Joint Submission to the Consultation on the Issues Paper by the Productivity Commission on Intellectual Property (IP) Arrangements in Australia

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) Issues Paper on "Intellectual Property Arrangements" ("Issues Paper").

We represent research-based pharmaceutical companies and national pharmaceutical associations from across the globe. As associations representing companies engaged in groundbreaking research in the pharmaceutical sector, we are in a unique position to comment on and identify the relevant incentives that drive innovation in pharmaceutical technology.

The Commission's Issues Paper is wide-ranging and raises a number of important questions. At this initial stage, we limit our comments only to certain critical issues raised by the Commission's work on this project. Furthermore, we are aware of the valuable inputs that Medicines Australia is providing the Commission on this Issues Paper. We look forward to being able to make further, more detailed comments as the process continues.

In Chapter 3 of the Issues Paper, the Commission defines the following framework for assessment of IP rights:

> The Commission's proposed approach will rely on applying the principles of effectiveness, efficiency, adaptability and accountability in assessing and recommending changes to the IP system. Such an approach is designed to make sure that the ultimate goal of improving the wellbeing of Australians — by having a well-functioning IP system — is achieved.[1]

In this submission, we place before the Commission evidence indicating that strong patent protection improves wellbeing by providing critical incentives for research and development, by making more innovative medicines available to patients earlier, and by ensuring that innovators enjoy fair protection when their inventions are marketed in other countries.

For decades, Australia has recognized the importance of IP protections 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 TRIPS agreement, which establishes global rules for IP protection and enforcement. We urge the Commission to take into account Australia's obligations under this and other international agreements and the critical role

[1] Issues Paper, p. 14.

intellectual property rights play in incentivizing and sustaining pharmaceutical research and development.

This submission is organized as follows: *first*, we present the Commission with evidence indicating that strong patent protection is essential for continued innovation in the pharmaceutical sector; *second*, we emphasize why patents should continue to reward innovation, and not merely effort; *third*, we highlight certain difficulties that currently exist in the Australian framework for enforcement of patent rights; *finally*, we briefly discuss the importance of supplementing the patent regime through effective data protection.

1. Strong Patent Protection maximizes public wellbeing by fostering innovation and making innovative medicines available

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 a combined $1 billion per year in R&D and generate nearly $2.9 billion in exports each year. These numbers evidence the importance of the innovative pharmaceutical industry in Australia. Like several other advanced economies, Australia has created certain market conditions conducive for innovation, which includes a system of IP protection. This innovation ecosystem has enabled Australian innovators to contribute pharmaceutical innovations which have promoted public wellbeing not only in Australia, but also in the more than 30 countries that import pharmaceutical products from Australia.

Medicines Australia has already placed before the Commission a rich body of literature highlighting the importance of strong patent protection. Of these, particularly important are (i) the OECD studies indicating that strong IP protections attract FDI and result in technology transfer,[2] and a study by the US Patent and Trademark Office indicating that IP intensive industries (including the pharmaceutical sector) contribute to nearly 35% of the US Gross Domestic Production, and to nearly a third of all the jobs in the United States.[3]

Further, a study conducted based on eight different countries (Brazil, Colombia, China, India, Malaysia, Russia, South Africa and South Korea) in different regions concluded that countries with strong patent protection fared better in terms of innovation, publications and clinical trials in comparison to their regional neighbours. That study concluded that "sound intellectual property rules" were among "foundational elements required to encourage innovative activity".[4] Similarly, in our own study on incentive structures in biopharmaceutical innovation, after examining several alternative innovation

[2] Park, WG and Lippoldt, D (2003). "The impact of trade-related intellectual property rights on trade and foreign direct investment," OECD publishing; Cavazos, R et al (2010) "Policy complements to the strengthening of IPRs in developing countries," OECD Trade Policy working papers, No.104, OECD publishing).

[3] Economics and Statistics Administration and the United States Patent and Trademark Office. "Intellectual Property and the US economy: Industries in Focus", March 2012

[4] Tim Wildson, et al., "Policies that encourage innovation in middle-income countries", (Charles River Associates), available at http://www.crai.com/publication/policies-encourage-innovation-middle-income-countries.

incentives, we concluded that "each [incentive system] requires a sound intellectual property environment in order to succeed."[5]

The economic merit of strong IP protections is reflected in a consensus amongst policy makers in advanced economies similar to Australia not only to guarantee strong IP protections domestically, but also to promote strong IP protections internationally. That consensus serves Australia's interests as a hub of innovation and an exporter of innovative products.

The fact that almost all Nobel prizes in the field of medicine and physiology in the last few decades have been awarded to research undertaken in advanced economies with strong IP is telling.[6] A study by WTO, WIPO and WHO found that between 1960 and 1990, more than 90 per cent of all new drugs were discovered and developed by pharmaceutical companies operating in Belgium, France, Germany, Italy, Japan, the Netherlands, Sweden, Switzerland, the United Kingdom and the United States – all countries that feature the world's most robust and developed IP systems.[7]

In addition to triggering domestic innovation, IP protections also incentivize innovators from other countries to market their products in Australia. Insufficient IP protections expose innovators from all over the world to the risk that their innovation, if marketed in a particular country, would be copied by local competitors. This deters foreign innovators from making their latest products readily available to patients in a country with suboptimal IP protections. In fact, a major 2014 study found that firms launch innovative medicines sooner in countries with effective patent protection and enforcement. Looking at data from the launch of more than 600 drugs in almost 80 countries, the study found longer and more extensive patent protection accelerates the launch of new medicines in higher and lower income countries alike.[8]

2. Patents should continue to reward innovation, not effort.

The Commission enquires whether "patents provide rewards that are proportional to the effort to generate IP" and how the "effort be measured".[9] An attempt to compare the rewards from individual patents against the efforts or costs involved in developing the specific inventions that are subject to those patents would ignore the economic realities of sectors like pharmaceutical research.

Currently, all advanced economies reward innovation, not effort, through patent protection. The market determines the amount of the reward for the innovation. What the Commission appears to be considering is an alternative system that would reward only instances of successful innovation, in a

[5] IFPMA, The New Frontiers of Biopharmaceutical Innovation, available at http://www.ifpma.org/fileadmin/content/Publication/2012/IFPMA_New_Frontiers_Biopharma_Innovation_2012_Web.pdf, p. 43.

[6] Official Website of the Nobel Prize, "All Nobel Laureates in Physiology or Medicine", available at http://www.nobelprize.org/nobel_prizes/medicine/laureates/.

[7] WHO, WIPO, and WTO, Promoting Access to Medical Technologies and Innovation Intersections between public health, intellectual property and trade, p. 103, 2012

[8] Cockburn, Iian M., "Patents and the Global Diffusion of New Drugs," NBER Working Paper 20492, September 2014.

[9] *Id.*, p. 18.

manner proportionate to the effort involved in achieving those particular successes. Such a framework would ignore the economic realities of research intensive sectors, which are characterized by considerable uncertainties as to whether the large investments would ever result in returns.[10] As Kenneth Arrow, a Nobel prize winning economist, notes "by the very definition of information, invention must be a risky process, in that the output (information obtained) can never be predicted perfectly from the inputs".[11] These enormous disincentives for private investment in research can be countered only if successful inventions result in rewards that can recuperate the costs and efforts, not only of the successful invention, but also of the unsuccessful efforts.

The uncertainties relating to research investments are even more pronounced in the pharmaceutical sector than in other sectors. As noted by the Centre for International Economics, and brought to the attention of the Commission by Medicines Australia, "there are success stories, but overall the sector's R&D story is characterized by sunk costs and high failure rates". Studies in the past have shown that it takes between 10 and 15 years to develop a new medicine, costs have been reported to reach, in certain cases, US$ 2.6 billion.[12] Also, for every single medicine that successfully receives regulatory approvals, tens of thousands of compounds have been screened and evaluated. There are also studies indicating that even medicines that reach clinical trials have less than a 12% chance of being approved,[13] and that only 20% of approved drugs generate revenues sufficient to break even.[14] Given these significant disincentives that operate against R&D investment in the pharmaceutical sector, a sound policy approach mitigates these risks by creating sufficient rewards to induce investments.

The Commission refers to the idea of "patent evergreening" in Box 3, in Chapter 3 of its Report. The "patent evergreening" line of criticism loses sight of the fact that patents associated with a medicine based on incremental innovation do not affect the term of exclusivity for an existing medicine. In other words, patents relating to an improvement of an existing medicine will not prolong the term of exclusivity of that existing medicine. Any step to exclude or restrict patent protection to incremental inventions would ignore two key facts – (i) incremental inventions involve effort and investment; and (ii) they contribute to public wellbeing.

Patents, as they currently operate, allow innovators a period of time when they can try to convince markets to reward them for the innovation. The innovations which are valuable to the public receive

[10] *See* "R&D and Productivity Growth: A Background Paper", Congressional Budget Office of the Congress of the United States (June 2005).

[11] K. Arrow, "Economic Welfare and the Allocation of Resources for Invention", in *The Rate and Direction of Inventive Activity: Economic and Social Factors,* p. 616 (Princeton University Press, 1962).

[12] International Federal of Pharmaceutical Manufacturers and Associations, Geneva. 2013. Incremental Innovation: Adapting to Patient Needs; Tufts Centre for the Study of Drug Development, Boston, 2014.

[13] PhRMA adaptation based on Dimasi JA. Cost of developing a new drug. Tufts Center for the Study of Drug Development (CSDD). R&D Cost Study Briefing (Nov. 18, 2014), available at http://csdd.tufts.edu/files/uploads/Tufts_CSDD_briefing_on_RD_cost_study_-_Nov_18,_2014..pdf.

[14] J. A. Vernon, J. H. Golec, and J. A. DiMasi, *Drug Development Costs When Financial Risk Is Measured Using the Fama-French Three-Factor Model*, Health Economics Letters (2009).

rewards from the market, while others do not. This system allows markets to encourage and reward those innovations which are most valuable. Undermining this system would distort this market mechanism and would artificially force inefficient outcomes.

For all these reasons we consider that a sound policy approach requires continuation of the current approach of rewarding innovation, rather than effort, through patents. Having made that point, we now turn to the specifics of such rewards. In this regard, the Commission enquires whether there is scope to alter the "criteria for patentability",[15] so as to include "economic criteria" or to "gradually reduc[e]"[16] the term of patent protection. Furthermore, the Commission enquires whether certain "areas of innovation"[17] should be "excluded"[18] from patent protection.

Subject to certain narrow exceptions, Article 27 of the TRIPS Agreement requires that patents be available "in *all* fields of technology, provided that they are new, involve an inventive step and are capable of industrial application."[19] This provision further requires that "patents shall be available and patent rights enjoyable without discrimination as to […] the field of technology". The requirements of Article 27 reflect a sound policy choice by the global community, made after extensive negotiations and lengthy deliberations. Adding additional criteria, such as economic criteria, would dissuade inherently risky R&D investments and would have a negative impact on innovation in R&D intensive sectors like pharmaceuticals.

Similarly, any reduction in patent term would be inconsistent with Article 33 of the TRIPS Agreement, which provides that "the term of protection available *shall not end before* the expiration of a period of *twenty years* counted from the filing date".[20] We believe that this provision in the TRIPS Agreement again reflects a sound policy choice as to a minimum threshold for patent term.

This minimum term, which applies to all patents, increases efficiencies by ensuring predictability in the system. It gives R&D investors the certainty of knowing that if they are successful – the odds of which are in any case low – their inventions will receive 20 years of patent protection. This advance knowledge allows them to make rational investment decisions over long time horizons.

In some instances, adjustments may be required to the patent term to guarantee the enjoyment of patent rights to the full extent. In this regard, we note that Australia's bilateral commitments[21] appropriately contemplate maintenance of the existing framework for patent term restoration, which seeks to compensate pharmaceutical innovators for any delays during the regulatory review process

[15] IP Issues Paper, p. 18.

[16] *Ibid*.

[17] *Ibid*.

[18] *Ibid*.

[19] Article 27 of the TRIPS Agreement (emphasis added).

[20] Article 33 of the TRIPS Agreement (emphasis added).

[21] See, e.g., Article 17.9(8)(b) of the Australia-U.S. Free Trade Agreement.

that governments require to assess the quality, safety and efficacy of the medicines. These delays prevent the adequate enjoyment of the market exclusivity period awarded in a patent. This scheme helps to ensure that the efficient incentives for innovation in the pharmaceutical sector are not stifled, as compared with the incentives for other innovators, merely because of delays in the government marketing approval process.

3. Enforcement mechanisms

We fully agree with the Commission's views in stating that

> [t]he value of IP rights to creators – and the value of exceptions to users – depends on the ability of both sides to enforce their rights. Enforcement mechanisms weighted too far in favour of rights holders may increase the value of IP rights over and above what is necessary to incentivise creative or innovative works. Conversely, enforcement mechanisms that are too costly or lengthy, or have rules of evidence or procedure that are too stringent, can unduly lower the value of IP.[22]

We seek to draw the attention of the Commission to one aspect of the Australian enforcement landscape that makes it too costly and "lower[s] the value of IP"[23] for pharmaceutical patent holders.

In 2012 Australia's Department of Health and Ageing (DOHA) announced an unprecedented policy that enabled the Federal Government to seek compensation for the impact of interim injunctions upon Australia's Pharmaceutical Benefits Scheme (PBS). Specifically, under this policy, the DOHA may claim damages where an interim injunction in the infringement proceedings prevented operation of the PBS price reduction mechanism for generic medicines, in cases in which the court ultimately finds the relevant patent invalid or not infringed.

This policy effectively circumvents the rights afforded to inventors through the patent and court systems. It disadvantages inventors who have sought to defend patent rights in court by imposing a retrospective financial penalty in the form of compensation to the PBS. Such measures effectively void the value of interim injunctions by creating an unknown and potentially costly risk for inventors who wish to prevent others exploiting their invention pending resolution of the matter by the competent court.

It is pertinent to note that pharmaceutical innovators would be severely disadvantaged if they do not seek preliminary injunctive relief in Australia. If a generic product launches, PBS price reduction mechanisms are triggered, thus significantly lowering the PBS price. Even if a court later determines that the generic company infringed the originator's patent, restoring PBS prices to prior levels is at the discretion of the DOHA. Thus, if an innovator does not seek preliminary injunctions, it could face potentially irreparable damage.

Furthermore, it is to be noted that interim injunctions in Australia are granted only when a court finds that the criteria for an interim injunction are met, including: (i) the applicant showing that it has a prima facie case, and (ii) that the balance of convenience favors the injunction. The policy then requires the IP

[22] IP Issues Paper, p. 27.

[23] *Ibid.*

rightsholder to essentially indemnify the decision of the Australian Court to grant the interlocutory injunction if a subsequent Court determines that the patent was invalid or not infringed. This policy threatens to make it too costly for genuine complainants to protect their IP rights.

Recognizing the importance of interim injunctions to patent enforcement, Article 50 of the TRIPS Agreement provides obligations for WTO Members to provide such remedies through their judicial bodies. In particular, Articles 50(3) and 50(7) provide a carefully considered and delicate balance between the rights of patent holders to effective injunctive remedies and the need to protect potential defendants from abuse. The Australian policy disturbs that balance, making resort to such remedies prohibitively risky for patent holders.

We recommend that the Commission call for a discontinuation of this policy.

4. Australia's mechanism for data protection

The Commission enquires whether "data protection arrangements limit the ability of parties to understand breakthroughs and build on innovation".[24] Data protection is not an impediment for knowledge diffusion or incremental innovation, as it simply prevents generic or biosimilar manufacturers from relying on the innovator's data to obtain regulatory approval for a limited period. We refer to the discussion above, relating to the significant risks, and associated disincentives, faced by private investment in research-intense sectors like pharmaceuticals. To counteract these disincentives, it is imperative that successful research efforts result in suitable opportunities to reap economic rewards.

Data protection often complements patents as a means to incentivize innovation, particularly in research-intensive sectors like pharmaceuticals. This is substantiated in a recent study by Goldman, et al., which found that if the United States were to extend the data exclusivity period for conventional "small-molecule" drugs to twelve years—the same exclusivity period already extended to large-molecule biologic drugs under the Affordable Care Act (instead of the current five years), this "would result in 228 extra drug approvals between 2020 and 2060".[25]

Australia currently employs a data exclusivity term of 5 years, which is among the shortest in the Organisation for Economic Cooperation and Development (OECD). Data exclusivity provision in the United States is up to twelve years for biologics, in Canada and Japan eight years and in the EU up to eleven years. This brevity in the term of protection may compromise the ability of the Australian data protection regime to effectively foster and incentivize innovation. We recall that the 2013 "Strategic Review of Health and Medical Research in Australia" called on the Government to extend the term of data protection to better reflect global best practices. We also note that Medicines Australia has brought to the Commission's attention the fact that there is a disconnect between data protection for pharmaceutical products for humans (5 years) and for veterinary medicines (10 years).

[24] IP Issues Paper, p. 19.

[25] "The Benefits From Giving Makers of Conventional 'Small Molecule' Drugs Longer Exclusivity Over Clinical Trial Data," Health Affairs, 30, no. 1, (2011):84-90 (http://content.healthaffairs.org/content/30/1/84.full.html).

With a view to ensuring that the Australian regulatory system fosters innovation, secures Australia's competitiveness in IP, and aligns itself with global best practices, we urge the Commission to recommend an extension of the term of data protection for pharmaceutical products.

Conclusion

We would like to thank you for the opportunity to provide comments to this Issues Paper 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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