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VIA EMAIL

Senate Standing Committees on Economics
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Re: Comments on the Intellectual Property Laws Amendment (Productivity Commission Response Part 2 and Other Measures) Bill 2019

The Pharmaceutical Research and Manufacturers of America ("PhRMA") thanks the Senate Economics Legislation Committee of the Commonwealth of Australia ("Australia") for the opportunity to submit these comments regarding the Intellectual Property Laws Amendment (Productivity Commission Response Part 2 and Other Measures) Bill 2019 (the "Bill").

PhRMA member companies and the many women and men they employ across Australia and around the world are devoted to discovering and developing medicines that enable patients to live longer, healthier and more productive lives. They work in partnership with universities, health care providers and others to bring new treatments and cures to patients who need them.

Effective protection and enforcement of patents and other intellectual property ("IP") based on clear rules that provide predictability and certainty is critical to incentivize innovation in all fields of technology, including the discovery and clinical development of new medicines.

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. So we are very concerned that, if adopted, the Bill's changes to Australia's IP laws concerning compulsory licensing of patents, including Crown use,[1] could significantly weaken IP protections in Australia that facilitate access to today's inventions and drive future breakthroughs.[2]

The proposed changes to compulsory licensing of patents are unnecessary and would only inject uncertainty into Australia's patent regime. They would not serve the interests of the Australian public, including the interests of patients. In key respects, they appear to be inconsistent with Australia's obligations under the U.S.-Australia Free Trade Agreement ("U.S.-AUS FTA").

[1] "Crown use" refers to the mechanism allowing federal, state and territorial governments in Australia to access and use patented technology without the consent of the right holder, a mechanism that has been available under Australian law for decades.
[2] See, for example, Cockburn, I.A., J.O. Lanjouw and M. Schankerman, "Patents and the Global Diffusion of New Drugs," 2014, available at http://www.nber.org/papers/w11321 (last visited August 12, 2019).

Effective IP protection and enforcement benefits the public, patients and the economy

The Bill appears to be a missed opportunity to further improve IP protection and enforcement in Australia to the benefit of the public, patients and the wider economy.

The Explanatory Memorandum to the Bill rightly states that one "objective of the intellectual property (IP) rights system is to support innovation by encouraging investment in research and technology in Australia."[3] But an effective IP system not only helps drive investment in basic research and other innovation inputs. It also supports innovation outputs, including the commercialization and diffusion of new technologies.

As the World Intellectual Property Organization's 2019 Global Innovation Index (GII) makes clear, Australia is a global leader in innovation inputs. It ranks 13th in the world in public R&D expenditures.[4] It ranks 10th in the world in human capital and 8th on "market sophistication" metrics like access to credit and investor protections.[5] In the biopharmaceutical sector alone, Australia is host or home to hundreds of firms that together employ approximately 40,000 people and invest more than $1 billion in R&D annually.

But the country trails many others when it comes to innovation outputs. For all its investment in R&D, the GII currently ranks Australia just 36th in the world in terms of patents, knowledge impact and other outputs.[6] That relatively low score puts Australia behind other Asia-Pacific economies it should be beating. Further improving IP protection and enforcement would not only encourage R&D investment and other innovation inputs but also strengthen investment performance and the outputs delivered for firms and the wider economy.

The Bill would weaken IP protection and expand the grounds for compulsory licensing

Rather than improve IP protection and enforcement, the Bill unfortunately proposes changes to compulsory licensing, including Crown use, that are unnecessary and would add uncertainty, weaken patent protection, discourage investment and limit the potential benefits of innovation for Australians.

As the Bill's Explanatory Memorandum states: "safeguards in the Patents Act [1990] that allow a patented invention to be used without the authorization of its owner … can be invoked in exceptional circumstances."[7] Yet the Bill appears to expand the grounds on which a compulsory license could be issued by establishing a vague "public interest" test. The Bill does not define what might be considered "in the public interest," and thereby may potentially broaden the circumstances under which the courts might grant compulsory licenses well beyond "exceptional circumstances."

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[3] Explanatory Memorandum, Intellectual Property Laws Amendment (Productivity Commission Response Part 2 and Other Measures) Bill 2019 ("Explanatory Memo") at 1, available at https://parlinfo.aph.gov.au/parlInfo/download/legislation/ems/s1216_ems_2d30b94a-4f04-46e8-bbe4-4be1e39bad05/upload_pdf/712877em.pdf;fileType=application%2Fpdf (last visited August 14, 2019).
[4] World Intellectual Property Organization, Global Innovation Index 2019, July 2019, p.8, available at https://www.wipo.int/edocs/pubdocs/en/wipo_pub_gii_2019-chapter1.pdf (last visited August 14, 2019).
[5] *Id.*, p.222.
[6] *Id.*
[7] Explanatory Memo, at 3 (emphasis added).

The Bill further proposes to add a Section 160A to the Patents Act that would expand the understanding of "Crown purposes" from not only services of the Commonwealth or a State, but also to services that the Commonwealth, State and/or Territory Governments have the primary responsibility for providing or funding. This expanded definition would take account of all providers of similar services and would appear to potentially broaden Crown use beyond limited and exceptional circumstances. In doing so, the Bill could erode the rights of patent holders and thereby discourage investment in research and development in Australia.[8]

Some proposed amendments are not consistent with Australia's international obligations

Australia and the United States have long recognized that a strong and predictable patent system is vital to increasing investment in innovation. The Preamble to the U.S.-AUS FTA, sets out the countries' shared objectives to "[f]oster creativity and innovation" and to "[p]romote a predictable, transparent and consistent business environment that will assist enterprises to plan effectively and use resources efficiently."

IP protections, as enumerated in Chapter 17 of the U.S.-AUS FTA, are at the heart of achieving the FTA's objectives. The temporary protection afforded by patents provide innovators with the incentives they need to invest significant resources in the risky research required to develop and bring new products and processes to market. In most cases, new products will fail to deliver returns that meet or exceed investment. And even those that succeed often fail to make a profit. Biopharmaceutical firms face similar challenges. Just two of every ten marketed medicines achieve returns that match or exceed average research and development costs.[9] Strong patent protection enables the developers of medicines to generate consistent future returns which provides an incentive for investment from a competitive global investment industry. Patent protection is meaningless, however, unless it is provided in a manner consistent with the objectives outlined in the Preamble to the FTA, i.e., is "predictable, transparent and consistent".

Those objectives particularly extend to Article 17.9.7 of the U.S.-AUS FTA, which governs the use of the subject matter of a patent without the authorization of the right holder. That Article states that a party *shall not* permit such use except when necessary "to remedy a practice determined after judicial or administrative process to be anti-competitive" or "in cases of public non-commercial use, or of national emergency, or other circumstances of extreme urgency."[10]

The Bill appears to expand these grounds far beyond the scope of what is permitted under the U.S.-AUS FTA. Specifically, the proposed amendment to Section 133(3) of the Patents Act would permit compulsory licensing on broad and vague grounds that are not related to a judicially or administratively determined remedy for anticompetitive behavior (already addressed by the

[8] If despite these objections Australia proceeds with amending the Crown Use Provisions, it should expressly provide, consistent with the Explanatory Memo at 18, that no-one should profit from their use of an invention under Crown use. To this end, we would propose amending Section 167(1) to read: "The right to exploit an invention under subsection 163(1) includes the right to sell products made in exercise of that right, as long as the relevant authority or a person authorized by the relevant authority (as defined in Section 160A(1)(b)) does not make a profit from their use of the invention." (Proposed addition underlined.)

[9] Vernon, J.A., J.H. Golec and J.A. DiMasi, "Drug development costs when financial risk is measured using the fama-french three-factor model," *Health Economics*, Aug. 2010, available at http://onlinelibrary.wiley.com/doi/10.1002/hec.1538/abstract (last visited August 14, 2019).

[10] U.S.-AUS FTA, Article 17.9.7.

Competition and Consumer Act 2010) or to a national emergency or other circumstance of extreme urgency. If Australia is going to amend the compulsory licensing provisions of the Patents Act, it should do so with a view to bringing those provisions into conformity with its U.S.-AUS FTA commitments rather than exacerbating the inconsistency of the current language.

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For the reasons stated above, PhRMA urges the Senate Economics Legislation Committee to reconsider the proposed amendments to Australia's Patents Act concerning compulsory licensing, including Crown use, and to ensure the Bill supports innovation, provides certainty to investors and is consistent with Australia's international obligations.

We appreciate this opportunity to submit comments and to provide feedback on the important issues raised by the Bill. We would be pleased to provide further input or clarification of these comments, as needed, and remain at your disposal for a constructive dialogue on continuing to improve Australia's IP system.

Sincerely,

[redacted]

Chris Moore
Deputy Vice President, International