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Opinion

THE PATENT FILES

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A change in attitude towards making generics "clear the way"?

Is the UK about to dismantle a hurdle to the launch of a generic pharmaceutical product, asks Nabarro's **Jonathan Radcliffe**

Pharmaceutical companies have long regarded the United Kingdom as a favourable venue for patent disputes. The English patents court has an outstanding reputation for quality, sophistication, and speed, and the UK also happens to be one of Europe's key markets.

But, following a theorem first propounded by Lord Justice Jacob[1], the English patent litigation deck of cards is somewhat more stacked in favour of pharmaceutical companies – and against would-be competitors – by the obligation on the generics competitor to "clear the way". The recent case of *Cephalon Inc v Orchid Europe*[2] may have begun to redress this.

The obligation to "clear the way"

The general rule in patent litigation is that if a potential defendant suspects it is about to be sued, it is under no obligation to start its own proceedings for a declaration of non-infringement and/or revocation. It can do nothing, and wait and see what happens, without any adverse inferences being drawn against it.

The position is different when the English patents court is considering whether to injunct a generic pharmaceutical product launch. Until now, in this scenario, the court has drawn adverse inferences if the would-be competitor has not first attempted to "clear the way". This requires the competitor to use the procedures for revocation and/or a declaration of non-infringement to clear the potentially problematic patent out of the way first before competing, so that when the new product is launched all the problems of an interim injunction are avoided.

The court can take a failure to do so – or very late notification to the patentee - into account as an important factor in favour of the patentee in deciding the injunction. This has led to a number of interim injunctions being granted in recent years to prevent the launch of generics products.

This obligation is undoubtedly onerous and is a real commercial disincentive to a would-be competitor considering launching in the UK.

It must decide which is the lesser of two evils. It must either finalise its product and challenge the incumbent patentee some 18 months before it can get onto the market, or run the risk of being injuncted immediately on launch in circumstances where the court will err in the patentee's favour by interpreting the patent potentially more widely than at trial. The court does not examine infringement and validity in interim injunction proceedings, other than to determine that there is an arguable case, which then makes it easier for the patentee to prevent the launch.

This English case law theorem arouses strong feelings. It is elevated to the status of an unimpeachable doctrine by patentees when applying for an injunction, but to would-be competitors it is anti-competitive and unjustifiably extends the scope of the rights given to a patent by forcing competitors into litigation, or penalising them if they do not.

Developments in *Cephalon Inc v Orchid Europe Ltd*

The English patents court recently ruled on an interim injunction application by Cephalon to prevent Orchid and Generics UK (trading as Mylan) infringing its modafinil patent for narcolepsy treatment.

The defendants' failure to clear the way formed a central part of Cephalon's attack. They had secured their regulatory approvals some nine months beforehand, without taking any steps to clear the way or to launch their competing product until the UK trade press announced that Mylan was offering modafinil tablets in the UK. Not surprisingly, that announcement led to the interim injunction application.

Modafinil was originally discovered by a third party in 1976, and licensed to Cephalon. During subsequent US clinical trials Cephalon discovered that a reduced particle size increased efficacy and reduced dosages, and therefore reduced side effects. Cephalon's patents protected a modafinil composition with this particle size.

The court held that Cephalon had narrowly demonstrated a good enough arguable case of infringement and validity. The judge criticised Cephalon's experimental evidence on infringement based on particle size as "very weak" that "just about clear[ed] the threshold of establishing … a serious question to be tried". Although he then held that Cephalon's non-obviousness arguments were "not very promising" and the evidence "incomplete and inconclusive", he nonetheless considered Cephalon's validity arguments also cleared the relevant threshold.

The judge therefore had to base his decision on the linked questions of irreparable harm and the balance of convenience. This involves weighing the likely injustice of granting an injunction, which it later turns out should not have been granted against the injustice of withholding one which should. One of the relevant factors in this analysis was clearing the way, and the judge made a number of important comments on this.

- He characterised clearing the way not as a legal doctrine, but as only a "theme … which has emerged from the cases [as] a factor in the balance of convenience".
- Clearing the way was a consideration, which may be material in some cases, depending on the evidence. But he expressly stated

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that there is a danger in treating this theme as a principle of law. Whether it applies at all in any given case, and if so whether it outweighs the other factors, is to be decided on the evidence.

- He concluded that no injunction should be granted, although he ordered an expedited trial. The balance of convenience was in favour of allowing Mylan to continue to sell its product. He was not convinced that Cephalon would be unable to increase its prices after a period of generic competition; there was a strong likelihood that Mylan would lose the unique market opportunity of being first to market if injuncted; and the market for modafinil was a mature one where any lost profits suffered by Cephalon could readily be assessed.
- He expressly took Mylan's failure to clear the way into account, but held that he was "not obliged to give it so much weight that it necessarily swamped all the other [factors]". This was a case where the other factors carried more weight.

Is the pendulum swinging away from the obligation to clearing the way?

Pharmaceutical companies have undoubtedly enjoyed a golden bonus for the 10 years that clearing the way has been in existence. This theorem has extended the scope of protection for their patents, whilst creating a penumbra of uncertainty for would-be competitors.

But clearing the way looks increasingly unfair and anachronistic, especially in the light of the kind of scrutiny and emphasis on competition for the public benefit being given to the pharmaceutical sector by the European Commission. It only applies in pharmaceutical cases (and in no other sector), and puts the entire burden to start litigation on the would-be competitor when that competitor may be firmly of the opinion that it does not infringe and/or that the patent may be no good.

This recent judgment is the first sign that this theorem may have had its day. The judge's description as no more than "a theme that has emerged from the cases" is telling. But more telling is the result. No injunction was granted because the other factors on balance of convenience were more important than a failure to clear the way. In expressly not allowing this failure to swamp the other factors the judge has given a signal as to its relative importance.

Whilst this case makes strong inroads into the importance of clearing the way, until the Court of Appeal's judgment in *SmithKline Beecham v Apotex* is overruled or suitably distinguished, it can still be an important factor. Would-be generics competitors should not yet conclude that this factor has gone. Equally – and as is clear from this judgment – pharmaceutical companies must pay closer attention to their arguments on irreparable harm.

Footnotes

1. *SmithKline Beecham v Generics (UK)*, 23 October 2001, Mr Justice Jacob (as he then was), approved and extended by Lord Justice Jacob in the Court of Appeal in *SmithKline Beecham v Apotex Europe* [2003] FSR 30.
2. *Cephalon Inc v Orchid Europe Ltd & Anor* [2010] EWHC (Pat) 2945, Mr Justice Floyd.