Case C-224/20

Request for a preliminary ruling

Date lodged:

29 May 2020

Referring court:

Sø- og Handelsretten (Denmark)

Date of the decision to refer:

3 April 2020

Applicants:

Merck Sharp & Dohme B.V.

Merck Sharp & Dohme Corp.

MSD DANMARK ApS

MSD Sharp & Dohme GmbH

Novartis AG

H. LUNDBECK A/S

FERRING LÆGEMIDLER A/S

Defendants:

ABACUS MEDICINE A/S

PARANOVA DANMARK A/S

2CARE4 ApS

SØ- OG HANDELSRETTEN (Maritime and Commercial Court)

ORDER

delivered on 3 April 2020

Case [omissis]

Merck Sharp & Dohme B.V.
[omissis]
and
Merck Sharp & Dohme Corp.
[omissis]
and
MSD DANMARK ApS
[omissis]

v

ABACUS MEDICINE A/S
[omissis]

and

Case [omissis]

Novartis AG
[omissis]

v

ABACUS MEDICINE A/S
[omissis]

and

Case [omissis]

Novartis AG
[omissis] **[OR. 2]**

v

ABACUS MEDICINE A/S
[omissis]

and

Case [omissis]

Novartis AG
[omissis]

v

PARANOVA DANMARK A/S

and

Case [omissis]

H. LUNDBECK A/S
[omissis]

v

PARANOVA DANMARK A/S

and

Case [omissis]

MSD DANMARK ApS
[omissis]
and
MSD Sharp & Dohme GmbH
[omissis]
and

Merck Sharp & Dohme Corp.
[omissis]

v

2CARE4 ApS
[OMISSIS] **[OR. 3]**

and

Case [omissis]

FERRING LÆGEMIDLER A/S
[omissis]

v

PARANOVA DANMARK A/S
[omissis]

The Sø- og Handelsretten [omissis] has decided to make a reference to the Court of Justice of the European Union for a preliminary ruling pursuant to Article 267 of the Treaty on the Functioning of the European Union.

The reference concerns in particular any consequences which the rules laid down in Directive 2011/62/EU 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 of falsified medicinal products into the legal supply chain, and 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, may have for a parallel importer's right to repackage medicinal products imported in parallel in new external packaging, as occurred in those cases.

The dispute in the main proceedings and the relevant facts

1. The seven present cases concern parallel imports/parallel distribution (hereinafter referred to jointly as 'parallel imports') and repackaging of medicinal products. The applicants are manufacturers of medicinal products and proprietors of the trade marks for the medicinal products which each of them manufactures and sells. The defendants carry out parallel imports into Denmark of medicinal products which the applicants have placed on the market in other countries of the European Union.

2. The defendant parallel importers repackage the medicinal products imported in parallel in new external packaging to which they reaffix the applicants' respective trade marks (product names) or in new external packaging to which they do not reaffix the applicants' respective trade marks **[OR. 4]** (product names), but which they instead give a new product name before the medicinal products are marketed in Denmark.

3. The question in these cases is whether the manufacturers of medicinal products are able to object to that repackaging, with the result that the parallel importers are required to market the medicinal products in Denmark in the same packaging as that in which they were marketed in the State of export and must therefore confine themselves to carrying out relabelling or supplementary labelling, replacing the package leaflet, attaching a new, unique identifier, and resealing the packaging by affixing a new device to verify whether the packaging has been tampered with ('anti-tampering device') on top of or in place of the broken anti-tampering device.

4. The manufacturers of pharmaceutical products submit that the trade mark rules give a trade mark proprietor the right to object to repackaging in new external packaging in circumstances such as those in the main proceedings. The parallel importers argue that the repackaging in new external packaging is necessary and therefore lawful.

5. The first case concerns the parallel import and repackaging of medicinal products manufactured and marketed by Merck Sharp & Dohme B.V. and others under the

EU trade marks Janumet, Januvia, Elonva, Stocrin, Bridion and Puregon. Abacus Medicine A/S purchases Janumet, Januvia, Elonva, Stocrin, Bridion and Puregon in other countries of the European Union and places them on the market in Denmark after repackaging them in new external packaging, to which the trade mark has been reaffixed.

6. The next three cases concern the parallel import and repackaging of medicinal products manufactured and marketed by Novartis AG under the EU trade marks Travatan, Eucreas and Miflonide. The defendant in two of the cases, Abacus Medicine A/S, purchases Travatan and Eucreas in other countries of the European Union and places them on the market in Denmark after repackaging them in new external packaging, to which the trade mark has been reaffixed. The defendant in the latter case, Paranova Danmark A/S, purchases Miflonide in other countries of the European Union and places them on the market in Denmark after repackaging them in new external packaging, to which the trade mark has been reaffixed.

7. The fifth case concerns the parallel import and repackaging of medicinal products manufactured and marketed by H. Lundbeck A/S under the EU trade marks Brintellix and Clopixol. Paranova Danmark A/S purchases Brintellix and Clopixol in other countries of the European Union and places them on the market in **[OR. 5]** Denmark after repackaging them in new external packaging, to which the respective product-specific trade mark has been reaffixed, but without reaffixing the other trade marks and commercial indications which H. Lundbeck A/S had affixed to the original external packaging.

8. The sixth case concerns the parallel import and repackaging of a medicinal product manufactured and marketed by a company in the Merck Sharp & Dohme group in Germany under the trade mark Nacom. In Denmark Merck Sharp & Dohme B.V. and others market the medicinal product under the trade mark Sinemet. 2Care4 ApS purchases Nacom in Germany and places it on the market in Denmark, after repackaging it in new external packaging which bears the product name 'Carbidopa/Levodopa 2care4', and at the same time states, as required by the Danish Medicines Agency, that the packaging contains a blister packet marked Nacom. 2Care4 ApS reuses the original blister packet bearing the German trade mark Nacom, which belongs to MSD Sharp & Dohme GmBH, and the EU trade mark MSD, which belongs to Merck Sharp & Dohme Corp. As required by the Danish Medicines Agency, 2Care4 ApS has printed its product name, 'Carbidopa/Levodopa 2care4', on one side of the blister packet. The new package leaflet states that the product corresponds to Sinemet.

9. The seventh case concerns the parallel import and packaging of two strengths of a medicinal product manufactured by Ferring B.V. In Denmark the medicinal product is marketed by Ferring Lægemidler A/S under the EU trade mark Nocdurna. However, the UK Medicines and Health Care Products Regulatory Agency objected to the use of the name Nocdurna and therefore the medicinal product is marketed in the UK under the trade mark Noqdirna. Paranova Danmark A/S purchases the medicinal product in the UK and places it on the market in

Denmark after repackaging it in new external packaging which bears the product name 'Desmopressin Paranova'. The new external packaging also states that the medicinal product is manufactured by Ferring GmbH, that the medicinal product corresponds to the medicinal product Nocdurna, that Nocdurna is a registered trade mark belonging to Ferring B.V and that the packaging contains blister packets marked Noqdirna. Paranova Danmark A/S reuses the original blister packets but has printed, as required by the Danish Medicines Agency, the product name 'Desmopressin Paranova' on one side of the blister packets. The other side of the blister packets is unchanged and states that the medicinal product is called 'Noqdirna' and originates from 'Ferring'. The new external packaging contains a new package leaflet which states that the medicinal product corresponds to the medicinal product Nocdurna. **[OR. 6]**

10. The first five cases have the following in common:

- in most of the cases, the parallel importers market, in Denmark, medicinal products imported in parallel in the same packaging sizes as those used by each of the manufacturers of the medicinal products for the initial marketing of the medicinal products concerned in the European Union,

- in several of those cases, the Danish Medicines Agency referred to its guidelines (Q&A) when asked specifically about the possibility of additional labelling,

- prior to marketing in Denmark, the parallel importers broke the original anti-tampering devices and opened the packaging in order to replace the package leaflets and/or attach new labels to the inner packaging, and

- prior to marketing in Denmark, the parallel importers repackaged the medicinal products imported in parallel in new external packaging and reaffixed the applicants' respective trade marks (product names) thereto.

The final two cases have the following in common:

- the parallel importers market the medicinal products in Denmark imported in parallel in the same packaging sizes as those used by each of the manufacturers of the medicinal products for the initial marketing of the medicinal products concerned in the European Union,

- prior to marketing in Denmark, the parallel importers broke the original anti-tampering devices and opened the packaging in order to replace the package leaflets and/or attach new labels to the inner packaging, and

- prior to marketing in Denmark, the parallel importers repackaged the medicinal products imported in parallel in new external packaging to which the applicants' respective trade marks (product names) were not reaffixed, but which were instead given new product names. Furthermore, the package leaflet states that the medicinal products correspond to the medicinal

products marketed by each of the applicants under their respective trade marks (product names). **[OR. 7]**

Provisions of [EU] law and [EU] case-law

Trade marks

11. 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 ('the Trade Mark Directive') concerns exhaustion of the rights conferred by a trade mark. Under Article 15, a trade mark is not to *'entitle the proprietor to prohibit its use in relation to goods which have been put on the market in the Union under that trade mark by the proprietor or with the proprietor's consent'* (paragraph 1) unless *'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.'* (paragraph 2).

12. EU trade marks registered with the same legal effects throughout the European Union are governed by Regulation (EU) 2017/1001/EU of the European Parliament and of the Council of 14 June 2017 on the European Union trade mark ('the Trade Mark Regulation'), Article 15 of which contains a provision which is essentially identical to Article 15 of the Trade Mark Directive.

13. In connection with Articles 34 and 36 [TFEU] (formerly Articles 28 and 30 TEC) [omissis] the Court of Justice has ruled on the interpretation of Article 15(2) of the Trade Mark Directive (corresponding to Article 7(2) in the previous version thereof) in a range of judgments concerning the repackaging of medicinal products imported in parallel, in particular in the judgments in Joined Cases C-427/93, C-429/93 and C-436/93, *Bristol-Myers Squibb and Others* (ECLI:EU:C:1996:282); Case C-443/99, *Merck, Sharp & Dohme* (ECLI:EU:C:2002:245); Case C-143/00 *Boehringer Ingelheim and Others* (ECLI:EU:C:2002:246) ('*Boehringer I*'); Case C-348/04, *Boehringer Ingelheim and Others* (ECLI:EU:C:2007:249) ('*Boehringer II*'); and Case C-297/15, *Ferring* (ECLI:EU:C:2016:857).

In those judgments the Court of Justice of the European Union found, inter alia, as follows:

- the specific purpose of a mark is to guarantee the origin of the product bearing that mark and that a repackaging of that product carried out by a third party without the authorisation of the proprietor is likely to create real risks for that guarantee of origin (see paragraph 14 of *Boehringer II* and paragraph 14 of *Ferring*);

- the change brought about by any repackaging of a trade-marked pharmaceutical product — creating by its very nature the risk **[OR. 8]** of

interference with the original condition of the product — may therefore be prohibited by the trade mark proprietor unless it is established that reliance on trade mark rights by the proprietor in order to oppose the marketing of repackaged products under that trade mark would contribute to the artificial partitioning of the markets between Member States. A trade mark proprietor's opposition to repackaging contributes to artificial partitioning of the markets where the repackaging is necessary in order to enable the marketing of the products imported in parallel in the importing State and the legitimate interests of the proprietor are also safeguarded (see paragraph 56 of *Bristol-Myers Squibb and Others*, paragraphs 18 and 19 of *Boehringer II*, and paragraphs 18 and 19 of *Ferring*);

- repackaging must be regarded as having been carried out in circumstances not capable of affecting the original condition of the product where, for example, the trade mark proprietor has placed the product on the market in double packaging and the repackaging affects only the external layer, leaving the inner packaging intact, or where the repackaging is carried out under the supervision of a public authority in order to ensure that the product remains intact (see paragraph 60 of *Bristol-Myers Squibb and Others*);

- while the trade mark proprietor may oppose the parallel importer's use of replacement packaging, that is conditional on the relabelled pharmaceutical product being able to have effective access to the market concerned (see paragraph 29 of *Merck, Sharp & Dohme* and paragraph 50 of *Boehringer I*);

- the criterion that the repackaging is to be necessary must be assessed in the light of the circumstances prevailing at the time of marketing in the importing State, which render repackaging objectively necessary for the medicinal product to obtain effective access to the market in the importing State (see paragraph 25 of *Merck, Sharp & Dohme* and paragraph 20 of *Ferring*);

- 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 the product to be marketed in the importing Member State and not at the manner or style in which it has been repackaged (see paragraphs 38 and 39 of *Boehringer II*);

- the trade mark proprietor cannot oppose the repackaging of the medicinal product in new external packaging when the size of packet used by the proprietor in the exporting State cannot be marketed in the importing State by reason, in particular, of rules on **[OR. 9]** packaging size, a national practice of using packaging only of a certain size, sickness insurance rules or well-established medical prescription practices based on standard sizes recommended by professional groups and sickness insurance institutions (see paragraph 53 of *Bristol-Myers Squibb and Others* and paragraph 21 of *Ferring*).

- conversely, a trade mark proprietor may object to the continued marketing of a medicinal product which a parallel importer has repackaged in a new, outer packaging and to which it has reaffixed the trade mark, where the medicinal product can be marketed in the importing State in the packaging which was used for marketing the medicinal product in the exporting State (see paragraph 29 of *Ferring*) as in that situation the trade mark proprietor can require the parallel importer to reuse the original packaging and merely affix to the original external or inner packaging new labels in the language of the importing State and add a new package leaflet in the language of the importing State (see paragraph 55 of *Bristol-Myers Squibb and Others*, paragraph 28 of *Merck, Sharp & Dohme*; and paragraph 49 of *Boehringer I*).

- the condition that repackaging be necessary to market the medicinal product in the importing State is not fulfilled if the repackaging of the medicinal product is explicable solely by the parallel importer's attempt to secure a commercial advantage (see paragraph 27 of *Merck, Sharp & Dohme* and paragraph 37 of *Boehringer II*);

- resistance to relabelled pharmaceutical products does not always mean that repackaging, in the form of a replacement packaging, is necessary (see paragraph 51 of *Boehringer I*), but 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, a repackaging of the pharmaceutical products would not be explicable solely by the attempt to secure a commercial advantage, but also has the purpose of achieving effective market access (see paragraph 52 of *Boehringer I*);

- the presentation of the repackaged product must not be such as to be liable to damage the reputation of the trade mark and of its proprietor (see paragraph 76 of *Bristol-Myers Squibb and Others* and paragraph 40 of *Boehringer Ingelheim II*); and

- the fact that a parallel importer does not affix the trade mark to the new exterior packaging ('de-branding') or applies either its own logo or a house-style ('co-branding') is, in principle, liable to damage the trade mark's reputation **[OR. 10]** (see paragraph 45 of *Boehringer II*). The question whether those circumstances damage the trade mark's reputation is a question of fact for the national court to decide in the light of the circumstances of each case (see paragraph 46 of *Boehringer II*).

- it is for the parallel importer to prove the existence of the conditions preventing the trade mark proprietor from lawfully opposing further marketing of those medicinal products (see paragraph 23 of *Ferring*). As regards the condition that it must be shown that the repackaging cannot affect the original condition of the product inside the packaging, and *a fortiori* the condition that the presentation of the repackaged product must

not be such as to be liable to damage the reputation of the trade mark and of its proprietor, it is sufficient, however, that the parallel importer furnishes evidence that leads to the reasonable presumption that that condition has been fulfilled (see paragraphs 52 and 53 of *Boehringer II*).

The obligation to affix and verify safety features on the packaging of medicinal products

14. On 9 February 2019 [omissis] Directive 2011/62/EU [omissis] ('Directive 2011/62') and [omissis] Regulation (EU) 2016/161 [omissis] ('Regulation 2016/161') entered into force.

15. The provisions of Directive 2011/62 and Regulation 2016/161 seek to prevent medicinal products which are falsified in relation to their identity, history or source from entering the legal supply chain of medicinal products, which poses a particular threat to human health and may lead to a lack of trust of the patient also in the legal supply chain (see recitals 2 and 3 of Directive 2011/62).

16. Article 1(11) and (12) of Directive 2011/62 inserted, inter alia, a new point (o) of Article 54 and a new Article 54a of Directive 2001/83/EC on the Community code relating to medicinal products **[OR. 11]** for human use ('the Medicinal Products Directive') [omissis]. Article 54a, in conjunction with point (o) of Article 54, provides that the packaging of the medicinal products is to bear two safety features, namely a unique identifier allowing verification the authenticity of the medicinal product (unique identifier/UI), and an anti-tampering device allowing verification of whether the outer packaging has been tampered with (anti-tampering device/ATD).

17. Article 10 of Regulation 2016/161 provides that when verifying the safety features, *'manufacturers, wholesalers and persons authorised or entitled to supply medicinal products to the public'* are to verify the authenticity of the unique identifier and the integrity of the anti-tampering device. Articles 24 and 30 of Regulation 2016/161 further provide that *'wholesalers'* and *'persons authorised or entitled to supply medicinal products to the public'* may not resell or supply medicinal products where they have reason to believe that the packaging of the medicinal product has been tampered with or in case of suspected falsification.

18. With reference to the case-law of the Court of Justice of the European Union, recitals 21 to 24 of Directive 2011/62 state that account should be taken of the fact that specific conditions for retail supply of medicinal products to the public have not been harmonised at Union level and, therefore, Member States may impose conditions for supplying medicinal products to the public within the limits of the EU Treaty.

19. Finally, recital 29 of Directive 2011/62 states:

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

Parallel imports and replacement of safety features on the packaging of medicinal products

20. Recital 12 of Directive 2011/62 is worded as follows:

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

21. Article 47a of the Medicinal Products Directive, which was inserted by Article 1(8) of Directive 2011/62, provides that the holder of a manufacturing authorisation, including a parallel importer, may not remove or cover, either fully or partially, the safety features referred to in point (o) of Article 54 (a unique identifier and anti-tampering device), unless a number of specific conditions are satisfied.

22. Article 16 of Regulation 2016/161 contains a provision which, with reference to Article 47a of the Medicinal Products Directive, sets out the verifications to be performed before removing or covering the safety features.

23. The European Commission drew up and published a document entitled 'Questions and Answers', which is regularly updated, in response to a series of questions concerning the rules relating to safety features on the packaging of medicinal products. The answers to Questions 1.20 to 1.22 (as set out in version 17, published on 9 March 2020) describe the precautions which a parallel importer is to take when replacing the original security features.

24. The European Commission set up an expert group, 'Delegated act on safety features for medicinal products for human use' (E02719) ('Commission expert group on safety features'). The published minutes of the expert group's meetings show that it discussed the interpretation of Article 47a of Directive 2011/62.

25. The European Medicines Agency ('EMA') dealt with parallel imports and safety features in its 'Frequently asked questions about parallel distribution' ('EMA's Q&A'). Point 7 of the 'Parallel distribution notification check' section states,

under point 2 of the heading 'Exceptions', that a person who breaks 'the seal' to attach new labels to the packaging or replace the package leaflet and then seals the original packaging with 'a clear seal', is to remove **[OR. 13]** the indication *'Sealed pack. Do not use if box has been opened'* and replace it with *'Sealed pack has been opened for the purpose of parallel distribution'.* The relevant section of the EMA's Q&A was inserted before Directive 2011/62 was adopted. None of the relevant EMA-approved products covered by the cases contains the indication 'sealed pack' in the relevant annexes.

Provisions of national law and national case-law

26. The Trade Mark Directive was transposed into Danish law by the Varemærkeloven (Law on trade marks), Paragraph 10a of which contains a provision which is essentially identical to Article 15 of the Trade Mark Directive.

27. Like the manufacturers of medicinal products, parallel importers of medicinal products operate on the basis of rules on authorisation and public oversight. Thus, medicinal products imported in parallel may be marketed in Denmark only if the parallel importer is the holder of a marketing authorisation to import in parallel under Chapter 4 of Bekendtgørelse nr. 1239 af 12. december 2005 om markedsføringstilladelse til lægemidler m.m (Order No 1239 of 12 December 2005 on marketing authorisations for medicinal products etc.). A medicinal product imported in parallel is at all times subject to the conditions which apply to directly imported medicinal products (see Paragraph 38 of the order). Parallel importers which carry out additional labelling or repackaging in new external packaging in order to meet the conditions for marketing in Denmark must hold, in addition to a marketing authorisation, a manufacturing authorisation under Chapter 3 of the Lægemiddelloven (Law on medicinal products).

28. Article 54a of the Medicinal Products Directive, relating to safety features on the packaging of medicinal products, was transposed into Danish law, with effect from 9 February 2019, by the insertion of Paragraph 59a into the Law on medicinal products (see Lovbekendtgørelse nr. 99 af 16. januar 2018 (Consolidated Law No 99 of 16 January 2018; 'the Law on medicinal products'). The relevant parts of Paragraph 59a are worded as follows:

'Medicinal products at risk of falsification shall have safety features attached to their packaging in accordance with the regulation on safety features (see subparagraphs 2 and 3). The safety features shall consist of a unique identifier allowing verification of the authenticity of the medicinal product and identification of the individual packaging, and an anti-tampering device allowing verification of whether the packaging of the medicinal product has been tampered with.

Subparagraph 2. Manufacturers of prescription medicinal products for human use shall provide medicinal products with safety features. … **[OR. 14]**

Subparagraph 5. The Ministry of Health and Senior Citizens may lay down specific rules to underpin the purpose and function of safety features.'

29. On 18 December 2018, the Danish Medicines Agency published a series of 'Questions and Answers about safety features on the packaging of medicinal products' ('Danish Medicines Agency's Q&A'), which were most recently updated on 20 January 2020 and which state, inter alia, as follows under the heading 'Parallel imports':

'28. Would it be against the regulation for a parallel importer to replace the anti-tampering device with another device?

Yes. 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 etc. in the packaging must therefore, 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 on the packaging, as well as upload information etc.

The Commission stated in its Q&A 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 GMP (Good Manufacturing Practice) 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/EC.

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 **[OR. 15]** *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 marketing … 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.'

30. Finally, in Denmark there is a rule on generic substitution (see Paragraph 62(1) of Bekendtgørelse nr. 1297 af 28. november 2019 om recepter og dosisdispensering af lægemidler (Order No 1297 of 28 November 2019 on prescriptions and unit dispensing of medicinal products)), which, as a rule, requires pharmacists to supply the cheapest medicinal product within a category of approved medicinal products which may replace the medicinal product indicated by the doctor (substitution).

The questions referred

31. Since clarification of the questions is of decisive importance to the outcome of the present cases and the doubts raised concern the interpretation of the rules of EU law, the Sø- og Handelsretten considers that it is necessary to ask the Court of Justice of the European Union to answer the questions below.

It is hereby ordered:

The Sø- og Handelsretten requests the Court of Justice to answer the following questions: **[OR. 16]**

Question 1:

Must Article 15(2) of Directive 2015/2436/EU of the European Parliament and of the Council on trade marks and Article 15(2) of Regulation 2017/1001/EU of the European Parliament and of the Council on the EU trade mark 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/EC of the European Parliament and of the Council of 6 November 2001 on medicinal products (as amended by Directive 2011/62/EU of the European Parliament and of the Council) and Article 16 of Commission Delegated Regulation (EU) 2016/161 on safety features appearing on the packaging of medicinal products?

(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/EC of the European Parliament and of the Council of 6 November 2001 on medicinal products (as amended by Directive 2011/62/EU of the European Parliament and of the Council) and Article 16 of Commission Delegated Regulation (EU) 2016/161 on safety features appearing on the packaging of medicinal products?

Question 2:

Must Directive 2001/83/EC of the European Parliament and of the Council on medicinal products (as amended by Directive 2011/62/EU), including, in particular, Articles 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 **[OR. 17]** 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 (a) displays visible signs that the original anti-tampering device has been tampered with, or (b) 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 Directive 2011/62/EU of the European Parliament and of the Council,

Article 54a(2)(d) and Commission Delegated Regulation 2016/161, Article 10(b) and Articles 25 and 30), or

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

Question 3:

If the answer to Question 2 is in the negative:

Must Article 15 of Directive 2015/2436/EU of the European Parliament and of the Council on trade marks, Article 15 of Regulation 2017/1001/EU of the European Parliament and Council on EU trade marks, 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/EC of the European Parliament and of the Council of 6 November 2001 on medicinal products (as amended by Directive 2011/62/EU of the European Parliament and of the Council), that is to say without the packaging of the medicinal products (a) displaying visible signs that the original anti-tampering device has been tampered with, or (b) that can be established by touching the product, as described in Question 2, in a manner which is not in accordance with Article 47a?

Question 4:

Must Directive 2001/83/EC of the European Parliament and of the Council on medicinal products (as amended by Directive 2011/62/EU of the European Parliament and of the Council) and Commission Delegated Regulation (EU) 2016/161, in conjunction with Articles 34 and 36 TFEU and Article 15(2) of Directive 2015/2436/EU of the European Parliament and of the Council on trade marks, 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 **[OR. 18]** 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/EC of the European Parliament and of the Council on medicinal products and Article 16 of Commission Delegated Regulation (EU) 2016/161?

Question 5:

Must Article 15(2) of Directive 2015/2436/EU of the European Parliament and of the Council on trade marks and Article 15(2) of Regulation 2017/1001/EU of the European Parliament and of the Council on trade marks, 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 of the European Union,

(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?

(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?

Question 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')?

Question 7:

Must Article 15(2) of Directive 2015/2436/EU of the European Parliament and of the Council on trade marks and Article 15(2) of Regulation 2017/1001/EU of the European Parliament and of the Council on EU trade marks 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 **[OR. 19]** and/or commercial indications which the trade mark proprietor had affixed to the original external packaging?

[omissis]