

INFRINGEMENT OF PATENTED METHOD CLAIMS: THE NEED TO THINK BEYOND AUSTRALIA

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Legal Briefings - By **Helen Macpherson** and **Rachelle Downie**

In the much anticipated decision of *Apotex Pty Ltd v Warner-Lambert Company LLC (No 2)* [2016] FCA 1238, the Federal Court has held that the importation and sale in Australia of products made overseas using a method or process which is the subject of an Australian patent can amount to patent infringement. The decision confirms the extra-territorial scope of the meaning of 'exploit' in the Patents Act for method or process claims and in doing so, highlights the importance for importers to know how overseas products are made.

BACKGROUND

The 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 - it is its second highest product by revenue in Australia.

The case considered both the validity of the pregabalin patent as well as whether generic versions of this drug (marketed by Apotex and Generic Partners) infringed the pregabalin patent. In this article, we discuss the impact the infringement aspect of the decision has on manufacturers of products made overseas, particularly for importers of pharmaceutical products. [Click here](#) to read our article on Justice Nicholas' validity decision.

INFRINGEMENT OF PATENTED METHOD OR PROCESS CLAIMS

A key issue in dispute was whether the importation and sale in Australia of medicaments made outside the patent area could infringe a Swiss claim in an Australian patent. In the context of infringement, the parties assumed that a Swiss claim was to be characterised as a method or process claim. This assumption was correct – Justice Nicholas agreed with such an approach, noting that the infringement of Swiss claims is to be considered through the prism of the ‘method or process’ limb of the definition of exploit.

Central to his Honour’s finding about the scope of the ‘method or process’ definition of exploit, was the fact that the definition does not include any express territorial limitation. Rejecting Apotex’s argument, Justice Nicholas held that there was no reason to read down the meaning of exploit for method or process claims to be limited to Australia.

Critically, the extra-territorial reach of the definition of ‘exploit’ was tied to the fact that the definition includes a reference to the act of importation. Justice Nicholas pointed out that it was the act of importation and sale in Australia of a product made using the patented method, rather than use of the patented method outside of Australia, that amounted to infringement. His Honour stated: *“The fact that the patented method is performed outside the patent area does not avoid infringement of a method claim (including a Swiss claim) if the product imported and sold in Australia was made using the patented method because the acts of importation occur within the patent area”*.¹

LESSONS AND NEXT STEPS

The extra-territorial scope afforded to method or process patent claims is relevant to importers of products, particularly for pharmaceutical products which are often protected by patents covering the products themselves and their methods of manufacture. Importers of products manufactured overseas need to ensure that manufacturers provide details of how the product is made so that patent infringement risks can be considered. While the pregabalin decision provides clarity where the imported product is made using a patented method, one question which remains unanswered is the extent to which importation of a product that involves the use of a patented method or process as part of an early or intermediate stage of manufacturing the final product amounts to infringement.

In terms of next steps, no appeal has yet been filed from Justice Nicholas’ decision, with the patent due to expire in July 2017.

Endnotes

1. [2016] FCA 1238 at [297]

KEY CONTACTS

If you have any questions, or would like to know how this might affect your business, phone, or email these key contacts.



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