NABARRO
CLARITY MATTERS

The consequences of failing to "clear the way": *Novartis -v- Dexcel-Pharma*

The English Patents Court has given pharmaceutical companies a strong reminder of the importance of clearing the way of any relevant patents before introducing a competing product, and of the consequences of not doing so.

THE DOCTRINE OF "CLEARING THE WAY"

The general rule 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 from such conduct.

The position is different where the Patents Court is considering whether or not to injunct the launch of a generic product.

If the generics company knows that there are relevant patents, yet decides to wait until there is insufficient (or no) time between notifying the patentee of its plans and the launch date, the Court can take this into account as an important factor in favour of the patentee.

The underlying logic is that the generics company should know that litigation was inevitable, unless the patentee's case was hopeless (in which case if there had been open disclosure of the proposed generic product and how it was made, the patentee would have had to accept that it did not infringe, meaning there would be no litigation).

This doctrine was summarised in SmithKlineBeecham -v- Apotex Europe as follows:

> *"Where litigation is bound to ensue if the defendant introduces his product he can avoid all the problems of an interim injunction if he clears the way first. That is what the procedures for revocation and declaration of non-infringement are for."*

The failure to clear the way has led to the English Patents Court granting a number of interim injunctions in recent years to prevent the launch of generics products.

Ask a question

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THE NOVARTIS – DEXCEL-PHARMA LITIGATION

Novartis sued Dexcel for infringement of its patent for a cyclosporin formulation in the form of a micro-emulsion pre-concentrate. Cyclosporins are used in the treatment of transplant patients to prevent transplanted tissue being rejected.

The Judge held that there was a serious prospect that Novartis would be able to show at trial that its patent was infringed. He therefore considered the factual background to decide whether to grant an interim injunction until trial.

Novartis had found out in June 2007 that Dexcel had been granted a conditional UK marketing authorisation. Novartis then wrote to Dexcel warning it that its product might infringe, and pointing out that Dexcel had not tried to clear the position on the UK patents with Novartis.

Dexcel made no attempt to clear the way, but agreed to give 28 days written notice of any launch. In March 2008 Dexcel gave written notice, which led to the litigation.

The Judge held that Dexcel was in no doubt from June 2007 that Novartis would sue if it launched in the UK. If it had any such doubt, it should have taken the matter up with Novartis. It did not do so. The Judge held that Dexcel should have put Novartis under pressure by stating its view that there was no infringement, or by seeking a declaration of non-infringement. Instead, Dexcel told Novartis it had no immediate intention to launch and gave Novartis an undertaking which effectively prevented Novartis from suing it.

The Judge therefore held that it was unmistakably Dexcel's fault that the legal position was not clear before Dexcel's planned launch date. Moreover, Dexcel's undertaking did not prevent an action by Dexcel to seek a declaration of non-infringement; Dexcel should have done so.

On this basis the Judge imposed an injunction on Dexcel until trial. He said: "I am impressed by the fact that Dexcel had it within its power to clear its product in time for its launch and neglected to do so. The fact that it claims the product to be a strategic and important one makes its strategy all the more surprising."

PRACTICAL LESSONS

Companies must take this doctrine fully into account when dealing with the launch of a competing product in the United Kingdom (and in particular its effect on the timing of the planned product launch).

The English Patents Court will expect positive steps from a generics company to clear the way of any relevant patents (either a revocation action or seeking a declaration of non-infringement). A failure to do so significantly increases the risk of an injunction being granted.

This doctrine favours patentees. They should therefore monitor potential competitors and put them on notice as soon as they discover a potential infringement (this will maximise the chances of an injunction being granted).