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ALERT

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EU Court of Justice Latest Rulings[1] Clarifying the Position on Repackaging of Parallel-Imported Medicinal Products

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What are the issues?

Consistent with the single internal market principle under EU law, parallel importation is lawful subject to specific derogations that seek to protect human health and industrial and commercial property. Medicinal products are subject to the same rules governing the internal market. The established case law of the Court of Justice of the European Union ("CJEU") provides that repackaging is permitted only if it is necessary in order for the parallel-imported product to gain effective access to the importing Member State, i.e. the "Necessity Test."

On 17 November 2022, the CJEU adopted preliminary rulings on three separate cases referred by the national courts in Denmark and Germany. These rulings clarify the extent to which a trademark owner of a medicinal product may oppose a parallel importer making significant alteration(s) of the original packaging.

The circumstances in which trademark owners may exercise their rights to oppose the repackaging of parallel-traded medicinal products are well trodden according to the established case law. The new rulings were made, particularly in the context of the EU regulatory framework introduced in 2011, to prevent falsified medicines entering into the legitimate supply chain (the "Falsified Medicine Framework" or "FMF").

For the purpose of protecting public health and patient safety, the Falsified Medicine Framework details the characteristics of the safety features for authentication purposes to ensure the security of the supply chain. It also prohibits wholesalers and persons authorised or entitled to supply medicinal products, such as pharmacists, from supplying products having packaging that shows signs of tampering.[2] The European Commission in its published guidance indicates that parallel traders covering or removing existing safety features are required to place equivalent safety features according to the requirements set out in the FMF.[3]

What are salient points of the Court rulings?

- Re-labelling, repackaging or re-boxing (i.e. providing a new secondary packaging) of parallel-imported products would be considered as equivalent—without one prevailing over the other—in order to preserve the efficacy of the safety features to enhance the supply chain security for medicinal products consistent with the overarching objective of the FMF.

- The trademark proprietor may oppose the marketing by a parallel importer of a medicinal product repackaged in new outer packaging where it is objectively possible to re-label the parallel-imported product in order to comply with the requirements under the FMF, particularly if the re-labelled product could be effectively accessed in the market of the importing EU Member State. This is consistent with the established CJEU ruling on "effective access."[4]

[1] Case C-204/20 *Bayer Intellectual Property GmbH v kohlpharma GmBH*; Joint Cases C-147/20 *Merck Sharp & Dohme BV and others v Abacus Medicine A/S and others*; *Novartis Pharma GmbH v Abacus Medicine A/S.*
[2] *See* Articles 24 and 30 of Commission Delegated Regulation (EU) 2016/161.
[3] *See* Article 47a of Directive 2001/83/EC (as amended).
[4] Case C-443/99 *Merck, Sharp & Dohme.*

- A determination of effective access should take account of whether there may exist on a market or on a substantial part of it such strong resistance from a significant proportion of consumers to, essentially, an altered product that there must be held to be a hindrance to effective market access.

- The trademark proprietor may also oppose the marketing of a parallel-imported product repackaged in new outer packaging if the following conditions are met: (a) there exist visible traces of opening of the original outer packaging resulting from re-labelling that would be clearly attributable to repackaging carried out by the parallel importer; and (b) such traces of opening could be viewed as constituting a barrier to effective access to that market according to the established case law (see above). Point (b) requires a factual assessment in order to establish whether effective market access is hindered as a result of repackaging.

- As explained by the Advocate General in his Opinion, which was specifically referenced by the CJEU, a parallel importer cannot rely on a general presumption of consumer resistance to re-labelled medicinal products the anti-tampering devices of which have been replaced. Existence of such resistance by consumers and its extent must be assessed with reference to verifiable facts, taking into account, in particular, the circumstances prevailing in the Member State of importation at the time at which the medicinal product concerned was marketed. The fact that traces of opening were visible or could be detected should be based on a thorough verification by wholesalers and persons authorised or entitled to supply medicinal products having particular regard to the specific obligations set out in the FMF.[5]

- Consistent with the established case law, the CJEU re-emphasised that repackaging of medicinal products should aim at securing effective access to the market of the importing Member State. This condition is not fulfilled if the repackaging is explicable solely by the parallel importer's attempt to secure a commercial advantage.

What is the significance of the latest CJEU rulings?

- The latest rulings clarify that parallel imported medicinal products should be subject to the same requirements of the Falsified Medicine Framework to protect public health and patient safety. Therefore, the safety feature of the original packaging of the imported product for product authentication should be preserved or otherwise replaced by an equivalent one.

- Re-labelling, re-boxing or repackaging of a parallel-imported medicinal product should be guided and justified essentially by an informed impact assessment.

- Having regard to the FMF requirements, trade mark owners may oppose the marketing of a re-packaged parallel-imported product provided that certain conditions are met according to the new rulings.

[5] *See* Articles 10, 24 and 30 of Delegated Regulation (EU) 2016/161.