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Nothing new under the sun: parallel importers must still prove that it is objectively necessary to replace the original package of medicinal products

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This post perhaps is a bit off topic since it concerns parallel imports and trademark rights. Nevertheless it could be interesting for the readers since it relates to the the pharma industry.

Background

It is well established EU case law that a parallel importer of medicinal products may only replace the original package if it is deemed objectively necessary in order to effectively access the market in the importing state (see e.g. C-297/15, *Ferring*). When making such an assessment, the national courts must consider the circumstances prevailing at the time of marketing in the importing state. Importantly, it is the parallel importer who carry the burden of proving that replacing the original package is objectively necessary.

On 9 February 2019, new rules on medical products went into effect. The relevant rules, which are found in dir. 2011/62/EU (the so called Falsified Medicines Directive) and the Commission Delegated Regulation (EU) 2016/161 (together the "Safety Rules"), was part of an attempt from the EU to stifle falsified medicines disguised as authentic products. The new rules require, *inter alia*, that the packaging include security features that make it possible to control the authenticity of the medicine, to identify individual packages and also a device allowing verification whether the outer packaging has been tampered with.

In view of the new Safety Rules – requiring higher security measures than previously – parallel importers have increasingly been raising the argument that it would now, as a main rule, be deemed objectively necessary to replace the original package of medicinal products instead of carrying out less intrusive measures.

The case before the Swedish courts

Novartis AG ("Novartis") filed a lawsuit against Abacus Medicine A/S ("Abacus"), claiming that Abacus infringed its trademarks by replacing the original package of certain parallel imported medicinal products. Abacus defended itself *inter alia* by claiming that the regulatory changes required replacement of the original package in order for Abacus to avoid sanctions from the Swedish Medical Products Agency (the "MPA") and thus, making the replacement objectively necessary.

To support its position, Abacus invoked evidence in the form of guidelines from the MPA as well as information from the MPA's website. Abacus argued that the evidence should be interpreted as the MPA holding the position that the new Safety Rules meant that it was now necessary in most cases to replace the original package. The company also invoked correspondence with the MPA and the EMA – it had even applied to the MPA to get a decision concerning one of the products subject to the dispute, on whether the company needed to replace the original package in order to effectively access the Swedish market. The MPA dismissed the application on the grounds that it was not authorized to make such a ruling, due to the product being authorised through the centralized procedure, and therefore that the MPA considered the EMA to be the competent body. However, the MPA still informed Abacus (*obiter dictum*) in its decision that it indeed considered it necessary to replace the original package. Also, Abacus invoked the hearing of a quality specialist from a known Swedish pharmacy retailer, in support of how Swedish pharmacies would handle repackaged medicinal products, and an e-mail sent from the head of the Swedish Pharmacies' Association to the EU Commission, stating that if the parallel importer would retain the original packaging, that would raise suspicion with pharmacists and therefore proposing that replacing the original package should become the main procedure.

The judgment

After losing in first instance, Abacus appealed to the Swedish Patent and Market Court of Appeal (case number PMT 8284-20). As the first instance court, the Patent and Market Court of Appeal also ruled – by final and non-appealable judgment on 18 February 2022 – in favour of the trademark holder. The court held that the statements made by the MPA, in its guidelines (which are per se non-binding), on its website and in its decision to dismiss Abacus' application, could not be considered a definitive position of the MPA. Therefore, Abacus had not proved that the MPA's interpretation and implementation of the new regulations meant a general requirement for parallel importers to replace original packages of medicinal products, or that the MPA had requested that Abacus replace the original package of the products in order to sell them on the Swedish market. The court also ruled that neither the statements from the quality specialist, nor the e-mail from the head of the Swedish Pharmacies' Association proved that Swedish pharmacies would not distribute resealed or re-labelled packages, where the original package was retained, to patients.

The Court accordingly found, after reviewing Abacus' evidence that Abacus had not proven that it was objectively necessary to replace the original packages. Abacus had therefore infringed Novartis' trademarks. The reasoning in the judgment makes it clear that the Court is not of the opinion that the new Safety Rules calls for a change of the established case law concerning the parallel importers' burden to prove that repackaging is objectively necessary. It is still necessary that the parallel importer must satisfy a high standard of proof when claiming that such replacing is objectively necessary in order to effectively access the market in the importing state.

However, trademark holders should be aware that in a case between Novartis Pharma GmbH and Abacus Medicine A/S in Landgericht Hamburg, a request for a preliminary ruling by the ECJ was lodged on 23 March 2020. The questions referred to the ECJ, which can be found in full here, address the core question: can it lead to an artificial partitioning of the markets if the required safety features of original outer wrapping/original packaging can, in the event that the parallel trader retains that original packaging, be replaced in compliance with dir. 2001/83/EC 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? The case has been given the number C-147/20, and is currently listed as a case in progress. The Advocate General has now delivered an opinion in that

matter, which is very much in line with the view taken by the Swedish Court. The Advocate General thus opined that the parallel importer must prove, with concrete and specific evidence, that any visible traces resulting from for example an exchange of a security seal, would indeed cause such a strong resistance from the consumers so that the medicines repackaged in such way *de facto* would be prevented from accessing the market in the importing Member State. There would thus not, regardless of the new Safety Rules, be any change of the established main rule that parallel importers have to prove that it is objectively necessary in order to be allowed to replace the original package.

As it currently stands, it therefore remains to be seen whether the ECJ will provide further clarification on the possibilities for parallel importers to replace outer packaging without infringing trademarks in the future.

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