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Court of Justice of the European Union

Cour de Justice de l'Union Européenne

L – 2925 Luxembourg

RE: Joint Cases C-253/20 *Novartis AG v. Impexeco NV* and C-254/20 *Novartis AG v. PI Pharma NV*

September 28, 2020

Amicus Submission – International Trademark Association

The International Trademark Association ("INTA") has prepared this Submission in relation to the joint cases C-253/20 "Impexeco" *Novartis AG v. Impexeco NV,* and C-254/20 "PI Pharma", *Novartis AG v. PI Pharma NV*, pending before the Court of Justice of the European Union (CJEU), which request preliminary rulings under article 267 of the Treaty on the Functioning of the European Union (TFEU) referred by the Brussels Court of Appeal.

A. INTA's interest in the cases

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 joint cases are significant to the development of trademark law and presents itself as an *amicus curiae* ("friend of the court") in these matters, as it has done in the past (see **Annex A** listing previous amicus interventions by INTA before European courts).

INTA hopes that this submission may be of assistance to the Court.

B. About INTA

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.

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 and 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 trademark related WIPO proposals. INTA has influenced WIPO trademark initiatives such as the Trademark Law Treaty, and also 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").

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

C. Questions referred to the CJEU

1) Must Articles 34 to 36 TFEU be interpreted as meaning that, where a branded medicine (reference medicine) and a generic medicine have been put on the market in the EEA by economically linked undertakings, a trade mark proprietor's opposition to the further commercialisation of the generic medicine by a parallel importer after the repackaging of that generic medicine by the affixing to it of the trade mark of the branded medicine (reference medicine) in the country of importation may lead to an artificial partitioning of the markets of the Member States?

2) If the answer to that question is in the affirmative, must the trade mark proprietor's opposition to that rebranding be assessed by reference to the BMS conditions?

3) Is it relevant to the answer to those questions that the generic medicine and the branded medicine (reference medicine) are identical or have the same therapeutic effect as referred to in Article 3(2) of the Koninklijk besluit van 19 april 2001 inzake parallelinvoer (Royal Decree of 19 April 2001 on parallel imports)?

The cases at hand ask whether the use by the importer on parallel imported generic products of the trademark of the original medicine, without the consent of the trademark owner, is legitimate.

D. Reasons why INTA is submitting this brief

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 Agreement on Trade-Related Aspects of Intellectual Property Rights (TRIPS) (cf. Article 6 TRIPS). That alone sheds a particular light on the case law of any larger jurisdiction dealing with exhaustion.

INTA has a long-standing position on exhaustion of trademark rights (see, in particular, the Board Resolutions of 1999 and 2015), supporting a principle of national or regional exhaustion 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.

We are not aware of any CJEU case law on the issue of whether branding parallel import generic pharmaceutical products with the name of the original product infringes the rights of the trademark owner.

Trademark rights may be infringed even in cases involving 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 and market players.

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

Under Article 15 of Regulation (EU) 2017/1001 of the European Parliament and of the Council of 14 June 2017 (the "EU TM Regulation" or "EUTMR"), a trademark 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).

INTA respectfully submits that the trademark rights in relation to the trademark of the original product are not exhausted when use of that trademark is made on the generic product. Since paragraph 1 of Article 15 EUTMR does not apply, as the rights are not exhausted in the cases at issue, there is no reason to examine its exception (paragraph 2) and the interpretation of Articles 34-36 TFEU and the BMS criteria.

F. INTA's analysis

1. Factual Background

In the cases at hand, two Belgian parallel traders claim that it must be equally possible to brand certain generic products with the name of the original product.

The facts are tied to the structure of Novartis and its distribution of both original medicines, as well as generics. In some cases, Novartis' group company Sandoz markets generic products, which are chemically identical to their "original" counterpart: they are manufactured in the same facility by the same entity, but are then marketed through different distribution channels and follow distinct regulatory procedures.

The referred cases concern Letrozole Sandoz and Methylphenidate Sandoz. The parallel traders purchased these generics and sold them in Belgium using the original product names, Femara and Rilatine, respectively.

Parallel traders sell the Letrozole Sandoz product affixing on it the trademark Femara in Belgium at roughly 30x the price of the originally purchased Letrozole Sandoz in the UK.

2. Legal Basis

In the cases at hand, there is, in particular, disagreement over whether to assess re-branding generics under the criterion of "objective necessity", considering the facts. INTA does not enter into the analysis as to whether, in these particular cases, changing the generic product name to the original product name was necessary or not, as this depends on the circumstances, evidence and facts of the cases, and is up to the national court to decide. However, INTA respectfully stresses that under parallel import provisions as interpreted by the CJEU, a parallel importer of a generic medicine shall, as a starting point, not have the right to use on this product the name/trademark of the original product, without the consent of the trademark owner.

3. De-branding

The CJEU has held that "*the function of investment of the mark includes the possibility for the proprietor of a mark to employ it in order to acquire or preserve a reputation capable of*

attracting customers and retaining their loyalty, by means of various commercial techniques. Thus, when the use by a third party […] interferes with the proprietor's use of its trade mark to acquire or preserve a reputation capable of attracting consumers and retaining their loyalty, the third party's use adversely affects that function of the trade mark. The proprietor is, as a consequence, entitled to prevent such use […]", (C- 129/17 *Mitsubishi Shoji Kaisha Ltd and Mitsubishi Caterpillar Forklift Europe BV v Duma Forklifts NV and G.S. International BVBA,* July 25, 2018, par. 36).

The CJEU has clarified that de-branding "*precludes the trade mark proprietor from being able to retain customers by virtue of the quality of its goods and affects the functions of investment and advertising*" (*ibid*, par. 46).

Furthermore, de-branding in the context of parallel imports has been found by the CJEU (*ibid*, par. 42-26) to be potentially detrimental to the functions of the trademark and, therefore, prohibited.

4. Exhaustion of the SANDOZ mark

The name "INN SANDOZ", as, in the cases at issue, the generic products were called by their manufacturer, communicates that the products originate from the Novartis group member Sandoz and have the specific characteristics of the said products (including their characteristic of being generic pharmaceuticals). In the same way, the original products' trademarks of Novartis communicate that the products originate from Novartis and have the specific characteristics of these other products (including that they are original).

If generic pharmaceutical products are sold as original products, namely using the original product name, the origin and the quality, and also the advertising functions, are all likely affected by such third-party use. Given that the goods in question are not put into the market by the trademark owner or with its consent under that specific trademark, it cannot be supported that the trademark rights are exhausted.

5. Lasting effects

The fact that, in the particular cases at issue, the generic product and the original product are both manufactured by the same entity in the large sense and in the same premises, does not alter the above. Otherwise, any parallel importer not only of pharmaceuticals but any product, could interchange the different names of a series of products of the manufacturer freely (e.g. different chocolates with different names of the same manufacturer could be sold by the parallel importer under any of these names in the country of import / different design series shoes of the same entity using different names could be sold under any of these names).

6. Different products under different marks

INTA supports that the generic product and the original product are different goods from the point of view of parallel trade and exhaustion. They are also different from a factual point of view, since generic products have different history and regulatory procedures. The use of the term "identical" in the relevant pharma legislation for generics composition serves identity in that context only, and not for trademark law/parallel import purposes. From the viewpoint of the relevant public, generics and original trademark products are not identical. Therefore, INTA proposes that the trademark rights are not exhausted in the cases at issue: the goods for

which the trademarks are used are not the ones which were put on the market by the trademark owner or with its consent. In particular:

7. As regards exhaustion of rights on FEMARA / RILATINE trademarks

Femora and Rilatine are – *inter alia* – protected as EU trademarks. Novartis as their owner has the sole right of putting these marks on products and putting the marked products on the market. INTA is of the opinion that there is no exhaustion of such rights but that, on the contrary, there is infringement of these marks based on Article 9 (1), 9 (3a), 9 (3b), and 9 (3c) EUTMR. Exhaustion is a matter of the very mark on the very product (C-173/98 *Sebago Inc. and Ancienne Maison Dubois et Fils SA v. GB-Unic SA*, July 1, 1999, paras 19, 20).

From the outset we, therefore, have a double trademark infringement: the de-branding of the Sandoz-mark and the affixing of the Femara/Rilatine mark.

8. As regards exhaustion of rights on SANDOZ trademark

As regards the question as to whether Sandoz can oppose the further commercialisation of the imported goods under Article 15 (2) EUTMR, INTA submits the following considerations:

First of all, there is a case of de-branding as the parallel importers have apparently deleted the Sandoz trademark from the imported generic (Letrozol and Methylphenidate packages). For such case, INTA respectfully submits that the BMS-criteria apply in the negative as the importers did not need to take off the Sandoz trademark to properly market the Letrozol and Methylphenidate in the importation member state. Such a de-branding interferes with the legitimate interests of Sandoz, as can be concluded from the CJEU-Mitsubishi/Duma judgment (C-129/17 of July 25, 2018). INTA supports that all arguments brought forward in the Mitsubishi/Duma case against a deletion of the mark prior to first putting the product out to the market also apply after the first putting out to the market. However, even if this were not the case, there is an argument based on the interpretation of the BMS case in the negative: "Re-branding" as a possible interference of the importer is restricted to the re-affixing of the same mark and not a different mark (see paras 34 ff). BMS does not cover the re-affixing of a different mark.

9. As regards Articles 34 and 36 TFEU

The only remaining question is whether Articles 34 and 36 TFEU have an impact on the interpretation of Articles 9 and 13 EUTMR in such a manner that they restrict the rights of Sandoz and Novartis because of an alleged artificial market partitioning.

INTA believes the answer to this question should be negative: Novartis is marketing its products under the original marks "Femara" and "Rilatine" which are legal and undisputed. After the cessation of patent-protection, Novartis took advantage of the option to market the products under the generic names "Letrozol" and Methylphenidate, respectively, an option which is open to all its competitors as well.

In order to still indicate the origin of this product and to distinguish it from other generics, Novartis also affixed the company-name "Sandoz" to the product. Again, this is perfectly legal. INTA is of the opinion that these activities cannot contribute to a partitioning of markets as long as the products are sold under both names in all EU-member states. Articles 34 and 36 TFEU are not triggered in this matter. Articles 34 and 36 TFEU would only apply if Letrozol and Femara / Methylphenidate and Rilatine were treated as identical products. However, they

are different from the points of view of public's perception, the way they are marketed, and the pricing.

Conclusion

INTA's views on the questions referred to the CJEU by the Brussels Court of Appeal are as follows:

a) Activities as those described in the cases at issue cannot contribute to a partitioning of markets. Articles 34 and 36 TFEU would only be applicable if Letrozol and Femara / Methylphenidate and Rilatine were treated as identical products. However, they are different from the points of view of the public's perception, the way they are marketed, and the pricing. The generic product and the original product are different goods from the point of view of parallel trade and exhaustion and also from a factual point of view, since generic products have different history and regulatory procedures.

b) Trademark rights in relation to the trademark of the original product are not exhausted when the use of that trademark is made on the generic product. Since paragraph 1 of Article 15 EUTMR does not apply, as the rights are not exhausted in the cases at issue, there is no reason to examine its exception (paragraph 2) or the interpretation of Articles 34-36 TFEU or the BMS criteria.

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 trademark 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'Oréal* 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)