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26 February 2013

Ms Alison McClelland
Dr Warren Mundy
Commissioners
Productivity Commission
Compulsory Licensing of Patents
LB 2 Collins Street East
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Email: patents@pc.gov.au

Dear Commissioners

Further information pertaining to draft report on compulsory licensing of patents

Many thanks for the opportunity to raise our concerns via teleconference about the compulsory licensing of patents. We appreciated your time.

During the discussion, Alphapharm was asked to provide further information that may assist you in finalising your report. The additional information follows.

Meaning of 'anti-competitive practices' in the context of the proposed 'public interest' test

The term 'anti-competitive practices' in Art. 17.9.7(a) AUSFTA does not mean conduct that constitutes a misuse of market power within Part IV (s.46) of the *Competition and Consumer Act, 2010*. This is because s.46 requires the offending company to hold "a substantial degree of power in a market". This is a significant threshold that should not apply to anti-competitive practices in the context of patents (and which is what compulsory licences are expected to remediate). The hint to this broader meaning advocated by Alphapharm is provided by footnote 17-49 AUSFTA which states: "With respect to sub-paragraph (a), the Parties recognize that a patent does not necessarily confer market power."

In Alphapharm's opinion, the term 'anti-competitive practices' as used in AUSFTA should mean "conduct that involves the unfair or inappropriate use of an Australian patent to hinder, interfere or delay the marketing of a product or the use of a method or process in Australia."

An example of such conduct is patent 'evergreening'. This involves the use of Australian patents to create patent thickets around medicines for the purpose of extending the period of patent protection around 'active pharmaceutical ingredients' beyond 25 years. This practice is widespread in the pharmaceutical sector and has been well documented in the European context. Alphapharm's confidential submission to the Pharmaceutical Patents Review also provides evidence of this practice in the Australian context. Evergreening relies on patents to unfairly or inappropriately "hinder, interfere or delay the marketing of a product or the use of a method or process in Australia."

As footnote 17-49 AUSFTA expressly states, such conduct does not necessarily confer market power on the patentee. Indeed, it is often said that the patent monopoly is not the same as a monopoly in the conventional competition law context. Nonetheless, a patent is a legal, enforceable monopoly that may, in certain circumstances such as in the case of evergreening, provide the holder with the power to unfairly or inappropriately limit competition in regard to anything that comes within the scope of the patent monopoly. And beyond if s.117 *Patents Act, 1990* (otherwise known as contributory infringement) is considered.

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Unfortunately, the proposed threshold for the 'public interest' test is confined to the situation where demand for a product or service is "not being met on reasonable terms and access to the patent invention is essential for meeting this demand."

This definition, in Alphapharm's opinion, is too restrictive. First, anti-competitive practices in the patent context should be a reference to the abuse of the patent system. Limiting the invocation of compulsory licensing to a situation contemplated by the definition will exclude virtually all kinds of evergreening except in the very rare situation where access to the patent invention is essential for meeting the demand not being met on "reasonable terms". The question, of course, is what are "reasonable terms"? In the patent context, this is a serious problem (and concern) given that the patentee's exclusive rights to the 'invention' mean just that. Second, anti-competitive practices do not necessarily relate to the demand for a product or service. For example, it may be that the demand for a medicine is met depending on how that medicine is defined e.g., is it by type (statins) or by trade name (Lipitor)?

Ultimately, Art. 17.9.7(a) AUSFTA is determinative. In Alphapharm's view, the proposed 'public interest' test may arguably not comply simply because the issue is not whether the demand for a product or service is being met on reasonable terms, but because whatever the circumstances are they do not come within the definition of 'anti-competitive practices'. The key is to define anti-competitive practices broadly enough to encompass conduct that constitutes an abuse of the patent system. Evergreening is one example such abuse.

Using patents to deny Australians timely access to quality, safe and affordable medicines

Alphapharm was also asked to provide examples of medicines that have not come to market or have been delayed in coming to market as a result of 'anti-competitive practices' in the pharmaceutical industry due to patents. This occurs when price negotiations between a pharmaceutical sponsor and the government reach an impasse and the medicine is withheld from the market by the sponsor, thus denying or delaying access for Australians to important medicines. There are many examples of these available through the outcomes reports of the Pharmaceutical Benefits Advisory Committee, which can be accessed at:
http://www.pbs.gov.au/info/industry/listing/elements/pbac-meetings/pbac-outcomes

One notable, historic example is that of valsartan, the world’s biggest selling calcium channel blocker medicine used for high blood pressure. Australian patients were denied access to it for ten years because the originator sponsor could not agree a price with government. No other sponsor could bring the medicine to market until after the patent expired.

Please feel free to contact Alphapharm if you believe we can assist you with further information.

Yours sincerely,

Alphapharm Pty Limited

Dr Martin Cross
Managing Director