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Client Alert



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# Goodbye Reboxing! European Court of Justice Restricts Parallel Imports of Medicines

On November 17, 2022, the Court of Justice of the European Union (CJEU) found in its latest principal judgment (*Novartis v. Abacus*, case file C-147/20) that the reboxing of parallel imported medicines in the European Union (EU) is unlawful. The ruling mirrors the arguments of plaintiff Novartis and King & Spalding attorneys Ulf Grundmann and Elisabeth Kohoutek as it prohibits parallel importers from repackaging imported medicinal products into new outer packaging. The landmark decision not only strengthens the position of drug manufacturers by enabling original manufacturers to object to the resale of reboxed parallel imports, but it also provides specific requirements that parallel importers must observe when resealing the medicines with new anti-tampering devices.

## BACKGROUND: EU'S FREE MOVEMENT OF GOODS, LABELLING OF MEDICINES, AND THE ANTI-TAMPERING DEVICE

In the EU and its single internal market, it is common practice to purchase medicines and goods in EU countries with lower price levels and to resell those imports in EU countries with higher price levels, such as Germany, Denmark, and Sweden. These so-called "parallel imports" are generally admissible and contribute to competition within the EU. The business impact is significant in the high-price markets: parallel imports reach market shares of up to forty percent!

When reselling medicines, however, parallel importers cannot distribute a drug as is. Imported medicines must be relabeled in the language of the EU country in which they are offered for sale. Therefore, parallel importers must open the sealed outer packaging to replace the information for use and equip the drugs with new labels in e.g., German language. Opening the outer packaging does not occur unnoticed; in the EU, most prescription medicines and some over-the-counter medicines for human uses are required to have an anti-tampering device (a safety feature that shows whether the packaging has been opened or altered since it left the manufacturing site) on their outer packaging. Such anti-

tampering devices may consist of glued insides or a seal that breaks when opening the medicine's outer packaging. Technically, parallel importers have two options: they can either stick new labels on the outer packaging and reseal the medicinal product with a new replacement anti-tampering device, or they can rebox the medicines into an entirely new and unique package.

For years, parallel importers have preferred the latter option and offered their imported medicines for sale in their own packaging. On these new pieces of outer packaging, parallel importers affix not only their own trademarks but also those of the original manufacturers. The repackaging and affixing of these foreign trademarks by parallel importers, however, constitutes trademark infringement according to the established case law of the CJEU, since the affixing of a trademark should only be permitted by the trademark owner, not a third party. Only in defined exceptional cases should repackaging be permissible under trademark law.

## REBOXING IS NOT PERMISSIBLE: PHARMACEUTICALS CAN BE RESEALED

Parallel importers argued that the reboxing of medicines is necessary because opening the original anti-tampering devices would leave visible opening marks. Parallel importers reasoned that due to such visible traces of having been opened, wholesalers, doctors, and pharmacists would not be able to confirm that the medicine has not been tampered with.

The CJEU rejected the parallel importers' objections and instead followed the arguments of Novartis and the opinion of the attorney general; the CJEU held that the presence of possible traces of having been opened is not, in itself, sufficient to classify a resealed parallel imported medicine as incompliant, when there is no doubt, on the part of wholesalers, doctors, or pharmacists that those traces of opening are attributable to the repackaging of that medicinal product by a parallel importer. Repackaging of medicinal products by parallel importers therefore infringes on the trademark rights of the original manufacturer.

The CJEU further held that any contrary opinions of governments of individual EU member states are irrelevant and do not prevent the enforcement of trademark rights. Repackaging is only permissible in exceptional cases, which have been defined by the CJEU and for which the parallel importer bears the burden of proof. With this ruling, the CJEU also rejects the views of individual governments of member states and restricts the previous position of the European Commission.

## ORIGINAL MANUFACTURERS TO EVALUATE NOTIFICATIONS AND SAMPLE PACKAGING

With its ruling, the CJEU strengthens the trademark rights of pharmaceutical manufacturers and follows the argumentation of Novartis. The clarifications of the Court enable manufacturers to take action against unauthorized parallel imports: when receiving notifications of parallel imports, original manufacturers can, unless indicated due to a change of packaging size, object to the repackaging of medicinal products into parallel importers' own outer packaging. If a parallel importer insists on reboxing, original manufacturers should consider taking further legal action. But manufacturers should also carefully examine the sample packaging of resealed outer packaging; according to the CJEU's strictly defined rules on parallel imports, parallel importers must ensure that the replacement anti-tampering device shows by whom the outer packaging was opened and resealed, so as to leave no doubt that the traces of opening are attributable to the repackaging of that medicinal product by a parallel importer. Relabeled packaging which does *not* undoubtedly show that it is a resealed import package likely does not meet these high standards for parallel imports.

King & Spalding's team of life sciences lawyers advises stakeholders whose business is related to parallel import and can advise on how to best address legal issues involved.

## ABOUT KING & SPALDING

Celebrating more than 130 years of service, King & Spalding is an international law firm that represents a broad array of clients, including half of the Fortune Global 100, with 1,200 lawyers in 23 offices in the United States, Europe, the Middle East and Asia. The firm has handled matters in over 160 countries on six continents and is consistently recognized for the results it obtains, uncompromising commitment to quality, and dedication to understanding the business and culture of its clients.



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