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Court of Justice of the European Union

Cour de Justice de l' Union Européenne

L – 2925 Luxembourg

Re: a) case C-147/20, *Novartis Pharma GmbH* v. *Abacus Medicine A/S*, Request for preliminary ruling referred from Landgericht Hamburg (Regional Court, Hamburg) (Germany) and **b)** case C-224/20, M*erck 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* v. *Abacus Medicine A/S, Paranova Danmark A/S, 2CARE4 ApS*, Request for preliminary ruling referred from Sø- og Handelsretten (Maritime and Commercial Court) (Denmark) before the Court of Justice of the European Union (CJEU)

August 27, 2020

Amicus Submission – International Trademark Association

Dear Sirs
The International Trademark Association ("INTA") has prepared this Submission in relation to the cases

a) C-147/20, *Novartis Pharma GmbH* v. *Abacus Medicine A/S*, and

b) C-224/20, *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* v. *Abacus Medicine A/S, Paranova Danmark A/S, 2CARE4 ApS*,

before the Court of Justice of the European Union (CJEU), both requests for preliminary rulings under article 267 of the Treaty on the Functioning of the European Union referred by, respectively, the Regional Court of Hamburg and the Maritime and Commercial Court of Denmark.

A. INTA's interest in the cases

1. INTA is not a party in the cases and acknowledges that the CJEU does not have a procedure for accepting an *amicus curiae* intervention *stricto sensu*. INTA however believes that the cases are significant to the development of trademark law and presents itself as a "friend of the court" in these matters and as done in the past (*cf.* **Annex A** listing previous amicus interventions by INTA before European courts).

2. INTA wishes to put forward a submission in the cases on behalf of its members and hopes that its comments (prepared through its European Amicus subcommittee) may be of assistance to the Court.

B. About INTA

1. INTA is a global association of brand owners and professionals dedicated to supporting trademarks and related intellectual property (IP) to foster consumer trust, economic growth, and

innovation. Members include nearly 6,500 organizations, representing more than 34,350 individuals (trademark owners, professionals, and academics) from 185 countries, who benefit from the Association's global trademark resources, policy development, education and training, and international network. Founded in 1878, INTA is headquartered in New York City, with offices in Brussels, Santiago, Shanghai, Singapore, and Washington, D.C., and a representative in New Delhi. For more information, visit www.inta.org.

2. An important objective of INTA is to protect the interests of the public by the proper use of trademarks. In this regard, INTA strives to advance the development of trademark, related IP and unfair competition laws and treaties throughout the world, based on the global public interest in avoiding deception and confusion. INTA has been an official non-governmental observer to the World Intellectual Property Organization ("WIPO") since 1979 and actively participates in all trade mark related WIPO proposals. INTA has influenced WIPO trade mark initiatives such as the Trademark Law Treaty and is active in other international arenas, including the Asia Pacific Economic Cooperation Forum ("APEC"), the Association of Southeast Asia Nations ("ASEAN"), the European Union (EU) and the World Trade Organization ("WTO").

3. Since 1916, INTA has acted in the capacity of advisor and has appeared as *amicus curiae* ("friend of the court") in the US and in other jurisdictions, including before the CJEU and the General Court of the EU. A list of some of these submission is attached as **Annex A** to this Submission.

4. The present brief was drafted by INTA independently of the parties in the case at issue.

The questions referred to CJEU

The questions referred to the CJEU by the two national courts are attached hereto as **Annex B**.

The Law

The legal provisions relevant to the questions referred by the two national courts are attached hereto as **Annex C**.

Procedural issues and arguments of the parties

The procedure and arguments of the parties are attached hereto as **Annex D**.

The cases referred to the CJEU

I. Case C-147/20

The Regional Court, Hamburg – Germany (Landgericht Hamburg) has referred to the CJEU its request dated 27.2.2020 (date lodged 23.03.2020) for a preliminary ruling under art. 267 of the Treaty on the Functioning of the European Union (**TFEU**), asking four questions with regard to the interpretation of Articles 9(2) and 15 of Regulation (EU) 2017/1001 of the European Parliament and of the Council of 14 June 2017 on the European Union Trade Mark (**Regulation or EUTMR**) in conjunction with Articles 54(o) and 47(a) 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 (**FMD**) and on Article 5(3) of Commission Delegated Regulation (EU) 2016/161 of 2 October 2015 (**Delegated Regulation**).

II. Case C-224/20

The Danish Maritime and Commercial Court (Sø- og Handelsretten) has referred to the CJEU its request dated 3.4.2020 (date lodged 29.5.2020) for a preliminary ruling under TFEU**,** asking seven questions with regard to the interpretation of Articles 54(o) and 47a FMD, Articles 34 and 36 TFEU, Article 16 of the Delegated Regulation, Article 15 of the Directive 2015/2436/EU of the European Parliament and of the Council on Trade Marks (**Directive** or **TMD**) and Article 15 of the Regulation.

D. Reasons why INTA is submitting this brief

1. The legal regime of exhaustion is not restricted to EU Trademark Law; it is a topic of IP-protection in many other jurisdictions as well. Exhaustion as a principle is however expressly excluded from the TRIPS-Agreement (Article 6 TRIPS). That alone sheds a particular light on the importance of exhaustion.

2. The rights of a trademark proprietor may be infringed even in case of genuine goods and the doctrine of exhaustion plays an important role in this assessment. The principle of exhaustion aims to balance the interests of trademark owners and the public, as well as competitors.

3. INTA has a long-standing position on exhaustion of trademark rights (see, in particular, the Board Resolutions of 1999 and 2015), supporting that a principle of national or regional exhaustion should apply as the one that applies in the EU. INTA believes that a standard of national/regional exhaustion is the best to protect trademark owners and consumers.
4. The coming into force of the Delegated Regulation and the FMD is of importance in the pharmaceuticals trademark exhaustion field. Especially in view of the debate as to whether such pieces of legislation change or affect the thus far followed EU jurisprudential principles on the matter, INTA believes it should express expert views and position on the matter.
5. There is no CJEU case law on this issue, namely whether the FMD and the Delegated Regulation affect the existing CJEU case law principles and rules on pharmaceuticals' exhaustion.

6. The extent of trademark protection afforded to owners in cases of exhaustion of rights, an issue of critical importance to brand owners, depends on the interpretation of such exception. It is noted that the above are of interest and apply not only to European Union Trademarks but also to all European Union member states' national trademarks, as the TMD and the EUTMR contain an identical provision in this respect.

7. Furthermore, the interpretative principles and rationale that will be followed, affect not only pharmaceuticals but also other goods / services in different areas of trade. Therefore, how the CJEU rules in these cases could potentially have a significant impact on parallel trade of pharmaceutical but also other goods in the EU and the extent of rights of trademark owners. The issue of exhaustion and its limitations is furthermore even more pertinent for the EU in view of Brexit.

8. In the present brief, INTA has focused on the interpretation of Article 15 of the Regulation and Article 15 of the Directive. The FMD and Delegated Regulation provisions are only taken into account for the interpretation of these articles.

9. In many Member States it is considered an infringement of the trademark to commercialize goods that have been re-packed, re-marked or otherwise interfered with, because the trademark no longer adequately indicates that the goods come unaltered from the originating enterprise (W. Cornish/D. Lewellyn, Intellectual Property Law, Sweet and Maxwell, 2019). It is important that an interpretation of the provisions at hand be in line with different Member States' view on the issue.

E. INTA's proposed answers to the questions referred to the CJEU

INTA respectfully submits that the questions shouldbe answered as follows:

i. As regards Case C-147/20

1) A trademark proprietor may oppose further commercialization of a medicinal product which a parallel importer has repackaged in new external packaging to which the trademark has been reaffixed, where 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;

2) Articles 47a and 54 (o) FMD must be interpreted as meaning that a new 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), may be "equivalent as regards the possibility to verify the authenticity, identification and to provide evidence of tampering [with] the medicinal product" within the meaning of Article 47a(1)(b) of FMD, and may be "equally effective in enabling the verification of authenticity and identification of medicinal products and in providing evidence of tampering with medicinal products", within the meaning of Article 47a(1)(b)(ii) of FMD.

Whether the new anti-tampering device affixed to the original packaging would indeed be in a particular given case equivalent and equally effective, shall depend on the factual circumstances of the case.

3) Given that the proposed answer to Question 2 is in the affirmative, Article 15 of the Directive, Article 15 of the Regulation and Articles 36 and 34 TFEU, may not be interpreted as meaning that repackaging in new external packaging is objectively, namely is always, necessary for effective access to the market of the State of importation.

ii. As regards Case C-224/20

Article 15(2) of the TMD and Article 15(2) of the Regulation shall be interpreted as meaning that a trademark proprietor may oppose further commercialization of a medicinal product which a parallel importer has repackaged in new external packaging to which the trademark has been reaffixed, where the importer is able to achieve packaging which may be marketed and gain effective access

to the market of the Member State of importation, in accordance with Article 47a FMD and Article 16 of Delegated Regulation.

The removal of the brand cannot be accepted without taking into account the alternative solution of leaving the brand on the product while indicating the interference of a third party through the placement of additional labels or stickers. Normally, additional labels have a lesser impact on the integrity of a branded product than the removal of the brand. In any case it is clear that the removal of the brand to avoid a harm to the origin function should not be performed in a manner causing harm to the quality function. Given that in exhaustion cases the goods are necessarily genuine goods, originating from the trademark owner, it should be up to the trademark owner to decide whether by such removal any of the trademark functions are harmed.

F. INTA's analysis

1. The referrals to the CJEU, in both cases, relate to, *inter alia*, the interpretation of Article 15 EUTMR and Article 15 of TMD which provide for a right of the trademark proprietor to interfere in the marketing of exhausted products.

2. INTA submits that repackaging is not the only possibility under the new requirements of the FMD and the Delegated Regulation. It is not a legal obligation stemming from those provisions. It is therefore not "objectively necessary" within the meaning of the five conditions for exhaustion in respect of the repackaging (see the judgments of 11 July 1996, Bristol-Myers Squibb and Others, C-427/93, C-429/93 and C-436/93).

CJEU existing case law

3. According to the CJEU, the power of the trademark owner to oppose the marketing of repackaged products should be limited only in so far as the repackaging undertaken by the importer is necessary in order to market the product in the Member State of importation (judgment of 11 July 1996, Joined Cases C-427/93, C-429/93 and C-436/93, Bristol-Myers Squibb and others v Paranova, para. 56).

4. This requirement that repackaging be necessary is directed at (i) the repackaging as such (i.e. does the parallel import need to change the packaging at all, be it through reboxing, be it through relabeling), and (ii) the choice between reboxing and relabeling (see judgment of 26 April 2007, Case C-348/04, Boehringer Ingelheim and Others, para. 38: "*Therefore, 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*"; see also judgment of 22 December 2008, case C-276/05, Wellcome Foundation v Paranova).

5. Thus, the trademark proprietor may oppose re-boxing/repackaging where the parallel importer is able to achieve a marketable packaging by, for example, affixing new labels and adding new user instructions in the language of the Member State of importation, or by replacing an additional article not capable of gaining approval in the Member State of importation with a similar article that has obtained such approval (judgment of 11 July 1996, Joined Cases C-427/93, C-429/93 and C-

436/93, Bristol-Myers Squibb and others v Paranova, para. 55; judgment of 23 April 2002, case C-443/99, Merck, Sharp & Dohme v Paranova Pharmazeutika Hamdels GmbH, para. 28).

6. For that assessment, the circumstances prevailing at the time of marketing in the importing State must be taken into account (CJEU, judgment of 10 November 2016, Ferring Lægemidler A/S v Orifarm A/S, C‑297/15, para. 20):

- In particular, the trademark proprietor cannot oppose the re-boxing when the packet size in the export country differs from the packet sizes in the importing country and the original packet size cannot be marketed in the importing country because of, in particular, a rule authorising packaging only of a certain size, or a prescription practice or reimbursement rules to the same effect (CJEU, judgment of 10 November 2016 2007, Ferring Lægemidler A/S v Orifarm A/S, C‑297/15, para. 21).

- In contrast, the trademark proprietor may oppose the repackaging if it is based solely on the parallel importer's attempt to secure a commercial advantage (judgment of 23 April 2002, case C-443/99, Merck, Sharp & Dohme v Paranova Pharmazeutika Hamdels GmbH, para. 27).

- According to the CJEU, resistance of prescribers and/or patients to relabeled pharmaceutical products does not automatically constitute an impediment to effective market access such that replacement packaging is allowed. If the parallel importer chooses to rebox a product only because reboxed products are better accepted than relabeled products among prescribers and/or patients, such reboxing would be based solely on an attempt to secure a commercial advantage, and reboxing would not be considered necessary. However, it is possible that there exists on a market such strong resistance from a significant proportion of consumers to relabeled pharmaceutical products that there must be held to be a hindrance to effective market access so that reboxing is legitimate (judgment of 23 April 2002, case C-443/99, Merck, Sharp & Dohme v Paranova, para. 31).

Legitimate reasons - repackaging not possible where trademark functions are affected

7. Under Article 15 (2) EUTMR and TMD, there can be legitimate reasons to render exhaustion inapplicable, if at least one of the functions of the trademark is adversely affected or is liable to be adversely affected. An adverse impact on the functions of the trademark will constitute legitimate reasons, reinstating the infringement test under the infringement provisions of the Regulation. The reasons have to be named, identified as legitimate and balanced with the property rights of the owner of the goods and the interests of the public. In the case of parallel imports of pharmaceuticals as follows from the case law of the CJEU (i) a complex set of rules has to be observed and (ii) the specific circumstances of the case have to be taken into account. Therefore, under the general EUTMR and TMD requirements, to the extent that any one of the trademark functions is liable to be affected in the context of Article 15 (2) EUTMR / Article 15 (2) TMD exhaustion shall not apply.

8. The CJEU has held in Joined Cases C-427, 328, 429 /93 Bristol Myers Squibb (paras 25 and 26) and C-352/05 Phyteron/Bourdon (para 17) that Article 7 which is the equivalent article in the previous version of the TMD (Directive 2008/95/EC of the European Parliament and of the Council

of 22 October 2008), with an identical wording, provides a final rule of exhaustion. The background of Article 7, however, is the balancing of the interests of trademark owners on one hand to control the further commercialization of their goods and the principle of the free flow of goods in the internal market on the other hand. Article 9 (2) EUTMR provides for a similar balance between the trademark owner's monopoly and the interests of the public to keep such monopoly under control. In the absence of other means to establish a balance in the framework of Article 13 (2) of the EUTMR in its previous version (Council Regulation (EC) No 207/2009 of 26 February 2009), trademark functions serve to achieve exactly the same result.

9. The CJEU has also held already in these joined cases C-427, 328, 429 /93 Bristol Myers Squibb (para 75) concerning the repackaging of trademarked goods, that the owner of a trademark has a legitimate interest, related to the specific subject-matter of the trademark right, in being able to oppose the commercialization of those goods if the presentation of the repackaged goods is liable to damage the reputation of the trademark (Bristol-Myers Squibb, cited above, paragraph 75) since "*even if the person who carried out the repackaging is indicated on the packaging of the product, there remains the possibility that the reputation of the trademark, and thus of its owner, may nevertheless suffer from an inappropriate presentation of the repackaged product. In such a case, the trademark owner has a legitimate interest, related to the specific subject-matter of the trademark right, in being able to oppose the marketing of the product*". The CJEU has already confirmed that the legitimate reasons (interest) are related to the specific subject matter of trademarks, namely the trademark functions, as currently recognized by CJEU to be the origin, guarantee and advertising functions.

10. As was held by the CJEU in Joined Cases C-427, 328, 429 /93 Bristol Myers Squibb (para 47) "*account must be taken of the essential function of the trademark"* and *"guarantee of origin means that the consumer or end user can be certain that a trade-marked product offered to him has not been subject at a previous stage of marketing to interference by a third person, without the authorization of the trademark owner, in such a way as to affect the original condition of the product {Hoffmann-La Roche, paragraph 7; Pfizer, paragraph 8)*".

11. The CJEU further held in the same cases that a repackaged product may be liable to damage the reputation of a trademark (paras 25 and 26): "*In assessing whether the presentation of the repackaged product is liable to damage the reputation of the trademark, account must be taken of the nature of the product and the market for which it is intended*".

12. It is therefore clear from the CJEU case law, interpreting the Directive and the Regulation that the owner of a trademark has a right, stemming from its legitimate interests, related to the specific subject-matter of the trademark rights, in being able to oppose the commercialization of repackaged trademarked goods.

FMD and Delegated Regulation Wording - Repackaging not an obligation

13. Under the FMD and the Delegated Regulation, repackaging is not an obligation. This follows from the wording of the said provisions.

14. The FMD specifically refers to both repackaging and relabeling of goods; it anticipates that both means of presentation of the goods will continue to be possible under the FMD. The FMD makes specific reference to parallel importation. It specifically provides that the provisions are without prejudice to intellectual property rights.

15. Nothing in the legislation itself suggests that the FMD is intended to restrict the scope of the principles established under the Bristol-Meyers Squibb ("BMS") jurisprudence referred to above. This follows from the wording of the FMD and the Delegated Regulation which specifically provide for repackaging (article 16 para. 1 of Delegated Regulation).

16. Furthermore, if relabeling always led to artificial market partitioning, a situation forbidden under general EU competition and single market rules, an EU piece of legislation, such as the Delegated Regulation, would not have included it as a possibility.

European Commission and National Authorities

17. This interpretation is confirmed by the European Commission and the Danish Medicines Agency documents mentioned by the Danish ruling above. These specify analytically how the lawful marketing in the country of import shall be done, in cases where the parallel imported goods are not repackaged. Therefore, these documents that draw from the FMD and the Delegated Regulation specifically provide for repackaging not being the only option.

18. Indeed, according to the European Commission and several national authorities, if a package has been opened lawfully, the parallel importer placing an equivalent anti-tampering device must ensure the pack is perfectly re-sealed and no signs of the original, broken anti-tampering device are visible. This therefore leaves room for the less drastic measure of relabeling instead of re-boxing. The European Commission therefore also considers that both re-boxing and relabeling can be achieved under the FMD.

19. Therefore, repackaging may not be considered as necessary under the FMD and the Delegated Regulation.

CJEU existing rules continue to apply

20. Given that under the FMD and the Delegated Regulation repackaging is not a legal obligation, it follows that repackaging is permissible to the extent it conforms with the so forth established rules of the CJEU.

21. Therefore, per the established CJEU case law, even under the new FMD and Delegated Regulation provisions, a trademark 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 trademark, 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 para. 29 of Case C-297/15 Ferring). That is because, in that situation, the trademark 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 para. 55 of Bristol-Myers Squibb and Others, para. 28 of Merck, Sharp & Dohme; and para. 49 of Case C-143/00 Boehringer Ingelheim and Others).

Commercial Advantage

22. According to established CJEU case law, 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 para. 27 of Merck, Sharp & Dohme and para. 37 of case C-348/04, Boehringer Ingelheim and Others). If repackaging is solely based on the parallel importer's attempt to secure a commercial advantage, the trademark proprietor may oppose to such repackaging (Case C- 379/97, Upjohn v. Paranova, para. 44).

23. As follows from the above, given that repackaging is not necessary under the FMD and the Delegated Regulation, it would be up to the national court to decide based on the facts and circumstances of each given case whether such commercial advantage is attempted.

Effective Market Access

24. While the trademark proprietor may oppose the parallel importer's use of repackaging, that is conditional on the relabelled pharmaceutical product being able to have effective access to the market concerned (para. 29 case C-443/99, Merck, Sharp & Dohme, para. 50 of Case C-143/00 Boehringer Ingelheim and Others). Whether this is the case is a matter of fact to be decided by the national court. In particular, where opposition to relabelled pharmaceutical products does not result from repackaging being necessary (para. 51 of Case C-143/00 Boehringer Ingelheim and Others), but on the existence on a market, or on a substantial part of it, of such strong resistance from a significant proportion of consumers to relabelled pharmaceutical products that there should be held that there is a hindrance to effective market access, this would be a matter to be assessed by the national court on any given case and on the basis of the facts and the evidence brought before it.

Brand removal should be up to trademark owner

25. The removal of the brand may serve to avoid a harm to the origin function in the sense of falsely suggesting that a party is related to the trademark owner. The origin function, however, is also harmed if the removed mark no longer serves to indicate the origin of manufacture. It appears that the CJEU in Mitsubishi/Duma (C-129/17) may give guidance on that issue, although it is expressly restricted to the scenario of a removal prior to the first putting on the market.

26. An answer cannot be given without taking into account the alternative solution to leaving the brand on the product but indicating the interference of a third party through the placement of additional labels or stickers. Normally, additional labels have a lesser impact on the integrity of a branded product than the removal of the brand.

27. In any case it is clear that the removal of the brand to avoid a harm to the origin function should not be performed in a manner causing harm to the quality function. However, given that in exhaustion cases the goods are necessarily genuine goods, originating from the trademark owner, it should be up to the trademark owner to decide whether by such removal any of the trademark functions are harmed. As stated above, the measures to be taken by a third party to avoid detriment

to the trademark (functions) in case of further commercialization of goods depend on the circumstances of such further commercialization.

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28. From all the above it follows, that **under the FMD and the Delegated Regulation, repackaging of the parallel imported pharmaceutical products is NOT the only way of marketing in the country of import nor is it an obligation imposed by the new provisions.** The FMD does not render it **necessary in every case** to rebox rather than relabel and the general principles of BMS are not changed or rendered obsolete by the requirements of the FMD.

29. It is for the parallel importer/reseller to demonstrate why in any given circumstances it is not appropriate to relabel and that as a matter of fact, supported by evidence, it is necessary to re-box in order to obtain market access. However, this is not something which may be predetermined across all Member States. There may be cases where it is necessary to rebox owing the local rules, insurance requirements or the type of product but, as a matter of principle, each case must still be examined on its merits in the context of all the facts. Even in these cases, per established CJEU case law, the presentation of the repackaged product must not be such as to be liable to damage the reputation of the trademark and of its proprietor (para. 76 of Bristol-Myers Squibb and Others and para. 40 of case C-348/04, Boehringer Ingelheim and Others).

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Conclusion

INTA' views on the questions referred by the Regional Court of Hamburg are as follows:

I. Case C-147/20

Proposed answers:

a) A trademark proprietor may oppose further commercialization of a medicinal product which a parallel importer has repackaged in new external packaging to which the trademark has been reaffixed, where 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,

b) Articles 47a and 54 (o) FMD must be interpreted as meaning that a new 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), may be "equivalent as regards the possibility to verify the authenticity, identification and to provide evidence of tampering [with] the medicinal product' within the meaning of Article 47a(1)(b) FMD, and may be "equally effective in enabling the verification of authenticity and identification of medicinal products and in providing evidence of tampering with medicinal products', within the meaning of Article 47a(1)(b)(ii) FMD.

Whether the new anti-tampering device affixed to the original packaging would indeed be in a particular given case equivalent and equally effective, shall depend on the factual circumstances of the case.

c) Given that the proposed answer to Question 2 is in the affirmative, Article 15 of the Directive, Article 15 of the Regulation and Articles 36 and 34 TFEU, may not be interpreted as meaning that repackaging in new external packaging is objectively and always, necessary for effective access to the market of the State of importation.

INTA expresses its view only for Questions 1-3 and not Question 4 as the latter concerns the FMD provisions *per se*.

INTA' views on the questions referred by the Maritime and Commercial Court, Denmark, is as follows:

II. Case 224/20

Proposed answers:

Article 15(2) of the TMD and Article 15(2) of the Regulation shall be interpreted as meaning that a trademark proprietor may oppose further commercialization of a medicinal product which a parallel importer has repackaged in new external packaging to which the trademark has been reaffixed, where the importer is able to achieve packaging which may be marketed and gain effective access to the market of the Member State of importation, in accordance with Article 47(a) FMD and Article 16 of the Delegated Regulation.

The removal of the brand cannot be accepted without taking into account the alternative solution of leaving the brand on the product but indicating the interference of a third party through the placement of additional labels or stickers. Normally, additional labels have a lesser impact on the integrity of a branded product than the removal of the brand. In any case, it is clear that the removal of the brand to avoid a harm to the origin function should not be performed in a manner causing harm to the quality function.

ANNEX A

INTA has filed the following *amicus*-type submissions in cases before European courts:

- Statement of Intervention on January 6, 2016, in the case *DHL Express (France) v EUIPO* (T-142/15).
- Statement of Intervention on April 25, 2014 in the case *Voss of Norway v OHIM* (C-445/13 P).
- Written Observations on March 16, 2010 in the case *Nokia Corporation v. Her Majesty's Commissioners of Revenue and Customs* (HMRC) (C-495/09).
- Letter of submission to Specsavers International Healthcare Limited on August 23, 2012 in the trademark case *Specsavers International Healthcare Limited & others vs Asda Stores Limited* (C-252/12).
- Letter of submission to Intel Corporation on September 5, 2007, in the tardemark case *Intel Corporation v. CPM United Kingdom Ltd.* (C -252/07).
- Letter of submission to Adidas and adidas Benelux on June 12, 2007 in the trademark case *Adidas and adidas Benelux* (C-102/07).
- Letter of submission to SARL Céline on April 25, 2006 in the trademark case *SARL Céline v. SA Céline* (C-17/06).
- Submission as intervener to the English Court of Appeals on October 16, 2006 in the case *Special Effects* v *L'Oreal* SA (HC 05C012224, Court of Appeal 2006 0744).
- Letter of submission to Bovemij Verzekeringen N.V. on June 17, 2005 in the case *Bovemij Verzekeringen N. V. v. Benelux Merkenbureau* (ECJ - C-108/05).
- Letter of submission to Schering-Plough Ltd. on December 5, 2003 in the trademark case *Schering-Plough Ltd* v. *European Commission and* EMEA (CFI T-133/03).
- Letter of submission to Merck Inc. on April 4, 2003 in the trademark case *Paranova A/S v. Merck & Co., Inc, Merck, Sharp & Dohme B. V. and MSD (Norge) A/S* (EFTA Court E-3/02).
- Letter of submission to Praktiker Bau - und Heimwerkermarkte AG on March 20, 2003 in the trademark case *Praktiker Bau - und Heimwerkermarkte AG* (ECJ C- 418/02).
- Letter of submission to Shield Mark on November 1, 2001 in the trademark case *Shield Mark v. J. Kist* (ECJ C-283/01).
- Letter of submission to Libertel Groep B.V. on July 6, 2001 in the trademark case *Libertel Groep B.V. v. Benelux Merkenbureau* (ECJ - C- 104/01)
- Letter of submission to Glaxo Wellcome Limited on October 10, 2000 in the trademark case *Glaxo Wellcome Limited* v. *Dowelhurst Limited and Swingward Limited* (ECJ - C-l43/00

ANNEX B

Questions

I. Case C-147/20

Question 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/EC 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?

Question 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 Regulation (EU) 2016/161, or may be overlooked in a superficial inspection?

Question 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?

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

II. Case C-224/20

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 (antitampering 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 (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 and/or commercial indications which the trade mark proprietor had affixed to the original external packaging?".

ANNEX C

Legal Provisions

i. FMD

Point (o) of Article 54 and Article 47a read as follows:

*"**Article 54***

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

54(o)

for medicinal products […] 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.

Article 47a

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

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

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

Safety features shall be considered equivalent if they:

(i) comply with the requirements set out in the delegated acts adopted pursuant to Article 54a(2); and

(ii) are equally effective in enabling the verification of authenticity and identification of medicinal products and in providing evidence of tampering with medicinal products;

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

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

2. Manufacturing authorisation holders, including those performing the activities referred to in paragraph 1 of this Article, shall be regarded as producers and therefore held liable for damages in the cases and under the conditions set forth in Directive 85/374/EEC".

ii. Delegated Regulation

Article 16 reads as follows:

"*Verifications to be performed before removing or replacing the safety features:*

1. Before removing or covering, either fully or partially, the safety features in accordance with Article 47a of Directive 2001/83/EC, the manufacturer shall verify the following: (a) the integrity of the anti-tampering device; (b) the authenticity of the unique identifier and decommission it if replaced. 2. Manufacturers holding both a manufacturing authorisation according to Article 40 of Directive 2001/83/EC and an authorisation to manufacture or import investigational medicinal products to the Union as referred to in Article 61 of Regulation (EU) No 536/2014 of the European Parliament and of the Council shall verify the safety features and decommission the unique identifier on a pack of medicinal product before repackaging or re-labelling it for the purpose of using it as authorised investigational medicinal product or authorised auxiliary medicinal product".

iii. EUTMR

Article 15 reads as follows:

"*Exhaustion of the rights conferred by an EU trademark: 1. An EU trademark 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 trademark by the proprietor or with his consent. 2. Paragraph 1 shall not apply where there exist legitimate reasons for the proprietor to oppose further commercialization of the goods, especially where the condition of the goods is changed or impaired after they have been put on the market*".

Article 9(2) reads as follows:

"Rights conferred by an EU trade mark […] 2. Without prejudice to the rights of proprietors acquired before the filing date or the priority date of the EU trade mark, the proprietor of that EU trade mark shall be entitled to prevent all third parties not having his consent from using in the course of trade, in relation to goods or services, any sign where: (a) the sign is identical with the EU trade mark and is used in relation to goods or services which are identical with those for which the EU trade mark is registered; (b) the sign is identical with, or similar to, the EU trade mark and is used in relation to goods or services which are identical with, or similar to, the goods or services for which the EU trade mark is registered, if there exists a likelihood of confusion on the part of the public; the likelihood of confusion includes the likelihood of association between the sign and the trade mark; (c) the sign is identical with, or similar to, the EU trade mark irrespective of whether it is used in relation to goods or services which are identical with, similar to or not similar to those for which the EU trade mark is registered, where the latter has a reputation in the Union and where use of

that sign without due cause takes unfair advantage of, or is detrimental to, the distinctive character or the repute of the EU trade mark".

iv. TMD

Article 15 reads as follows:

"Exhaustion of the rights conferred by a trade mark: 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".

v. Articles 34 and 36 TFEU

"Article 34: Quantitative restrictions on imports and all measures having equivalent effect shall be prohibited between Member States".

"Article 36: The provisions of Articles 34 and 35 shall not preclude prohibitions or restrictions on imports, exports or goods in transit justified on grounds of […] the protection of industrial and commercial property. Such prohibitions or restrictions shall not, however, constitute a means of arbitrary discrimination or a disguised restriction on trade between Member States".

On 9 February 2019 FMD and the Delegated Regulation entered into force. They seek to prevent medicinal products which are falsified in relation to their identity, history or source from entering the legal supply chain, 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 FMD). Under the new provisions, namely Article 47a, in conjunction with point (o) of Article 54, the packaging of the medicinal products is to bear two safety features, namely a unique identifier allowing verification the authenticity of the medicinal product (**UI**), and an anti-tampering device allowing verification of whether the outer packaging has been tampered with (**anti-tampering device**).

Article 47a of the FMD 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.

Article 10 of Delegated Regulation 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.

Article 16 of Delegated Regulation provides, with reference to Article 47a FMD, the verifications to be performed before removing or covering the safety features.

Finally, recital 29 of FMD 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*.'

National (Danish) guidelines

In Denmark the following national (Danish) guidelines are also in force (underlining is our own):

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 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. […]*.'

ANNEX D

Procedural history of the cases and summary of the arguments of the parties

INTA makes no comment on the application of the legal principles to the particular facts in the cases which is a matter for the national court.

Both cases concern the consequences which the FMD and the Delegated Regulation may have for a parallel importer's right to repackage medicinal products and for the trademark owner's possibility to prohibit such repackaging.

i. Case C -147/20

The case concerns the parallel trade of pharmaceuticals in Germany. The claimant is the producer of medicinal products and had been affixing on its original packaging an anti-tampering device since February 2019. The disputed matter is whether the defendant may import the claimant's original products and sell them in Germany in a new outer packaging, submitted to the claimant by the defendant, or whether the defendant must distribute the original – opened - packaging and affix on it a new anti-tampering device.

The packaging will be opened because prior to the distribution, the defendant must create a packet suitable for distribution in Germany, under German law.

Claimant requests that defendant is prohibited from selling the said medicines in repackaged configurations.

Arguments of the parties

A. Claimant

The claimant invokes its trademark rights under Article 9(2) of the Regulation. It maintains that its trademark rights are not exhausted for the purposes of Article 15(2) of the Regulation, because the defendant is able to affix adhesive labels to the original packaging, showing also the barcode as a unique identifier within the meaning of Article 3(2)(a) of Delegated Regulation. The same practice applied before the national laws transposing FMD came into force for all other labelling elements which a parallel trader had to affix under German law using adhesive labels in German.

Per the claimant it is possible to open the original packaging (and, in so doing, to open the anti-tampering device of the original manufacturer), insert the importer's own user information in German and seal the opened original packaging with a new anti-tampering device, for example a slightly larger seal that completely covers the traces of previous opening.

In order to dispel doubts as to the integrity of the medicinal products, parallel importers may also indicate that the newly affixed seal has been affixed by them, as part of an authorized repackaging process.

The opening of the packaging by the parallel importer shall be shown in any event, since, according to the case-law of the CJEU, it is necessary to indicate clearly on the packaging the fact that the medicinal product has been repackaged, who the repackager of the medicinal product is and the name of the manufacturer of the medicinal product.

Per the claimant, only two new elements were introduced with the FMD, in respect to the previous labelling requirements: the anti-tampering device and the unique identifier (UI). Both can be implemented by means of labels and it is not necessary to proceed to repackaging. Therefore, under the FMD new packaging is not necessary in principle.

The claimant's further arguments include a) that, it is safer for the patient to recognise that a product is a labelled original product, b) that wholesalers and pharmacies are accustomed to a wide variety of packaging, c) that patients, pharmacies and wholesalers and doctors are aware that parallel-imported products satisfy the labelling requirements in Germany by means of additionally affixed labels.

B. Defendant

The defendant maintains that a) the opening of the anti – tampering device (sealing label) leads to visible, irreversible damage or changes to the packaging or the label or adhesive tape, b) the defendant cannot affix the unique identifier to the original packaging by means of a label, because it can be removed again due to the silicone coating the packaging, c) printing pursuant to Article 5(3) of Delegated Regulation, which states that 'manufacturers shall print the barcode on the packaging on a smooth, uniform, low-reflecting surface', is not possible.

Per defendant, in the particular product, transparent adhesive seals are affixed to both the top and the underside of the packaging flap. The packaging surface required for the seal is not covered with a silicone coating, therefore when the sealing label is torn off it leaves visible signs of tampering. If the defendant's sealing label is affixed to this damaged surface, traces of tampering remain visible. Furthermore, the damage to the surface of the packaging is still noticeable despite the fact that a new seal has been affixed.

According to the defendant, under the FMD it is not permissible for the parallel trader to open the original packaging and reseal it using its own new anti-tampering device. The reason is that, in the case of the product in question, new anti-tampering devices cannot be affixed without leaving visible traces of opening, which, in turn, means that the safety features cannot be effective.

The defendant further states that affixing the new unique identifier by superimposing it on the old one is also not possible, because the new sticker might be peeled off, so that patients can see that the PC and SN number series specified in each case do not match. Such circumstances affect the integrity of the product.

Defendant takes therefore the view that, as a parallel importer, it is **forced** to use its own packaging for distribution in Germany, on which it can then print the unique identifier or barcode and which it can seal with its own anti-tampering device.

The defendant notes that the applicant's original packaging can no longer be used, since per the FMD, only completely clean medicinal product packaging showing no traces of tampering can be marketed.

Lastly, the defendant invoked that there is evidence that visible traces of opening are not accepted by three of the five leading companies in the pharmaceutical wholesale sector, which do not accept medicinal product packaging on which there are traces of opening. As the referring court states, the defendant has also submitted evidence to show that pharmacists and patients also consider

new packaging to be more trustworthy than original packaging that has a seal stuck on top of it or has been sealed for the first time.

National court findings

The national court finds that if Article 5(3) of Delegated Regulation imposes an obligation on the defendant to print the barcode directly on the packaging of the medicinal product, this may require the use of new outer packaging. Therefore, if the applicant's reliance on its trademark rights is capable of resulting in an artificial partitioning of the markets, the defendant's defense may be successful.

It also finds that the success of the defendant depends on whether the trademark owner can oppose the repackaging of the product in new outer packaging or not, namely the defendant is obliged under national law, the FMD and the Delegated Regulation to affix equivalent safety features to the packaging, but such replacement could leave visible traces. If, due to the obligations under the above mentioned legislation the fact that visible traces were left, would require the original outer packaging to be replaced by new one, the applicant would have no right of prohibition under Article 9(2) of the Regulation.

ii. Case C - 224/20

The case concerns the parallel trade of pharmaceuticals in Denmark. In particular, it concerns seven joined cases of parallel importation and repackaging of medicinal products. The claimants are manufacturers of medicinal products and proprietors of the trademarks and the defendants are parallel importers of the goods in Denmark.

The defendants repackage the medicinal products in new external packaging to which they reaffix the claimants' respective trademarks (product names) or in new external packaging to which they do not reaffix the claimants' respective trademarks (product names), but which they instead give a new product name before the medicinal products are marketed in Denmark.

The question is whether the manufacturers are able to object to that repackaging, and therefore parallel importers must therefore confine themselves to relabelling or supplementary labelling, replacing the package leaflet, attaching a new, unique identifier, and resealing the packaging by affixing a new anti-tampering device on top of or in place of the broken anti-tampering device.

In the first five cases, 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 in new external packaging and reaffixed the applicants' respective trademarks (product names) thereto.

In the last two cases, 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 claimants' respective trademarks (product names) were not reaffixed, but which were instead given new product names. Furthermore, the package leaflet stated that the medicinal products correspond to the medicinal products marketed by each of the claimants under their respective trademarks (product names).

Arguments of the parties

The manufacturers of pharmaceutical products argue that the trademark rules give a trademark 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.