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Proposed amendments to Australian patent law: Infringement exemption for acts for obtaining regulatory approval

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In brief

- A Bill to amend Australia's patent law is currently being considered that proposes exempting acts done solely for purposes connected with obtaining regulatory approval of a relevant product from infringement of a non pharmaceutical patent.
- The provisions of the Bill relevant to the exemption may be implemented as early as by the end of 2011.

An exemption to Australian patent infringement is proposed in respect of acts done solely for purposes connected with obtaining regulatory approval of a relevant product. The exemption is to apply to acts done in relation to agrochemicals, veterinarian medicines, medical devices, diagnostics and any other non-pharmaceutical subject matter for which there is a legally established regulatory approval regime. This proposal would significantly broaden the current narrow exemption that only applies to acts connected with obtaining regulatory approval of a pharmaceutical.

Current law

Presently, section 119A of the *Patents Act 1990* (Cth) provides for exemption from patent infringement for those acts done solely for purposes in connection with obtaining regulatory approval of a pharmaceutical. There is no legislative provision that exempts acts done for obtaining regulatory approval of non pharmaceutical subject matter from patent infringement.

The concern with the current law is that it puts Australian manufacturers at a competitive disadvantage to those companies that have operations in other countries that allow 'springboarding' (ie undertaking infringing acts required for regulatory approval of a non pharmaceutical product before patent expiry), in the sense that the latter companies, in having a head start in obtaining regulatory approval, are then able to launch products in Australia or elsewhere shortly after patent expiry and in advance of the Australian manufacturer.

Proposed amendment

According to the proposal, a person may undertake an act that would otherwise be an infringement of a patent claim **'if the act is done solely for purposes connected with obtaining an approval required by a law…to exploit a product, method or process; or purposes connected with obtaining a similar approval under a law of another country or region'**.

Analysis

The proposal is not prescriptive of what acts would be considered to be exempted, although it is clear that the acts done must be in connection with a regulatory approval process required by law. This lack of prescription makes sense given that the amendment is intended to cover current regulatory approval regimes, and those that may be established in the future. It also recognises that processes required under current regimes may change from time to time, necessitating particular acts at one time that were not required at another time.

Having said this, it is clear that the exemption will not apply to acts done in respect of a regulatory approval for a pharmaceutical, nor will it apply to acts done for experimental or research purposes.

The phrase '**solely** for purposes' is intended to exclude those acts done predominantly for a commercial purpose that might otherwise occur during the process of obtaining regulatory approval, including for example, manufacture, stockpiling and export of the relevant product.

According to the proposal, the party seeking regulatory approval of a generic product does not have to notify the patentee of his intention to undertake acts for obtaining regulatory approval of the generic product. What follows is that if the legislation establishing the relevant regulatory regime does not require the former to notify the patentee either, the patentee

will not receive such notice.

For further information on these developments, the Exposure Draft of the Explanatory Memorandum for the Bill can be found on the IP Australia website.[1]

This article was written by Tom Gumley, Partner, Freehills Patent & Trade Mark Attorneys.

Endnotes

1. Exposure Draft of the Explanatory Memorandum for the Bill

More information

For information regarding possible implications for your business, contact

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