Repackaging and relabelling of parallel imports of medicinal products

Judgments of the Court of Justice of the European Union of 17 November 2022

On 17 November 2022, the Court of Justice of the European Union (CJEU) issued four important judgments on parallel imports of medicinal products in cases Novartis Impexeco, C-253/20 and C-254/20; Novartis Pharma, C-147/20; Bayer Intellectual Property, C-204/20; and Merck Sharp & Dohme and Others; C-224/20.

The Novartis Impexeco judgments, C-253/20 and C-254/20, relate to the repackaging and rebranding of generic medicinal products by parallel importers. The remaining three judgments analyse to what extent the rules on unique identifiers and anti-tampering devices for medicinal products can justify the replacement of the original packaging of parallel imported medicinal products.

The Novartis Impexeco cases

Background

Novartis marketed reference medicines Femara® (letrozole) and Rilatine® (methylphenidate) in the Netherlands and Belgium. Sandoz (then Novartis' generics division) marketed the generic versions of Femara® and Rilatine® (Letrozole Sandoz and Methylphenidate HC1 Sandoz) in the Netherlands. Parallel importers purchased the generic versions of the products in the Netherlands, repackaged them using the Femara® or Rilatine® brands and, subsequently, marketed them in Belgium as reference medicines.

Novartis applied to a Belgian court for injunctive relief, as it considered that parallel importers had infringed its trademark rights. The Court of first instance accepted Novartis' arguments and ordered the cessation of imports. The parallel importers appealed the decision, and the Court of Appeal decided to refer several questions to the CJEU for a preliminary ruling.

Requirements for the repackaging of medicinal products

The CJEU holds that the trade mark owner may oppose the application of its trade mark to a repackaged product unless two cumulative conditions are met.

The first requirement is that the reference medicinal product is "identical in all respects" to the generic version. The CJEU stressed that a medicinal product may be repackaged in new packaging bearing the brand name of another medicinal product if, and only if, they are identical. Otherwise, there would be a risk of misleading healthcare professionals and patients as to the exact composition of the medicinal product.

When are reference medicinal products and a generics considered identical? The CJEU does not analyse this question thoroughly, but merely states that "identity" exists in the case of a "common origin". In other words, when the reference medicinal product and the generic medicinal product are manufactured by the same entity or by economically linked undertakings. But can there be identity without common origin? The CJEU does not resolve this point.

In the case at hand, the CJEU assumes that "identity in all respects" existed between the reference medicinal products and the imported generics as determined by the referring court.

The second requirement to enable repackaging of parallel traded medicinal products is a set of five conditions stemming from the landmark Bristol-Myers Squibb ruling of 1996.

According to the Bristol-Myers Squibb judgment, the parallel importer may repackage the imported product if (1) repackaging is objectively necessary to commercialise the product in the Member State of importation, (2) repackaging does not alter the original condition of the product; (3) the entity who repackaged the product and the name of the manufacturer of the repackaged product are clearly indicated on the new packaging; (4) the new presentation of the repackaged product does not cause damage to the reputation of the trademark or the owner; and (5) the importer warns the owner before the product is placed on the market and provides the latter, upon its request, with a copy of the repackaged product.

However, in the case at stake, the Court only analyses the first condition and queries whether it is objectively necessary to present the products as reference medicinal products for parallel importers to market generic medicines in Belgium.

The CJEU puts forward the following three ideas to enable the national court to answer this question.

Firstly, the condition of objective necessity is not met "where the parallel importer is able to market the product under its brand of origin by adapting, where necessary, the packaging to meet the requirements of the Member State of importation".

Secondly, a Member State may not, in principle, refuse to grant a parallel import authorisation for a generic medicinal product where the corresponding reference medicinal product holds a marketing authorisation in the Member State of importation (CJEU judgment in the Delfarma case).

Thirdly, the owner of the trade mark may oppose repackaging "where the replacement of the original trade mark by another trade mark of the owner is motivated exclusively by the pursuit of an economic advantage". This may be the case, for example, "where an economic operator seeks to take advantage of the reputation of the brand name of a reference medicinal product or to position a product in a more profitable category".

The Novartis Pharma, Bayer and Merck Sharp & Dohme cases

Background

These cases concern the repackaging of parallel imported medicinal products in Germany/ Denmark. Here we explain the dispute between the parallel importers and the trademark holders of the imported products.

Parallel importers, on the one hand, argued that, in order to market the products in the Member States of importation, the original outer packaging of the products had to be replaced in its entirety. According to these importers, the opening of the sealing label can lead to visible and irreversible changes in the outer packaging, which would require replacement.

The trademark owners, on the other hand, argued that repackaging was not necessary and that, in order to market the products in Germany/Denmark, it would be sufficient to place "on the original outer packaging the bar

code with the unique identifier (…) by means of an adhesive label and, (…) new anti-tampering device covering the traces of the opening of the packaging".

Relabelling as a preferred option to repackaging

The CJEU begins by addressing two basic questions recognised by its case law. First, repackaging of a medicinal product is a more significant interference than relabelling. Secondly, a trade mark owner may oppose repackaging if the parallel importer is able to market the product by simply relabelling it.

However, the key question is: do the rules on security features (unique identifier/anti-tampering device) justify the replacement of the original packaging of products by parallel importers?

The CJEU holds that, with a few exceptions, the answer is no. Parallel importers cannot justify the replacement of the original packaging of imported goods on the grounds that the handling of the original packaging required by local regulations causes visible and irreversible changes to that packaging, thus necessitating a complete replacement.

The CJEU makes two clarifications to this position.

Firstly, relabelling must be possible in such a way that wholesalers and persons authorised to dispense medicinal products have no doubt that traces of opening in the original packaging are attributable to the parallel importer. In case of doubt, it may be justified to replace the original packaging.

Secondly, the replacement of the original packaging may be considered objectively necessary (and therefore permitted) where a significant proportion of consumers in the importing Member State strongly object to relabelled medicinal products with replaced anti-tampering devices. In such cases, repackaging may be considered necessary to achieve effective market access. However, parallel importers cannot rely on a "general presumption of consumer resistance", as resistance must be assessed on a case-by-case basis.

Conclusions

The above judgments help to clarify the already well-developed regime of parallel imports for medicinal products. With respect to the rebranding of generic products, the CJEU holds that trade mark owners may, in principle, oppose rebranding unless the reference and generic products are "identical in all respects" and the conditions of the Bristol-Myers Squibb and subsequent judgments (in particular the requirement of objective necessity) are met. As regards the rules on unique identifiers and anti-tampering devices for medicinal products, the CJEU concludes that, with some exceptions, they are not sufficient to justify the total repackaging (with replacement of the original packaging) of products.

Although the clarifications provided by the judgments are extremely useful, other questions remain to be resolved, namely: Can "identity in all respects" exist between a reference medicinal product and a generic without a "common origin"? What requirements must be met so as to consider that there is resistance in the importing country to relabelled medicinal products with replaced anti-tampering devices?