015/2436.

187. In the absence of such a risk for the guarantee of the origin of the product, the fact that the parallel trader does not affix to the new packaging, following the repackaging of a product, all the marks that were on the original packaging, or that he or she affixes other signs to the new packaging, must be assessed solely by reference to the requirement that the presentation of the repackaged product is not such that it may damage the reputation of the mark and that of its proprietor. That assessment, which is an assessment of fact, must be carried out by the national court in each specific case.[76]

188. Furthermore, it must be observed that, according to settled case-law, the condition that packaging be necessary, referred to in the sixth question in Case C-224/20, is directed solely at the fact of repackaging the product – and the choice between new packaging and a new label – for the purposes of allowing that product to be marketed in the State of importation, and not at the manner or style in which it has been repackaged.[77] In my view, de-branding is an aspect of the style or the manner in which the product is repackaged.

189. I therefore propose that the answer to the sixth and seventh questions in Case C-224/20 should be that Article 15 of Regulation 2017/1001 and Article 15 of Directive 2015/2436 must be interpreted as meaning that the proprietor of a trade mark on a product is entitled to oppose the marketing of that product in the situation where the parallel trader has repackaged that product in new packaging, to which he or she has affixed only some of the trade marks belonging to that proprietor which appeared on the original packaging or has replaced them with other signs,

[73] Judgment of 8 July 2010, *Portakabin* (C-558/08, EU:C:2010:416, paragraph 86).

[74] Judgment of 8 July 2010, *Portakabin* (C-558/08, EU:C:2010:416, point 3 of the operative part).

[75] See, in particular, judgment in *Bristol-Myers Squibb and Others* (paragraph 48).

[76] See point 183 of this Opinion.

[77] Judgment of 2007 in *Boehringer Ingelheim and Others* (paragraph 38).

using those trade marks solely as references to the name of the product and of its manufacturer, unless the conditions defined by the Court in its judgment in *Bristol-Myers Squibb and Others* and its judgment of 2007 in *Boehringer Ingelheim and Others* are satisfied. However, where, in such a situation, there is a risk of damage to the essential function of the mark, which is to indicate and guarantee the origin of the product, the proprietor of the trade mark on that product is entitled to oppose its being marketed without there being any need to verify whether those conditions are satisfied.

Conclusion

190. Having regard to the foregoing considerations, I propose that the Court answer the questions for a preliminary ruling referred by the Landgericht Hamburg (Regional Court, Hamburg, Germany) in Case C-147/20 as follows:

(1) 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 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 fact that the replacement by a parallel trader of the anti-tampering device referred to in point (o) of Article 54 of Directive 2001/83/CE 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 2011/62/EU of the European Parliament and of the Council of 8 June 2011 leaves traces which are visible or can be detected following inspection of that device or after the package has been opened by the patient is not sufficient to support the conclusion that the opposition of the proprietor of the trade mark to any repackaging of that medicinal product in new packaging would contribute to the artificial partitioning of the markets between Member States and would therefore be contrary to the principle of the free movement of goods, unless that visibility of traces of the opening of the packaging causes resistance to the medicinal products thus repackaged that is so strong that it constitutes a real barrier to effective access to the Member State of importation, which it is for the referring court to verify.

(2) Article 5(3) of Commission Delegated Regulation (EU) 2016/161 of 2 October 2015 supplementing Directive 2001/83/EC of the European Parliament and of the Council by laying down detailed rules for the safety features appearing on the packaging of medicinal products for human use must be interpreted as meaning that the barcode containing the unique identifier, referred to in Article 3(2)(a) of that delegated regulation, may be affixed by means of a label glued to the packaging, provided that that label, in addition to complying with the requirements of Articles 5, 6 and 17 of that regulation, is affixed to the packaging in such a way that it is impossible to remove it without destroying it and without damaging the packaging or leaving traces of its removal.

191. Having regard to all of the foregoing considerations, I propose that the Court answer the questions for a preliminary ruling referred by the Landgericht Hamburg (Regional Court, Hamburg, Germany) in Case C-204/20 as follows:

(1) Article 47a(1)(b) of Directive 2001/83, as amended by Directive 2011/62, must be interpreted as meaning that a safety feature, within the meaning of point (o) of Article 54 of that directive, reaffixed by a manufacturing authorisation holder when the medicinal products are repackaged, is equivalent to the original safety feature, within the meaning of the first of those provisions, when it makes it possible to verify the authenticity, identification and to provide evidence of tampering in accordance with the requirements arising from that directive and from Delegated Regulation 2016/161. That is the case, in particular, where the replacement anti-tampering device, within the meaning of Article 3(2)(b) of that delegated regulation, presents the same technical characteristics as the original device.

(2) Article 15 of Directive 2015/2436 must be interpreted as meaning that the proprietor of a trade mark on a medicinal product may oppose the repackaging of that medicinal product in new packaging in the context of parallel trade when the parallel trader is able to use the original packaging and replace the safety features in accordance with the provisions of Directive 2001/83, as amended by Directive 2011/62, and of Delegated Regulation 2016/161, including where that replacement leaves traces which are visible or can be detected following inspection or after the packaging has been opened by the patient, unless that visibility of the traces of the opening of the packaging causes resistance towards the medicinal products thus repackaged that is so strong that it constitutes a real barrier to effective access to the market of the Member State of importation, which it is for the referring court to verify.

192. Last, having regard to all of the foregoing considerations, I propose that the Court answer the questions for a preliminary ruling referred by the Sø – og Handelsretten (Maritime and Commercial Court, Denmark) in Case C-224/20 as follows:

(1) Article 47a(1)(b) of Directive 2001/83, as amended by Directive 2011/62, must be interpreted as meaning that the anti-tampering device, within the meaning of Article 3(2)(b) of Delegated Regulation 2016/161, reaffixed by a manufacturing authorisation holder when the medicinal products are repackaged, is equivalent to the original device, within the meaning of Article 47a(1)(b) of that directive, even if the packaging in question shows, in the course of an inspection under Articles 16, 20 or 25 of that delegated regulation or after the packaging has been opened by the end user, perceptible signs that the original anti-tampering device has been tampered with, provided that it is clear that that tampering was lawful.

(2) Article 15 of Regulation 2017/1001 and Article 15 of Directive 2015/2436 must be interpreted as meaning that the proprietor of a trade mark on a medicinal product may oppose the repackaging of the medicinal product in new packaging in the context of parallel trade, where the parallel trader is capable of using the original packaging and replacing the safety features in accordance with the provisions of Directive 2001/83 as amended by Directive 2011/62 and of Delegated Regulation 2016/161, including where that replacement leaves traces which are visible or can be detected following inspection or after the packaging has been opened by the patient, unless that visibility of the traces of the opening of the packaging causes resistance towards the medicinal products thus repackaged that is so strong that it constitutes a real barrier to effective access to the Member State of importation, which it is for the referring court to verify.

(3) Article 47a(1) of Directive 2001/83 as amended by Directive 2011/62 must be interpreted as meaning that the national authorities responsible for supervising the pharmaceutical market are not entitled to lay down rules requiring that medicinal products provided with the safety features referred to in point (o) of Article 54 of that directive, which have been parallel imported from other Member States, must, as a general rule, be repackaged in new packaging, limiting relabelling to exceptional cases.

(4) Article 15 of Regulation 2017/1001 and Article 15 of Directive 2015/2436 must be interpreted as meaning that the proprietor of a trade mark on a product is entitled to oppose the marketing of that product in a situation in which the parallel trader has repackaged that product in new packaging, on which he or she has affixed only some of the trade marks belonging to that proprietor that appeared on the original packaging or has replaced them with other signs, using those marks solely as references to the name of the product and of its manufacturer, unless the conditions defined by the Court in its judgment of 11 July 1996 in *Bristol-Myers Squibb and Others*, C-427/93, C-429/93 and C-436/93, EU:C:1996:282, and its judgment of 26 April 2007 in *Boehringer Ingelheim and Others*, C-348/04, EU:C:2007:249, are satisfied, which it is for the referring court to verify. Where, however, in such a situation there is a risk of damage to the essential function of the trade mark, which is to indicate and guarantee the origin of the product, the proprietor of the trade marks on that product is entitled to oppose its being marketed without there being any need to verify whether those conditions are satisfied.