JOINT SUBMISSION TO THE CONSULTATION ON THE DRAFT REPORT ON INTELLECTUAL PROPERTY ARRANGEMENTS BY AUSTRALIA'S PRODUCTIVITY COMMISSION

1. INTRODUCTION AND GENERAL REMARKS

The International Federation of Pharmaceutical Manufacturers and Associations (IFPMA), along with the Pharmaceutical Research and Manufacturers of America (PhRMA), the European Federation of Pharmaceutical Industries and Associations (EFPIA), the Japanese Pharmaceutical Manufacturers Association (JPMA), and INTERPAT appreciate the opportunity to provide comments on the Productivity Commission's (Commission) April 2016 Draft Report on Intellectual Property Arrangements (Draft Report).[1]

Our associations represent research-based pharmaceutical companies and national pharmaceutical associations from across the globe. As associations representing companies engaged in ground breaking research in the pharmaceutical sector, with currently over 7000 medicines in development worldwide, we are in a unique position to comment on and identify the relevant incentives that drive innovation in pharmaceutical technology.

We agree with the Commission on the importance of basing its recommendations on evidence and analysis.[2] In that spirit, we offer some comments, below, which we hope will contribute to the Commission delivering an evidence-based, final report. In particular, and for reasons further detailed, below, we would respectfully urge the Commission to abandon draft recommendations 6.1, 9.1, 9.2, 9.3 and 9.4.

Below, we first provide some general remarks (section 1). We then proceed to provide specific remarks on extension of patent term (section 2),[3] manufacture for export (section 3),[4] regulatory data protection (section 4)[5] and alleged "strategic behaviour" (section 5).[6]

[1] Australian Government, Productivity Commission, "Intellectual Property Arrangements: Productivity Commission Draft Report", April 2016 (link).
[2] *See*, *e.g.*, Draft Report, *supra* note 1, p. 2, 5, 10, and 254.
[3] Draft Report, *supra* note 1, chapter 9.2.
[4] Draft Report, *supra* note 1, chapter 9.3.
[5] Draft Report, *supra* note 1, chapter 9.4.
[6] Draft Report, *supra* note 1, chapter 9.5.

1.1 Medicines improve the wellbeing of Australians

Life-saving and innovative medical products , including medicines and vaccines, provide value to patients, healthcare systems, the Australian economy and improve the wellbeing of Australians overall.

The pharmaceutical industry plays a critical role in ensuring that patients have a continuing supply of the innovative medicines they need to live longer, healthier and more productive lives. Pharmaceutical companies have driven advances in medicines and new therapies have contributed to significant declines in death rates. In Australia, there has been a 21% decline in cancer mortality rates since 1991, an approximately 20% decline in non-communicable diseases from 2000 to 2012, and an 88% decline in HIV/AIDS age-standardized death rates from 1995 to 2011.[7]

Intellectual property (IP), by incentivizing the development of new medicines, provides value to healthcare systems and helps put them on more sustainable paths forward. The proper use of medicines helps patients avoid expensive hospitalizations and emergency room visits. Furthermore, medicine use yields significant health gains and savings on other services. A study has shown that new cardiovascular medicines led to direct savings on hospitalizations in 20 OECD countries, including Australia, and concluded that per capita expenditure on cardiovascular hospitalizations would have been 70% higher in 2004 had new medicines not been introduced from 1995 to 2004.[8]

The pharmaceutical industry also generates essential economic value in terms of job creation, research and development (R&D) investment and medications that improve patient productivity. Innovations in medicines can also deliver significant societal value by getting patients back to work faster so that they can better contribute to their communities. For example, chronic disease has proved not only to be a health but an economic issue. Debilitating chronic diseases decrease the ability to participate in the workplace and prevent patients from contributing to their communities. In Australia, over one million people are not participating in the workforce due to chronic disease.[9] In 2011, the Australian economy lost

[7] WHO Mortality Database.
[8] Lichtenberg, "Have newer cardiovascular drugs reduced hospitalization? Evidence from Longitudinal Country-Level Data on 20 OECD Countries, 1995-2003" (2008).
[9] Business Council of Australia 2011 Facts and Statistics on Australia's Healthcare Sector; Australian Institute of Health and Welfare 2009 Chronic Disease and Participation in Work.

537,000 full-time person years and 47,000 part-time person years due to chronic diseases, reducing productivity by 10%.[10]

1.2 IP facilitates and accelerates access to medicines

The role of IP as an incentive for innovation and long-term access is well versed. R&D of the pharmaceutical industry has contributed to nearly every important medicine over the past century, including antibiotics, vaccines, HIV and HCV treatments, cancer and cardiovascular medicines. The industry has developed over 550 medicines in the last 15 years for the world's emerging health needs, including oncology, cardiovascular disease, and diabetes.[11] Today, the industry continues to be instrumental in exploratory research, as well as in translating research into patient-ready treatments, with more than 7000 medicines in development across all therapeutic fields.

Launching a new medicine into a country has significant costs for the originator company. To be successfully distributed to patients in a new country, companies must first bear the cost of conducting additional clinical trials to meet local requirements, obtaining local regulatory approval, setting up local distribution and marketing networks, educating healthcare providers about the benefits of the new product, and undertaking post-marketing research and surveillance. IP rights can provide a company financing the launch of a new medicine in a market with the opportunity to recoup these costs before a generic competitor can free-ride on them.

A number of studies confirm the importance of IP in accelerating the global diffusion of new medicines. A 2005 study covering a large number of developed, as well as developing countries found that stronger patent protection increased the speed of new drug launches in those countries.[12] Similarly, a comprehensive 2014 study of drug launch data comprising over 600 drugs in almost 80 countries from 1983-2002 showed that robust patent protection accelerates new product launches in higher and lower income countries alike.[13]

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[10] Australian Health Policy Collaboration 2014 Chronic Disease in Australia; Business Council of Australia 2011 Facts and Statistics on Australia's Healthcare Sector. Person years reflects loss in workforce participation associated with chronic disease due to non-participation, absenteeism and death.

[11] PhRMA, "Medicines in Development", *PhRMA*, 2015.

[12] Lanjouw, J.O., Patents, Price Controls and Access to New Drugs: How Policy Affects Global Market Entry (2005), available at: http://www.nber.org/papers/w11321.

[13] Cockburn, I.A., Lanjouw, J.O. and Schankerman, M., Patents and the Global Diffusion of New Drugs (2014), available at: http://nber.org/papers/w20492. Strong patent protection is defined as providing for product patents (as opposed to only providing for process-only patents) and the duration of patent terms.

1.3 IP facilitates knowledge diffusion

The Commission appears to ignore one of the most important features of the patent system that requires patentees to fully disclose to the public their invention. Scholars refer to this disclosure requirement as the "social contract"[14] implicit in the patent system because once a patent expires the disclosed invention is freely available to the public, thus "maximis[ing] the wellbeing of all Australians".[15]

Scholars have recognized that the disclosure function is at least as important as the innovation incentive, in particular in light of economic evidence which suggests that secrecy/confidentiality agreements are frequently being used.[16] In the latter case, there is, naturally, no disclosure of the invention, stressing again the importance of the disclosure function in the patent system.

The importance of the disclosure function was confirmed in a speech by WIPO Director-General Francis Gurry.[17] As Gurry notes, studies have shown that about 80% of the technology that is disclosed through the patent system is not disclosed through other sources. Further, the disclosure function has led to the patent system constituting the most comprehensive, the most accessible and the most systematic record of humanity's technology, allowing constant furthering of the world scientific knowledge.

The disclosure function also helps to facilitate collaboration. Knowing who is doing what is often the first step to collaboration. The importance of collaboration in innovation is well-documented and noted in several Australian government reports,[18] and in reports by the

[14] *See* http://www.wipo.int/edocs/mdocs/scp/en/scp_20/scp_20_ref_thumm.pdf.
[15] Draft Report, *supra* note 1, p. 51. We note that the publication of a patent and in many countries patent applications give the public access to information regarding new technologies in order to stimulate innovation and contribute to economic growth. *See* "How does the patent system work?", WIPO Guide to Using Patent Information, WIPO Publication, update July 2015.
[16] For instance, Cotter writes "... possible public benefits of the patent system is that patents encourage — indeed, require — the inventor to disclose her invention to the public. In theory, the patent system's role in encouraging inventors to disclose could be as important or even more important than its role in encouraging innovation." Comparative Patent Remedies: A Legal and Economic Analysis, Thomas Cotter, Oxford University Press (p. 27). *See also* Scotchmer and Green, "Novelty and disclosure in patent law," *RAND Journal of Economics*, Vol. 21, no. 1, Spring 1990.
[17] Speech by Francis Gurry, Director-General, WIPO, "The Disclosure of Technology in the Patent System", Technical Symposium on Access to Medicines, Patent Information and Freedom to Operate, 18 February 2011 (link).
[18] *See*, *e.g.*, The Australian Innovation System Report 2015; IP Australia's IP Report; and various IP Australia's Patent Analytics Hub reports including "A patent analytics study on the Australian pharmaceutical industry," Sept. 2015, ch. 6).

Organisation for Economic Co-operation and Development (OECD).[19] The disclosure function of the patent system helps to facilitate collaboration by increasing transaction efficiencies by reducing search costs.

Past Australian Government reports, including by the Advisory Council on Intellectual Property (ACIP), have similarly underscored the key role of the protection and enforcement of IP rights as contributing to the promotion of technological innovation and to the transfer and dissemination of technology, to the mutual advantage of producers and users of technological knowledge and in a manner conducive to social and economic welfare, and to a balance of rights and obligations.[20]

Article 7 of the World Trade Organization (WTO) Agreement on Trade-Related Intellectual Property Rights (TRIPS Agreement), to which Australia is a signatory, similarly mentions the key roles protection and enforcement of IP rights play.[21]

Implementation of the draft recommendations that are based on the current, narrow interpretation of the objective of the patent system may have unintended consequences of stifling innovation in life-saving drugs and thus decrease – not increase – the wellbeing of Australians.

1.4 Australia would benefit from becoming a global IP hub

According to the Commission, the basic premise underlying the unsuitability of Australia's current IP framework is that Australia is a significant net importer of IP intensive goods and services, and in particular a net importer of pharmaceuticals. It is the Commission's view that, as a consumer in the global IP chain, the costs associated with deficits in Australia's IP arrangements are borne by Australian consumers, largely to the benefit of overseas rights holders.[22]

We disagree with the characterization of Australia as solely a net importer of pharmaceuticals, as it disregards Australia's vision of being a global IP hub. It further sets an adverse precedent

[19] *See, e.g.*, "Collaboration in innovation," Measuring Innovation: A New Perspective, OECD, 2010.
[20] Advisory Council on Intellectual Property (ACIP), Options Paper – Patentable Subject Matter, Sept. 2009 (link).
[21] Article 7 of the TRIPS Agreement states:

> The protection and enforcement of intellectual property rights should contribute to the promotion of technological innovation and to the transfer and dissemination of technology, to the mutual advantage of producers and users of technological knowledge and in a manner conducive to social and economic welfare, and to a balance of rights and obligations.

[22] Draft Report, *supra* note 1, pp. 90-91, 255.

in jurisdictions with developed patent protection. Australia has for decades recognized the importance of IP protection for encouraging innovation, and has been at the forefront of internationally advocating for a sound international IP framework. Australia, in collaboration with its WTO counterparts, carefully negotiated the WTO TRIPS Agreement, which rewards innovation and maximises the benefits to the community.

As Medicines Australia has brought to the Commission's attention, over 50 pharmaceutical companies and around 400 locally-owned medical biotechnology firms operate in Australia. Together, they employ approximately 40,000 highly-skilled Australians, invest more than $1 billion combined per year in R&D and generate nearly $2.9 billion in exports each year. These numbers evidence the existence of a strong innovative pharmaceutical industry in Australia which could grow with the right incentives and policies.

2. EXTENSION OF (PATENT) TERM (EOT)

2.1 EOT is an integral part of IP incentives needed to foster pharmaceutical R&D

The Commission proposes that EOT for pharmaceuticals should be "calculated based only on the time taken for regulatory approval by the Therapeutic Goods Administration over and above one year".[23] This would likely contravene international commitments made in the US-Australia FTA, which provides that a patent be granted an adjustment for the patent term to compensate for "unreasonable curtailment" of the patent term due to marketing approval delays.[24]

The policy rationale behind extensions of term is to compensate pharmaceutical innovators for the time taken to prove quality, safety and efficacy of a product[25] to the standards required by governments. The significant lead time between patent filing and regulatory approval makes the period of effective protection under the patent insufficient to justify the investment put into research and therefore discourages future pharmaceutical R&D.[26] EOT is therefore a necessary compensation to ensure that incentives for innovation in the pharmaceutical sector are not stifled.

[23] Draft Recommendation 9.1.
[24] US-AUS FTA Article 17.9.8(b).
[25] Lipsky, M and Sharp, L. From Idea to Market: The Drug Approval Process, JABFP September–October 2001 Vol. 14 No. 5
[26] *See* Regulation (EC) No 469/2009 concerning the supplementary protection certificate for medicinal products, Recitals 4 and 5.

2.2 Australia should not follow the Singapore model

The Commission stated that, even if there was evidence that EOT resulted in pharmaceuticals coming to the market that would not have otherwise, the IP framework should still better target extensions of term. The Commission outlined an emerging approach where pharmaceutical term extensions are granted only where there has been delay due to the regulator, and provided Singapore as the primary example.[27]

It is highly questionable whether the Singapore model would be adequate and result in the most appropriate patent term policy for Australia. The Singapore patent extension system deviates from other developed countries', which compensate patentees for delay resulting from clinical testing phases and administrative phases for obtaining marketing approval. Singapore only compensates patentees for delay from administrative phases for obtaining marketing approval and erroneously excludes the clinical testing phase from the calculated term of the process of obtaining marketing approval, thereby ignoring the very rationale for patent term extension in the first place.

Clinical trials represent an indispensable part of the marketing approval process required to obtain a product license for a pharmaceutical product. Accordingly, excluding the period taken to conduct clinical trials in the calculation of eligibility for patent term extension reduces incentives for innovation.

2.3 The Commission incorrectly infers that EOTs have been ineffectual simply because there is no increase in R&D investment in Australia

In further attempting to justify a reduction in EOT, the Commission states that the aim of the EOT scheme provided for in the Patents Act of 1990 to attract investment has "not been realised".[28] But there is no credible or rigorous empirical evidence presented in the Draft Report that supports this statement.

In making the claim that evidence suggests that the EOT policy has been ineffectual in attracting R&D to Australia, the Commission cites Harris, Nicol and Gruen (2013).[29] Yet those authors make the statement apparently based solely on one bar chart showing annual pharmaceutical R&D in Australia for 1992-93 versus 2010-11.

[27] Draft Report, *supra* note 1, p. 268.
[28] Draft Report, *supra* note 1, p. 263.
[29] Draft Report, *supra* note 1, p. 263.

To the extent that the relationship between EOT and investment is worth examining, then a more rigorous and data-driven analysis would be more reliable. For instance, this might entail detailed data, such as firm-level data, over time, with the time period spanning before and after the EOT scheme of 1990.

3. MANUFACTURE FOR EXPORT

3.1 Permitting manufacturing for export of patented medicines would contravene the objectives of Australia's patent system and would be inconsistent with Australia's international obligations

The Commission's recommendation that "extensions of term ... only be granted through a tailored system which explicitly allows for manufacture for export in the extension period",[30] undermines the incentives noted above by weakening patent rights. Extensions of patent term are designed to compensate for the erosion of the standard 20-year patent term due to the lengthy development and regulatory approval timelines in the pharmaceutical sector (and in other high-regulated industries). Thus, the protections during this period should be the same as those afforded during the standard patent term. These mechanisms reflect the need to provide innovators with a period of exclusivity over which they have the opportunity to recoup their R&D costs and fund future biomedical research.

Moreover, such provisions are inconsistent with the protection envisioned and, indeed, required under the US-Australia Free Trade Agreement. The US-Australia FTA provides that a patent be granted an adjustment for the patent term to compensate for "unreasonable curtailment" of the patent term due to marketing approval delays.[31] A side letter to the Agreement clearly explains the understanding of both Parties to the Agreement that where such a term is granted, Australia may permit export during such term "only for the purposes of meeting the marketing approval requirements of Australia or another territory."[32] Recommendation 9.2 is clearly not limited to these purposes and, if implemented, would render Australia's law inconsistent with this obligation.

Furthermore, generic companies already have the option of approaching patent holders to negotiate a licensing agreement. The holder of the patent will examine the specifics of the case and, if the parties agree, can license out the product through a voluntary license. One of the

[30] Recommendation 9.2.
[31] US-AUS FTA Article 17.9.8(b).
[32] Letter from Mark Vaile, Australian Minister for Trade, to Ambassador Robert Zoellick, US Trade Representative (May 18, 2004) and corresponding reciprocal letter from Ambassador Zoellick to Minister Vaile.

main advantages of this approach is that it often includes transfer of the know-how needed to ensure high-quality medicines are produced efficiently.

3.2 Enforcement of such a measure is difficult and limited

In addition, we believe that it would be difficult and burdensome, if not impossible, to enforce such a measure to ensure that products manufactured under this exemption are only exported to, and remain in countries without patent protection. For example, it would be difficult to distinguish whether manufacturing activities are being carried out for export to countries without IP protection, in support of export to countries where there is still IP protection or to stockpile products to be launched in the domestic market immediately upon protection expiry.

In light of the increased risks of infringements, there would need to be strict obligations to ensure that products only reach permitted countries (i.e., those export markets where IP protections are not in effect in relation to the manufacture), for example by requiring the originator to be notified of quantities produced and the intended destination of those products. These notifications requirements do not exist and would need to be implemented. These considerations underscore the complexity of this matter, and it is our view that such a recommendation to allow advanced manufacturing should be rejected as causing unintended consequences.

Finally, there are risks of facilitating infringement in countries with weak judicial enforcement systems that do not provide appropriate enforcement. If such a recommendation was implemented, it would be difficult or impossible for Australian courts to assess the existence and/or validity of patent claims in the importing countries to ensure that the exception is not used in a manner to facilitate infringement in the importing country.

4. REGULATORY DATA PROTECTION

As previously noted, the Productivity Commission takes a concerning and sweeping position that strong IP protections, including regulatory data protection (RDP), do not benefit Australia because Australia is a "net importer of pharmaceuticals." As a result, the Commission posits that RDP afforded to test data used for regulatory approval is "detrimental on competition." The Commission improperly rationalizes that robust RDP is reserved for "countries that are large net exporters of brand name pharmaceuticals" and that Australia's relatively small innovative pharmaceutical sector does not stand to benefit. Specifically, the Commission recommends:

> "There should be no extension of the period of data protection, including that applicable to biologics."
>
> "[I]n the context of international negotiations, the Australian Government should work with other nations towards a system of eventual publication of clinical trial data in exchange for statutory data protection."

For the reasons articulated below, neither of these recommendations should be included in the Commission's Final Report.

4.1. Australia should promote innovation through appropriate regulatory data protection terms

The Commission correctly identifies that "data protection should not be seen as a substitute for patents," but conflates the policy rationale of patent rights and RDP. RDP complements the patent system by stimulating pharmaceutical research and development. Patents protect inventions, whereas RDP incentivizes drug developers to conduct resource intensive clinical trials by protecting the resulting clinical trial test and other data submitted to marketing approval authorities. RDP is especially helpful in incentivizing the development of medicines which have long R&D timelines. RDP may also incentivize the development of new medical uses for previously approved medicines or first medical uses for substances only known to have non-medical uses. This is particularly true when patents on substances may no longer be available.

RDP is a balanced mechanism that can accelerate access to follow-on medicines. Notwithstanding the incentives RDP creates for developing new medicines, it allows generic and biosimilar manufacturers to rely on the originator's proprietary test data once the limited RDP term expires, thus eliminating the need to conduct independent clinical studies. It must be remembered that prior to RDP regimes, generic manufacturers were required to generate their own regulatory data that further delayed the introduction of lower cost medicines. For these reasons, the Commission should eliminate the proposal to restrict the RDP term in Australia to 5 years. Given the incentives that RDP can provide to introduce innovative medicines to Australia and the broader benefits such innovations provide to Australian society, the Productivity Commission should recommend that Australia adopt terms of protection for regulatory data that reflect international best standards.

4.2. RDP does not inhibit responsible clinical trial data sharing

The Draft Report states that regulatory "data is kept confidential indefinitely," thereby denying researchers access to data that could provide substantial public health benefits. What the report does not address is that pharmaceutical companies routinely publish their clinical research, collaborate with academic researchers, and share clinical trial information on public web sites at the time of patient recruitment, after new drug approvals, and when investigational research programs have been discontinued. In 2014, the innovative pharmaceutical industry committed to "Principles for Responsible Clinical Trial Data Sharing"[33] to promote legitimate medical and scientific research.

The Draft Report also states that failure to ensure that confidential clinical dossiers are not disclosed would likely result in pharmaceutical companies not launching new medicines in Australia until protection in other jurisdictions has expired. However, the report does not discuss the protections afforded by Article 39 of the WTO Agreement on Trade Related Aspects of Intellectual Property Rights (TRIPS) and Australia's obligations to protect regulatory data. Instead, the Commission concludes that Australia could avoid providing these protections by encouraging other countries to also disclose confidential clinical dossiers.

It is neither necessary nor appropriate for the Commission to propose that the "Australian government should work with other nations towards a system of eventual publication of clinical trial data in exchange for statutory data protection." The innovative pharmaceutical industry is committed to responsible data sharing and believes such sharing should not undermine Australia's existing international obligations to protect RDP. We welcome the opportunity to discuss further how these objectives are achieved in other countries.

5. ALLEGED "STRATEGIC BEHAVIOUR"

5.1.1 The Commission's recommendations related to so-called "Evergreening" are unsubstantiated and do not reflect the complexity of the biopharmaceutical discovery process and the value of improvements to existing innovations

The Commission asserts in Chapter 9 that "evergreening…is a strategy of obtaining multiple patents that cover different aspects of the same products" that extends a pharmaceutical company's market exclusivity. This reasoning undervalues subsequent innovations, which

[33] *See* "Principles for Responsible Clinical Trial Data Sharing," http://phrma.org/sites/default/files/pdf/PhRMAPrinciplesForResponsibleClinicalTrialDataSharing.pdf.

expand therapeutic classes and new treatment options with great value for patients. Furthermore, contrary to the perception expressed in the Draft Report, seeking patents for follow-on inventions does not "extend…protection of [pharmaceutical] products." Regardless of whether a patent has been granted for a follow-on invention stemming from the same active pharmaceutical ingredient (API), competitors are free to seek marketing approval for copies of the original invention as soon as the patents covering the originally marketed product expire.[34] In fact, generic manufacturers are increasingly seeking patent protection for improvements on existing inventions, including enantiomers, formulations, combinations, second medical uses, and methods of production.

The Commission rightly points out that "follow-on patents … can be a step-change with real benefits for the community", and the Draft Report should acknowledge the significant work involved in pharmaceutical R&D of all kinds. For example, despite properly noting that "a racemate is a mixture of equal parts of both enantiomers," the Draft Report does not address the difficultly and importance of isolating specific enantiomers. The safety and efficacy of many small molecules depends on isolating one enantiomer versus the other. For instance, enantiomers of a single molecule may produce drastically different effects – one may express therapeutic effect and the other may be toxic.[35] In other circumstances, one enantiomer may express bioavailability that greatly reduces dosage amounts. Moreover, isolating or synthesizing a single enantiomer is not trivial. In fact, the Nobel Prize in Chemistry in 2001 was awarded to researchers for a novel enantioselective synthesis.[36]

5.1.2 The Commission's recommendations to redefine inventive step are unnecessary and inappropriate

The Commission further confuses pharmaceutical patenting by using inaccurate "evergreening" assertions to add "further impetus to the adoption of draft recommendation 6.1 to raise the threshold of inventive step."[37]

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[34] *See, e.g.,* "Ganguli, Prabuddha, "Inside Views: Can Patents Ever be "Ever-Greened'? The Answer … They are 'Never-Greened,' IP-Watch (May 20, 2016), *available at* http://www.ip-watch.org/2016/05/20/can-patents-ever-be-ever-greened-the-answer-they-are-never-greened/; Incremental Innovation: Adapting to Patients Needs," http://www.ifpma.org/wp-content/uploads/2016/01/IFPMA_Incremental_Innovation_Feb_2013_Low-Res.pdf.

[35] See "Thalidomide Drug Crisis 1960s," http://guides.main.library.emory.edu/c.php?g=50422&p=325039.

[36] See http://www.nobelprize.org/nobel_prizes/chemistry/laureates/2001/.

[37] That draft recommendation states:

The Australian Government should amend ss. 7(2) and 7(3) of the *Patents Act 1990* (Cth) such that 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.

As an initial matter, draft recommendation 6.1 seems to omit well-defined principles of "inventive step" already reflected in Australia's *Patents Act 1990* and Patent Manual of Practice & Procedure. §7(2) of the *Patents Act* provides:

> For the purposes of this Act, an invention is to be taken to involve an inventive step when compared with the prior art base unless the invention *would have been* obvious to a person skilled in the relevant art in the light of the common general knowledge as it existed (whether in or out of the patent area) *before the priority date of the relevant claim*, whether that knowledge is considered separately or together with the information mentioned in subsection (3).[38]

One critical inquiry in assessing inventive step is to determine whether the invention *would have been* obvious before the relevant priority date. Otherwise, an assessment of inventive step would be biased by hindsight. Draft recommendation 6.1 fails to address this hindsight bias and seems to recommend retracting the high standard promulgated in §7(2) of the *Patents Act 1990*. Similarly, Section 2.5.1.5 of Australia's Patent Manual of Practice & Procedure provides various "tests for inventive step," including an "obvious to try" standard. It seems the Commission may be unaware of Australia's existing high patentability standards.

Furthermore, it is unclear what the Commission means by "explor[ing] opportunities to further raise the overall threshold for inventive step in collaboration with other countries in international forums." The innovative pharmaceutical industry supports high patentability standards, and encourages Australia to maintain patentability criteria consistent with best international practices.[39]

5.2 The proposal to implement a five year reporting and monitoring period for so-called "Pay-for-Delay" agreements is unsubstantiated and unnecessary

Despite finding no evidence to suggest that so-called "pay-for-delay" agreements have been reached in Australia, and concluding that such agreements "likely constitute an offence under the Competition and Consumer Act 2010 (Cth)" the Draft Report arbitrarily concludes that

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The Australian Government should state the following in the associated Explanatory Memorandum:

- the intent of this change is to better target socially valuable inventions
- the test should be applied by asking whether a course of action required to arrive at the invention or solution to the problem would have been obvious for a person skilled in the art to try with a reasonable expectation of success.

The Australian Government should explore opportunities to further raise the overall threshold for inventive step in collaboration with other countries in international forums.

[38] Emphasis added.

[39] *See* "Study on Inventive Step," World Intellectual Property Organization, *available at* http://www.wipo.int/edocs/mdocs/scp/en/scp_22/scp_22_presentation_inventive_step.pdf.

such agreements are harder to detect than other competition law violations and thus that a five year reporting and monitoring system should be implemented (Draft Recommendation 9.4). Patent settlements do not extend the patent term of an innovator's drug and generally permit generic drugs on the market earlier than patent expiration, generating significant savings for consumers. In fact in many cases, restricting patent settlements can delay generic entry. If a generic company loses a patent litigation – and data shows that innovator companies in the US prevail in the majority of patent cases litigated to court decisions[40] – it cannot enter the market until the end of the patent term for the innovator drug. Restricting patent settlements would diminish the value of patents by restricting options with respect to settlement of patent litigation, which could impact decision-makers considering investing in biopharmaceutical R&D. This could stifle long-term future innovation to the detriment of patients in need. Absent, therefore, contrary evidence to demonstrate the need for this burden, this recommendation is unnecessary and should not be pursued in the final report.

Conclusion

We would like to thank you for the opportunity to provide comments to this Draft Report and reiterate that we and our members companies remain at your disposal for a constructive dialogue on how to improve Australia's IP system.

Yours sincerely,

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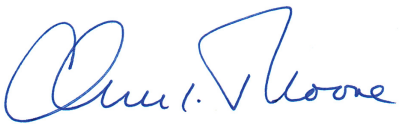

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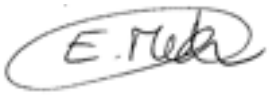
[40] PwC, "2014 Patent Litigation Study: As Case Volume Leaps, Damages Continue General Decline," July 2014.



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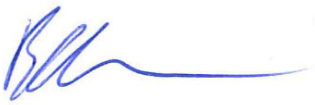

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