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CLIENT ADVISORY

THE GLAXO/BOEHRINGER CASE-COURT OF APPEAL'S MOST RECENT DECISION, "FOR THE PRESENT"

INTRODUCTION

This decision of the English Court of Appeal¹ serves as the latest instalment in a series of cases heard in both the English national courts and European Court of Justice ("ECJ"), on the application of trade mark law to re-labelled and re-packaged pharmaceutical products. Brand owners will be disappointed, though not surprised, by the decision, which implements the findings of the ECJ, given in April last year, on questions referred to it. Followers of the *Glaxo/Boehringer* saga will also be disappointed to find out that we are still not at the end of the line: at the request of the claimants, the Court of Appeal's decision is somewhat temporary, as it will be reviewed following the ECJ's decision in a pending reference from the Austrian Court in Case C-276/05, *Wellcome v Paranova*.

This series of cases has 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, now twice in the English Court of Appeal, and has required questions to be referred twice to the ECJ. These respective decisions have spanned eight years, leaving, to this day, a legacy of uncertainty in this area of the law, and inconsistency between Member States in the law's application².

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 summary is intended to be a general summary of the law and does not constitute legal advice. You should consult with competent counsel to determine applicable legal requirements in a specific fact situation.

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¹ Boehringer Ingelheim & Others v Swingward Limited & Dowelhurst Limited, Court of Appeal, [2008] EWCA (Civ) 83.

² An overview of these decisions can be found in our April 2003, February 2004, March 2004, April 2006 and April 2007 client advisories. If you would like a copy of any of these, please let us know.

Jacob L.J., sitting in the English Court of Appeal³ asked the ECJ to provide guidance on, amongst other things, the following main points:

- 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;
- 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.

The ECJ decision 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 repackages and re-applies a trade mark will infringe the mark unless it satisfies all 5 BMS conditions, namely that:

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

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

- The BMS conditions <u>DO</u> apply to over-stickering. The ECJ recognised that the re-labelling of medicinal products could be equally as damaging to trade marks as re-packaging.
- 2. The need for "necessity" only applies to the fact of re-boxing, and not to the way in which it is done.
- Damage to reputation is <u>NOT</u> limited to defective, poor quality, or untidy packaging.
- 4. It is for the national courts to decide, on a case by case basis, the question of damage and, in particular, whether actions such as 'de-branding' and 'co-branding' by a parallel importer are liable to damage the trade mark's reputation.
- 5. In most cases, the burden of proof falls upon 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 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.
- 6. An importer that fails to give notice will be considered to have infringed the relevant trade mark. 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 damages to be awarded, if any.

THE COURT OF APPEAL DECISION

In this latest *Glaxo* decision, the English Court of Appeal's task was predominantly to re-assess the question of whether or not the fourth BMS condition was satisfied by the parallel importers, in light of the ECJ's findings. Essentially, therefore, the question was whether or not 'co-branding' and 'de-branding' by the parallel importers caused damage to the reputation of the trade marks and their proprietors.

³ Glaxo Group Limited & Others v Dowelhurst Limited and Swingward Limited, Court of Appeal, [2004] EWCA (Civ) 129.

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

In the High Court, Laddie J. had thought that de-branding reduced the prominence of a mark, and could therefore damage its reputation. In the Court of Appeal, however, Jacob L.J. stated 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 As stated above, the ECJ considered that it is for national courts to assess the question of damage, on a case by case basis. It is hardly surprising, therefore, that in this latest decision Jacob L.J. decided the following:

 Co-branding and de-branding do not, in principle, damage a trade mark's reputation. Whether or not there is damage is a matter of fact for the national court to decide on a case by case basis. Jacob L.J. stressed that:

"...as I see it, "fact" means just that. Mere assertion or counter-assertion will not do.⁶"

 In this case, the importers' co-branding did nothing to disparage or harm the manufacturers' marks. Jacob L.J. stated:

> "I am quite unable to see how it follows that there is damage to either of the trade marks Atrovent or Becloforte. True it is that Munro have promoted their own mark. But it is made plain in context that it is an *importer's* mark. Nothing is done so as to disparage the claimants' trade marks...If this harmless type of co-branding were illegal, many an importer or dealer would find himself in trouble. Harrods are apt to put their name on everything they sell. Berry Brothers and Rudd, the distinguished wine dealers, often put their own label on the back of the wine bottles they have imported. Should all this stop if the manufacturer or other ultimate source says so? Just because the dealer or importer is promoting himself? The answer is obviously not. And the reason is that no harm, no damage, is done.⁷"

This is not to say that co-branding will never be considered to damage a trade mark. Jacob L.J.

7 Paragraph 43.

stated that a court would have to look at the way in which the co-branding was done.

- 3. Total de-branding cannot be an infringement, since "there is simply no use of the trade mark in any shape or form⁸", and without use, there can be no infringement. Significantly, Jacob L.J. pointed out that the commercial objection that a manufacturer may have to an importer using the generic name for a drug, i.e. the fact that consumers would, by familiarity, be more open to accepting generic versions of the drug, was simply a commercial objection and did not constitute damage.
- 4. Partial de-branding may be an infringement, depending, again, on how it is done. There was no evidence, however, in these proceedings that this was the case. Jacob L.J. commented:

"...a trade mark owner has no <u>right</u> to insist that his trade marks stays on the goods for the aftermarket. Because that is so, it seems to me impossible to say that partial de-branding is damaging <u>in itself</u>...whether there is damage is a question of fact. The manner or form of partial de-branding could indeed in principle hurt the image or prestige of a trade mark. It would all depend on how it was done.⁹"

5. The parallel importers had therefore complied with the fourth BMS condition, and had not caused damage to the manufacturers' trade marks.

As stated above, this decision is not final, but is the Court of Appeal's view "for the present", pending the outcome of a further reference to the ECJ by the Austrian Supreme Court¹⁰. This reference concerns whether or not there is a principle of "minimum intervention" to be applied to the presentation of new packaging; in other words, whether the parallel importer may only re-package so far as is necessary to comply with national regulations. Jacob L.J. in the Court of Appeal thought that this was not the case, since the manner of re-packaging was only relevant to the

⁵ See our April 2003 and March 2004 client advisories.

⁶ Paragraph 41.

⁸ Paragraph 52.

⁹ Paragraphs 53-54.

¹⁰ Case C-276/05, Wellcome v Paranova.

question of damage. Nevertheless, the *Glaxo/Boehringer* case is clearly not over yet.

COMMENTS

Jacob L.J. astutely commented that:

"Notwithstanding two references to the ECJ and its answers, each "side" claims to have won. That is a sorry state of affairs. European trade mark law seems to have arrived at such a state of uncertainty that no one really knows what the rules are...The compromises which have emerged have very fuzzy lines. So it is that in this case, notwithstanding two references (and a host of cases about relabelling parallel imports going back at least 30 years...), there is still room for argument.¹¹"

We agree. What is clear, however, is that the ECJ has given national courts considerable discretion in setting the parameters for what they consider constitutes "damage". This can only lead to further uncertainty and disparity between Member States. Nevertheless, in view of the English Court of Appeal's latest contribution, brand owners should consider very carefully whether they have sufficient evidence of "damage" to their marks, before contemplating bringing proceedings against parallel importers in the UK. Such damage will need to be clear, and easy to understand and prove. "Damage" that appears to be less than obvious, or an academic construct, is unlikely to be persuasive.

The judgment is particularly clear that de-branding will not constitute damage in the UK (though other national courts may decide differently on this point). Whilst the reasoning is clear that, if a trade mark is not used, it cannot be infringed, it seems counter-intuitive that de-familiarisation with a brand name is not harmful. Jacob L.J. accepted that the de-branding of drugs was likely to make patients more readily accept generic versions of those drugs, yet he considered this to be merely a "commercial objection". In our view, it is difficult to see how such a "commercial objection" does not constitute damage to a brand. This aspect of the judgment is likely to be particularly difficult for brand-owners to digest.

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¹¹ Paragraph 2.