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EU Medicine Reboxing Ruling Gives Guidance To Pharma Cos.

By **Ulf Grundmann and Elisabeth Kohoutek** (January 19, 2023, 3:47 PM GMT)

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Medicine is one of the largest business sectors across the globe, but the issue of parallel imports has been a particular legal headache for pharmacal companies for many years when it comes to the packaging and distribution of a product.

The practice of parallel importing involves branded medicines being imported into a market, only to be removed from the initial packaging and placed into new outer packaging to be resold.

Put simply, it creates gray market goods where branded medicines can be imported and sold on without the trademark owner's consent in that jurisdiction.

However, a trio of landmark rulings from the Court of Justice of the European Union in November last year will seriously hamper third parties attempting to rebox goods by prohibiting parallel importers from repackaging imported medicinal products into new outer packaging.

The cases were Novartis Pharma GmbH v. Abacus Medicine A/S, Bayer Intellectual Property GmbH v. kohlpharma GmbH and Merck Sharp & Dohme BV and others v. Abacus Medicine A/S and others.[1]

Background

The regulation of parallel imports of medicine into the EU stems from the 2019 implementation of delegated regulations to the 2011 Falsified Medicines Directive.

As explained by the European Medicines Agency,[2] from Feb. 9, 2019, most prescription medicines and some over-the-counter medicines for human use supplied in the EU were required to have a unique identifier — a barcode — and an anti-tampering device on the outer packaging.

The latter allows suppliers or consumers to see if the packaging of a medical product has been opened or tampered with after it has left the manufacturer.

The goal of the regulations is to ensure that EU consumers are protected from medicine that may have either been compromised or counterfeit products packaged as genuine therapies, which could ultimately lead to serious health complications.

Manufacturers are required to provide the unique identifier for each individual medicine to a central EU repository, meaning it can be tracked and authenticated through the entire supply chain.

However, the Falsified Medicines Directive regulations had a knock-on impact for parallel importers by creating confusion about whether repackaging falls foul of intellectual property law.

Labeling Options

The conundrum for importers is that once a product is sold into the EU, the trademark rights are largely voided and the goods, in this case medicines, could be freely resold on the market to third parties on the basis that they are the original product.

Technically, parallel importers have two options: They can either place new labels on the outer packaging and reseal the medicinal product with a replacement anti-tampering device, or they can rebox the medicines into an entirely new and unique package.

Reboxing has been the preferred option because it is cheaper and does not require the attachment of new anti-tampering protections.

There are also perks when it comes to branding. Reboxing products means a fresh new outer packaging, which allows parallel importers to include their own branding alongside that of the medicine's original producer.

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.[3] The recent CJEU rulings are pivotal because they have ruled that the reboxing of parallel imported medicines in the EU is unlawful.

Infringe Movement

The argument at the center of the Novartis case was one that parallel importers have been making for a long time. Put simply, the claim is that the reboxing of medicines is necessary because opening the original anti-tampering devices would leave visible marks.

Parallel importers reasoned that due to such visible traces of opening the package, wholesalers, doctors and pharmacists would not be able to confirm that the medicine had 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 opening is not, in itself, sufficient to classify a resealed parallel imported medicine as noncompliant, when there is no doubt on the part of wholesalers, doctors or pharmacists that evidence of the package being opened is attributable to the repackaging of that product by a parallel importer.

Repackaging of medicinal products by parallel importers therefore infringes the trademark rights of the original manufacturer.

The CJEU further held that any contrary opinions of individual EU member states are irrelevant and do not prevent the enforcement of trademark rights.

Repackaging is only permissible in exceptional cases that have been defined by the CJEU and for which the parallel importer bears the burden of proof.

With this ruling, the CJEU also rejected the views of individual governments of member states and restricts the previous position of the European Commission.

Lessons Learned

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.

The requirements go a long way in providing certainty in what was a somewhat unclear regime.

Indeed, the ruling is something of a compromise in trying to factor in what were some complex and intricate intersections of various strands of EU regulation, including consumer product protection, free market principles and IP rights.

Parallel importers must reseal imported medicines with new anti-tampering devices that are capable of verifying, to the same extent as the original anti-tampering device, that the outer packaging of a medicinal product has not been unlawfully opened between the time of repackaging of that drug and the time of its distribution to the public.

Parallel importers must therefore use anti-tampering devices that leave no doubt that any visible traces of opening are due to the repackaging of that drug product by a parallel importer.

This can be ensured, for example, by placing appropriate instructions on how to use the product on the package.

If parallel importers nevertheless rebox medicinal products without following the appropriate steps, original manufacturers should consider further legal steps.

In the case of a trademark violation, original manufacturers can issue a warning letter and request a cease-and-desist declaration. If the admonished party refuses giving the requested declaration, original manufacturers can enforce their claims in court and file an action on the merits.

If the claim is urgent, manufacturers can even seek legal protection in summary proceedings and apply for an interim injunction.

What is sure is that the CJEU has given pharma companies a much-needed framework for handling parallel imports.

The companies producing the medicine have better protections for the trademarks while the third-party entities are much clearer on the protocols for handling imported products.

The additional protection provided by the clarifications of the court also mean that manufacturers can take legal action against any parallel imports that do not follow the protocols.

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Disclosure: The authors represented Novartis before the CJEU on this case.

[1] Novartis Pharma GmbH v. Abacus Medicine A/S C-147/20), Bayer Intellectual Property GmbH v kohlpharma GmbH (C 204/20) and Merck Sharp & Dohme BV and others v Abacus Medicine A/S and others (C 147/20).

[1] https://www.ema.europa.eu/en/news/new-safety-features-medicines-sold-eu#:~:text=As%20of%209%20February%202019,device%20on%20their%20outer%20packaging.

[3] CJEU judgment of 11 November 1996 — case files C-427/93, C-429/93 and C-436/93 'Bristol-Myers Squibb'.