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Article Information

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Productivity Commission makes pharma-specific patent reform recommendations

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The Productivity Commission (**Commission**), as independent advisory agency of the Commonwealth Government, has released a draft report (**Draft Report**) following a 12 month inquiry into Australia's intellectual property (**IP**) system. The Draft Report dedicates an entire chapter to IP issues arising in the pharmaceutical industry and provides five draft recommendations for reform, focussing on extensions of term (**EoT**) for pharmaceutical patents, data protection arrangements and potential anticompetitive use of the patent system, which can be summarised as follows:

1. EoT should only be granted for eligible pharmaceutical patents in circumstances where the Therapeutic Goods Administration (TGA) takes more than one year to approve the product.
2. The EoT system should be specifically tailored to the pharmaceutical industry and, in particular, should explicitly allow 'infringing' products to be manufactured for export purposes during the extension period.
3. Section 76A of the Patents Act 1990 (Cth) (Act) should be amended to improve data collection and ensure EoT are only granted once satisfactory data is received, with a view to using this data to undertake a review of the costs and benefits of the EoT scheme in five years.
4. The data protection period should not be extended and the Australian Government should, in international negotiations, push for a system of eventual publication of clinical trial data in exchange for statutory data protection.
5. The Commonwealth Government should introduce a five year transparent reporting and monitoring system, to be administered by the Australian Competition and Consumer Commission (ACCC), to detect any pay-for-delay settlements between originator and generic pharmaceutical companies, following which there should be a review of potentially anticompetitive arrangements specific to the pharmaceutical sector.

EoT for pharmaceutical patents

In addition to the 'standard' patent protection available in Australia, the Act currently allows an EoT of up to five years for eligible pharmaceutical patents, with a view to compensating patentees for the effective reduction in patent life caused by the delay in obtaining regulatory approval for pharmaceutical products from the TGA.

However, the duration of the EoT is currently calculated as five years less than the length of the 'delay' between the date the patent is filed and the date approval is granted by the TGA, with a maximum five year extension (equating to a 25 year patent life and maximum effective market life of 15 years). Therefore, patentees are able to control the 'delay' period by putting off applying to the TGA for regulatory approval, effectively delaying entry of generic products into the Australian market, and the operation of any resulting statutory price-drop applicable to products subsidised under the Pharmaceutical Benefits Scheme (**PBS**), and reducing the incentive for sponsors of originator products to apply pressure on the TGA to maintain efficient approval timelines.

With this in mind, the Commission contends that the current EoT policy is ineffective; particularly because (in addition to the risk of exploitation by patentees discussed above) there is a lack of evidence that the standard patent term in insufficient to compensate pharmaceutical patentees, aims to attract investment in pharmaceutical development have not been realised and EoT are costly and of limited benefit to the Australian pharmaceutical industry. With this in mind, the Commission has made the draft recommendation that the Act should be amended so that an EoT is only granted in circumstances where the TGA takes more than one year "reasonable period", to approve the product.

The Commission further notes that, where an EoT is granted in Australia, the average patent life becomes 12 months longer than that in the United States (**US**), thus delaying the ability of Australian generic manufacturers to penetrate the US market and generate sales during that period. On this basis, the Draft Report includes a draft recommendation that the Act be amended to explicitly allow manufacture for export during the extension period.

Data protection

Safety, quality and efficacy data submitted by sponsors to the TGA in support of applications for regulatory approval are currently subject to a five year data protection period, during which the TGA cannot refer to those data when determining whether to approve similar (normally generic) products. As outlined in the Draft Report, the length of data protection afforded must strike a balance between the need for originator companies to see a return on the significant investment required to produce these data (in order to encourage such investment) and the desirability of the public having access to the data and/or generic products.

Observing that some pharmaceutical companies "*simply prefer the automatic protection by data protection over the expense of obtaining patents*", the Draft Report indicates that data protection is particularly an issue for biologics due to inherent issues with the patentability of those substances, noting that there was significant debate on the issue of the appropriate length of the data protection period for biologics during the negotiations of the Trans-Pacific Partnership Agreement (**TPP**), with the final outcome being that parties can either provide eight years' effective market protection through data protection or five years' data protection along with other measures (some already existing in Australia).

However, citing a lack of evidence that patents are not providing sufficient protection for all pharmaceutical products, including biologics, and that data protection lacks some features of the patent system designed to promote innovation (*e.g.* it is an automatic, unreviewable right, reduces disclosure of information), the Commission concludes that data protection should not be used as a substitute for patent protection and makes the draft recommendation that the data protection period should not be extended.

Competition issues

In the Draft Report, the Commission expresses concern with the possible existence of anticompetitive behaviour involving pharmaceutical patents; namely, the potential for "evergreening" (obtaining multiple patents covering different aspects of the same product – such as improved versions – to strategically maximise exclusivity) and 'pay-for-delay' settlements or agreements whereby patentees pay generic manufacturers to keep a generic product out of the market beyond the scope of the patent (*i.e.* where the generic product does not infringe the patent, the patent may be invalid or entry of the generic is delayed beyond expiry of the patent term). In this regard, acknowledging that there is a lack of data or evidence that such practises are, in fact, widespread in the Australian pharmaceutical industry the Commission has made the draft recommendation that there be a five year monitoring regime, followed by a review of anticompetitive practised in relation to pharmaceutical patents.

Public submissions in response to the Draft Report and the draft recommendations are now being sought by the Commission and are due by Friday, 3 June 2016. To date, there have been no public submissions published on the Commission website responding to the pharmaceutical section of the Draft Report. If you would like to make a submission, or have any questions regarding the Draft Report, please do not hesitate to contact us.