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Via email: Adam.Wright@industry.gov.au

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Dear Mr Wright,

Submission in Relation to the Productivity Commission Inquiry Report: Intellectual Property Arrangements Overview and Recommendations (23 September 2016)

The Intellectual Property Committee of the Business Law Section of the Law Council of Australia (IPC) has previously made a comprehensive submission in relation to the Productivity Commission's Draft Report¹. The IPC re-iterates its previous submission and makes the following submission in response to the Productivity Commission Final Report; Intellectual Property Arrangement (September 2016) (Final Report).

1 Copyright and Licensing

Recommendation 5.1

The IPC opposes the first part of this recommendation. The Copyright Act provides for a large number of defences and exceptions to infringement allegations and the exclusive rights conferred on copyright owners. None are identified as, or only as, "exceptions". The defences and exceptions serve a very wide range of different objectives and purposes and have the potential to operate in a very wide and diverse range of situations. The IPC considers the diverse nature of the defences and exceptions and the widely varying circumstances in which they may operate means that a "blanket rule" as proposed by the Productivity Commission is not appropriate and requires much more considered and nuanced consideration.

Recommendation 5.4

This recommendation was not the subject of discussion in the draft report and was not addressed by the IPC. In the time available it has not been possible for IPC to formulate a considered response to this recommendation.

¹ Law Council of Australia, Intellectual Property Committee: Business Law Section's Response to the Draft Report – Australia's IP Arrangements, (3 June 2016), 11-14.

Recommendation 6.1

The IPC notes that this recommendation adopts the position that the IPC proposed in its submission on the draft “fair use” recommendation and accordingly supports this recommendation for the reasons advanced in the IPC’s response to the draft report. However, the IPC notes that, since the ALRC’s report was finalised there has been further consideration of, in particular, “out of commerce” works in other countries. When considering how to implement this recommendation, therefore, it will be desirable to monitor and take into account those developments.

2 The Patent System – Getting the Fundamentals Right

Recommendation 7.1 – Objects Clause

The Commission, in its Final Report, has changed the language of its recommendation regarding the introduction of an objects clause. The new recommendation sets out that the objects clause would state that the purpose of Act is: 'enhancing the wellbeing of Australians by promoting technological innovation and the transfer and dissemination of technology'.²

The IPC does not support the introduction of an objects clause for reasons previously advanced.³ The changes made to the Commission's recommendation have not remedied the difficulties that would arise if an objects clause was introduced. Legislation should be drafted clearly: trying to modify or qualify legislation by use of objects clauses is undesirable in principle because it gives rise to potential for inconsistency and uncertainty.

There are specific problems with the proposed wording as amended by the final report.

First, its aim is to introduce a subjective analysis of “wellbeing” into the interpretation of patent litigation. If effective this will almost certainly cause increased cost and complexity in litigation including, for example, the need to adduce evidence of matters such as contribution to wellbeing which would otherwise be of no relevance.

Secondly, the proposed objects are inconsistent in principle with Australia’s international obligations to provide the same treatment to foreign nationals as to Australians.

Thirdly, the exclusive right to exploit (including the right not to transfer) an invention during the term of a patent is a fundamental right of a patentee. The suggestion that this is to be construed subject to an overarching object requiring transfer is inconsistent with

² Inquiry Final Report, 219.

³ Op.cit n.1

the express rights to exclusive use granted by the statute and embodied in international treaties.

Recommendation 7.2 – Changes to the inventive step test

Despite receiving a detailed submission on the topic,⁴ the Commission has continued to recommend a change to the inventive step requirement for standard patents, with the new test being: 'an invention is taken to involve an inventive step if, having regard to the prior art base, it is not obvious to a person skilled in the relevant art.'

The legislative change proposed is unnecessary and the final report exposes that it is based on a misunderstanding.

Box 7.6 of the final report purports to compare national obviousness tests.⁵ If the Australian legislation is presented in the same summarised form as other countries', particularly by omitting the definition of prior art base, it would read:

An invention is to be taken to involve an inventive step... unless the invention would have been obvious to a person skilled in art in the light of the prior art base.

This can be compared to the European wording:

An invention shall be considered as involving an inventive step if, having regard to the state of the art, it is not obvious to a person skilled in the art.

In fundamental terms, the only difference in expression is the Australian provision is expressed in the language "unless it is obvious" rather than "if it is not obvious". It is not explained why this would make a difference, and it is submitted it would not. No court has made a decision on the basis that that difference in language leads to a different consequence.

Prior to the *Raising the Bar (RTB)* reforms there were material differences in the definition of the prior art base to that which applied in our major trading partner nations and for a long period examiners in Australia have had a tradition of granting the benefit of the doubt to patent applicants. The latter issue (if and to the extent it persists) could be addressed by tighter administration.

The RTB changes to the inventive step requirement (supported by the IPC) were specifically designed to align the Australian test with that applied by its major trading partners.⁶ The Commission noted that the RTB reforms moved the law on inventive step

⁴ Op.cit n.1 6-11.

⁵ Inquiry Final report, 225.

⁶ Explanatory Memorandum, Intellectual Property Laws Amendment (Raising the Bar) Bill 2011, 41-43.

in the "right direction".⁷ However, the Commission has failed to recognise that the RTB reforms have effectively aligned the legal tests as between Australian and European law. Further reform of the nature proposed is unnecessary.

The other aspects of the recommendations on obviousness, discussed below, reflect errors in legal understanding on the part of the Commission.

In the final report, the Commission changed the wording it recommended be included in the Explanatory Memorandum to the amending Act from that recommended in the draft report. The new recommendation is that the Explanatory Memorandum should specify that a 'scintilla' of invention, or a scenario where the skilled person would not 'directly be led as a matter of course', are insufficient thresholds for meeting the inventive step.

The idea behind the 'scintilla' in modern jurisprudence is simply that once the test of inventive step is satisfied, a court or patent examiner is not to undertake an analysis of just how 'inventive' the invention is, or whether the patentee has spent a sufficient sum of money on research to 'deserve' the patent. It would be impractical to require courts and patent examiners to try to make assessments of such a subjective nature. The Commission says that the idea of the "scintilla" is what sets the bar of inventive step,⁸ but the actual bar is clearly set out in s 7(2) of the *Patents Act 1990* (Cth). The words of the UK Court of Appeal on this topic apply with equal force in Australia:⁹

The criterion for deciding whether or not the claimed invention involves an inventive step is wholly objective. It is an objective criterion defined in statutory terms.... We do not consider that it assists to ask whether the patent discloses something sufficiently inventive to deserve the grant of a monopoly. Nor is it useful to extract from older judgments expressions such as "that scintilla of invention necessary to support a patent". The statute has laid down what the criterion is to be: it is a qualitative not a quantitative test.

It is submitted this proposed change is based on a misconception as to the history and significance of the reference to 'scintilla'.

As to 'directly be led as a matter of course', this appears to involve a similar misconception. The phrase, in the words adopted by the High Court, continues: 'to try [the invention as claimed] in the expectation that it might well produce a useful [result]'.¹⁰

There is no need for these proposed changes.

⁷ Inquiry Final Report finding 7.1.

⁸ Inquiry Final Report, 223.

⁹ *Mölnlycke AB v. Procter & Gamble Ltd* [1994] RPC 49, 112.

¹⁰ *Aktiebolaget Hassle v Alphapharm Pty Ltd* (2002) 212 CLR 411, 433.

Recommendation 10.1 – Extensions of term for pharmaceutical patents

The wording of the Productivity Commission's recommendation regarding the period by which a pharmaceutical patent can be extended has been changed.¹¹ However the underlying problems with the recommendation in relation to Australia's international treaty obligations have not been remedied.

The Australia-United States Free Trade Agreement (**AUSFTA**) requires extensions of patent term to "compensate the patent owner for unreasonable curtailment of the effective patent term as a result of the marketing approval process".¹²

The Commission has recommended that the period of extension be limited to the period in which the Therapeutic Goods Administration (**TGA**) deals with an application, minus a year. The time spent conducting trials prior to the making of an application to the TGA is not to be taken into account at all.¹³ The years of delay typically associated with the marketing approval process are not usually delays in bureaucratic processing of documents but are the time required to conduct detailed studies and trials showing efficacy and safety.¹⁴ It would appear to be a strained reading of the term "as a result of the marketing approval" process to exclude time spent collecting the data required by the regulator in order to grant an approval. As a result the proposal would appear not to comply with the AUSFTA, notwithstanding that the proposed provision is consistent with the patent extension regime in Singapore.¹⁵

The Commission has now recommended that it be "made clear" that extensions of term can only be obtained for patents claiming new active pharmaceutical ingredients.¹⁶ The Commission criticised the outcome reached by the Federal Court in *Spirit Pharmaceuticals Pty Ltd v Mundipharma Pty Ltd*,¹⁷ where an extension of term was allowed in relation to a patent claiming a controlled release oxycodone formulation.

The AUSFTA provides that the availability of extensions must apply:

"(b) With respect to a pharmaceutical product¹⁷⁻²⁴ that is subject to a patent..."

¹¹ Compare draft recommendation 9.1 and Final Report recommendation 10.1.

¹² *Australia – United States Free Trade Agreement*, signed 18 May 2004 (came into force 1 January 2005), Article 17.9.8.

¹³ Inquiry Final Report recommendation 10.1.

¹⁴ This data is needed to satisfy the requirements for the registration of therapeutic goods in Australia, see *Therapeutic Goods Act 1989* (Cth) ss 25 (1).

¹⁵ Singapore has similar requirements to Australia regarding pharmaceutical patent extension, due to Article 16.8.4 of the *Singapore – United States Free Trade Agreement*, signed 6 May 2003 (came into force 1 January 2004).

¹⁶ Inquiry Final Report recommendation 10.1.

¹⁷ (2013) 216 FCR 344.

With the footnote: [24]:

"For Australia, the term pharmaceutical substance as used in Section 70 of the Patents Act 1990 on the date of entry into force of this Agreement may be treated as synonymous with the term **pharmaceutical product** as used in this sub-paragraph."

It would appear that that the term 'pharmaceutical product' is not limited to new chemical entities and that the proposal, which does not have the benefit of the protection of footnote [24], goes beyond what is permitted under the treaty.

Recommendation 10.2 – Reporting of settlement agreements

The Commission has recommended the reporting and monitoring of settlements between originator and generic pharmaceutical companies to detect potential pay-for-delay agreement, based on the US approach.¹⁸

This is a significant business red tape issue. Neither the draft nor final final report includes any evidence that suggests there is a problem requiring the imposition of such an obligation including on perfectly law abiding businesses. The regulator already has the capacity to obtain documents if there are particular areas of concern.

3 Trademarks and Geographical Indications

Recommendations 12.1 and 12.2

The IPC makes the following comments on those aspects of Recommendations 12.1 and 12.2 that differ from the Draft Report.

Non-Use Grace Period

The IPC agrees in substance with the recommendation in the first bullet point of Recommendation 12.1 that the grace period within which a registered mark cannot be challenged on the grounds of non-use should be reduced from five to three years. The Productivity Commission did not, however, specify the date from which the grace period should commence. We recommend that the three year period should start from one month after the date the mark is entered on the Register, and not from the filing date. The IPC's recommendation is consistent with the position that has been adopted in the EU.¹⁹

¹⁸ Inquiry Final Report recommendation 10.2.

¹⁹ See Directive (EU) 2015/2436 of the European Parliament and of the Council of 16 December 2015 to approximate the laws of the Member States relating to trade marks, Arts 16(1) and 19(1).

Requirement to indicate use or intent to use

The IPC acknowledges the preliminary work that has been undertaken by the Productivity Commission on whether the Register is becoming 'cluttered' by unused marks. However, the IPC does not support the recommendation contained in the fourth bullet point of Recommendation 12.1. The full implications of the recommendation have not been thought through, in particular the way in which any new requirement for applicants and owners to specify whether they are using their marks or intend to use them intersects with the grounds of opposition to registration and cancellation of registration. More generally, the IPC believes that the Commission has not made a sufficient case that its recommendation represents the best option for reform. The IPC's view is that further research into the issue of 'cluttering' is needed to determine the scope of the problem and the best way that it might be addressed.

Mandatory disclaimers

The IPC notes that the following recommendation contained in the Draft Report is no longer contained in the Final Report:

In order to improve the effectiveness of the trade mark system, the Australian Government should:

- *restore the power for the trade mark registrar to apply mandatory disclaimers to trade mark applications, consistent with the recommendation of the Advisory Council on Intellectual Property in 2004.*

The IPC urges the government to adopt this recommendation. We refer the government to the IPC's submission on the Draft Report, which reflects its long-standing view that mandatory disclaimers are desirable and should be reintroduced. The Productivity Commission's reason for its change of position seems to be that reintroducing mandatory disclaimers would be too costly, a position that was reached without a careful identification of such costs or an analysis of why such costs would outweigh the considerable benefits of mandatory disclaimers.

Geographical Indications

The IPC does not support Recommendation 12.2. The Productivity Commission has not made a case that its proposed reform is the best way of dealing with the problem identified, or whether there is in fact a need for the changes proposed. The IPC also has concerns about the scope of the power that would be given to the GIC if the

recommendation were adopted. The IPC's view is that to the extent that there may be some issues with the current operation of the GI system, these are best dealt with by the AGWA and its legislative review committee, which we understand is currently looking at such issues.

4 Compliance and Enforcement of IP Rights

Recommendation 19.2

The IPC generally supports this recommendation but does not, at this stage, support the expansion of the jurisdiction of the Federal Circuit Court (FCC) to include patents. The IPC submits that the potential expansion of the FCC jurisdiction to include patents should be considered again in the future after any new IP rules of practice and procedure and/or practice notes have been in place within the FCC for IP matters currently within its jurisdiction for sufficient time to permit reflection on their manner of operation and effectiveness.

5 General comment in relation to the implementation of the Productivity Commission recommendations.

The IPC acknowledges that the Productivity Commission has been charged with a huge task of reviewing Australia's IP arrangements and making recommendations for reform. The recommendations therefore, understandably, traverse a broad range of IP rights, administrative processes and procedures and policies. The recommendations also range from very high level proposals to more intricate detail on very specific issues.

Consequently, it seems likely that, if some of the recommendations are accepted in whole or in part by the Government, legislative amendments will be required. The IPC trusts that all stakeholders will be afforded further opportunity to comment upon and react to any future proposed legislative, administrative or policy change to which the Productivity Commission's recommendations in its Final Report may give rise.

If you have any questions in relation to this submission, in the first instance please contact the Committee Chair, Wayne Condon, on 03-9243 8344 or via email:

wayne.condon@griffithhack.com

Yours sincerely,



Teresa Dyson, Chair
Business Law Section