

The Repackaging of Pharmaceutical Products and Parallel Trade in the EU

Héctor Armengod and Laura Melusine Baudenbacher examine how European case law affects trademark owners' ability to lawfully oppose further marketing of their repackaged product.

The question of whether pharmaceutical products can be repackaged by parallel traders has been – and continues to be – a recurrent topic before the European Court of Justice.

In the European Union, each member state, based on its own healthcare policy, dictates the prices of the drugs sold in its territory. This leads to significant differences in the price of pharmaceuticals across the EU. These differences create business opportunities for parallel importers who can buy the drugs in those countries where they are cheaper and import them in the more expensive ones, thereby obtaining a lucrative margin.

The packaging and labelling of pharmaceuticals is highly regulated both at EU and member state level, and a product acquired in a given member state often needs to be repackaged before it is placed on the market of a different member state. Repackaging can interfere with the trademark rights of the original supplier of the product. The protection of trademark rights has been recognised by the ECJ as an essential element in the system of undistorted competition which the EC Treaty seeks to establish and maintain¹. The exercise of these rights can, however, be in conflict with the principle of free movement of goods, which is one of the cornerstones of the EU internal market.

When deciding on repackaging cases the ECJ has had to strike a balance between this principle and the protection of trademark rights. This paper examines ECJ case law, the impact it has had on trademark owners' ability to protect their rights and the areas that remain ambiguous.

The BMS conditions

The principle of free movement of goods is laid down in Article 28 of the EC Treaty, which prohibits restrictions on trade between member states. Article 30 EC exempts from this prohibition restrictions justified on grounds of the protection of industrial and commercial property, as long as they do not constitute a means of arbitrary discrimination or a disguised restriction on trade.

In 1988, the EU Council adopted the Trade Marks Directive, which was aimed at harmonising disparities in the trademark laws of the member states that had the potential to impede the free movement of goods – it was later repealed and replaced by Directive 2008/95/EC². Article 7 of the 2008 directive enunciates the principle of the European Economic Area-wide exhaustion of trademark rights. According to this principle, the owner of a trademark is not entitled to prohibit its use in relation to goods that have been put on the market in the EEA under the trademark by the owner or with his consent.

Also, according to Article 7, exhaustion does not apply if there are "legitimate reasons for the proprietor to oppose further commercialisation of the goods, especially where the condition of the goods is changed or impaired after they have been put on the market". This provision has been interpreted by the ECJ in *Bristol-Myers Squibb*³, where it held that the trademark owner cannot legitimately oppose the further marketing of a repackaged pharmaceutical product if:

- repackaging is necessary to market the product in the country of importation;
- it does not affect the original condition of the product inside the packaging;
- the new packaging clearly states who repackaged the product and the name of the manufacturer;
- the presentation of the repackaged product is not liable to damage the reputation of the trademark or of its owner; and
- the importer gives notice to the trademark owner before the repackaged product is put on sale, and, on demand, supplies him with a specimen of the repackaged product.

These are known as the five BMS conditions. It is sufficient for one of them not to be met to enable the trademark owner to lawfully oppose further marketing of the repackaged product⁴. The conditions apply to both the re-boxing of the original internal packaging in a new package and to over-stickering, ie the attachment of a label without altering the original internal or external packaging⁵.

The scope of the BMS conditions has been interpreted in subsequent ECJ rulings as explained below.

Price differences among EU member states lead to business opportunities for parallel importers

Directive 2008/95/EC deals with trademark issues

The BMS conditions apply to re-boxing and over-stickering products

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Necessity

The condition of necessity is satisfied if, without repackaging, effective access to the markets of the importing member state is hindered⁶.

Repackaging meets the necessity condition if it is required to comply with national rules on packaging

Repackaging meets the necessity condition if it is required to comply with national rules on packaging, sickness insurance rules making reimbursement of medical expenses subject to certain packaging or where well-established medical prescription practices are based, *inter alia*, on standard sizes recommended by professional groups and sickness insurance institutions⁷. The condition of necessity will not be satisfied if repackaging is only an attempt by the parallel importer to secure a commercial advantage⁸.

The owner of the trademark can oppose re-boxing, if marketing the product in the country of destination is possible by simply "affixing to the original packaging new labels in the language of the member state of importation, or by adding new user instructions or information in the language of the member state of importation, or by replacing an additional article not capable of gaining approval in the member state of importation with a similar article that had obtained such approval"⁹. Repackaging cannot, however, be opposed if there is "strong resistance from a significant proportion of consumers to relabelled pharmaceutical products"¹⁰.

Further, in the recent *Wellcome v Paranova* judgment, the ECJ held that there is no requirement of minimum intervention on the parallel importer, ie that the importer is obliged to repackage the product with the minimum possible adverse effect on the trademark¹¹. As long as it is necessary to repackage the product, the only limitation to the importer's right to choose the style and presentation of the repackaging is the fourth BMS condition, ie the reputation of the trademark and its owner.

The rationale for the ECJ's restrictive interpretation of the rights of the trademark owner can be found in the European Free Trade Association Court's ruling in *Paranova AS v Merck & Co Inc*¹². In this case the EFTA Court held that once the right to repackage is established and market access is thereby ensured, the parallel importer must be considered as an operator on basically equal footing with the manufacturer and trademark owner. This view is contrary to the principle of proportionality as enunciated by AG Jacobs in *Merck v Paranova*, according to which "a particular method of repackaging cannot be regarded as necessary if another method which interferes less with the trademark owner's rights will suffice to give the parallel importer effective access to the market in the importing State"¹³.

The burden of proving necessity lies with the parallel importer

The burden of proving necessity lies with the parallel importer, who has an obligation to provide the trademark owner with sufficient information to enable him to determine whether repackaging is necessary¹⁴. That information must only include the disclosure of the member state of destination if without it the trademark owner would be prevented from evaluating the need to repackage.

Effect on the original condition of the product

The trademark owner may oppose repackaging if there is a real risk that the product inside the package is exposed to tampering or to influences affecting its original condition. The ECJ has held that the requirement only applies to the condition of the product inside the packaging¹⁵.

In *Hoffmann-La Roche*, the ECJ held that, in order to determine whether such effect exists, account must be taken of the nature of the product and the method of repackaging¹⁶. The court noted that while repackaging may in some cases inevitably affect the condition of the product, in others such effect is far from obvious. In particular, the ECJ found that no such effect existed where the product had been marketed in a double packaging and the repackaging only affected the external packaging, or where the repackaging was inspected by a public authority for the purpose of ensuring that the product was not adversely affected.

In *Bristol-Myers Squibb*, the ECJ held that "the removal of blister packs, flasks, phials, ampoules or inhalers from their original external packaging and their replacement in new external packaging, the fixing of self-stick labels on the inner packaging of the product, the addition to the packaging of new user instructions or information, or the insertion of an extra article" would not affect the original condition of the product inside the packaging¹⁷.

However, the original condition of the product inside the packaging might be indirectly affected where, for example "the external or inner packaging of the repackaged product, or a new set of user instructions or information, omits certain important information or gives inaccurate information concerning the nature, composition, effect, use or storage of the product", or "an extra article inserted into the packaging by the importer and designed for the ingestion and dosage of the product does not comply with the method of use and the doses envisaged by the manufacturer"¹⁸.

The burden of showing that repackaging does not affect the product's condition was held to lie with the importer

In *Boehringer Ingelheim*, the ECJ held that the burden of demonstrating that the repackaging does not affect the condition of the product lies with the importer. However, to satisfy that burden the importer only needs to furnish evidence that leads to a reasonable presumption that the condition is fulfilled¹⁹.

Identification of the manufacturer and importer

This requirement was first established by the ECJ in *Hoffmann-La Roche* and *Pfizer*²⁰. It is based on the need to protect the trademark owner's interest that "the consumer or end user should not be led to believe" that he (ie the trademark owner) is responsible for the repackaging²¹.

The identification of the manufacturer and importer must be "...in print such that a person with normal eyesight, exercising a normal degree of attentiveness, would be in a position to understand..." Further, where the parallel importer has added to the packaging an extra article from a source other than the trademark owner, he must indicate the origin of the extra article so as to avoid giving the impression that the trademark owner is responsible for it.

Finally, it is not necessary to indicate that the repackaging was carried out without the authorisation of the trademark owner, since such a statement could cast doubts as to the legitimacy of the repackaged product²².

It is not necessary to indicate that repackaging was carried out without the trademark owner's authorisation

Protection of the reputation of the trademark and its owner

The ECJ has recognised the importance of protecting the reputation of the owner of a pharmaceutical trademark. It recognises that this is "a sensitive area in which the public is particularly demanding as to the quality and integrity of the product, and the presentation of the product may indeed be capable of inspiring public confidence in that regard". Consequently, a trademark owner can oppose repackaging if the carton or the label are "defective, of poor quality or untidy"²³.

In *Boehringer Ingelheim*, the ECJ held that the following activities are, in principle, liable of damaging the trademark's reputation:

- failing to affix the trademark to the new exterior carton ("de-branding");
- applying the importer's own logo or a house-style, or a design used for a number of different products ("co-branding");
- positioning the additional label so as wholly or partially to obscure the proprietor's trademark;
- failing to state on the additional label that the trademark belongs to the owner; or
- printing the name of the parallel importer in capital letters²⁴.

However, the assessment of whether any of the above actually damages the trademark's reputation has to be carried out on a case-by-case basis.

It is sufficient for the parallel importer to establish a "reasonable presumption" that the condition relating to the reputation of the trademark owner and its proprietor is fulfilled. Where the importer furnishes such initial evidence, the burden of proof shifts to the owner of the trademark, "who is best placed to assess whether the repackaging is liable to damage his reputation and that of the trademark"²⁵.

Assessment of whether parallel import activities damage the trademark's reputation must be on a case-by-case basis

Prior notice

The fifth BMS condition was first established by the ECJ in *Hoffman-La Roche*²⁶. The owner is also entitled to require the importer to supply him with a specimen of the repackaged product before it goes on sale, so that he can check that neither the original condition nor his reputation is affected²⁷.

The requirement to give notice must be fulfilled "in any event" by the parallel importer, even if the trademark owner might receive notification from other sources such as authorities issuing parallel import licences²⁸.

The notice should be given with a reasonable time before the sale of the product so as to allow the trademark owner to react. The ECJ has held that a period of 15 working days appears reasonable, but this is only indicative²⁹.

According to the ECJ, the sanctions for failing to provide notice must be determined by the national authorities. Those sanctions must be "not only proportionate, but also sufficiently effective and a sufficient deterrent"³⁰.

Notice should be given with a reasonable time before the sale of the product

Observations

The courts in Luxembourg have gone a long way in fleshing out the boundaries of the BMS conditions. Yet, there are a number of questions that remain open and that the ECJ will likely have to address in future cases.

In particular, in light of the ECJ's view in *Wellcome v Paranova* that the choice of style and presentation of the repackaging is only limited by the fourth condition in *BMS*, the court will likely be called upon to delineate further what forms of repackaging are liable to damage a trademark's reputation.

Finally, the compatibility of parallel trade restrictions with the competition laws of the EC Treaty has also been the subject of considerable litigation before the ECJ and the Court of First Instance. The courts' case law on this topic has evolved considerably. Their initial strict stance

against parallel trade restrictions has given way to a more nuanced and balanced approach in most recent rulings. In these rulings, the courts have held that the specific features of the pharmaceutical sector, in which pricing is regulated by the state, must be taken into account when assessing the legality of parallel trade restrictions, and that there are legitimate reasons under which these restrictions can be justified^{31,32}.

Pharma companies could use the sector's specificity as an argument to justify repackaging restrictions

The specificity of the sector could also be brought forward by pharmaceutical companies as an argument to justify certain restrictions on repackaging. For instance, the EU institutions are well aware of the health risks posed by counterfeiting and the illegal distribution of medicines^{33,34}. Restrictions aimed at strengthening the supply chain of medicines in order to prevent counterfeit products could thus resonate well with the courts.

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