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Pharmaceutical Patent Infringement and the Specific Mechanism – Merck Canada Inc and Merck Sharp & Dohme Ltd v Sigma Pharmaceuticals Plc [2012] EWPC18

Brian Cordery (Bristows) · Tuesday, June 19th, 2012

The following summarises another interesting decision for the rejuvenated Patents County Court which is continuing to flourish as a forum for smaller intellectual property disputes of all kinds.

Merck is the proprietor of European Patent (EP (UK) 1 480 717) which, in relation to the product montelukast (Singulair, used for the treatment of adult and paediatric asthma conditions), has been extended by an SPC. The SPC is due to expire on 24 February 2013. Sigma is a company which regularly parallel imports Singulair from Italy into the UK. Ordinarily the parallel importing of a patentee's product on sale in one Member State and selling it in the UK would not infringe a UK patent. The dispute in this case arose when Sigma imported Singulair into the UK from Poland. Merck submitted that the Singulair imported from Poland and sold in the UK was an infringement because of the Specific Mechanism which forms part of the Act of Accession by which Poland joined the EU.

Under the Specific Mechanism, in certain circumstances, derogation from the general EU principles of free movement of goods and exhaustion of IP rights is possible. These circumstances include that a patentee can prevent a pharmaceutical product on the market in one of the new accession member states (e.g. Poland), from being imported into a country like the UK where there is a patent in place. This is possible if at the time that patent was applied for it was not possible to obtain a patent for the same product in the accession member state.

Merck applied for damages. Sigma argued that Merck was given advance notification that Sigma was to import Singulair from Poland and Merck did not reply to give notice it intended to rely on its patent rights to prevent such importation. Sigma argued it was a requirement of the Specific Mechanism that Merck could only exercise their patent rights once it had demonstrated its intention to do so. Sigma also argued that Merck should be estopped from invoking its patent rights in relation to the past acts as once Merck had exercised its rights, Sigma had stopped selling the product.

In his judgment on 27 April 2012, Judge Birss QC ruled that Sigma's interpretation of the Specific Mechanism was unsupported and that Merck not estopped from bringing a claim to damages. There was nothing in the wording of the Specific Mechanism which stated that prior notice from the patentee to a parallel importer was a necessary precondition of patent rights being exercised. Further, the notification sent in this case about the potential import of Polish Singulair was not sent

by Sigma but by Pharma XL. It was also addressed to a company in the Merck group which was not the patentee. Judge Birss noted that the patentee could have been easily identified and there was no evidence that any checks had been carried out to confirm that the letter had been received by the intended recipient. On the facts it was not reasonable for Sigma to consider Merck's lack of response to the letter as akin to it not objecting to the import. Merck's inadvertent failure to reply did not mean they had lost their right to claim damages.

On 3 May 2012, Judge Birss ordered an interim injunction and a cross undertaking pending trial. He also ordered the destruction of the imported products; the import was itself an infringing act and if Sigma were allowed to keep the products in the UK until the expiry of the SPC an illegal act would give them an unfair advantage.

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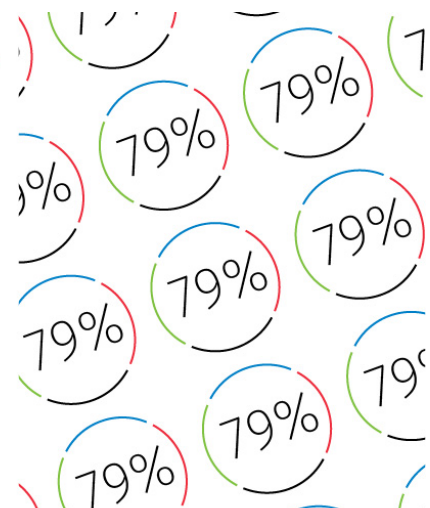
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