Mylan is a global pharmaceutical company offering a growing portfolio of more than 7,500 products including prescription generic, branded generic, brand-name drugs and over-the-counter remedies. Mylan believes true innovation should be rewarded through the grant of patents – Mylan has more than 4000 patent assets. Mylan also supports timely competition. Promoting innovation and increased competition for generics and biosimilars is crucial to lowering drug prices, ensuring the sustainability of the Pharmaceutical Benefits Scheme and reducing out-of-pocket costs to patients.

In Australia, Mylan is the leading supplier by volume of prescription medicines to the Pharmaceutical Benefits Scheme (PBS). About one in six of all PBS prescriptions are dispensed with a Mylan medicine. This contributes to the sustainability of the PBS by providing timely access for patients to quality, safe, efficacious and affordable medicines. Mylan supplies a broad range of branded, generic and over the counter products in Australia - more than 700 individual formulations. We are one of the largest pharmaceutical manufacturers in the country. In 2018, Mylan’s internationally accredited manufacturing plant at Carole Park, Queensland, will produce over 3 billion doses of oral, solid-dose medicines, more than half of which will be exported to around 45 countries.

Australia’s intellectual property laws provide the legislative framework for Australia’s intellectual property rights system (the IP system). The proposed Intellectual Property Laws Amendment (Productivity Commission Response Part 2 and Other Measures) Regulations 2018 (the Regulations) is, therefore, critically important to the operation of the IP system.

**The Abolition of the Innovation Patent System**

The Productivity Commission recommended to the Australian government:

> The Australian Government should **abolish** the innovation patent system. (emphasis added)

The Australian government responded:

> The Government **supports** this recommendation. (original emphasis)

The Government notes that both the Productivity Commission and the former Advisory Council on Intellectual Property (ACIP) have recommended that the innovation patent system be abolished. Both found that the innovation patent system is unlikely to provide net benefits to the Australian community or to the small and medium sized enterprises (SMEs) who are the intended beneficiaries of the system. **The Commission found that the majority of SMEs who use the innovation patent system do not obtain value from it, and that the system imposes significant costs on third parties and the broader Australian community.** (emphasis added)

The Government notes that the innovation patent system was established with the objective of stimulating innovation in Australian SMEs. The Government considers

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1 Measured in doses
that more targeted assistance would better achieve this objective, while avoiding the broader costs imposed by the innovation patent system.

Along with initiatives to support SMEs introduced through the National Innovation and Science Agenda (NISA) and existing programs such as the R&D Tax incentive, the Government has already implemented a number of measures to support SMEs to better understand, secure and utilise their IP. These include the IP Toolkit for Collaboration, Source IP, the Patent Analytics Hub and aspects of the Entrepreneur’s Programme, which provide grants and advisory services for businesses in certain industry sectors seeking to leverage their IP. IP Australia is continually improving its services and processes to benefit business, including the establishment of a new IP Counsellor to China, trialing the provision of Patent Analytics services under the Entrepreneur’s Programme, and raising education and awareness of IP issues with start-ups.

The Government will seek legislative amendments to the Patents Act 1990 to abolish the innovation patent system, with appropriate arrangements to maintain existing rights. The Government will continue to explore more direct mechanisms to better assist SMEs to understand and leverage their IP, secure and utilise IP Rights and access affordable enforcement. (emphasis added)

Mylan submits that the Draft Regulations (and the corresponding Bill) are inconsistent with the Productivity Commission's recommendation and the Australian Government's response to that recommendation. The inconsistency is apparent on the face of the document. The Explanatory Statement states:

Part 1 – Innovation patents

- makes amendments to the Patents Regulations consequential to the amendment of the Patents Act to phase out the innovation patent system. (emphasis added)

The phasing out of the Innovation Patent System is not the same as its abolition. Indeed, if the Productivity Commission and the Australian Government wished the Innovation Patent System to be “phased out”, both could have stated precisely that. But neither did.

Mylan understands the Australian Government’s response also makes it clear that “appropriate arrangements” be made to “maintain existing rights”. Neither the draft Bill nor the draft Regulations are consistent with this qualification. Indeed, neither the Bill nor the Regulations take into account the rights of the parties that are affected by the continuing operation of the Innovation Patent System. The Australian Government in its response acknowledged the Productivity Commission’s finding that the Innovation Patent System “imposes significant costs on third parties and the broader Australian community”. These “significant costs” impinge on the rights of those “third parties and the broader Australian community”. Mylan respectfully submits that “appropriate arrangements to maintain existing rights” is not a one-sided directive designed to maintain the Innovation Patent System for the immediate future disregarding the rights of “third parties and the broader Australian community”. Rather by employing the term “appropriate arrangements” the Australian government was referring to a balancing of “existing rights” in the context of the abolition of the Innovation Patent System, not in respect to its phasing out.
The error in both the Bill and the Regulations is that instead of abolishing the Innovation Patent System, they achieve the precise opposite. First, they establish a deadline from which the Innovation Patent System will continue to operate for a period of at least a further eight years. Second, during this period the strategic uses to which it has already been put and with respect to which has been the subject of significant criticism by the Productivity Commission, will also continue. This result is clearly the opposite of what was intended.

In so doing, the Bill and the Regulations completely ignore the existing rights of “third parties and the broader Australian community” to be able to lawfully operate in an economy without the impost created by a myriad of “low value patents”, as the Productivity Commission called them, that have been and will, foreseeably, continue to be used strategically to undermine the Australian economy, more specifically, in regard to the provision of generic medicines to the Australian community under the Pharmaceutical Benefits Scheme (PBS).

An example of the strategic use to which innovation patents have been put in the context of medicines concerns the psychotropic substance, citalopram.

Citalopram was the subject of broad patent protection in Australia for a period of 16 years, the then standard patent term, between 5 Jan 1977 and 4 Jan 1993. The scope of the patent monopoly captured the compound regardless of how it was made and how it was used, including its use in a medicine to treat depression. The compound per se was patent protected in Australia. After the expiry of the compound patent, Lundbeck, the patent owner, applied for a further standard patent (200013748) over a method of producing citalopram “Formula IV”. By this time, a variety of processes had been patented that produced citalopram in one form or another. This particular standard patent application sought patent protection over citalopram defined as “Formula IV”. The principle advantage, it was claimed, was that citalopram was produced “in high yield thus reducing costly purification processes”. The standard patent application did not seek patent protection over the Formula IV form of citalopram, but it did cover any “method” used to produce it (claim 1). Effectively it sought patent protection over citalopram Formula IV. It also sought patent protection over “an antidepressant medicine comprising citalopram” Formula IV manufactured by any method (claim 13). This standard patent application was, however, converted into an innovation patent application on 26 September 2001 and accepted a few weeks later, on 10 October 2001. On 18 October 2001, an innovation patent (2001100433) giving Lundbeck patent protection over citalopram Formula IV was sealed. As a result, Lundbeck secured patent protection over citalopram Formula IV for the period 19 Nov 1999 to 19 Nov 2007. This is not, however, the end of the story.

Lundbeck also sought patent protection over other forms of citalopram under the guise of “method” patents. No less than 11 patents, either innovation or standard, have been granted in Australia by the title: “Method

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2 “Abolishing the innovation patent system is not intended to affect existing rights. The system will continue to operate for innovation patents that were filed before these amendments commence. In addition, existing rights to file divisional applications and convert a standard patent application to an innovation patent application will be maintained for any patent or application that was filed prior to the commencement date of these amendments. This is achieved under the legislation by requiring that any innovation patent filed after the commencement date must have a date of patent and a priority date for each claim that is before the commencement date.” Explanatory Memorandum to the Bill.


4 Ibid, Box 8.4, 254.

5 The standard patent term became 20 years after Australian joined the World Trade Organisation in 1995.

6 2001100433, 2001100440, 2001100271, 2001100278

7 738526, 737610, 759716, 746665, 742554, 778751, 2001258239
for the preparation of citalopram” and providing actual or potential patent protection\(^8\) between 19 Nov 1999 and 10 May 2021, a period of 22 years, over a variety of forms of citalopram.

Given the incentive to do so, it is foreseeable that patent attorneys will advise their clients, some of which are sophisticated users of patent systems around the world, to file innovation patent applications before the deadline foreshadowed in the Bill and the Regulations.

Accordingly, Mylan strongly objects to the Bill and the Regulations. Mylan submits that the Bill and the Regulations do not satisfy the Productivity Commission’s recommendation nor the Australian Government’s response to it.

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\(^8\) A number of the standard patents ceased as patent renewal fees were not paid, but these could have been retrospectively enlivened at any time during their respective patent terms by the payment of the respective renewal patent fees.