Ms. Patricia Kelly  
Director General, IP Australia  
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47 Bowes Street  
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AUSTRALIA

Dear Ms. Kelly:

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 for IP Australia’s public consultation on the implementation of the Productivity Commission’s 2016 report on Australia’s intellectual property arrangements.

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 many of the potential changes to Australia’s IP laws and policies proposed in the public consultation documents on inventive step,¹ Crown use of patents and designs,² compulsory licensing of patents³ and an objects clause for the Patents

¹ IP Australia, Paper 1: Amending the inventive step requirements for Australian patents, Aug. 2017 (IP Australia Consultation Paper 1).
Act 1990,⁴ are unnecessary and would significantly weaken IP protections in Australia that facilitate access to today’s medicines and help drive discovery of future treatments and cures for patients.

These potential changes proceed from the Productivity Commission’s deeply flawed and demonstrably false premise that IP protections favor foreign innovators to the detriment of Australian society.⁵ They do not appear designed to solve any practical problems encountered by stakeholders. They are either unsupported by evidence or based on faulty assumptions. For these reasons, we urge IP Australia to reconsider its approach to the Commission’s Report and the value of acting on its recommendations.

I. Amending the Inventive Step Requirements

As part of the IP Laws Amendment (Raising the Bar) Act of 2012, Australia enacted significant reforms to its “inventive step” requirement for patentability.⁶ The Productivity Commission’s argument that this requirement is now insufficient or otherwise out of step with European Patent Office (EPO) standards or broader international best practice is based on flawed and unsubstantiated assumptions. Further amendments as outlined in IP Australia Consultation Paper 1 – whether accepting the Commission’s proposal to raise the “inventive step” threshold (option IS-1), adopting either of two variations on that proposal (options IS-2 and IS-3), enshrining the EPO “problem-and-solution” approach in the Patents Act 1990 (option IS-4) or implementing new “technical features” (options TF-1 through 3) – are unnecessary to facilitate “genuine innovations” or to discourage “low value” patents. They would promote subjectivity, create significant uncertainty and weaken Australia’s climate for innovation in a wide range of sectors.

In recommending further changes to the “inventive step” requirement, the Productivity Commission appears to have relied on two deeply flawed and unsupported assumptions. Specifically, the Commission claims that Australia has “a materially greater propensity to grant patents when the [EPO] does not”⁷ and that companies are abusing an allegedly low “inventive step” requirement to “evergreen” patents with multiple patents covering different aspects of the

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⁶ In particular, under this Act, Australia: (1) broadened the scope of allowable prior art; (2) expanded the assumed background knowledge of the person of ordinary skill in the art against which the prior art is assessed; and (3) required that the specification of the invention be clear and complete enough for it to be performed by a person of ordinary skill in the art and that the claims be fully supported by the description. Id. at 221.

⁷ Id. at 224.
same product.\(^8\) The Commission failed to provide any evidence to support these assertions. On the contrary, it presented compelling evidence that the 2012 reforms have “narrow[ed] the grant rate between IP Australia and the European Patent Office” and that IP Australia’s grant rate is nearly identical to the European Patent Office’s (86.8 percent to 82.6 percent).\(^9\) Rather than focusing on these data, however, the Commission’s recommendations appear to rest on a flawed table showing that IP Australia grants applications that received a “first report” at a higher rate than the EPO – a fact that is meaningless without further information or context. The statistics presented are not direct comparisons and it is not even clear at what rate, and for what deficiencies, applications receive a first report in Australia versus Europe.

Moreover, as we noted in our comments on the draft Productivity Commission report, 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.\(^10\) Seeking a patent for a follow-on invention does not extend protection for the originally patented invention. Regardless of whether a patent has been granted for a follow-on invention stemming from the same active pharmaceutical ingredient, competitors are free to seek marketing approval for copies of the original invention as soon as the patents covering the originally marketed products expire.\(^11\) Australia’s existing patent laws, including the current “inventive step” requirement, already prohibit the granting of two patents on the same invention. In addition, Article 27 of the WTO Agreement on Trade-Related Aspects of Intellectual Property Rights (TRIPS) requires that patents be available for all inventions that are new, involve an inventive step and are capable of industrial application with limited exceptions. This obligation also includes a list of the types of subject matter that can be excluded from patent coverage, and that list does not include new uses of existing compounds. The myth of “evergreening” seeks to narrow this list of patentable inventions by improperly devaluing subsequent inventions, which expand therapeutic classes and new treatment options that deliver significant value for patients and can even lower overall health care costs.

Unfortunately, the specific options in IP Australia Consultation Paper 1 do not correct problems in the Commission’s analysis and would create many others. For example, Options IS-

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\(^8\) Id. at 19–20, 319–24.

\(^9\) Id. at 221 & Table 7.3. To the extent the Productivity Commission’s recommendations were driven by a perception that IP Australia grants too many “low-value” patents, this assumption also is unsupported and contradicted by the evidence presented in the Productivity Commission’s report. 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).


1 through 3 all omit well-defined international principles of “inventive step.” A critical question in assessing “inventive step” is to determine whether the invention would have been obvious before the relevant priority date. Without this important distinction that “inventive step” must be assessed from the perspective of a person at the time of filing, any assessment is biased by hindsight. This question already is reflected in the current language of the Patents Act 1990 and Section 7(2) of the Patent Manual of Practice & Procedure. Options IS-1 through 3, however, do not include such critical language to protect against hindsight bias, contrary to international best practice.

Likewise, options TF-1 and TF-3 would impose additional, burdensome and unnecessary application requirements, either by requiring an additional section in the specification or another separate document entirely. Also of significant concern, Option TF-1 proposes that failure to include these sections may result in a loss of rights for the applicant. Such unjustified regulatory requirements could therefore result in the imposition of onerous remedies that could stifle the legitimate grant of patent rights. Australian law already necessarily requires identification of technical features in order to distinguish the invention from the prior art.

II. Crown Use of Patents and Designs

It is equally unclear why any changes are needed to Australia’s “Crown use” mechanism. This mechanism, which allows federal, state and territorial governments to access and use patented technology without the consent of the right holder, has been available under Australian law for decades. As noted in IP Australia Consultation Paper 3, it has been used in at least two confirmed cases contested before the courts, and perhaps in others. The Productivity Commission has provided no compelling reason to alter Crown use, and the changes the Commission proposed are not supported by evidence. Particularly in the absence of an actual problem that might suggest a need to reconsider the Crown use mechanism, any further action at this time – whether promoting public awareness (option 1), changing the Patents Act (option 2) or implementing the Bandt Amendments (option 3) – is unnecessary and will only inject uncertainty into Australia’s patent regime and erode the rights of patent holders.

The Productivity Commission has recommended significant changes to “clarify the scope of Crown use and improve transparency and accountability of governments seeking to use the

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12 Section 7(2) of the Patents Act 1990 reads:

“For 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).”
provisions” without providing clear evidence of a need for such changes. Indeed, the Commission acknowledged that “the Australian government chose not to implement” prior proposed changes to Crown use due to the lack of “evidence that the provisions were being misused.” It states that the “costs of initiating reforms solely for the Crown use provisions, given the dearth of evidence that there is a problem, argue for retaining the status quo,” yet urges that changes to the Crown use provisions be packaged in with other changes “at relatively low cost.”

It further is difficult to conceive of any pressing need for greater transparency and accountability concerning the “Crown use” mechanism. To the extent that the recommendation was motivated by the *D’Arcy v. Myriad* case and issues regarding patenting of isolated genetic sequences, that motivation no longer exists following the determination of non-patentability in that case. The risk of uncertainty and erosion of patent rights if “Crown use” is exercised broadly, as well as the outcome of the *D’Arcy v. Myriad* case, suggest that there is no need for greater education (Option 1) and weighs strongly against any of the proposed reforms under Options 2 and 3.

Biopharmaceutical innovators support strong national health systems and timely access to quality, safe and effective medicines for patients who need them. Patents drive and enable research and development that delivers new treatments and cures. A strong and predictable patent system is vital to increasing investment in innovation, as well as ensuring access to the latest medical treatments. This is why governments should grant licenses – whether for Crown use or use by third parties – in accordance with international rules and only in exceptional circumstances and as a last resort. This is consistent with the Productivity Commission’s observation that “[c]ompulsory licensing is a safeguard that is only needed in exceptional circumstances” and should remain “rarely needed.”

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. For example, it does not necessarily lower prices in the short-term, or provide

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14 Id. at 19, 167.
15 Id. at 179.
16 Id. at 180.
17 See D’Arcy v. Myriad Genetics Inc. & Anor [2015] HCA 35; see also IP Australia Consultation Paper 3 at 4 (noting that “[f]urther consideration of the PC recommendations on Crown use and compulsory licensing provisions was put on hold pending the decision of the High Court in [Myriad], and the release of the 2016 Productivity Commission inquiry” but that the ruling “made it clear that isolated gene sequences are not patentable which brought to an end a period of legal uncertainty”).
sustainable or comprehensive solutions to longer-term challenges. It does not address systemic barriers to access – from weak healthcare delivery systems to low national healthcare funding and high taxes and tariffs on medicines. 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, voluntary licensing and non-assert declarations.

The Productivity Commission itself noted that Crown use provisions were intended “to be 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 rightly 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, all of the options proposed by IP Australia for amendments to Crown use would provide the government with a broad mandate to interfere with the rights of patent owners. Each of the presented options would expand Crown use beyond situations of exceptional circumstance or last resort.

For example, option 2(a) would permit Crown use to be invoked in any situation where negotiations have failed to obtain use of a patent concerning “provision of a service” that a government, whether Commonwealth, State, or Territory, funds. In discussing the need to clarify the purposes for which Crown use might be invoked, IP Australia noted “uncertainty among stakeholders as to whether ‘for the services’ of the government would extend to non-government service providers in areas that are traditionally the responsibility of government” and whether such uncertainty may have been an impediment to the “effective use” of these Crown use provisions. Thus, we are concerned about the intent of this proposal to expand Crown use beyond limited circumstances, and despite the fact, as noted above, that the examples provided were subsequently addressed by the Australian High Court. Option 2(b) similarly could expand Crown use if outside proposals regarding the scope of the “specified services,” such as that

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22 Id.

23 IP Australia Consultation Paper 3 at 7–8.

24 Id. at 5 (citing, as an example, the failure of the Department of Health to use the Crown use provisions “to provide better and/or cheaper access to the breast cancer gene test patented by Myriad Genetics, despite pressure from some stakeholders”).
offered by the Australian Law Reform Commission, to limit Crown use to one sector were adopted. Such proposals to limit government mandated licensing to a single sector would likely run afoul of Australia’s international obligations not to discriminate between fields of technology.

Moreover, Crown use provisions must also ensure that adequate remuneration that protects the rights of patent holders and compensates for their economic loss is provided. Such provisions are necessary to recognize the economic value of patents, safeguard against unjustified use, and comply with Australia’s international obligations. We therefore disagree with option 2(c), which would eliminate consideration of a patent owner’s return on investment and deemphasize consideration of the economic value of the license — risking significant erosion of rights of patent holders. IP Australia’s concern that such considerations may “unduly discourage the exercise of Crown use in circumstances where it is justified” is unwarranted and unsupported by evidence. As IP Australia recognized, Crown use is appropriately limited to extreme circumstances justifying the imposition of a patent license. IP Australia’s remuneration proposal also is inconsistent with Australia’s international obligations, which specifically require consideration of the economic value of the unauthorized license. Lastly, IP Australia’s recommended remuneration standard, that remuneration only be “just and reasonable taking into consideration the circumstances of the case,” is a standard that without more provides inadequate guidance for courts and injects unnecessary uncertainty by failing to provide specific considerations or define the “circumstances of the case.”

We share IP Australia’s concerns regarding the Bandt Amendments and agree that Option 3 should not be adopted. The Bandt Amendments would provide an even broader and more unacceptable mandate to the Australian government, expanding Crown use to “research” or any other “service” funded by the government. Beyond the obvious contradictions with Australia’s international obligations to strictly limit unauthorized patent use, we agree with IP Australia that the optional accountability and transparency provisions in the Bandt Amendments defeat their very purpose and risk significant erosion of patent rights and an unjustified increase in the invocation of Crown use.

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25 Id. at 8 (Australian Law Reform Commission proposed limiting Crown use to exploitation of a patent “for the provision of healthcare services or products to members of the public”).

26 See TRIPS Article 27.1.

27 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”); see also U.S.-Australia Free Trade Agreement (U.S.-AUS FTA) Article 17.9.7(b) (“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.”).
III. Compulsory Licensing of Patents

As noted above, governments should grant compulsory licenses in accordance with international rules and only in exceptional circumstances and as a last resort. With this guiding principle in mind, we believe Australia’s current compulsory license laws are sufficient and that none of the options proposed in Part 1 of IP Consultation Paper 4 are needed. Changes that would encourage and/or make it easier for third parties to acquire innovative technologies without authorization would 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 “a safeguard that is rarely needed”, as suggested in the public consultation document, then there appears to be little value in promoting greater “public education and awareness” (Part 1, Option 1) of relevant provisions in Australian law. Moreover, it would be particularly unfortunate for IP Australia, which grants patents and appears to have invested considerable time and resources in developing creative tools to inform local inventors about the value of IP and the means to secure and enforce their rights at home and abroad, to promote the use of patents without the consent of the right holder. Rather than encourage actions that are “rarely needed” and would undermine IP protections, the Australian Government should consider additional opportunities to promote domestic innovation in line with Prime Minister Turnbull’s National Innovation and Science Agenda.

We have serious concerns about the recommendations in Part 1, Option 2. In particular, we share IP Australia’s reservations regarding Productivity Commission Recommendation 6.1 and urge that it be rejected. IP Australia is correct in noting that “[Section] 133(2)(b) of the Patents Act [already] provides a clear and transparent statement that a compulsory licence is available under the Patents Act as a remedy for anti-competitive conduct.”\(^\text{28}\) Despite this clear statement, the Productivity Commission recommended that this language be moved instead to the Competition and Consumer Act 2010, while again failing to present any evidence of an existing problem this recommendation is designed to remedy. We therefore agree that “[t]here is insufficient evidence of particular problems that would be specifically resolved by implementing Recommendation 6.1.”\(^\text{29}\) The Productivity Commission’s unsupported proposal would upset settled law and create uncertainty for patent owners regarding the availability of compulsory licensing as a remedy for anti-competitive conduct.

We strongly object to Recommendation 6.2, which would require a “substantial public interest in providing access to the applicant.” As stated above, compulsory licensing is intended only as an option of last resort to be invoked in exceptional circumstances. Indeed, Australia’s

\(^{28}\) IP Australia Consultation Paper 4 at 6.

\(^{29}\) Id. at 7.
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.”\textsuperscript{30} Expanding this list to allow compulsory licensing when there is deemed to be a “substantial public interest,” particularly for the broad purposes cited in the Consultation Document,\textsuperscript{31} appears to go well beyond the limited circumstances permitted under Australia’s international obligations and could open the door to abuse of compulsory licensing. For this reason, we find Option 3, which would drop the term “substantial,”\textsuperscript{32} even more troubling. In justifying this further expansion of exceptions to patent rights, IP Australia suggested that this would “balance the right of the patentee to obtain an appropriate economic return on their investment and the rights of the public to the invention being exploited efficiently.”\textsuperscript{33} Such permissive exceptions to Australia’s patent law are unwarranted and should be rejected.

We also strongly agree with IP Australia’s opposition to Commission Recommendation 6.3, which would repeal the requirement under Section 136 of its Patents Act that compulsory licenses be issued in accordance with Australia’s international obligations. As IP Australia notes, this provision importantly “provides certainty that a court cannot make an order that is inconsistent with Australia’s international law obligations.”\textsuperscript{34} The Productivity Commission’s proposal to introduce specific amendments for international obligations in a piecemeal fashion imposes a significant and unnecessary regulatory burden and risks compliance with Australia’s international obligations.

As to compulsory licensing for dependent patent owners (Part 2), we do support adoption of Option 2 because a specific doctrine for dependent patent owners is unnecessary, duplicative, and introduces risk for the unwarranted expansion of compulsory licensing. Existing compulsory license requirements sufficiently provide for circumstances of dependent patent owners and separate requirements are unnecessarily complicated. As the Productivity Commission’s report makes clear, separate requirements already have introduced unnecessary risk due to potential misinterpretation, specifically ambiguity as to whether dependent patent applicants qualify.

\textsuperscript{30} U.S.-AUS FTA Article 17.9.7; see also TRIPS Article 31(b).

\textsuperscript{31} As noted in the consultation document, this test would consider: “benefits to the community from meeting the relevant unmet demand; commercial costs and benefits to the patent holder and licensee from granting access to the patented invention; and other impacts on community wellbeing, including those resulting from greater competition and from the overall effect on innovation.” IP Australia Consultation Paper 4 at 7.

\textsuperscript{32} IP Australia explained that dropping “substantial” would create a new test that “would focus on whether there is unmet demand for a product or service, which would be remedied by access to the patent. It would also require the court to consider whether access to the patent would be in the public interest.” Id. at 8.

\textsuperscript{33} Id. at 9.

\textsuperscript{34} Id. at 8.
IV. Introducing an Objects Clause

Finally, we appreciate IP Australia’s desire to add an objects clause to the Patent Act to help promote greater certainty and predictability, including by providing a “clear statement of intent for the guidance of the courts in the interpretation of the Act.” It is important, however, that any such clause recognize the vital role that patent rights play in promoting the sharing of new discoveries and incentivizing technological innovation, and the resulting social and economic benefits. The key functions that are served by the protection and enforcement of IP rights are well-recognized. For example, Article 7 of TRIPS 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.

We share IP Australia’s concerns regarding the language proposed by the Productivity Commission, presented as Option A, which specifically references the “wellbeing of Australians.” We agree that the wording of Option A could unintentionally result in improper preferential treatment to Australians and Australian interests, contrary to Australia’s national treatment obligations not to discriminate. While the effort to repeal section 136 of the Patents Act, which requires that Australia’s patent laws be consistent with its international obligations, rightly was rejected, the reference to the “wellbeing of Australians,” introduces an unnecessary risk of misinterpretation by courts.

While Option B more appropriately emphasizes the benefit of a patent system in Australia to the “wellbeing of society,” we have concerns about IP Australia’s premise for adding a reference to “the public.” In IP Australia Consultation Paper 2, the agency suggests adding “the public” to the objects clause in order to consider “the rare case” where “promoting technological innovation and the transfer and dissemination of technology might not be in the interest of society as a whole.”

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35 Option A states: “The purpose of the legislation is to enhance the wellbeing of Australians by promoting technological innovation and the transfer and dissemination of technology. In so doing, the patent system should balance over time the interests of producers, owners and users of technology.” IP Australia Consultation Paper 2 at 7 (emphasis added).

36 Option B states: “The purpose of this Act is to provide a patent system in Australia that enhances the wellbeing of society by promoting technological innovation and the transfer and dissemination of technology. In so doing, the patent system should balance over time the interests of producers, owners, users of technology, and the public.” Id. (emphasis added).

37 Id.
proposed by the Productivity Commission for such an objects clause, including to “help to improve the likelihood that decisions align with policy objectives” (citing favorably to the High Court decision in *D’Arcy v Myriad Genetics*) and to “help shield the system against further expansion in the scope and strength of rights ….”38 Such purposes would be inconsistent with TRIPS, which guarantees minimum standards of protection for IP rights and limits the ability of governments to revoke or limit those rights.39 Because Australia appears to seek the inclusion of an objects clause in order to provide a vehicle to weaken IP rights, we do not agree with either option proposed in this document.

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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,

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38 *Id.* at 6.

39 For example, TRIPS provides that a Party may provide “more extensive protection than is required by this Agreement,” but not less. Article 1.1 (emphasis added).