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# LEGAL ALERT

## NEW LABELLING *VS.* EXTERNAL PACKAGING FOR MEDICINAL PRODUCTS

### THE RIGHTS OF TRADEMARKS HOLDERS IN THE PHARMACEUTICAL SECTOR IN THE LIGHT OF RECENT DECISIONS OF CJEU

On 17 November 2022, the Court of Justice of the European Union (CJEU) issued three important decisions in the following cases: *Merck Sharp & Dohme BV and others v Abacus Medicine A/S and Novartis AG C-224/20 ("Merck")*, *Bayer Intellectual Property GMBH v Kohlpharma GMBH C-204/20 ("Bayer")*, and *Novartis Pharma GMBH v Abacus Medicine A/S C-147/20 ("Novartis")*, concerning the possibility of trademark proprietors opposing the marketing of a medicinal product repackaged in new outer packaging, particularly in situations involving the replacement of the outer packaging's tamper device and leaving traces of its opening.

It has been common practice in the EU market to purchase medicines in one EU Member State for lower prices and resell the same medicines in other EU Member States for a higher price. Parallel importation is a mechanism that allows a medicine with a valid marketing authorisation (MA) in one EU country to be imported and marketed in another. This practice is generally admissible and is considered an integral part of the EU single market principle.

However, the distribution of medicinal products imported under the parallel importation mechanism must comply with certain requirements. Indeed, repackaging and labelling of the imported medicinal products must be carried out in the language of the Member State in which they are to be distributed. Consequently, parallel importers have to open the packaging of the medicines by removing the tamper-proof device affixed to the packaging and insert the information concerning the use of the medicine in the language of the Member State.

Faced with this requirement, most parallel importers have chosen to repackage the medicines in new outer packaging, on which they place their trademark as well as the trademark of the original manufacturer of the medicines.

In the "Merck", "Bayer" and "Novartis" cases, the parallel importers argued that repackaging of the drugs in new outer packaging was necessary because relabeling of the original packaging would be inappropriate due to the traces of manipulation that would result from the removal of the original tampering prevention device, which would still be visible after opening the relabeled original packaging. Parallel importers further claimed that the existence of traces of manipulation considerably reduces the possibility to access the market of the pharmaceutical sector and of the wholesalers, as pharmacists and wholesalers cannot confirm that the packaging and the medicines have not been manipulated.

In the "Novartis" case, Novartis Pharma GmbH submitted that the exclusive rights conferred on it by the trademarks, have not been exhausted within the meaning of Article 15(2) of Regulation (EU) 2017/1001 and that parallel importers should be prohibited from placing on the market and marketing medicinal products repackaged in a new packaging.

Novartis further considered that repackaging of medicinal products in new outer packaging was not necessary, as the requirements imposed by Articles 47-A and 54-A of Directive 2001/83/EC could be met by affixing to the original outer packaging the barcode containing the unique identifier, using an adhesive label, as well as a new anti-tamper device covering the traces of the opening of the packaging.

The CJEU rejected the parallel importers' arguments in all three cases, upholding the arguments of the plaintiffs (*i.e.*, the pharmaceutical companies). It ruled that the presence on the outer packaging of a medicinal product of possible traces of it having been opened is not, in itself, sufficient for the view to be taken that the replacement anti-tampering device is not equivalent, particularly where there is no doubt, on the part of wholesalers and persons authorised or entitled to supply medicinal products to the public (*i.e.*, the pharmacies and hospitals), that those traces of opening are attributable to the repackaging of that medicinal product by a parallel importer. Indeed, the parallel importers were concerned with the impression that these traces of opening and replacement anti-tampering devices cause on the consuming public.

Therefore, the court further held that Article 9(2) and Article 15 of Regulation 2017/1001 (EU) must be interpreted as meaning that the proprietor of an EU trademark is entitled to oppose the marketing, by a parallel importer, of a medicinal product repackaged in new outer packaging to which that trademark is affixed if *(i)* the visible traces of opening of the original outer packaging which, where applicable, would result from relabeling of that medicinal product would be clearly attributable to the repackaging thus carried out by that parallel importer; and *(ii)* traces do not give rise, on the market of the Member State of importation or on a significant part of that market, to such strong resistance, that constitutes a barrier to effective access to that market.

The CJEU's decisions thus give medicines manufacturers the right to object to the marketing of a medicine repackaged in new outer packaging by a parallel importer.

Until the CJEU decisions in the "Merck", "Bayer", and "Novartis" cases, parallel importers held, by application of Directive 2001/83/EC, that only the repackaging of medicines in new outer packaging could comply with the protection, and safety requirements of the directive.

The CJEU decisions constitute a paradigm shift in the interpretation, and application, of the Directive 2001/83/EC, together with the protection and safeguarding of the exclusive rights of trademarks owners.

Pharmaceutical companies were greatly encouraged by the content of the above-mentioned decisions, since parallel importers will be limited in their ability to alter and modify the original packaging of medicines, on which the trademark of the original manufacturer of the medicines is affixed.

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