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CLIENT ADVISORY

ECJ Decision in the Glaxo/Boehringer Case

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INTRODUCTION

This decision marks, what is hopefully, the end to a series of ECJ cases on the application of trade mark law to re-labelled and re-packaged pharmaceutical products. While perhaps the last significant ECJ decision, it is unlikely that this is the last case that national courts will have to grapple with, as the ECJ has left several matters to be decided by those courts.

The ECJ cases sought to reconcile the tension between, on the one hand, protecting a company's trade mark rights whilst, on the other hand, ensuring the free movement of goods throughout the EU.

Glaxo/Boehringer has been heard three times in the English High Court, once in the English Court of Appeal, and has required questions to be referred twice to the European Court of Justice ("ECJ"). These respective decisions have spanned seven years, leaving, until now, uncertainty in this area of the law and inconsistency between Member States in the law's application[1].

BACKGROUND

Infringement cases were brought by Glaxo Wellcome, Boehringer Ingelheim, Smithkline Beecham and Eli Lilly against two parallel importers into the UK; Swingward and Dowelhurst. The parallel importers had altered, to varying degrees, packaging and patient information leaflets in respect of the manufacturers' products. The manufacturers objected to this, claiming that such alterations were not "necessary" in order for the products to be marketed in the UK, and that therefore the importers infringed the manufacturers' respective trade mark rights.

This latest referral to the ECJ was made by Jacob L.J., sitting in the English Court of Appeal[2]. In his judgment, he stated that if it were his decision alone, he would allow the importers' appeals (relating to re-boxed products) and dismiss the manufacturers' cross-appeals (relating to re-stickered boxes). Jacob L.J. was however concerned with the disparity of views between, on the one hand, a number of national courts, and, on the other hand, the Commission and EFTA

[1] An overview of these decisions can be found in our April 2003, February 2004, March 2004 and April 2006 client advisories. If you would like a copy of any of these, please let us know.

[2] *Glaxo Group Limited & Others v Dowelhurst Limited and Swingward Limited,* Court of Appeal, [2004] EWCA (Civ) 129.

Court. Laddie J., in the English High Court, interpreted the "necessity" requirement as being applicable both to the need to re-package and to the presentation of the re-packaged goods. The Commission and EFTA Court of Appeal, however[3], considered that the "necessity" test applied to the act of re-packaging alone.

Jacob L.J. therefore asked the ECJ to provide guidance on, amongst other things, the following main points:

1. whether the English High Court (and other national courts) or the EFTA Court, the English Court of Appeal, and the Commission are correct in their interpretation of "necessity";
2. guidelines for co-branding and de-branding;
3. guidelines as to the form of over-stickering and re-boxing, and whether over-stickering is a form of re-packaging and, therefore, subject to the same rules;
4. guidelines as to the treatment of goods where adequate notice had not been provided.

ECJ DECISION

In many respects the ECJ has followed the opinion of Advocate General Sharpston ("AG"), which was handed down on 6 April 2006. However, there are significant differences that, in our view, favour the brand-owner and provide clarity where the AG's decision was vague.

Both the ECJ decision and the AG's opinion focussed on the conditions formulated in *Bristol-Myers Squibb and Others v Paranova*[4] (the "BMS conditions"). The BMS conditions aimed to set out when and how it would be acceptable for parallel importers to make changes to branded products. In *Glaxo*, Jacob L.J. summarised the test as being that an importer who re-packages and re-applies a trade mark will infringe the mark unless it satisfies all 5 BMS conditions, namely that:

1. it was necessary to re-package to market the product;
2. there was no effect on the original condition of the packaging and proper instructions were enclosed;
3. the manufacturer and importer were clearly identified;
4. the presentation of the packaging was otherwise "non-damaging"; and
5. proper notice was given of the intention to re-package.

In its decision, the ECJ sets out its conclusions on the following six main points.

1. **The concept of re-packaging – the BMS conditions <u>DO</u> apply to over-stickering.** This was the only significant point in which the ECJ's decision differed fundamentally from the AG's opinion. The AG considered that, since in cases of over-stickering the original packaging, both internal and external, remains intact, there could be no impairment to the guarantee of origin function of the trade mark. The ECJ held, however, that:

> "…relabelling of the trade-marked medicinal products, just like reboxing of those products, are prejudicial to the specific subject-matter of the mark…Such a change may thus be prohibited by the trade mark proprietor unless the new carton or relabelling is necessary in order to enable the marketing of the products imported in parallel and the legitimate interests of the proprietor are also safeguarded.…It follows that the five requirements set out in *Bristol-Myers Squibb*…if met, prevent the proprietor from opposing further commercialisation of a pharmaceutical product which has been repackaged by the importer, also apply when the repackaging consists in the attachment of a label to the original packaging."

The ECJ's decision, in this respect, is in our view favourable to brand owners, as it recognises that the re-labelling of medicinal products can be equally as damaging to trade marks as re-packaging.

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3 In *Paranova AS v Merck & Co., Inc, and Others*, Case E-3/02. This was discussed in our February 2004 advisory.

4 Joined Cases C-427/93, C-429/93 and C-436/93 [1996] ECR 1-3457.

2. **The need for "necessity" only applies to the fact of re-boxing, and not to the way in which it is done**. The ECJ favoured the Commission's approach to the question of necessity. As stressed in the AG's opinion, to have decided otherwise would "…place an intolerable burden on national courts, which would have to take numerous decisions on trivial details of pattern and colour which are obviously not within their judicial remit". If this approach had been adopted, the national courts would have been placed in an awkward position, as they would have needed to decide when the whole, or part, of a pack design was unnecessary. Indeed, the ECJ's decision on this point favours the parallel importer, but considerable hurdles remain to be cleared.

3. **Damage to reputation is not limited to defective, poor quality, or untidy packaging**. The ECJ referred to Article 7(2) Trade Marks Directive (89/104/EEC), which stipulates that there must be a "legitimate reason" to allow a trade mark owner to limit the further commercialisation of its goods. A parallel importer must satisfy the court that there has been no damage to the brand owner's trade mark in order to comply with this rule. In their submissions, those acting for the parallel importers had sought to limit damage to defective, poor quality or untidy packaging. However, the ECJ held that a re-packaged product:

> "…could be presented inappropriately and, therefore, damage the trade mark's reputation in particular where the carton or label, while not being defective, of poor quality or untidy, are such as to affect the trade mark's value by detracting from the image of reliability and quality of such a product and the confidence it is capable of inspiring in the public concerned."

This aspect of the decision again favours the brand owner, as it does not limit the circumstances in which a re-packaged product may, in fact, damage the brand. As is clear from the next finding, it will be for national courts to cut that particular Gordian knot.

4. **Circumstances likely to damage the trade mark's reputation**. It is for the national courts to decide, on a case by case basis, the question of damage and, in particular, whether any of the following actions by a parallel importer is liable to damage the trade mark's reputation:
   - failing to affix the trade mark to the new exterior carton ('de-branding'), or
   - applying either his own logo or a house-style or a get-up or a get-up used for a number of different products ('co-branding'), or
   - positioning the additional label so as wholly or partially to obscure the proprietor's trade mark, or
   - failing to state on the additional label that the trade mark in question belongs to the proprietor, or
   - printing the name of the parallel importer in capital letters.

   What constitutes "damage" is likely to be the subject of further litigation in the national courts. For example, in the English court decisions in the *Glaxo* case there was disagreement between the High Court and the Court of Appeal over the damage that could be caused by de-branding. In the High Court Laddie J. thought that de-branding reduced the prominence of a mark, and could therefore damage its reputation; In the Court of Appeal Jacob L.J. said that a brand owner had no right to require any subsequent dealer in the goods to apply his mark, and that therefore de-branding should be permissible.[5] Accordingly, brand-owners have an opportunity to explore the limits of this idea of damage in correspondence with importers and, ultimately, before national courts.

5. **The burden of proof**. In most cases, the burden of proof falls onto the importer, who must, for example, establish that re-packaging is necessary, and that the other BMS conditions have been complied with. However, where the parallel importer has

[5] See our April 2003 and March 2004 client advisories.

supplied evidence that leads to a "reasonable presumption" that the BMS conditions have been satisfied, it is then for the trade mark owner—who is best placed to assess whether re-packaging is liable to damage its trade mark—to prove that damage has, in fact, been caused. While, again, the decision is more favourable to the brand-owner than the importer, there is room for further squabbling over matters such as whether the importer has, indeed, provided sufficient evidence to give rise to the "reasonable presumption" that the conditions have been met. Again, this is likely to lead to disputes being resolved in the national courts.

6. **The consequences of the absence of prior notice.** An importer that fails to give notice will be considered to have infringed the relevant trade mark. The trade mark owner will be able to claim financial remedies, such as damages or an account of profits, as such remedies will not be considered contrary to the principle of proportionality. The national courts will decide what remedy is appropriate, and in the English courts this will mean that the court has discretion as to the amount to be awarded, if any. The ECJ noted that the national courts should take into account the extent of damage caused by the infringement.[6]

COMMENTS

The ECJ's decision is surprisingly succinct. Whilst it does provide clear answers on the questions referred, there is little analysis or guidance for national courts to follow. In fact, significant issues, such as damage and the remedies for lack of notice, are left to national courts to determine based on the particular circumstances before them. It is therefore likely that, whilst this decision may mark the end to related litigation in the ECJ, the national courts will be dealing with such issues for some time yet. It is very likely, given the historically different approaches to IP protection taken by the various Member States, that this will lead to different courts reaching somewhat different conclusions.

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6 The AG had suggested a two stage test depending on how many of the other BMS conditions the parallel importer had satisfied, but this approach has not been adopted by the ECJ.