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Comments on the Pharmaceutical Patents Review Draft Report 2013

The Intellectual Property Committee of the Business Law Section of the Law Council of Australia (the IPC) makes the following comments in relation to the Pharmaceutical Patents Review Draft Report 2013 (the Draft Report). The IPC has chosen not to comment on all of the recommendations contained in the Draft Report.

Draft recommendation 4.1
As an interim measure, the Government should actively seek the agreement of the owners of Australian pharmaceutical patents to voluntarily agree not to enforce their patents in respect of manufacturing for export.

In relation to this recommendation, the IPC notes that the Government is still considering public submissions on the Draft Exposure Intellectual Property Laws Bill 2012. Under Schedules 1 and 2 of this Bill, Australian generic medicine producers would be able to export patented pharmaceuticals to developing and least developed countries under a compulsory licence from the Federal Court. Such a licence would only be granted under strict conditions that balance the interests of patent owners, generic manufacturers and importing countries. These amendments to the *Patents Act 1990* (Cth) (the Patents Act) will bring about Australia's compliance with the requirements of the 2003 Doha Declaration on public health and the terms of proposed art 31bis of the TRIPS Agreement. Given the present state of the parliamentary agenda in an election year, however, it may be that these amendments will not be passed for some time.

Draft recommendation 4.1 is essentially concerned with a distinct and further issue, namely the possibility that generic manufacturers should be allowed freely to manufacture pharmaceutical products covered by Australian patents where this is done for export generally. This is on the basis that, as a matter of principle, the exclusive rights of the patentee should be limited to those that are necessary for commercial exploitation in the domestic market and that, in this regard, these rights should not extend to preventing the manufacture of products for export (as these will not compete in the domestic market). Members of the IPC have differing views on the acceptability of this principle, but it is noted that the Panel accepts that, in any event, such an interpretation of the exclusive rights of patentees probably runs counter to the provisions of the TRIPS Agreement and

the Australian US Free Trade Agreement (the AUSFTA), subject perhaps to some minor exceptions where the manufacture is done for the purposes of seeking regulatory approval in another country (as presently allowed under s 119A(1)(b) of the *Patents Act 1990*). Accordingly, the Panel's proposal is a much more limited one, namely that the Australian Government, as an interim measure (presumably while TRIPS and AUSFTA are renegotiated), should actively seek the agreement of Australian pharmaceutical patentees not to enforce their patents where generic producers manufacture for export.

As this recommendation does not involve any change to existing laws, the IPC offers no comment on its desirability other than as follows.

1. A general exhortation to Australian pharmaceutical patentees along the lines of the recommendation is likely to be of limited value as it would be directed at a wide range of circumstances in which generic manufacturers might desire to engage in domestic manufacture for export.
2. Having said this, there will certainly be some situations involving epidemics and major health emergencies in developing and least-developed countries in which it might well be appropriate for the Australian Government to approach Australian pharmaceutical patentees to allow manufacture for export, particularly in the absence of the proposed compulsory licence amendments. In such cases, the IPC believes that patentees, as good corporate citizens, would be amenable to such requests and that this should be encouraged in the interests of public health.

The IPC reserves its position on whether, assuming it were TRIPS- and AUSFTA compliant, Australian patent law should be amended so as to exclude manufacture for export from the exclusive rights of patentees.

Draft recommendation 5, Option 5.1
The current model of using the patents system to subsidise pharmaceutical R&D indirectly should be replaced with a direct subsidy. To this end, the Government should reduce extensions of term for pharmaceutical patents and use part of the associated savings to fund R&D directly. Some of this funding should be targeted to socially beneficial research for which patents provide inadequate incentives to conduct. Such areas include new antibiotics which, once developed, must be used as sparingly as possible to prevent the development of antibodies and pharmaceuticals to address rare diseases, paediatric illnesses and endemic health issues in low income countries.
This option could also include an annual review of the savings delivered through any reduction in the length of extensions of term to be used in allocating funding to the replacement R&D subsidies.

The IPC does not support the replacement of the existing patent term extension regime (or reduction in the current level of available patent term extension) to be replaced by a direct pharmaceutical R&D subsidy.

The avowed intention of the current patent term extension regime is to provide an effective patent term of 15 years following regulatory approval of a pharmaceutical product.

Although patent term extensions may provide originator drug companies with some compensation for the cost of bringing drugs to market this is clearly not the primary rationale for the extension regime. As the Draft Report itself notes[1]:

> "*Extensions of term provide some compensation for the costs of bringing drugs to market, but the extent of this compensation would only be a small percentage of total R&D expenditure."*

The IPC considers that no logical correlation has been disclosed between the length of pharmaceutical patent term extensions and the amount of pharmaceutical R&D expenditure in Australia.

The patent term extension regime currently in place can be seen as a quid pro quo for the period during which the patentee of a pharmaceutical product is unable to put that product into the Australian market place by reason of it having to apply for and obtain regulatory approval. The cost to the Pharmaceutical Benefits Scheme during that period, when of course the product the subject of that patent is not on the market, is nil.

Even the data referred to in the Draft Report establishes the proposition that many pharmaceutical products the subject of a patent term extensions do not receive 15 years of effective protection because of the existing 5 year cap on such extensions. The Draft Report includes Figure 5.8 entitled "*Effective patent life provided under current provisions – frequency histogram*"[2].

The Draft Report states[3]:

> "*More than half of all patents extended under the current provisions have received the maximum effective patent life after marketing approval of 15 years…*"

And:

> "*The <u>median</u> effective patent life provided by the extension of term has remained at or close to 15 years each since its introduction." (emphasis added)*

The IPC notes that another way of considering the data in figure 5.8 included in the Draft Report is to say that 47% of all extended patents, in fact, fail to achieve a 15 year effective term.

Given that the rationale for the introduction of the current patent term extension regime was to provide an effective 15 year pharmaceutical patent term and in light of the fact that there is no logical correlation between the duration of pharmaceutical patent term extension and the incentive for drug companies to conduct pharmaceutical R&D in Australia there would appear to be no demonstrated basis for the proposition that the maximum duration of patent term extensions for pharmaceutical products in Australia ought to be reduced or removed.

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[1] See Draft Report page 66.
[2] See Draft Report page 78.
[3] See Draft Report page 78.

Draft recommendation 5, Option 5.2
The Government should change the current extension of term provisions such that patents receiving an extension of term in Australia will not expire later than the equivalent patents in major trading partners.
Potential ways of achieving this include:
(a) Providing an extension expiring up to 5 years after the original patent term or upon the expiry of the equivalent patent extension in one of a list of other jurisdictions including the United States and European Union.
This option ensures Australian extended patents would not expire later than equivalent patents elsewhere. If originators are unable to seek regulatory approval in Australia at the same time as elsewhere, this option would reduce the effective patent life.
(b) Changing the method of calculating the length extensions of term to provide an incentive to submit applications for regulatory approval in Australia earlier than is currently the practice. This could be similar to the US method described above.
This option creates an incentive to seek regulatory approval in Australia as soon as possible, reducing delays in access to medicines for Australian health consumers. Under this system, one-to-one compensation is still provided for the time taken to process applications for regulatory approval.

The IPC does not support replacing the current method of calculating extensions of term contained in section 77 of the Patents Act with the alternative methods set out in draft recommendation 5, option 5.2.

The IPC considers that in order to justify any change there must:

- first, be a compelling economic, social or legal reason (in the sense of within power, constitutional, and compliant with international commitments) to do so; and

- second, an alternative provision that is clear, simple, and sufficiently certain to be easily understood and applied.

The Draft Report does not in the IPC's view advance a compelling case justifying change for the following reasons:

(a) as the Draft Report concludes, the Draft Report figures 5.12, 5.13 and 5.14 and table 5.6 do not result in a significantly longer exclusive period in the Australian market compared especially to the United Kingdom and the United States.

(b) the two suggested alternative methods of calculating an extension do not appear to the IPC to necessarily and effectively address the two stated reasons for the proposed change namely:

    - prevention of Australian generic manufacturers being able to manufacture during the Australian patent term for export to countries where corresponding patents have expired and/or

    - disadvantage to Australian generic manufacturers as against overseas based manufacturers resident in jurisdictions where corresponding patents have expired who could stock pile for immediate entry into the Australian market upon expiry of the Australian patent.

The current section 77 of the Patents Act is legally sound in that it is compliant with the AUSFTA which refers to adjusting the patent term to compensate the patent owner for unreasonable curtailment of the effective patent term as a result of the marketing approval process. The AUSFTA does not specify a specific length of time for an extension but the Draft Report shows that the outcome of application of the section 77 formula is to achieve an effective patent life comparable to two of Australia's major trading partners, namely the United Kingdom and the United States. Furthermore, the extension available under section 77 of the Patents Act is designed to compensate for delay due to the marketing approval process.

The section 77 formula is clear and has been successfully applied without complaint since introduction of the current extension regime in 1999. In the IPC's opinion the current clear, simple, easily understood and applied system should be retained and not replaced with a system that is either subject to the vagaries of a system dependant, for example, upon the timing and success of obtaining approval to conduct, and to recruit and conduct clinical trials, or a complicated formula requiring identification of expiry of patent term extensions in other jurisdictions.

Draft recommendation 7.2
The Government should establish an external patent oversight committee that is tasked with reviewing grants and decisions issued by IP Australia and auditing the processes involved in making such decisions.

The IPC does not support the recommendation to establish an external patent oversight committee charged with the task of reviewing grants and decisions issued by IP Australia and auditing the processes involved in making such decisions.

Australia has a well established legal process by which decisions of IP Australia with relation to the grant or refusal of a patent application are subject to review by the Administrative Appeals Tribunal and/or the Federal Court.

The interposition of a “patents oversight committee” simply would add another level of bureaucracy leading to increased complexity and cost that would appear to offer no additional practical benefit to stakeholders.

The IPC observes that it is also unclear as to what status any such oversight committee would have. Indeed, it might be questioned whether such a committee would have constitutional validity.

Draft recommendation 8.2
A transparency register linking therapeutic goods registered with the TGA with related patents should be introduced.

The Draft Report recommends the introduction of a so-called “Transparency Register” linking therapeutic goods registered on the ARTG with related patents.
As a matter of general principle the IPC supports a recommendation that would facilitate the early identification and resolution of patent disputes relating to pharmaceutical products.

The IPC notes that the recommendation includes a proposal that only patents that are "directly related" to the listed product would be required to be listed on the "Transparency Register" by the sponsor/patentee. This would not, for example, include a patent for a new method of use of a product.

If the Transparency Register were to include only patents "directly" related to the listed pharmaceutical product it is submitted that there would need to be a clear definition of what "directly" means and there would have to be equally clear consequences arising as a result of inclusion or omission of a patent from the Register. Any ambiguity in relation to these matters would undermine the utility of the Register.

Many pharmaceutical patent disputes relate to patents which, on the recommendation in the Draft Report, would be excluded from the Register. For example, would the Register identify patents for new indications, new formulations, new salt forms or new crystalline structures? These types of patents are equally likely to be the subject of dispute as are patents relating to active pharmaceutical compounds themselves (and, arguably, more so).

The recommendation would also still require generic manufacturers to provide a section 26B certificate under the Therapeutic Goods Act and would require generic manufacturers to conduct their own freedom to operate searches. The recommendation also appears to require the generic manufacturer to notify the relevant patentee (presumably ascertained from reviewing the Register) of the filing of an application of the generic product for inclusion on the ARTG. The retention of section 26B certificates is undesirable.

A Transparency Register would only be sensible if:

- all patents directly relevant to a particular pharmaceutical product registered on the ARTG are listed by the relevant patent owner (not just a product sponsor);
- directly relevant patents not listed on the Register cannot be enforced against a generic manufacturer;
- an applicant to register a generic product on the ARTG is required to give notice to the TGA and to each owner of a relevant patent;
- the Register supplants any other type of certification required to be given by a sponsor of a new generic product (those currently described in section 26B of the Therapeutic Goods Act);
- a time frame (perhaps extendable for good cause with the leave of the court) is prescribed for the commencement of any legal proceedings which may follow as a consequence of the certification.

Draft Recommendation 9.1

The Government should actively contribute to the development of an internationally coordinated and harmonised system where data protection is provided in exchange for the publication of clinical trial data.

Although the Panel is correct in saying a biosimilar cannot rely *solely* on the clinical data of the reference product, if the biosimilar can satisfy the regulator of sufficient similarity to the reference product based on the Module 3 data, the regulator can dispense with the

need to submit full Module 4 or 5 data sets, the same as a generic with a small molecule product.[4]

Draft recommendation 10.1
The Government should establish a non-statutory Pharmaceutical System Coordinating Committee (PSCC) that reports to Parliament on an annual basis on the success and effectiveness of the patent, marketing approval and PBS systems, particularly where these interface. The PSCC should ensure there is sufficient engagement and coordination between the relevant agencies and take account of costs to government, efficiency of registration and approval processes and respond to issues raised by industry. The PSCC should comprise senior officials from at least DIICCSRTE, IP Australia, DoHA (Pharmaceutical Benefits Division and TGA), DFAT, Finance and Treasury (as chair).

The IPC does not support the recommendation to establish a non-statutory Pharmaceutical System Co-ordinating Committee reporting to Parliament on the success and effectiveness of the patent, marketing approval and PBS systems.

The IPC considers that there ought to be sufficient levels of transparency and co-operation between the relevant governmental bodies charged with the responsibility for maintaining and operating the relevant schemes and processes to ensure that they function in an effective, efficient and complimentary way without the necessity for further levels of bureaucracy to be created.

Draft recommendation 10.2

When drafting the objects clause to be inserted in the Patents Act, as agreed to in the Government's response to the Senate Community Affairs Committee's Gene Patents report, the Government should take into account that the purpose of the legislation is to:

- further Australia's national interest and enhance the well-being of Australians, including by providing reasonable access to healthcare; and
- provide strong, targeted IP protection - but only up to the point at which the costs (to consumers and the impediment of 'follow on innovation') are no greater than the benefits of incentivising innovation that would otherwise not occur.

Section 15AA of the *Acts Interpretation Act 1901* (Cth) was inserted by section 23 of the *Acts Interpretation Amendment Act 2011* (Cth). Section 15AA provides:

> "In interpreting a provision of an Act the interpretation that would best achieve the purpose or object of the Act (whether or not that purpose or object is expressly stated in the Act) is to be preferred to each other interpretation."

Clearly, the 2011 amendment to the Acts Interpretation Act permits a tribunal to take into account the stated object of any legislation. However, the objects clause suggested by draft recommendation 10.2 is fundamentally flawed in the IPC's view for two reasons.

[4] Australian Government, Department of Health and Ageing, Discussion Paper on SPMP's.

First, the Patents Act is technology neutral thereby covering technologies as broad and diverse as mechanical, electronic, biotechnology, pharmaceutical, nanotechnology, organic and inorganic chemistry, chemical engineering, and there is therefore no justification for the introduction of an objects clause that is to a significant extent industry specific (in this case access to health care).

Second, the second limb of the clause:

> "provide strong, targeted IP protection - but only up to the point at which the costs (to consumers and the impediment of "follow on innovation") are no greater than the benefits of incentivising innovation that would otherwise not occur"

would be impossible to fairly consider even with detailed evidence; and

Thirdly, and fundamentally, both limbs could be applied to undermine the exclusive right granted to the patentee which is contrary to the very purpose of the patent system enshrined in, and governed by, the Patents Act.

The IPC would be glad to expand on the above or to meet with you. Please contact the Committee Chair, Richard Hamer at Allens on 03-9613 8853 or via email:richard.hamer@allens.com.au to facilitate further discussions.

Yours faithfully,

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