Parallel Import of (Re)branded Generic Medicines: a Brand New Day?

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Picture this: company A, a multinational pharmaceutical concern, owns a registered trademark in territory X. In this territory, one of the divisions of company A markets a pharmaceutical product under the registered sign. In territory Y, another division commercialises an unbranded version of this product at a significantly lower price. Company B smells an opportunity. They purchase the unbranded version of the product in territory X, import it into territory Y, repackage it, rebrand it under the registered sign, and sell it for a price lower than that charged by company A, but still with a comfortable profit margin. Does this constitute trademark infringement? The question may seem simple enough, but answering it requires a foray into the complex, multifaceted doctrine of trademark exhaustion, all the while taking due account of internal market considerations. On the basis of two analogue fact sets, the Brussels Court of Appeal filed a preliminary reference on this issue with the European Court of Justice (ECJ) in May 2020. The ongoing waiting game for the Opinion of Advocate General Szpunar and the ensuing ECJ judgment provides us with the perfect opportunity to delve into the debacle.

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1 Parallel importation of pharmaceutical products

In the example above, company B is a parallel importer. Such companies purchase products at a relatively low price in a certain territory and redistribute them in another, usually after having repackaged and relabelled the product. Usually, the initial manufacturers object to parallel importation, since it undercuts their prices in the importing territory, and thus interferes with their own commercial strategy.

Throughout the years, trademark law has been the primary tool used to curtail the effects of parallel importation. A trademark offers its owner the right to prevent third parties from using the registered sign—or a similar one—without their consent in the course of trade under certain circumstances, such as in case the goods at issue are identical or similar and the existence of a likelihood of confusion on the part of average consumers may be proven. As parallel importation in the circumstances described above entails the (re)affixing of signs, it makes sense for the initial producers to seek to rely on their registered trademarks vis-à-vis parallel importers.

In accordance with the doctrine of exhaustion, trademarks do not allow their owner the right to object against the use of 'their' signs in relation to goods that have been put on the market in the European Economic Area (EEA) under that trademark by the owner or with their consent. Once the product has been sold in the EEA, the owner is deemed to have realised the economic value of the trademark and their right is considered to have been 'exhausted'. This prevents them from invoking the trademark to oppose the further commercialisation. Yet, if the owner has legitimate reasons therefor, trademark

protection may still be invoked. Such reasons include situations where the condition of the products is changed or impaired after the first sale has taken place.

The free movement of goods within the EU internal market adds an important dimension to the debate. Article 36 TFEU permits proportionate prohibitions or restrictions on imports between EU Member States that are justified on grounds of the protection of industrial and commercial property, provided they do not constitute a means of arbitrary discrimination or a disguised restriction on trade between Member States. The question is therefore whether the reliance on trademark protection in parallel import cases violates the free movement of goods. The matter is not at all clear-cut. It is therefore unsurprising that, over the years, the appropriate scope of the doctrine of exhaustion has resulted in a string of case law. In particular, the ECJ judgments in the cases *Hoffmann-La Roche* (Case C-102/77), *Bristol-Myers Squibb (BMS)* (Joined Cases C-427/93, C-429/93 and C-436/93), *Upjohn* (Case C-379/97) and *Boehringer II* (Case C-348/04) are noted. These cases all concern the parallel importation of pharmaceutical products that have first been sold under the trademarked sign.

The BMS case sets five cumulative conditions for the repackaging and rebranding of pharmaceutical products to be considered legitimate, since then referred to as the 'BMS conditions'. First, it must be proven that the owner's reliance on the trademark(s) at issue would contribute to the artificial—not necessarily deliberate—partitioning of the markets between Member States. This will in particular be the case if the packaging in separate territories varies to the extent that the importer *must* repackage in order to be able to market the product. The parallel importer may only replace the sign used by the trademark owner in the export territory by the sign used in the import territory if it is objectively necessary to do so. Second, the repackaging may not affect the original condition of the product. Third, the new packaging must clearly and comprehensibly indicate the repackaging company and the initial manufacturer. Fourth, no reputational damage for the trademark (owner) may arise, and, finally, the importer must notify the owner of their intention to commercialise the product and provide a specimen upon request.

2 Factual background

This brings us to the facts leading up to the preliminary references under review in this blogpost. The protagonists are, on the one hand, Belgian parallel importers Impexeco (Case C-253/20) and PI Pharma (Case C-254/30), and, on the other hand, the pharmaceutical concern and trademark owner Novartis (Cases C-253/20 and C-254/30). The former case concerns the trademark Femara, pertaining to a hormonal breast cancer treatment. An identical product—both in composition and therapeutic effect—is marketed under the generic name Letrozol by Novartis' division Sandoz. The latter case relates to the trademark for Rilatine, a central nervous system stimulant. Its generically labelled counterpart, methylphenidate, is again marketed by Sandoz. While the factual specifics of both cases differ slightly, their essence is the same: the parallel importer purchases Sandoz' product abroad (in the Netherlands), imports it into Belgium, affixes the Femara/Rilatine trademark and goes on to commercialise the product under that name in Belgium, against a price below the one charged by Novartis. What sets these cases apart from earlier parallel import disputes is that the trademarks affixed in the context of repackaging do not figure on the products as initially marketed in the export territory.

Novartis opposes the parallel importers' activities and files injunction proceedings with the Dutch-speaking division of the Brussels Commercial Court (since then rebranded as the Enterprise Court). The parallel importers counter that this constitutes an undue restriction of the free movement of goods. On 12 April 2018, the Court finds in favour of Novartis in both cases. The parallel importers must cease the infringement, on pain of a financial penalty. The decision is based on two primary grounds. First, the argument of exhaustion is not accepted, since the trademark has not been used on the products marketed by Sandoz. Second, the Court holds that Novartis' reliance on its trademarks does not result in any artificial market partitioning, considering that the market for generic medicines is separate from the market for branded medicines—and that, since the market segments are already distinct, no partitioning can take place. In this context, the Court refers to regulatory and medical considerations, differences in pricing and reimbursement, and the perception of the general public.

Interestingly, in March 2015, the President of the Brussels Commercial Court had already had the opportunity to rule on the (re)branding by parallel importers of products marketed by Sandoz, in relation to the trademarked signs Femara (again) and Co-Diovane. In those cases, it was found that the trademarks *had* been exhausted, and that the absence of separate market segments resulted in Novartis' reliance on its trademarks leading to artificial market partitioning.

In view of this contradictory case law, it should come as no surprise that the parallel importers filed an appeal against the 2018 first instance decision. On 25 May 2020, this led to two analogue interim judgments of the Brussels Court of Appeal, in which the Court refers three questions to the ECJ with a view of settling the (re)branding controversy.

3 Questions referred to the ECJ

The first question expressly refers to the free movement of goods and asks whether the objection by a trademark owner to the commercialisation of a repackaged pharmaceutical product that entails the affixing of a trademark may lead to artificial market partitioning if the manufacturer of the unbranded product and the trademark owner are economically linked. If this is the case, the second question asks whether the BMS conditions apply. Third, the Court of Appeal wishes to know whether the identical nature or therapeutic effect of the unbranded and branded product have a bearing on the answer to the other questions.

Since the 2020 judgment, the parties have filed written observations. Subsequently, the ECJ decided to forego an oral hearing and instead request additional observations from the parties on a number of topical questions. The next step, which is undoubtedly eagerly awaited by those involved as well as the EU IP community at large, is the Opinion of Advocate-General Maciej Szpunar.

4 Discussion

In a wholly on-brand move, Novartis submits that the first question should be answered in the negative, arguing that generic medicines and branded medicines are different products that operate in different market segments. In view of this, the second question need in their view not be answered.

Finally, Novartis deems the identical composition of the products and the economic links between the undertakings at issue to be irrelevant.

Conversely, the parallel importers submit—equally unsurprisingly—that the first question merits a positive answer. In this context, it is argued that the assessment should not take place on the basis of *product* markets, but on the basis of *territorial* markets. Moreover, the parallel importers consider that there is a single market for pharmaceutical practices, as doctors have the therapeutic freedom to prescribe either branded or generic medicines. Both types of medicines are interchangeable—the only potential distinction being the therapeutic efficacy of the product at issue. In this context, the parallel importers understandably stress that, in the national proceedings, the unbranded and branded products are the same. Consequently, they argue, the essential function of a trademark as a quality guarantee for consumers is safeguarded. In other words, the trademark still does what it is supposed to do, namely indicate the origin of the pharmaceutical product. Therefore, from an internal market perspective, the argument of the parallel importers appears to hold water. However, it bears reminding that, from a trademark law perspective, the first BMS condition requires the repackaging to be objectively necessary. Given that the parallel importers are free to commercialise the unbranded product in the import country—albeit presumably at a much more modest price—, it may be difficult to convince the ECJ of the objective need to use Novartis' trademarks in this particular case. Presumably, an important factor in the ECJ's reasoning will be whether the parallel importers may effectively access the market in view of the ubiquity of the branded product in the importing territory.

The interests at play are conflicting, the positions are diametrically opposed, and the commercial stakes are exceedingly high. As usual, the intersection between internal market law and intellectual property offers a choice opportunity for both the AG and the ECJ to leave their mark.

Note: Until the end of 2018, the author of this blog post was active as an associate at one of the law firms representing the parallel importers in the proceedings that lie at the basis of the pending preliminary references. In this capacity, she was involved in an earlier stage of these proceedings.