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FEDERAL COURT WAXES LYRICA(L) ON PBS LISTING AND PATENT INFRINGEMENT

16 February 2017 | Australia
Legal Briefings – By **Patrick Sands** and **Steve Wong**

In a decision handed down yesterday (15 February 2017), the Australian Federal Court held that applying for Pharmaceutical Benefits Scheme listing does not exploit a patent.

UPDATED ON 18 APRIL 2017

Apotex Pty Ltd v Warner-Lambert Company LLC (No 3) [2017] FCA 94 has important implications for both originator and generic pharmaceutical companies, by clarifying the extent to which originator companies can rely on their patent rights to limit the preparatory steps taken by generic suppliers in anticipation of launch.

Subject to any appeal, the position under Australian law has been confirmed to be that a generic supplier can take the following steps during the term of a patent:

- apply for PBS listing of generic products, at least where such listing would only take effect after patent expiry; and
- provide notice to its customers that it intends to commence offering to supply generic products once the patent expires.

However, generic suppliers still need to remain vigilant that any preparatory steps taken in anticipation of launch do not convey anything that could be construed as an offer to supply their products during the patent term.

THE KEY ISSUE – PBS LISTING AND PATENT INFRINGEMENT

The key issue that Justice Nicholas was required to resolve was whether an application for listing on the Pharmaceutical Benefits Scheme (**PBS**) would amount to an act of infringement.

In order to take advantage of the PBS scheme, generic suppliers are required to obtain PBS listing for their products. In the usual course, such listing can only take effect a number of months following an application for PBS listing.

In this case, Apotex proposed to take steps during the patent term to apply for PBS listing for its generic pregabalin products, so that it was in a position to commence offering them for sale at subsidised prices under the PBS scheme once the patent expired (due to occur in July 2017).

While there was one previous case in which the Federal Court held that the act of applying for PBS listing did not constitute an exploitation of a patent,[1] a number of subsequent interlocutory judgments had been seized upon as suggesting otherwise.[2]

This decision is the first in which the Federal Court has given detailed consideration to this issue in the context of considering orders for final relief for patent infringement.

PBS LISTING IS NOT AN ACT OF INFRINGEMENT

Justice Nicholas held that the taking of steps by a generic supplier to obtain PBS listing would not infringe a patent. This is because such steps would not amount to 'an offer to sell or otherwise dispose of' a product (being one of the acts that fall within the definition of 'exploit' in the *Patents Act 1990* (Cth)), and would not otherwise constitute an act of exploitation.

Justice Nicholas characterised an application for PBS listing as a 'mere preparatory step' which may enable a generic supplier to exploit the invention after the expiry of the patent, without amounting to an 'offer' to sell or dispose of its products.

Justice Nicholas also indicated that other preparatory steps taken by a generic supplier in anticipation of launch would not infringe a patent. Justice Nicholas accepted that an offer for sale during the patent term could amount to an act of exploitation even though the products would not be supplied until after patent expiry, and also noted that the word 'offer' should be construed broadly such that it could encompass an expression of a willingness to sell.

However, if a generic supplier, acting in good faith, merely states that it proposes to offer to supply a product once a patent expires, Justice Nicholas did not consider that this would constitute an 'offer' (within the statutory definition of 'exploit').

BACKGROUND

This case relates to Warner-Lambert's patent for methods of use of the drug, pregabalin. Pregabalin is used to treat neuropathic pain, epilepsy, fibromyalgia and neuralgia, and is sold by Pfizer under the brand name Lyrica.

This decision considered the form of injunctive relief following the earlier decision of Justice Nicholas in December 2016 upholding the validity of the pregabalin patent and finding that generic versions of this drug infringed the patent. Click here and here to read our two articles on Justice Nicholas' earlier decision.

UPDATE (18 April 2017): Pfizer subsequently appealed Justice Nicholas' decision to the Full Court. On 13 April 2017, the Full Court handed down judgment on the appeal, affirming Justice Nicholas' finding that an application for PBS listing was not an act of infringement. In its judgment, the Full Court also expressly noted that the provision of an undertaking for guaranteed supply, as required in order to obtain PBS listing, was not 'an offer to sell or otherwise dispose of' a product that would amount to exploitation of a patent.

ENDNOTES

1. *Sanofi-Aventis v Apotex (No 4)* (2011) 202 FCR 56 at [49].

2. See for example *Otsuka Pharmaceutical Co Ltd v Generic Health Pty Ltd* [2012] FCA 239 and *Eli Lilly and Company v Generic Health Pty Ltd* [2013] FCA 1254.

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