

New ECJ guidance on repackaging of parallel-traded medicinal products

On April 26, the European Court of Justice delivered a judgment concerning the circumstances in which trade mark owners may rely on their trade mark rights to prevent the repackaging of their parallel imported medicinal products. This judgement is reviewed here by Elisabethann Wright and Susan Jane Clements of international law firm Hogan & Hartson.

The judgement refers, in particular, to circumstances in which a parallel trader uses the original internal and external packaging of the product but applies an additional external label printed in the language of the European Union member state of import (overstickered products) or uses the original internal packaging but with a new exterior carton printed in the language of the member state of import (reboxed products).

This decision of the Court, in case C-348/04 Boehringer Ingelheim, was something of a departure from the Court's traditional approach to the, sometimes very detailed, questions that national courts sometimes pose to the ECJ. In the present judgement, the Court revisited its previous judgement in the same matter, in which it provided initial guidance to the circumstances in which a parallel trader might be permitted to re-package trade marked products imported from one EU member state from another.

The medicinal products concerned by the disputes in the main proceedings were marketed under various trade marks by German drug major Boehringer Ingelheim and other manufacturers of medicinal products in the EU, where they were bought by Swingward and Dowelhurst and imported into the UK. In order to market them in Britain, Swingward and Dowelhurst altered the packaging of those products and the information leaflets which were included with them to a certain extent.

Variations in labeling

The alterations made varied from one case to the next. In some cases, a label setting out certain critical information, such as the name of the parallel trader and its parallel import licence number, was attached to the original packaging. On such packaging, wording in languages other than English thus remained visible and the trade mark was not covered over. In other cases, the product was repackaged in boxes designed by the parallel trader on which the original manufacturer's trade mark was reproduced. Finally, in some cases, it was re-packaged in boxes designed by the parallel trader and which did not bear the trade mark of the manufacturer but the generic name of the product. Where this was the case, the pack-

aging inside the box bore the original trade mark but a self-adhesive label was attached indicating the generic name of the product as well, as the identity of the manufacturer and of the parallel import licence holder.

The initial judgement of the Court in the matter, rendered in April 2002, in case C-143/00, contributed to a clarification of the circumstances in which parallel traders are permitted to repackage medicinal products. However, the judgement also raised questions, particularly of interpretation, as to both the circumstances and the extent to which re-packaging would be permitted.

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The second judgement, rendered in April 2007, provides a useful and straightforward indication of how the guidance in the Court's first judgement is to be interpreted and practically applied.

In its first judgement in case C-143/00, the Court concluded that Article 7(2) of Council Directive 89/104/EEC to approximate the laws of the member states relating to trade marks (hereafter "the Trade Marks Directive") must be interpreted as meaning that trade mark proprietors should be permitted to rely on their trade mark rights in order to prevent a parallel trader from repackaging pharmaceutical products unless the exercise of those rights contributed to the artificial partitioning of the markets between member states.

The Court concluded that re-packaging of pharmaceutical products was objectively necessary within the meaning of the Court's case-law if, without such re-packaging, effective access to the market concerned, or to a substantial part of that market, must be considered to be hindered as the result of strong resistance from a significant proportion of consumers to relabeled medicines.

PI trader must give prior notice

The Court specified, however, that, in order to be considered entitled to repackage trade-marked pharmaceutical products, a parallel trader must provide the trade mark holder with prior notice of his intentions. Failure by the parallel trader to take such a step would permit the trade mark proprietor to oppose the marketing of the re-packaged pharmaceutical product.

The High Court of Justice (England and Wales) applied the judgment of the Court in case C-143/00 to the case before it and ruled in favour of the claimants in the main proceedings. However, the High Court's decisions were the subject of an appeal before the Court of Appeal. In its judgment of March 5, 2004, the higher court set out a number of findings which differed from those of the

High Court. Consequently, the Court of Appeal decided to refer further questions to the Court.

The second judgement of the Court, in case C-348/04, clarified a number of aspects of its original judgement in case C-143/00.

These clarifications included correction of the perception, drawn from the Court's judgment in case C-143/00, that the requirement that presentation of re-packaged product must not damage the reputation of the trade mark was limited to circumstances in which repackaging resulted in defective, poor quality, or untidy packaging.

Damage to trade mark's reputation

In its judgement in case C-348/04, the Court explained that damage to the reputation of a trade mark was not limited to these types of circumstances. It could occur where, even if re-packaging were neither poor quality nor untidy, it was such as to affect the trade mark's value by detracting from the image of reliability and quality attached to the product and the confidence it was capable of inspiring in the public concerned.

As examples of the circumstances in which such damage to the reputation of the trade mark could occur, the Court continued that, if a parallel trader did not affix the original trade mark to new external packaging (de-branding), or applied his own logo, house-style or get up or a get-up used in a number of different products (co-branding), or positioned the additional label to wholly or partially obscure the proprietor's trade mark, or failed to state on the additional label that the trade mark in question belonged to the proprietor, or printed the name of the parallel trader in capital letters this, in principal, would be liable to damage the trade mark's reputation.

The Court added that, whether damage to the trade mark's reputation had, in fact, occurred was a question of fact in each case. However, it added that, if it were a matter for the national law of the EU member states to determine the question of the onus of proving the existence of those conditions, which, if fulfilled, would prevent the proprietor from opposing further commercialization of a packaging pharmaceutical product, the consequence for trade mark proprietors could be that protection would vary according to the legal system concerned.

The Court thus considered that, in situations such as that in the present case where repackaging had taken place, it was for the parallel traders to prove the existence of conditions that justified repackaging.

While trade mark holders may be gratified with the clarification by the Court of where the onus of proof should lie in such circumstances, the Court nevertheless added that, as regards the need to demonstrate that re-packaging would not affect the original condition of the product inside the packaging, or that the presentation of the

repackaged product would not affect the reputation of the trade mark and its proprietor, the test was simply the provision of evidence that would lead to the reasonable presumption that the condition had been fulfilled.

Amplification of the extent of the obligation on parallel traders to give notice to the proprietor concerning re-packaging may be particularly welcome to trade mark holders. Not only did the Court highlight the need for the parallel trader to give notice before import took place, it underlined the fact that the parallel trader infringed the right of the trade mark holder on the occasion of any subsequent importation of the pharmaceutical product, so long as he has failed to give the trade mark holder such notice.

Responsibility of national authorities

Commenting on the claim by the Plaintiffs that they should be entitled to financial damages for breach of the obligation on the parallel traders to give notice, the Court, as would be expected in such circumstances, concluded that, where Community law did not lay down a specific sanction where infringements have been committed, it was incumbent on the national authorities to adopt appropriate measures to deal with such a situation. It added, however, that such measures must be not only proportionate, but also sufficiently effective and a sufficient deterrent to ensure that the Trade Mark Directive was fully effective.

Recalling that, in case C-143/00, it had identified five criteria on which the need for repackaging of medicinal products by parallel traders was to be determined, the Court concluded that, for a trade mark proprietor to lawfully oppose further marketing of a re-packaged pharmaceutical product it was sufficient that one of the conditions that justify repackaging has not been fulfilled. This is an interesting conclusion. The manner in which the five criteria were presented in the original judgement did not lead to the inevitable conclusion that they were cumulative.

Furthermore, the Court agreed with the Plaintiffs that their right to redress arising from the marketing of parallel imported goods that have been repackaged without giving notice to the trade mark holder was "not different from" that enjoyed by a trade mark proprietor in respect of spurious goods. The Court concluded that, in both cases, the products ought not to have been marketed on the market concerned. It further concluded that a national law that permitted financial remedies in such circumstances was not, in itself, contrary to the principle of proportionality. Diluting what could be interpreted as an opinion by the Court on suitable national remedies in such circumstances, the Court added that it was for the national court to determine the amount of the financial remedy in light, in particular, of the extent of the damage caused to the trade mark proprietor by the parallel trader's infringement.