August 31, 2018

Dr. Frances Roden  
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AUSTRALIA

Dear Dr. Roden:

The European Federation of Pharmaceutical Industries and Associations (EFPIA), the International Federation of Pharmaceutical Manufacturers and Associations (IFPMA), the Japan Pharmaceutical Manufacturers Association (JPMA) and the Pharmaceutical Research and Manufacturers of America (PhRMA) appreciate the opportunity to provide the following comments on IP Australia’s Exposure Draft of the Intellectual Property Laws Amendment (Productivity Commission Response Part 2 and Other Measures) Bill 2018 and the accompanying Draft Explanatory Memorandum.

Our member companies and the many women and men they employ across Australia and around the world are devoted to inventing, manufacturing and delivering valuable new medicines and vaccines that enable people to live longer, healthier and more productive lives. They work in partnership with universities, healthcare providers and others to bring new treatments and cures to patients who need them – leading groundbreaking biopharmaceutical research and investing in many of the more than 7,000 medicines in development worldwide.

Effective protection and enforcement of patents and other intellectual property (IP) based on clear rules that provide certainty and predictability is critical to incentivizing the development of new medicines and to ensuring that Australian patients are able to receive the latest advances as quickly as possible. For decades, Australia has recognized the importance of a robust IP system that values and rewards innovation and that maximizes the social and economic benefits of new discoveries.

As explained further below, we believe several of the changes proposed in the draft legislation – including changes on inventive step, Crown use of patents and designs, and compulsory licenses – are unnecessary and would introduce uncertainty into Australia’s IP laws. These proposed changes would also significantly weaken IP protections in Australia that facilitate access to today’s medicines and help drive discovery of future treatments and cures for patients. In light of these unintended consequences (the primary focus of these consultations), we encourage IP Australia to not adopt these changes. To the extent Australia continues to proceed with implementation of amendments to its patent legislation, we offer the following comments.
I. Inventive Step

IP Australia’s stated goal for the inventive step amendments is to raise the inventive step threshold, and to do so by adopting the European approach for assessing inventive step. But as discussed in our prior comments, the Productivity Commission’s position that Australia’s current inventive step requirement is insufficient or otherwise out of step with European Patent Office (EPO) standards is based on flawed and unsubstantiated assumptions. For example, the Productivity Commission’s conclusion that EPO’s threshold is more effective at filtering out “low-value” patents than Australia’s threshold is contradicted by the evidence. Further, the nearly identical grant rates in Australia and the EPO (86.8 percent and 82.6 percent) indicate that Australia’s and EPO’s standards are similarly effective in facilitating genuine innovations. Thus, the notion that Australia’s current inventive step threshold is lower than EPO’s threshold is simply unsupported, and changing Australia’s law as proposed would create significant uncertainty and weaken Australia’s climate for innovation in a wide range of sectors.

Moreover, IP Australia’s proposed amendments, while raising the inventive step threshold, would set the bar even higher than EPO’s standard. The Memorandum explains that, “[b]y adopting wording similar to Article 56 of the EPC [European Patent Convention], the purpose of this item is to expand the approaches for assessing inventive step to include the EPO problem-and-solution approach.” The Memorandum makes clear that the EPO’s problem-and-solution approach would not be the exclusive approach to assessing inventive step, and that “there will be flexibility for the Commissioner and the courts to adopt other tests, in accordance with existing case law in Australia.” Particularly concerning is the Memorandum’s instruction that, “if there are circumstances where a claimed invention is considered obvious when assessed using one approach, but not using another, the approach to be followed is the one where the invention is considered obvious.”

Such an approach promotes subjectivity and uncertainty, and it surpasses the inventive step threshold applied across jurisdictions, including the EPO. The EPO Guidelines for Examination state: “In order to assess inventive step in an objective and predictable manner, the so-called ‘problem-and-solution approach’ should be applied. Thus deviation from this approach should be

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3 Australian Government, Productivity Commission, “Intellectual Property Arrangements: Productivity Commission Inquiry Report,” No. 78, 23 (September 2016); compare id. at 202, Fig. 7.1 (the distribution of composite patent value index in Australia) with id. at 203, Fig. 7.2 (same for the United States and Europe).
4 Id. at 221 & Table 7.3.
5 As the Memorandum acknowledges, “[c]urrently the approach that is generally used by the Australian courts and the Commissioner to assess inventive step is a problem-solution approach.” Memorandum at 11. While the Memorandum goes on to discuss EPO’s problem-and-solution approach, it fails to explain why Australia’s current problem-solution approach needs to be changed.
6 Memorandum at 13 (emphases added).
7 Id.
8 Id. at 14.
exceptional.” Accordingly, under EPO practice, deviation from the problem-and-solution approach is reserved for exceptional cases, in contrast to IP Australia’s proposal, where deviation would be appropriate whenever it would increase the inventive step threshold and lead to a determination of obviousness. While the Memorandum states that the problem-and-solution approach is not EPO’s only approach, citing EPO Decision T465/92 (1994), in that case the EPO deviated from the problem-and-solution approach but found the claimed invention to have inventive step. In other words, the EPO did not deviate from the problem-and-solution approach to impose a higher threshold and arrive at a finding of obviousness.

The proposed amendments, therefore, would not achieve IP Australia’s goal of making Australia’s inventive step standard the same as EPO’s standard, and instead would move Australia’s standard above and beyond EPO’s standard in a manner that could discourage innovation. Indeed, the concern expressed in Consultation Question 1 highlights the difficulty of achieving full alignment, since other parts of Australia’s Patents Act differ from EPO law. Unless IP Australia adopts EPO’s laws and rules wholesale, Australia’s inventive step rule may never be entirely aligned with EPO’s standard (as discussed above, Australia’s current threshold is already in line with EPO’s threshold), and changing the law would only introduce uncertainty and weaken Australia’s patent system.

We also are concerned that the assessment of an invention’s technical features conducted as part of the problem-and-solution approach could be used to restrict the eligibility of certain classes of inventions, such as diagnostic methods and methods of treatment, for patent protection. As explained in the Memorandum, assessment of an invention’s technical features as part of the problem-and-solution approach would “complement,” and could “overlap” with, the assessment of whether the invention satisfies the “manner of manufacture” requirement of paragraph 18(1)(a) of the Patents Act. To the extent the assessment of an invention’s technical features for inventive step purposes could be used to heighten the threshold for satisfying paragraph 18(1)(a), IP Australia’s proposal would introduce yet more uncertainty and weaken Australia’s patent system.

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10 Case T465/92 – 3.2.2 (OJ EPO, Oct. 14, 1994) addressed a situation in which there were a number of different references, each teaching a different solution to the same problem solved by the claimed solution, and inventiveness depended solely on whether they contained any direction to the claimed solution; thus no particular reference was the closest reference for applying the problem-and-solution approach. The EPO noted that deviation from the problem-and-solution approach may be appropriate where the facts are clear, either for or against inventiveness, such as where an invention breaks entirely new ground and is therefore inventive.

11 Question 1 concerns the difference in wording in proposed section 7(2) and EPC’s Article 56. Proposed section 7(2) states “an invention is taken to involve an inventive step when compared with the prior art base if the invention is not obvious to a person skilled in the relevant art” (emphasis added), and EPC’s Article 56 states “[a]n 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” (emphasis added). Question 1 notes that the change in wording “was made for consistency with the rest of the Act, but differs from the wording used in the European Patent Convention,” and asks what consequences there may be from the change in wording.

12 Memorandum at 14.
II. Crown Use of Patents and Designs

The proposed amendments to the Crown use provisions, if implemented, would have significant unintended consequences, including introducing uncertainty and unnecessary complexity to the exercise of Crown use, and eroding patent rights by inviting broader use of a mechanism intended only as “a safeguard for rare instances in which the patents system is hindering government action to address an urgent issue (for example, providing treatment in an epidemic).” As the Productivity Commission correctly recognized, Crown use “involve[s] significant interference with the rights of patent holders” and, “[i]f the provisions were relied upon too readily, confidence in the patents system could be damaged.” Despite this caution, the proposed amendments would provide the government with a broad mandate to interfere with the rights of patent owners. The proposed amendments would expand Crown use beyond those “rare instances” of exceptional circumstance or last resort.

For example, the proposed amendments specify that Crown use of inventions and designs is available for “services” that are “primarily provided or funded” by the government. This “services” definition introduces a “primary responsibility test,” whereby a service by any provider – including a private, non-government entity – is eligible for Crown use so long as the service is largely provided or funded by the government. Thus, we understand the intent of the proposed amendment to be that, if the government provides or funds the majority of a given service (e.g., genetic testing), it would have primary responsibility for that service, and any private provider would be eligible for Crown authorization to exploit a patent for the provision of that service.

Such a “services” definition and its accompanying “primary responsibility test” would introduce uncertainty as to which services qualify for Crown use. It is unclear what level of government responsibility would be required to constitute “primary responsibility” for a service, such that Crown use would be available to providers of that service. The Memorandum’s genetic testing example merely indicates that, where governments provide or fund “the vast majority” of a service, they would have primary responsibility for the service.

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13 Productivity Commission Inquiry Report on Compulsory Licensing of Patents (March 28, 2013), at 166; see also Memorandum at 20 (“Crown use provisions provide a rarely-used safeguard where the patent system may otherwise hinder government in taking necessary action to deal with urgent or major issues of concern to the public.”).


15 See proposed sections 160A(4) (Patents Act) and 95(5) (Designs Act).

16 Memorandum at 21 (explaining that the proposed “services” definition “makes it clear that Crown use can be invoked for the provision of a service that the Commonwealth, State and/or Territory Governments have the primary responsibility for providing or funding,” and that “this primary responsibility test will take account of all providers of similar services to those provided or funded by a government, including non-government providers”); see also id. at 32 (explaining the same for designs).

17 Both the current Crown use provisions (section 163(3) of the Patents Act 1990, and section 96(3) of the Designs Act 2003) and the proposed amendments (sections 160A(3) and 95(4)) require that the exploitation of an invention, or the use of a design, be “necessary for the proper provision” of the service for the exploitation or use to be considered by the Crown, or for Crown purposes.

18 Memorandum at 22 (emphasis added).
Notwithstanding this ambiguity, it is clear that the “services” definition would expand the circumstances under which Crown use – a safeguard intended for rare, exceptional situations – can be obtained. Under both the current law and the proposed amendments, for an invention to be exploited for or by the Crown and therefore exempt from infringement liability, the invention must be exploited “for the services” of the government and by the government or a person (e.g., a private provider) authorized by the government. But under the proposed amendments, we understand that the new “services” definition and its “primary responsibility test” would enable any private entity providing a service largely funded by the government to seek Crown use to exploit another’s patent for that service. In the health care industry – a sector heavily funded by the Australian government – the potential for would-be licensees to seek Crown use if license negotiations fail would place significant pressure on patentees during such negotiations and would undermine the value of their patents. Moreover, such expansion of Crown use would inappropriately interfere with the property rights of innovators who have made substantial investments to bring new medicines to the Australian market.

IP Australia’s proposed amendments appear to be motivated in part by a concern that patents somehow hinder access to medicines. But experience and recent research demonstrates that the imposition of a license by a government is not an effective way to improve access to medicines or achieve other public health objectives. Government-mandated licensing is particularly ineffective relative to the many alternatives available. Biopharmaceutical innovators support different tools and programs that make medicines available to patients who could not otherwise afford them, including drug donation and differential pricing programs, as well as voluntary licensing.

Biopharmaceutical patents drive research and development that delivers new treatments and cures, which support strong national health systems and timely access to quality, safe and effective medicines for patients who need them. A strong and predictable patent system is vital to increasing investment in innovation, as well as ensuring access to the latest medical treatments. For this reason, governments should grant licenses – whether for Crown use or use by third parties

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19 See section 163(1) of the Patents Act 1990; see proposed sections 163(2) and 160A(1).
21 In addition, the Memorandum states that private providers authorized to exploit a patent under Crown use would not make a profit from their use of the invention in such scenarios, see Memorandum at 22, but nothing in the proposed amendments or the Memorandum ensures such a restriction on profits, or otherwise explains how such profits would be monitored and accounted.
– in accordance with international rules and only in exceptional circumstances and as a last resort.\(^{25}\) The proposed Crown use amendments would instead expand Crown use beyond the limited circumstances that justify imposition of a patent license. IP Australia should, therefore, reconsider such amendments.

### III. Compulsory Licensing of Patents

As discussed above, governments should grant compulsory licenses in accordance with international rules and only in exceptional circumstances and as a last resort. While their limited use to address a national health emergency can be appropriate when other access schemes have failed, compulsory licenses should not be used to support industrial policy objectives or as a routine cost containment measure when other alternatives are available. With this guiding principle in mind, we believe Australia’s current compulsory license laws are sufficient and that no amendments are needed. Changes that would encourage or make it easier for third parties to acquire innovative technologies without authorization would have significant unintended consequences, and unnecessarily undermine the usefulness and effectiveness of the Australian patent system by weakening patent protections, reducing investment in research and development, and creating uncertainty in the long-term enforceability of patent rights.

If compulsory licensing is intended only as an option of last resort to be invoked in exceptional circumstances, as IP Australia agrees that it is,\(^{26}\) IP Australia’s proposal to replace the “reasonable requirements of the public” test with a “public interest” test would inappropriate expand compulsory licensing. Indeed, Australia’s international obligations require that compulsory licensing be limited to circumstances involving “anti-competitive practices” or, “in cases of public non-commercial use, or of national emergency, or other circumstances of extreme urgency.”\(^{27}\) Expanding this list to allow compulsory licensing when there is deemed to be a “public interest,” based on the broad factors enumerated in proposed subsection 133(3)(e),\(^{28}\) goes well beyond the limited circumstances permitted under Australia’s international obligations and could open the door to abuse of compulsory licensing.

For example, the Memorandum explains that the term “public interest,” unlike the current term “reasonable requirements of the public,” “is a commonly used legal term with an existing body of case law which applies this terminology in a wide range of circumstances and will assist in its interpretation.”\(^{29}\) This clear invitation for courts to look to “a wide range of circumstances”

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\(^{25}\) As the Productivity Commission correctly observed, “[c]ompulsory licensing is a safeguard that is only needed in exceptional circumstances” and should remain “rarely needed.” Productivity Commission Inquiry Report on Compulsory Licensing of Patents, at 114–15 (Mar. 28, 2013).

\(^{26}\) See IP Australia, Paper 4: Compulsory Licensing of Patents (August 2017), at 3.

\(^{27}\) U.S.-Australia Free Trade Agreement (U.S.-AUS FTA) Article 17.9.7; see also WTO Agreement on Trade-Related Aspects of Intellectual Property Rights (TRIPS) Article 31(b).

\(^{28}\) Proposed subsection 133(3)(e) provides that “public interest” be determined with regard to: “(i) the benefits to the public from meeting the demand for the original invention; (ii) the commercial costs and benefits to the patentee and the applicant from providing authorisation to exploit the original invention; (iii) any other matters the court considers relevant, including matters relating to greater competition and any impact on innovation.”

\(^{29}\) Memorandum at 42.
– instead of exceptional circumstances – outside the patent context to determine whether exploitation is in the “public interest” contravenes the mandates of the U.S.-AUS FTA.\textsuperscript{30} Similarly, allowing courts to consider “any other matters” they deem relevant, “including matters relating to greater competition and any impact on innovation,” in deciding whether there is a “public interest” and ultimately whether to impose a patent license, permits courts to become policy-makers with respect to a particular patentee’s rights. In justifying this further expansion of exceptions to patent rights, IP Australia suggests it would “recognise the balance required between the rights of the patent holder and the interests of the broader public.”\textsuperscript{31} But such permissive exceptions to Australia’s patent law are unwarranted and contravene Australia’s international obligations.

Compulsory licensing provisions also must ensure that patent holders receive adequate remuneration that protects their rights and compensates them for their economic loss. Such remuneration provisions are necessary to recognize the economic value of patents, safeguard against unjustified use, and comply with Australia’s international obligations, which specifically require consideration of the economic value of the unauthorized license.\textsuperscript{32} While the proposed amendments would retain consideration of the economic value of the license, as currently provided in section 133(5)(b) (which governs the amount to be paid to the patentee), they would include two additional considerations: “the right of the patentee to obtain a return on investment commensurate with the regulatory and commercial risks involved in developing the invention,” and “the public interest in the efficient exploitation of the invention.”\textsuperscript{33} While we agree that the right of the patentee to obtain a return on its investment should be considered, these particular proposals (\textit{e.g.}, including the unnecessary qualification “commensurate with the regulatory and commercial risks involved in developing the invention”) would inject subjectivity and invite courts to potentially devalue patent rights, in violation of Australia’s international obligation to ensure patentees receive adequate and reasonable compensation, and that exceptions to patent rights do not unreasonably prejudice patentees’ legitimate interests.

Lastly, with respect to dependent patents, we do not believe the additional requirements set forth in proposed sections 133(3)(f) and 133(3A) are warranted. Existing compulsory license requirements sufficiently provide for circumstances of dependent patent owners, and additional provisions for dependent patents are unnecessarily complicated. If, however, these provisions are implemented, we believe section 133(3A) should also include a restriction on assignability consistent with TRIPS Article 31(I)(iii).\textsuperscript{34}

\begin{itemize}
\item \textsuperscript{30} \textit{See} U.S.-AUS FTA Article 17.9.3 (“A Party may provide limited exceptions to the exclusive rights conferred by a patent, provided that such exceptions do not unreasonably conflict with a normal exploitation of the patent and do not unreasonably prejudice the legitimate interests of the patent owner, taking account of the legitimate interests of third parties.”).
\item \textsuperscript{31} Memorandum at 42.
\item \textsuperscript{32} \textit{See} TRIPS Article 31(h) (patent holders must “be paid adequate remuneration in the circumstances of each case, taking into account the economic value of the authorization”); \textit{see also} U.S.-AUS FTA Article 17.9.7(b) (“A Party shall not permit the use of the subject matter of a patent without the authorisation of the right holder except in the following circumstances: . . . the Party shall ensure that the patent owner is provided with reasonable compensation for such use . . . .”).
\item \textsuperscript{33} \textit{See} proposed section 133(5)(b).
\item \textsuperscript{34} TRIPS Article 31(I) provides that, “where use is authorized to permit the exploitation of a patent (‘the second patent’) which cannot be exploited without infringing another patent (‘the first patent’), the following additional
IV. Specifications and Section 40(3A) of the Patents Act 1990

We believe that adding noncompliance with section 40(3A) as a ground for opposing the grant of or revoking a patent is unnecessary and could have the unintended consequences of introducing inefficiencies into the patent system. Under section 40(3A), claims must not rely on references to descriptions or drawings “unless absolutely necessary to define the invention.” The Commissioner, when examining patent applications, determines in the first instance whether specifications comply with this prohibition. Allowing third parties to later challenge a patent for such compliance would invite parties to argue over whether a claim’s reference to a figure was “absolutely necessary.” Further, to the extent section 40(3A) was enacted to promote clarity of claim scope, the opposition and revocation provisions already allow third parties to challenge patents on the basis that the claims are not “clear and succinct.”35 Permitting another challenge on such a basis is unnecessary.

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We appreciate the opportunity to provide these comments during this public consultation on proposed amendments to the Intellectual Property Rights legislation and regulations. We and our members remain at your disposal for a constructive dialogue on continuing to improve Australia’s IP system.

Sincerely,

Kristine Peers
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EFPIA

Thomas B. Cueni
Director General
IFPMA

Akihiko Matsubara
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conditions shall apply: . . . (iii) the use authorized in respect of the first patent shall be non-assignable except with the assignment of the second patent” (emphasis added).

35 See sections 59(c) and 138(3)(f) of the Patents Act 1990, each of which refers to section 40(3); section 40(3) requires the claims to be “clear and succinct and supported by matter disclosed in the specification.”