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Can a Parallel Importer Rebrand Pharmaceutical Products in the EU?

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Abstract: *The European Union has established the free movement of goods, which covers the parallel import of goods in the EU. However, the free movement of goods should not infringe on the rights of trade mark owners. In some cases, parallel importer needs not only to repackage but also to rebrand pharmaceutical products. ECJ has stated that rebranding is permissible if objective necessity to rebrand exists. But it is the national court that has to determine what objective necessity is. This paper analyses the decisions of EU Member States. In some cases, objective necessity has been determined on similar grounds. However, in other cases, a necessity to enter some part of the market has been evaluated differently in different Member States. The different evaluation of the necessity criterion could be treated*

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as the infringement of uniform application of the free movement of goods in the EU.

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1. Introduction

The European Union as a single market guarantees that goods placed on the market in one Member State shall move freely in other Member States. The free movement of goods is one of the fundamental freedoms of the European Union as a single market. The free movement of goods leads to an economic integration and sustainable development in the area (Avgoustis, 2012, pp. 108–121). The free movement of goods was already instituted by the Treaty Establishing the European Community (2010). The same right was consolidated in the Treaty on the Functioning of the European Union (TFEU) where Articles 34–36[1] establish a prohibition of quantitative or similar restrictions on export and import between Member States:

> *The provisions of Articles 34 and 36 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 discriminatory or a distinguished restriction on trade between Member States.* (The Treaty Establishing the European Community, 2010)

Even though TFEU prohibits restrictions on free trade, restrictions can be applied to protect industrial and commercial property. Trade marks are treated as intellectual property and they are protected at the EU level.[2] Article 10 of Trade Mark Directive (2015/2436) establishes that "the proprietor of that registered trade mark shall be entitled to prevent all third parties not having his consent from using during trade, in relation to goods or services". Thus, on the one hand, trade mark rights are protected from the unlawful use of third parties, but, on the other hand, this could be treated as an obstacle to the free movement of goods. "Like any secondary legislation, however, the directive must be interpreted in the light of the Treaty rules on the free movement of goods" (*Bristol-Myers Squibb v. Paranova A/S* [1996]). In order to reconcile these two rights, i.e. the

[1] The numbering of articles in the EEC Treaty was changed in the TFEU.

[2] First Trade Mark Council Directive 89/104/EEC was adopted in 1988. Second Trade Mark Council Directive 2008/95/EC was adopted in 2008. Third Trade Mark Directive 2015/2436 was adopted in 2015.

protection of a trade mark and free trade, "the exhaustion of rights doctrine" is applied, which means that if goods under the trade mark have been placed on the market in one Member State with the consent of the owner of the trade mark, traders may acquire these goods in one Member State and sell them in another Member State without infringing on the rights of the owner of the trade mark. At a basic level, the exhaustion of rights doctrine, also known as the "first sale doctrine" (Calboli, 2002, pp. 47–48), prohibits the holder of an intellectual property right from exercising rights over a good or service once it is sold. The exhaustion of rights doctrine was established in Article 7 of the First Trade Mark Directive: "[t]he trade mark shall not entitle the proprietor to prohibit its use in relation to goods which have been put on the market in the Community under that trade mark by the proprietor or with his consent" (First Council Directive 89/104/EEC, pp. 1–7).

As "[t]he doctrine of exhaustion of trademarks is seen as a limitation to […] rights of the trademark proprietor" (Dobrin & Chochia, 2016, pp. 28–57) the problem lies in the different territories within which the doctrine is valid. For example, the exhaustion of rights doctrine can apply to national, regional and international level. Depending on the territorial level, product bearing the trade mark can be exhausted only in a specific territory. This could lead to the partitioning of national markets and restricting the trade between Member States of the EU. Therefore, the European Court of Justice (ECJ) through its jurisprudence and in line with Article 7 of the First Trade Mark Directive has clarified that the Community-wide exhaustion doctrine applies to the EU, i.e. regional level.

According to Advocate of the Court of Justice of the European Commission Nial Fennelly, the doctrine of Community exhaustion together with the notion of the specific subject-matter of each intellectual property were developed by the European Court of Justice in order to reconcile the conflict between Community free movement rules and national intellectual property rights (Fennelly, 2003, p. 33).

As the main purpose and the primal specific subject-matter of the trade mark is to guarantee its origin, the problem can accur when functions of trade mark are extended. In this case, more activites of the parallel importer who repackages increase the risk of damaging the specific subject-matter of the trade mark (Gross, Harrold & Smith, 2002, pp. 497–503). The ECJ has already "accepted that a trademark's communication, investment and advertising functions could be relevant to preventing the on-sale in the EEA of genuine goods. An analysis of the ECJ jurisprudence of the last two decades shows that the ECJ tends to extand the functions of the trade mark" (Robinson, Pratt & Kelly, 2013, p. 731).

Since the ECJ was assigned "the difficult task of resolving issues resulting from the inherent complexities of the subject-matter and overcoming fundamental differencies in national attitudes toward the underlying objectives of trademark protection" (Malliaris, 2010, p. 45), the balance between the free trade of goods and the protection of the trade mark was highlighted in numerous decisions of the ECJ.

The free movement of goods includes the parallel import of products. Parallel importers are treated as legal traders who acquire goods in one Member State and sell them in another Member State not through official distribution channels as the prices of goods in different Member States differ (Hays, 2004, p. 821). In some cases, in order to enter another market, the necessity to repackage the product arises, e.g., to meet requirements of the local language or to change the size of the package. When repackaging the product, the issue of the infringement of the trade mark should also be dealt with. The balancing of the interest of parallel importers and the trade mark when repacking products has been taken into consideration in many ECJ cases and ECJ considers that "a trademark right cannot be asserted to prevent the entry of pharmaceuticals even when the importer purchases the right holder's product and repackages it for resale in another state" (*Pfizer, Inc. v. Eurim-Pharm GmbH* [1981]). The ECJ has solved the tension between the owners of the trade mark and parallel importers in a series of decisions. "The European Court of Justice chose to favour the free movement of goods between member states at the expense of intellectual property rights" (Forrester & Nielson, 1997, pp. 11–37). Finally, in the case of *Bristol-Myers Squibb v. Paranova A/S*, ECJ proposed five BMS conditions according to which the parallel importer could repackage the product without the infringement of the rights of the trade mark proprietor:

> *The trade mark owner may legitimately oppose the further marketing of a pharmaceutical product where the importer has repackaged the product and reaffixed the trade mark unless: (1) it would contribute to the artificial partitioning of the markets; (2) it is shown that the repackaging cannot affect the original condition of the product inside the packaging; (3) the new packaging clearly states who repackaged the product and the name of the manufacturer; (4) the presentation of the repackaged product is not such as to be liable to damage the reputation of the trade mark and of its owner; (5) the importer gives notice to the trade mark owner before the repackaged product is put on sale, and, on demand, supplies him with a specimen of the repackaged product.* (*Bristol-Myers Squibb v. Paranova A/S* [1996])

In this respect, the owner of the trade mark cannot prevent the parallel importer from selling the pharmaceutical product which was put on the market in another Member State by the owner or with his consent, even if that importer repackaged the product and reaffixed the trade mark to it without the owner's authorisation. The ECJ explained that the parallel importer could repackage the pharmaceutical product and this would not constitute an infringement of the rights of the trade mark owner if all five BMS conditions were satisfied.

This article focuses on one sensitive aspect of repacking—does a parallel importer repackaging pharmaceutical products have the right to rebrand them using the trade mark that already exists in an export country? One the one hand, if parallel importers were allowed to rebrand freely without any restrictions, probably the rights of trade mark owners who invested in trademarks could be infringed. On the other hand, if rebranding was not permitted at all, this could constitute a hindrance to the free movement of goods (Hays, 2004, p. 821). Thus, most conflicts between parallel importers and trade mark owners have been solved by the ECJ by providing principles, guidance and explanations. However, not all issues have been dealt with as some of them have been left for national courts to be determined. One of the five BMS conditions is objective necessity to repackage the product. Nonetheless, the concept of objective necessity has not been defined by the uniform legislation of the EU (Dryden & Middlemiss, 2003, pp. 82–89); therefore, a national court of each Member State may make a decision which is not harmonised with the decision of a court of another Member State. Having analysed the decisions of other Member States, in the case of *Speciality European Pharma Ltd. v. Doncaster Pharmaceuticals Group Ltd & Anor* [2015], Lord Justice Floyd made a conclusion that "in any event, whilst entitled as decision to great respect, they are not binding on us". In the light of the above discussion, this article will analyse the jurisprudence of national courts and will draw up criteria under what circumstances parallel importers are entitled not only to repackage but also to rebrand the product. Criteria set in different Member States shall be compared and evaluated. As decisions of national courts have not been the focus of scholarly analysis so far, this paper could be of great help to practitioners.

2. The subjective criterion—the intention of the trade mark proprietor of artificial partitioning of the market

Each manufacturer of pharmaceuticals decides whether the same products shall be marketed in all Member States with the same trade mark or different trade mark. For centrally authorised products, it is mandatory to market the product in all Member States of the EEA under the same trade name, but nationally authorised products could be marketed in different countries with different trade marks (Commission Communication 98/C 229/03). These differences could occur due to the national language requirement. Article 63 of Directive 2001/83 requires that the relevant information on the packaging and on the patient information leaflet should appear "in the official language or languages of the member state where the product is placed on the market" (Directive 2001/83). For example, Astra Zeneka markets the stomach acid-lowering product Losec throughout the EU, but uses the brand name Mopral in France (because of the meaning of *I'leau sec*). Pfizer markets Norvasc in most Member States, but calls it Norvas in Spain because *c* cannot end a word in Spanish (Bjarnam, 2007).

It should be also noted that in some countries the Cyrillic alphabet is used. So, the manufacture and the marketing authorisation holder may decide to use a different trade mark for the same product.

The first case handled by the European Court of Justice was *Centrafarm BV v. American Home Products Corporation* in 1978. American Home Products Corporation (USA) marketed a pharmaceutical product which bore the trade mark Serenid in the United Kingdom and the same product named the trade mark Seresta in Belgium, Luxembourg and the Netherlands. The parallel importer Centrafarm bought products named Seredin in the United Kingdom, but repacked and renamed them Seresta. American Home Products Corporation sought to stop the newly branded pharmacies and applied to the Court of the Netherlands, whereas the Court of the Netherlands applied to the ECJ for a preliminary ruling. In the case of *Centrafarm BV v. American Home Products Corporation* [1998], the ECJ stated that only the owner of the trade mark can guarantee the identity of the origin of the product by affixing the trade mark, whereas the third parties are not allowed to put the trade mark:

> *The proprietor of a trade-mark which is protected in one Member State is justified pursuant to the first sentence of Article 36 in preventing a product from being marketed by a third party even if previously that product has been lawfully marketed in another Member State under another mark held in the latter state by the same*

> *proprietor. Nevertheless, such prevention may constitute a disguised restriction on trade between Member States within the meaning of the second sentence of Article 36 of the Treaty if it is established that the proprietor of different marks has followed the practice of using such marks for the purpose of artificially partitioning the markets.* (*Centrafarm BV v. American Home Products Corporation* [1998])

In its first decision regarding the rebranding of pharmaceutical products, the ECJ not only stated that the third parties cannot affix a trade mark but it also emphasised that if a manufacturer intends to partition the market artificially, the hindrance to use a trade mark by the third parties cannot be grounded. However, the Court pointed out that in some cases rebranding could be justified. Thus, the subjective criterion was determined. A parallel importer must prove that a trade mark owner created a few trade marks in different countries in order to partition the market artificially. For example, the use of a different package size is a common practice, which contributes to a partitioning of the markets, particularly in countries where national rules authorise only packages of particular size (Seville, 2016, p. 424). As Advocate General Jacobs states:

> *In* [Centrafarm v. American Home Products] *the Court indeed made it clear that, where the trade mark owner uses different marks in different Member States for the same product, a parallel importer is not entitled to substitute one mark for the other unless the use of different marks is deliberately intended to partition the markets.*[3]

The Court's initial approach to repacking was based entirely on the interpretation of the EC Treaty and relevant case law. Since these earlier cases were decided, the Trade Mark Directive has come into force, requiring significant harmonisation of national trade mark law (Seville, 2016, p. 425), "here the court appears to contemplate a subjective test where that conduct consists of having different trade marks for different Member States" (Norman, 2014, p. 452).

Even though the ECJ stated that it is permitted for manufacturers to use different trade marks in the Member States, this could lead to an artificial partitioning of single markets, which could be treated as an obstacle for free trade and could be treated as a legal ground for rebranding. Consequently, the question has been left open and national courts have been authorised to determine whether there is an artificial partitioning of the market when selling the same products under different trade marks or not.

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[3] See the opinion of A.G. Jacobs in joined Cases C-427, 429 and 436/93 *Bristol-Meyers Squibb v. Paranova* [1995], p. 84.

3. The right to rebrand pharmaceutical products due to objective necessity

In 1988, the Council adopted the First Trademark Directive to approximate laws relating to trademarks of the Member State (First Council Directive 89/104/EEC). The issue was whether the ECJ would continue its interpretations accepted prior to the Trade Mark Directive. In *Bristol-Myers*, the ECJ stated that:

> [I]*n accordance with the case law, Article 7(2) of the directive must therefore be interpreted as meaning that a trade-mark owner may legitimately oppose the further marketing of a pharmaceutical product where the importer has repackaged it and re-affixed the trademark, unless the four conditions set out in the Hoffmann-La Roche judgment* […] *have been met.* (the case *Pharmacia & Upjohn SA v. Paranova A/S* [1999])

In other words, repacking was allowed if certain conditions were met even after the First Trade Mark Directive had been accepted.

The issue whether a parallel importer can rebrand a pharmaceutical product was also decided by the ECJ in the case *Bristol-Myers Squibb v. Paranova A/S* [1996], twenty years after the first decision in *Centrafarm B v. American Home Corporation*. The *Upjohn* case was handled after the First Trade Mark Directive had been accepted. Even though after the First Trade Mark Directive had been accepted, the ECJ justified repackaging of pharmaceutical products in numerous cases. Thus, in this case, the question of rebranding was decided. According to the facts of the *Upjohn* case, the dispute occurred between the Upjohn Group and Paranova. The Upjohn Group marketed the pharmaceutical product clindamycin under the trade mark Dalacine in France, the trade mark Dalacin in Denmark, and the trade mark Dalacin C in other countries (e.g., in Greece). Paranova purchased clindamycin in France, marketed by the Upjohn Group under the trade mark Dalacine, and Dalacin C in Greece. Paranova repacked these products and marketed them in Denmark under the trade mark Dalacin. The ECJ ruled:

> *It follows that it is for the national courts to examine whether the circumstances prevailing at the time of marketing made it objectively necessary to replace the original trade mark by that of the importing Member State in order that the product in question could be placed on the market in that State by the parallel importer. This condition of necessity is satisfied if, in a specific case, the prohibition imposed on*

> *the importer against replacing the trade mark hinders effective access to the markets of the importing Member State. That would be the case if the rules or practices in the importing Member State prevent the product in question from being marketed in that State under its trade mark in the exporting Member State. This is so where a rule for the protection of consumers prohibits the use, in the importing Member State, of the trade mark used in the exporting Member State on the ground that it is liable to mislead consumers. In contrast, the condition of necessity will not be satisfied if replacement of the trade mark is explicable solely by the parallel importer's attempt to secure a commercial advantage.* (*Pharmacia & Upjohn SA v. Paranova A/S* [1999])

This was the first time when the ECJ decided in its jurisprudence that there exists a possibility to replace a trade mark with another trade mark if it is deemed necessary. The Court emphasised that a parallel importer is entitled to rebrand the product if otherwise effective access to the market would be hindered. The necessity shall be decided by national courts. But, in any case, the ECJ provided a legal ground for the replacement of trade marks. Thus, it is not prohibited, as rebranding does not constitute the infringement of a trade mark owner's rights. The ECJ extended the same rule to the right to repack a parallel imported product and to replace the trade mark if it is necessary. Every country in the EU determines the criterion of necessity for rebranding.

Even though the decision regarding the five conditions was intended for the repacking and naming of a product, in the case of rebranding, a parallel importer must also satisfy all these five conditions. The trade mark owner may not object to the rebranding of products if effective access to the market cannot be reached without it. Also, rebranding might be necessary if there is a possibility for a parallel importer to be excluded even from a part of the market.

The ECJ have made a lot of decisions in order to solve tensions between parallel importers and trade mark owners. For the first time, rebranding of pharmaceutical products was taken into consideration in the case *Centrafarm BV v. American Home Products Corporation*, where the Court stated that rebranding is not allowed unless owners of trade marks intend to partition the market artificially. In the second rebranding case *Pharmacia & Upjohn SA v. Paranova A/S*, the ECJ stated that rebranding is allowed if there exists objective necessity. However, the ECJ has not set a clear criterion as to when rebranding would be justified. It seems that the ECJ is concerned by the manufacturer's ability to protect its trademark or to invest in it. In addition, the courts of appeal can more

positively assess the position of the manufacturer that different packages of medicine are not intended to create barriers to parallel imports, but rather serve as a strategy for brand capitalisation for local markets (Bird & Chaudhry, 2010, p. 719). Consumers' hostility towards a particular drug practice, for example, the packaging of a medicine is over-labeled, or the attitude against a particular name can be recognised as a legitimate basis for repackaging, i.e. the criterion of objective necessity would be proven (Fuhrmeister, 2008).

Consequently, this question has been left for national courts of the Member States. The national courts of the Member States are not bound to adopt similar decisions according to the same factual circumstances. National courts are independent and it could happen that a court of one Member State decides that necessity exits, whereas a court of another Member State comes to a conclusion that there is no necessity to rebrand a product. These different evaluations of the necessity criterion could mean that the TFEU fundamental articles of the free movement of goods are applied in different ways, but, in other cases, this could condition hindrances to the free movement of goods. In the light of the above discussion, the following part of the paper focuses on the comparison of decisions of national courts. In addition, different criteria are presented which could be treated as objective necessity to rebrand pharmaceutical products.

4. Rebranding on the grounds that a trade mark from an export country is not allowed in an import country

In the case of *Roche AB v. Orifarm AB* [2006], the Supreme Court of Sweden addressed the issue of interim measures in reference to the claim of Roche against Orifarm. According to facts of the case, Roche marketed a drug, the active substances of which were levodopa and benserazide for Parkinson's disease under the trade mark Madopark Quick mite in Sweden and Madopar 62.5 Dispersible in the UK and Ireland. Orifarm parallelly imported the drug Madopar 62.5 Dispersible from the UK and Ireland into Sweden and rebranded them to Madopark Quick mite, because "the Swedish Medical Products Agency (MPA) decided that is not allowed to use the suffix 62.5 Dispersible in Sweden as the use of short abbreviations and suffixes, which do not carry an established and relevant meaning, is not acceptable as part of a name for a pharmaceutical product" (*Roche AB v. Orifarm AB* [2006]). For this reason, the parallel importer Orifarm was not allowed to use the trade mark Madopar 62.5 Dispersible from the export country. Roche brought an action against Orifarm stating that

Orifarm had infringed on Roche's registered trade mark. The question of interim measures was raised by the Court of the First and Second Instances. Both instances rejected the request of Roche. Finally, the question was dealt with in the Supreme Court of Sweden which, having analysed relevant legislation and court practice, stated that:

> [A]*ccording to the principle of free movement of goods there are exceptions to the principle under certain conditions that gives the importer a right to change the label or change the packaging before a product is marketed in the country of import. One of these conditions is when it is objectively necessary in order for a parallel trader to gain effective access to the market in the country of importation. According to the Supreme Court, Orifarm does not have the right to take broader measures than necessary to gain access to the Swedish market. Despite the fact that it has been necessary for Orifarm to rebrand the product it is uncertain that Orifarm automatically had the right to rebrand the product with Roche's protected trade mark. However, the issue of patient safety and resistance from consumers to a product marketed under a different name than the one marketed by the trade mark proprietor has to be considered* […] [T]*he Supreme Court found it likely that Orifarm's rebranding was necessary to gain effective access to the Swedish market. (Roche AB v. Orifarm AB* [2006]*)*

Thus, first of all, the parallel importer Orifarm could not use the trade mark Madopar 62.5 Dispersible, because the suffix 62.5 Dispersible was not allowed. However, the parallel importer must rebrand the product. The Court evaluated other theoretical possibilities to rebrand the product. The name Madopar could not be used either because it had been already taken for another prescription drug with a different content and composition of different pharmaceutical form, and with different routes of administration. Another alternative to use Madopar with a different suffix could meet a consumers' resistance and could confuse them to use another suffix for the same products. In *Roche AB v Orifarm AB* [2006], the Court stated that even though at the first glance it seemed that nobody could reaffix the other proprietor's trade mark, but, under objective necessity, this could be allowed. The Court examined the necessity criterion and decided that the necessity criterion had been met because the rules in the importing Member State prevented the marketing of the product with the trade mark from the exporting Member State. The usage of another trade mark could infringe on the rights of consumers and health care.

5. Rebranding on the grounds that a trade mark in an export country could be confused with a trade mark in an import country

The conflictual situation was handled in the case of *Roche v. Paranova* [2001] by the National Swedish Court. The facts of the case are as follows: Hoffman-La Roche sold a pharmaceutical under the trade mark Alganex in Sweden and under the trade mark Tilcotil in Spain. Paranova acquired pharmaceutical products in Spain named Tilcotil and rebranded it to Alganex and started selling them in Sweden. Hoffman-La Roche applied to the court due to the infringement on trade mark rights. The Court decided that the rebranding had been necessary because Tilcotil could be confused with an earlier registered trade mark in Sweden, Tiotil. Without rebranding, the parallel importer could not enter the Swedish market, so it was held objectively necessary to rebrand the product.

The ECJ stated a plain condition according to which rebranding is allowed in the case of the existence of objective necessity. National courts handling particular cases must evaluate whether objective necessity exits. Only when the parallel importer cannot enter the market with an original trade mark, the change of the trade mark is allowed. One of the objective reasons to change an original trade mark is when this trade mark could be confused with an earlier registered trade mark in the import country, because, without changing the trade mark, the consumers could be misled and this could jeopardise public health.

A similar situation took place in Germany. According to facts of the *Zantag/ Zantig* [2002] case, the plaintiff sold medicine for the regulation of gastric acid secretion named Zantac in Austria and other countries and under the name Zantic in Germany, because the trade mark Santax was already used in Germany and could confuse consumers as these trademarks seem similar. The defendant acquired medicine Zantac 150 Mg Film Tablets from Austria, repacked them and rebranded them to the trade mark Zantic 150 Film Tablets and sold in Germany. The Court pointed out that it is important to evaluate the objective situation why the trade mark owner could not use the trade mark Zantac in Germany. The trade mark Zantac had been rejected in Germany because of the earlier trade mark Santax, so the same reasons would have hindered the defendant from the usage of Zantac. In order to evaluate whether the defendant was allowed to rebrand the product, objective necessity should have been taken into consideration. If the defendant—the parallel importer—could not have entered the German market without changing the trade mark, this could have been treated as the necessity to rebrand. Had a parallel importer been prohibited to change a trade mark, it would

not have entered the German market. The hindrance to the use of an original trade mark does not exist solely because a manufacturer uses a different trade mark. In the discussed case, an earlier domestic trade mark Santax precluded the marketing of the medicinal product under the trade mark of the state of origin Zantac, so the defendant was allowed to change the trade mark to Zantic.

The practices of the national courts of Sweden and Germany are similar. If a trade mark from an export country could be confused with an already existing trade mark in an import country, this could be treated as objective necessity to rebrand the product.

6. A parallel importer's entry into the full market

6.1 An artificial partitioning of the market excluded a parallel importer from the submarket of the same product, Klacid Pro, only with a different dosage of the first day

The applicant, a pharmaceutical company, markets the medicines Klacid and Klacid Pro in Germany. The medicines are antibiotics containing the active substance clarithromycin. In Spain, the product is sold under the name Klacid 250 Comprimidos. The medicinal product Klacid Pro is distributed exclusively in Germany. The medicinal products Klacid and Klacid Pro have an identical composition and indication, and are intended for the same patient group. They differ only in the dosage instructions for the first day of ingestion, and the package is different as well. Selling Klacid Pro yields larger profit.

The defendants in the *Klacid PRO* [2008] case were parallel importers of medicinal products. They imported the medicinal product Klacid 250 Comprimidos from Spain and sold them in Germany under the rebranded name Klacid Pro. The Federal Court allowed rebranding because it was an artificial partitioning of the market. An artificial market partitioning is to be expected when a medicinal product is marketed in the Member State of export only with a dosing notice and in the importing Member State under different trade marks with different dosing instructions. The parallel importer is thus excluded from one of the submarkets by distributing the identical medicinal product with different brands and dosage indications in the importing Member State. The drugs marketed under the names Klacid and Klacid Pro in Germany are identical in their composition and indication. They are also intended for the same patient group without any differences. They differ only in dosage instructions. By restricting the distribution of Klacid Pro to Germany, the parallel importer is

prevented from the distribution of a correspondingly designated medicinal product with double dosage on the first day without the use of the brand name. The exclusion from this submarket justifies the assumption of an artificial market partitioning without the possibility of Klacid of the Spanish origin being marketed domestically under the designation.

6.2 A parallel importer's access to the full market including submarkets of less than 10 percent of Regurin trade mark market

Reconciling the interests of a parallel importer and trade mark owners, in *Bristol-Myers Squibb v. Paranova A/S*, the ECJ stated that a trade mark owner cannot oppose repacking if this leads to an artificial partitioning of the market. "Partitioning of the markets would exist if the importer were able to sell the product in only part of his market". Madaus GmbH produced Trospium Chloride and sold them under the trade mark Céris in France, Urivesc in Germany and Regurin in the United Kingdom. The distributor of the pharmaceutical product in the UK was Speciality European Pharma Ltd. In the UK, the prescriptions of medicines are both Regurin and Trospium Chloride. The UK rules allow a prescription written for Regurin. Doncaster Pharmaceuticals imported Céris and Urivesc and replaced them with the trade mark Regurin. "[I]t is [...] unclear when the rebranding of a product with the trademark owner's mark will not be considered necessary to access the UK market and therefore lawful. The value of a trademark owner's rights in a parallel import situation continues its steady decline" (Gilbert, Wilson & Waller, 2015). If read in isolation, the provisions of the TM Directive and CTM Regulation would provide the plaintiff, in circumstances such as these, with a straightforward infringement claim (INTA, 2017, p. 607). Speciality European Pharma brought a claim against Doncaster Pharmaceuticals. In the case of *Speciality European Pharma Ltd v. Doncaster Pharmaceuticals Group Ltd & Another* [2015], the Court said that Doncaster Pharmaceuticals had the right to rebrand:

> *Effective access to the market is not achieved by being able to place some goods on the market* […] *It may be necessary to re-brand where the parallel importer is not excluded from the whole of the market, but is merely excluded from a substantial part of it or from a significant proportion of consumers* […] *In determining whether it is necessary to re-brand, the court must consider what alternatives exist for the parallel importer, and whether they are realistic.*

Doncaster could not compete with generic products as generic products were much cheaper, also they could not get the market of Regurin if they were named

under Trospium Chloride. Finally, it would not be realistic that doctors would prescribe Doncaster trade mark, so it was decided that it was necessary to rebrand the product. The Court explained that 8.61% of the market was deemed substantial and rebranding was allowed:

> *The decision rested on a detailed analysis how the English market operates* (INTA, 2016, p. 611). *Where a court can establish artificial partitioning of the market, the rights of the trade mark owner are trumped by the principle of free movement of goods. This ruling may be welcomed by pharmacy importers seeking to gain or improve their access to markets by using third party's trade marks.* (Stretch, 2015)

It is worth mentioning that the Court of the First Instance decided that rebranding was not permissible, however, the Court of Appeal reversed the decision. In addition, this was not a decision made by the Supreme Court. It would be very interesting to find out if courts of other European Member States have come to a similar outcome when deciding and evaluating objective necessity. However, in the English ruling, one may also detect a greater sympathy than is typically displayed by continental EU courts for the defendant's inability to access a relatively small part of the overall market (INTA, 2016, p. 611).

Three cases from foreign jurisdiction were mentioned in the case *Speciality European Pharma v. Doncaster Pharmaceuticals*. The facts of these cases are similar but the decisions as to what is objective necessity differ. It should be noted that the Court of the First Instance in the UK indicated that there had been no objective necessity to rebrand. Only the Court of Appeal overruled the decision and held that there had been objective necessity to rebrand the product to the trade mark Regurin existing in the import country.

In Sweden, the Court of the First Instance decided that there had been no objective necessity to rebrand. According to the facts of the case handled by the Stockhom City Court in 1999, Aventis Pharma AB sold pharmaceutical products in Sweden under the name Imovane and in Spain under the name Limovan. Paranova Läkemedel AB purchased drugs under the trade mark Limovan from Spain and rebranded them under Imovane and sold in Sweden. The Stockholm Court decided that the existence of other non-patented drugs which were marketed under different names supported the conclusion that a marketing campaign might enable sales to be made under a different name. There were no Swedish rules that hindered the marketing of the pharmaceutical product under the trade mark Limovan. Also, in the case of *Aventis Pharma AB v. Paranova Läkemedel AB* [2001], the Stockholm Court stated that it is

irrelevant that most prescription practices in Sweden are based on the brand name.

In a similar case of *Orifarm A/S, Orifarm Supply A/S v. Merck Sharp & Dohme Corp, Merck Sharp & Dohme B.V.* [2014], in Denmark, three companies in the Merck group (hereinafter referred to as Merck) claimed *inter alia* that the parallel importer Orifarm was unentitled to market Merck's medicinal product in Denmark under the trademark Cozaar. The Maritime and Commercial Court assessed whether circumstances on the Danish market prevented Orifarm from marketing the product under the name Loortan, which was the name applied to the product by Merck in the export state. Thus, the Court assessed whether Orifarm's relabeling from Loortan to Cozaar was legitimate. The facts of the case showed that the product was marketed and sold on the Danish market under both the Danish trademark Cozaar and the Italian trade mark Lortaan. Furthermore, the data showed that the sale of the product under non-Danish trademarks in numbers was nearly as large as the sale under the Danish trade mark Cozaar. Consequently, the Court found that relabeling was not objectively necessary for Orifarm's effective access to the Danish market and relabeling was, therefore, an infringement of Merck's trade mark rights. The consequence of the decision is that a parallel importer cannot invoke the condition of necessity in the support of relabeling a parallel-imported medicinal product if the actual sales show that it has actually been possible in the import state to market the product under a trademark other than that of the manufacturer's. Due to the facts in the case, including the evidence relating to the actual sale, the Maritime and Commercial Court did not get the opportunity to rule on whether the relabelling could have been deemed objectively necessary for the effective access to the market if no actual sale had occurred in Denmark under another trademark than the manufacturer's.

In principle, a parallel importer might successfully claim objective necessity where the patient group and the doctors are reluctant to purchase, ingest and/or prescribe the medicinal product under a trademark other than the one used by the original manufacturer in Denmark (*Orifarm A/S, Orifarm Supply A/S v. Merck Sharp & Dohme Corp, Merck Sharp & Dohme B.V*. [2014]).

When comparing these three cases from the UK, Sweden and Denmark, the factual circumstances look very similar. The parallel importer wanted to rebrand in order to get assets. Even though the prescription was according to the trade mark, the parallel importer could not enter the market of Limovane, but this was not treated as an obstacle and objective necessity to rebrand. Thus, it is obvious that the decisions of the Member States' national courts, when

interpreting the same EU Treaty, the same Trade Mark Directive, applying the same ECJ decisions and evaluating objective necessity to rebrand, come to different conclusions. Uniformity could be achieved only if the ECJ will give an autonomous meaning to objective necessity criterion; otherwise, courts of different countries might come to different decisions.

7. Conclusions

In 1978, the ECJ decided for the first time that rebranding could be allowed due to a subjective criterion. In the case *Centrafarm BV v. American Home Product Corporation*, the ECJ stated that rebranding could be allowed if the proprietor of different trade marks used these marks for the purpose of an artificial partitioning of the market.

In the second case *Pharmacia & Upjohn SA v. Paranova A/* [1999] ECJ, the decision was made, according to which there could exist a possibility to replace a trade mark with another trade mark due to objective necessity. The Court emphasised that rebranding is permissible if effective access to the market would be hindered otherwise. But the necessity criterion should be also determined by the national courts of the Member States.

National courts are independent. In some cases, objective necessity is determined on similar grounds such as the existence of a trade mark in an export country (for example, Santax, Tiotil) which could be confused with a trade mark from an import country (for example, Zantac, Tilcotil).

But it could also happen that the court of one Member State states the existence of necessity, whereas the court of another Member State decides that the necessity to rebrand does not exist. Such different evaluations of the necessity criterion could mean that the TFEU fundamental articles of the free movement of goods are applied in different ways, and in some cases, this could constitute hindrances to the free movement of goods. A different interpretation is seen in the decision made by the UK Court regarding the rebranding of the product from Ceris and Urivest to Regurin, which was treated as objective necessity even though the market was 8.61%, while in similar decisions by the courts in Sweden it was not allowed to rebrand the product from Limove to Imovane and in Denmark it was allowed to rebrand the product from Loortan to Cozaar. It is obvious that the decisions of courts interpreting the same Treaty, the same Directive and applying the same ECJ decision would come to different conclusions. There

is no uniformity. This could be achieved only if the ECJ gave an autonomous meaning to objective necessity; otherwise, courts of different countries might come to different decisions and the free movement of goods might be hindered.

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