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Interim Injunctions – “You may not have the right to remain silent”

Brian Cordery (Bristows) · Thursday, April 5th, 2012

Merck Sharp Dohme Corp. and Bristol-Myers Squibb Pharmaceuticals Limited v. Teva Pharma B.V. and Teva UK limited

On 15 March 2012, the High Court in England and Wales delivered some useful guidance on when a patentee can obtain an interim injunction in a pharmaceutical patent infringement action. The case was Merck Sharp Dohme Corp. and Bristol-Myers Squibb Pharmaceuticals Limited v Teva Pharma B.V. and Teva UK limited and related to a patent (EP 0 582 455) owned by Merck and Bristol-Myers Squibb ('BMS') which provides compound protection for efavirenz, an anti-retroviral medicine used in the treatment of HIV and AIDS. An SPC obtained on the basis of the patent expires on 20 November 2013. Teva obtained an MA for its efavirenz product (which is generally considered not to be an infringing act in Europe), via the Centralised Procedure, 22 months before the expiry of the SPC.

Just before Teva's MA granted BMS' lawyers wrote to Teva seeking an undertaking that Teva would not launch its efavirenz product in any country in which patent remains in force. No undertaking was given by the requested deadline and BMS informed Teva that they therefore presumed Teva had an intention to market the product imminently. In light of this and taking into account that Teva launched its generic atorvastatin surreptitiously last summer, BMS applied for an interim injunction in the high court.

In his judgment from the inter partes injunction hearing Judge Birss clarified that in order to bring an action for interim relief on a quia timet basis, as BMS had here, the defendant must have threatened and intend to infringe the patent in question. The intention to launch did not have to be immediate – if the intention was to launch before expiry this would be enough. How this was proved would depend upon the facts of the case.

On the facts of this case, Judge Birss considered that it was a reasonable inference that Teva intended to launch before the expiry of the SPC. He considered the timing of the MA (as noted above, just less than 2 years before expiry) and the absence of a satisfactory explanation as to why this was necessary to be an important factor. He also noted that whilst a failure to offer satisfactory undertakings or indeed any form of response does not in itself prove the existence of an intention to infringe, at the interim stage it may, depending on the circumstances, be fair to draw an inference from the silence.

In arguing that an injunction should not be imposed Teva claimed that divulging its launch date

would expose a valuable commercial secret. Judge Birss agreed that the date of any launch could be a valuable commercial secret. However, the fact that a Gx company intended to launch a product on patent/SPC expiry would “not be news to anyone.” Therefore if this was Teva’s plan, they could simply have said so.

Accordingly, an interim injunction was granted to BMS pending trial on the merits.

This decision is in line with the rationale of English civil litigation that potential parties to litigation should communicate with each other and try to resolve disputes without recourse to litigation. Whilst the Judge has stressed that each case turns on its facts, it seems clear that a generic company may often have to be proactive in reacting to enquiries from patent holders.

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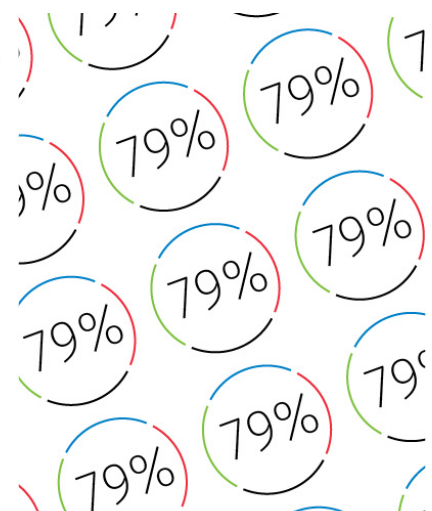
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