

Generics and Pharmac - again

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The ongoing battle between pharmaceutical companies and the manufacturers of generics, with Pharmac as a very interested party received another airing in court recently.(i)

Aventis Pharma SA is the patentee of the cancer treatment drug Taxotere, a derivative form of Docetaxel, which is due to expire on 2012. InterPharma (NZ) Ltd is the manufacturer of a generic copy, called Docetaxel EBEWE. It won a tender to supply the generic product to the government's pharmaceutical purchasing agency, Pharmac, in place of Aventis.

When it discovered the existence of the Docetaxel EBEWE drug on the Medsafe website, Aventis notified Interpharma of its concerns in April 2009. In October 2009 Pharmac awarded the tender to InterPharma, effective from December 2009. On seeing the medicine data sheet Aventis applied to amend its patent to ensure it covered the Interpharma product. Interpharma failed to oppose the amendments before they were made.

Aventis then sent a warning letter to Interpharma demanding that it stop selling its product to Pharmac. Interpharma responded by applying to the court to review the Commissioner of Patent's decision to grant the amendments.

Aventis applied for an interim injunction against InterPharma to stop InterPharma's distribution of Docetaxel EBEWE.

Both applications were heard together. Starting with the interim injunction, Harrison J held that the substantive issues of infringement and invalidity of the patent could not be dealt with until trial.

Turning to the balance of convenience, His Honour referred to evidence showing the drop in sales of the Aventis product following its delisting from the Pharmac schedule and the fact that hospitals would not purchase it once present supplies were exhausted. The market for those parties prepared to pay privately for was small.

Aventis's sales of Taxotere prior to delisting were considerable, at around \$4million a year and it claimed it would need to restructure and make staff redundant. Even if Docetaxel EBEWE were to be withdrawn, it claimed that it might not be viable to re-enter the market.

However InterPharma successfully argued that even if Aventis ultimately succeeded on patent infringement, damages could still be quantified in monetary terms using measures of gross sales, difference in supply price and direct market revenue comparison. The lack of substitutes and relatively stable demand in the market further strengthen the case that loss of future market opportunities need not be a consideration. The judge was also influenced by the provision by InterPharma of a \$5m bank guarantee.

Other factors also weighed in InterPharma's favour. The judicial review application on the amendments was finely balanced. If it succeeded, the infringement action might fail. InterPharma had contractual obligations to Pharmac, including penalties for non-supply, and its generic product was saving the taxpayer \$1.33m per annum.

Finally, Aventis did nothing between its first lawyers' letter in April 2009, and the award of the tender by Pharmac to InterPharma in October 2009.

Conclusion

In the end, Harrison J refused the application for the interim injunction, provided InterPharma produced a bank guarantee of balance of convenience favoured InterPharma

This case illustrates the importance of acting promptly when patent rights threatened by a generic product (including if necessary amending the patent) and also the peculiar factors that can come into play when Pharmac is the major purchaser of the particular product.

(i) *Aventis Pharma SA & Anor v Pharmaco (NZ) LTD and Interpharma(NZ) Ltd* HC AK CIV-2010-404-1670, 4 June 2010 Harrison J