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Cephalon v Orchid – A path less clear?

Brian Cordery (Bristows) · Tuesday, November 30th, 2010

The UK has long been considered a favourable jurisdiction for pharmaceutical patent holders to seek an interim or preliminary injunction. In particular, from 2001 the English Courts have imposed an obligation for generics companies to “clear the way” (i.e. obtain a declaration of non-infringement or start invalidity proceedings in respect of any relevant patents they are aware, or ought to be aware, of) before launching generic versions of patented branded products (see e.g. *SKB v Apotex* [2003] FSR 30). Many other European Patents Courts have started to follow the English approach and place a degree of responsibility on generics to show their hand at an early stage. However, in the recent English High Court judgment in *Cephalon v Orchid & Generics (UK) t/a Mylan* [2010] EWHC 2945 Floyd J. has made it clear that, while the fact that a generics company had not sought to “clear the way” was a consideration that “may be material in particular cases”, it was not a principle of law and it was open to the Court to attribute the weight that the consideration should be given based on the facts of the case. It remains to be seen if this decision will be a one-off from a Judge who, although explicitly not taking the merits of the parties’ cases into account at the interim stage, must surely have been subconsciously influenced by flaws in the patentee’s evidence of infringement. Alternatively, it may mark the start of a move away from the “clearing the way” doctrine as it has generally been understood for the past 10 years or so. Time will tell.

Turning to the detail, Cephalon own two so-called “secondary” patents that protect certain pharmaceutical compositions of a defined particle size of modafinil, a drug used in the treatment of sleeping disorders. Cephalon alleged that Orchid’s generic product, which was marketed by Mylan in the UK, infringed both patents and applied for preliminary relief prior to the main action proceedings scheduled for 6 to 8 months later. In considering the application Floyd J. held that the evidence of infringement “just about” established that there was a serious question to be tried although he had sympathy with the generics’ view that there were serious flaws in the infringement evidence presented to the Court. While observing that from a cursory review, the attack on the validity of the patent looked attractive, the Judge was “*not persuaded that the claimants..[had]...no arguable case on validity*”. Floyd J. then went on to consider irreparable harm.

The irreparable harm arguments raised by both parties will be familiar to all who have read pharmaceutical preliminary injunction cases in the past. However, importantly, while Floyd J. felt that both parties had identified heads of unquantifiable loss, the evidence that Cephalon had submitted was held to be either unconvincing or only relevant if the main infringement proceedings were not expedited. Floyd J. therefore found the potential loss to the defendants “*more likely to occur, more likely to be substantial and more difficult to quantify*”.

Considering the particular facts of the case, it would perhaps be an exaggeration to say that the English Court's attitude to the obligation for generics to "clear the way" has changed as a result of this decision. While it is plain from his judgment that Floyd J. thought the principal factors influencing the balance of convenience lay in the discrepancy between the parties' respective irreparable harm arguments; judicial perceptions as to infringement and patent validity would have been in the background too as the Judge weighed up in his mind how to exercise the broad discretion afforded to him. Overall, it is clear that Floyd J. thought the balance of convenience lay so far in the defendant's favour that it overrode any obligation to "clear the way". However it is fair to say that, while patent holders should continue to consider very carefully their irreparable harm arguments and should not be tempted to assume that irreparable harm to the patent holder will be found by the Judge, generics companies would be unwise to conclude that the UK obligation to "clear the way" is significantly weakened as a result of this case, especially where patents are probably valid and likely infringed.

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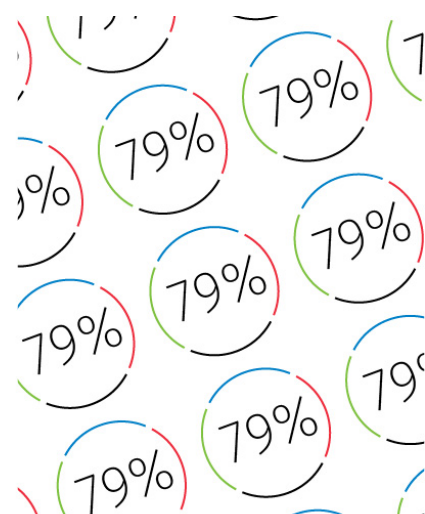
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This entry was posted on Tuesday, November 30th, 2010 at 11:43 am and is filed under [Injunction, United Kingdom](#)

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