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 medicines¹ 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) Bill 2018 (the Bill) is, therefore, critically important, to the operation of the IP system.

However, the IP system does not operate in isolation. Indeed, the Minister at the time, the Honourable Mr Hockey MP, in his referral to the Productivity Commission acknowledged this:

The Australian Government seeks to ensure that the appropriate balance exists between incentives for innovation and investment and the interests of both individuals and businesses, including small businesses, in accessing ideas and products.² (emphasis added)

The key word is ‘balance’ and the key question is whether the proposed legislation achieves the Australian government’s objective of ensuring that an “appropriate balance exists” between two policies; one of which seeks to encourage “innovation and investment” and one which is in the “interests of both individuals and businesses … in accessing ideas and products.” Restated in more simple terms, the objective is to achieve an “appropriate balance” between a system that creates, regulates and enforces statutory monopolies on the one hand and free competition on the other.

In 1984 the Australian government received a report from the Industrial Property Advisory Committee (IPAC). The IPAC Report was the product of a five-year inquiry, conducted into the Australian patent system “from the viewpoint of the national interest”.³ The IPAC Report itemised some of its considerations of the national interest, as follows:

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¹ Measured in doses
³ IPAC Report (August 1984), Executive Summary (emphasis added)
• social benefits which patents are intended to confer, deriving from their incentive effect on investment in innovation and from disclosure of inventions;

• the social costs which may be associated with the monopoly power conferred by patents - higher prices, restricted outputs, and the losses, from a national viewpoint, when the benefits of the monopoly accrue to foreigners plus the direct costs of administering the system;

• the relationship between patents and other market factors affecting innovation and competition;

• the effects of participation in the international patent system, noting that while the system provides a means of protection abroad for Australian goods, services and investment, many patents granted to foreigners in Australia frequently are utilised not to support the establishment of local enterprises or export trade but rather as non-tariff barriers to provide protection for imported products;

• the various interests of inventors, producers and consumers, recognising that they have a common interest as citizens in economic prosperity and growth; equity aspects in the operation of the system, where necessary valuing the welfare of nationals more heavily than that of foreigners; and

• Australia's economic circumstances and policies, including other and more direct ways in which the Australian Government is encouraging innovation.

The IPAC Report does, of course, pre-date the formation of the World Trade Organisation in 1995 and Australia’s founding membership of that organisation. That said, it is relevant nonetheless because the national interest remains paramount. An imbalance between statutory monopolies and free competition may be detrimental to the national interest. It is for this reason that the Minister referred this Inquiry to the Productivity Commission with the Australian government’s mandate to “ensure that the appropriate balance exists”.

Mylan submits that the Bill fails to achieve an “appropriate balance” for the following reasons.

The Innovation Patent System

The Bill does not abolish the innovation patent system per se, but merely prevents the grant of innovation patents after a specific date. This is an inadequate response to the Commission’s recommendation. Mylan submits that the far-reaching problems with the innovation patent system, which the Commission’s report identified, will continue to have an adverse impact on the national interest while innovation patents remain legally enforceable. As such, they can continue to be used strategically into the foreseeable future, as the Commission found they have been used, to undermine the national interest.

The Commission advised:

Abolishing the IPS would deliver greater benefits for the community. It would simplify the overall patent system, reduce administrative and transaction costs, and remove the ability for patent holders to use the system strategically.5 (emphasis added)

4 The Agreement on Trade Related Aspects of Intellectual Property Rights (TRIPS) is one of three key agreements establishing the WTO

5 Productivity Commission Inquiry Report No 78 (September 2016), Intellectual Property Arrangements, 239
Mylan submits that the Bill provide that all innovation patents, including any patent derived from an innovation patent, regardless of when the patents were granted, or applied for, be either revoked or made unenforceable with immediate effect.

**Inventive Step**

The Bill also does not change the inventive step patentability standard in any practical or meaningful manner.

The amendments to section 7 comprehensively fail to address any of the specific concerns expressed by the Commission of the existing problems in inventive step threshold as applied in Australia.

First, the Commission expressly rejected the High Court of Australia’s decisions in *Aktebolaget Hassle v Alphapharm Pty Ltd* (Alphapharm) in 2002 and *Lockwood Security Products Pty Ltd v Doric Products Pty Ltd (No 2)* (Doric Products) in 2007 because, in the Commission’s opinion, the Court’s interpretation of that threshold “put Australia behind the level of the inventive step applied in Europe.” More specifically, the Commission expressly rejected the following statement made by the same Court in *Doric Products*, namely:

> A "scintilla of invention" remains sufficient in Australian law to support the validity of a patent.

Second, the Commission was critical of the Institute of Patent & Trademark Attorneys submission which defended that statement. The Commission rebuttal was as follows:

IPTA (sub. DR562, p. 3), on the other hand, downplayed the role of the scintilla standard, arguing that once a claimed invention meets the threshold ‘there is nothing to be gained by discussing how much the threshold is exceeded’. IPTA drew an analogy to a pole vaulter, saying it does not matter how much the bar is cleared, just that it is cleared.

*However, in keeping with IPTA’s analogy, it is important to recognise that a scintilla does not describe the amount by which a pole vaulter must clear the bar. Rather, a scintilla sets the bar — and does so at a level that even pole vaulters of questionable ability can clear.* (emphasis added)

Third, the thrust of the Commission’s criticism of the current operation of the inventive step patentability standard in Australia as interpreted and applied by the High Court of Australia in *Alphapharm* and *Doric Products* was that it was not in the national interest for it to be below an equivalent international standard, such as that applicable in the European Union, for the simple reason that (and quoting from the decision of a very

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6 Art. 27.1 of the Agreement on Trade Related Aspects of Intellectual Property Rights (TRIPS) mandates signatory country members to grant patents that satisfy four specific criteria. These criteria are (a) patentable subject matter, (b) novelty, (c) inventive step and (d) industrial applicability.

7 *Aktebolaget Hassle v Alphapharm Pty Ltd* (2002) HCA 59

8 *Lockwood Security Products Pty Ltd v Doric Products Pty Ltd (No 2)* (2007) HCA 21 [at 52]

9 Productivity Commission Inquiry Report No 78 (September 2016), Intellectual Property Arrangements, 223 (emphasis added)

10 Ibid, 222
experienced and well respected UK patent judge) “patents are being upheld [in Australia] which are not upheld elsewhere”.11

Fourth, the Commission’s negative assessment of the inventive step threshold as applied under Australian patent law came after the Patents Act 1990 was reformed by the Intellectual Property Laws (Raising the Bar) Amendment Act 2012 (Raising the Bar Amendment Act 2012). At the time the Intellectual Property Laws (Raising the Bar) Amendment Bill 2011 (the Raising the Bar Bill) was introduced into Parliament the Explanatory Memorandum (EM) that accompanied the release of the Bill explained that the inventive step threshold as applied under Australian patent law was problematic for a number of reasons. In an attempt to address these problems the Raising the Bar Amendment Act 2012 removed from section 7(3) the terms “ascertained, understood and regarded as relevant.” Other changes to section 7 removed the geographical restriction that then existed over information that was to be considered relevant to the inventive step threshold prescribed in section 7 so that information available anywhere in the world, not merely in Australia, would be taken into account. The EM contained the following assessment:

... the current restrictions on the prior art base are out of alignment with the patent systems of our major trading partners. In other jurisdictions, the state of the art for the purpose of assessing an inventive step includes all information made publicly available before the priority date. This means that there are unnecessary differences in how the inventive step considerations are applied and, more significantly, foreign patentees may receive broader patent protection in Australia than they could in their own country.12

It is relevant to note that despite the reforms brought in by the Raising the Bar Amendment Act 2012, the EM to the Raising the Bar Bill explained that they were “not intended to substantially change the operation of the existing tests for inventive step as applied to the prior art base or to permit hindsight analysis.”13

The Commission concluded that while the impact of the reforms ushered in by the Raising the Bar Amendment Act 2012 were “unclear”,14 there is sufficient objective evidence to show that a patenting standards “gap remains”15 between Australia and its major trading partners as “Australia still has a materially greater propensity to grant patents when the EPO does not.”16 Indeed, the Commission’s finding is corroborated by the World Intellectual Property Organisation’s (WIPO) 2017 Annual IP Statistics Report.17 According to WIPO in 2016, as Table 51 on the next page shows, Australia rejected a mere 10 patent applications out of a total of 33,100 patent applications (a rejection rate of 0.0003%). Germany, on the other hand, rejected 8,228 out of a total of 35,759 (a rejection rate of 23%); Japan rejected 58,638 out of a total of 254,678 (a rejection rate of 23%); while

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12 Intellectual Property Laws (Raising the Bar) Amendment Bill 2011, 42
13 Ibid, 43
14 Productivity Commission Inquiry Report No 78 (September 2016), Intellectual Property Arrangements, 224
15 Ibid
16 Ibid (emphasis added)
17 World Intellectual Property Indicators 2017, WIPO.
the U.S., Australia’s most important trading partner after China in 2016, rejected 484,479 out of a total of 932,786 (a rejection rate of 52%). WIPO also confirms that in 2016 with the exception of Japan (75%), Australia granted the highest percentage of patents per patent application filed (71.6%) than Germany (43.7%) or the U.S. (32.5%).

Table S1
Procedural data for 2016

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19 Ibid, 26
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Source: World Intellectual Property Organisation

As was acknowledged in the EM to the Raising the Bar Bill, a consequence of the “gap” is that “foreign patentees may receive broader patent protection in Australia than they could in their own country”20. This is particularly disadvantageous economically given that, according to WIPO’s latest statistics report, 90.8% of all patent applications in Australia are filed by foreign residents.21

Fifth, in view of failure of the Raising the Bar Act reforms to practically and meaningfully raise the inventive step threshold the Commission recommended that an “all policy options”22 approach be adopted.

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20 Op cit 10
21 Ibid, 48 (Figure A8, Patent applications at the top 20 offices 2016)
22 Productivity Commission Inquiry Report No 78 (September 2016), Intellectual Property Arrangements, 226 (emphasis added)
Finally, the Commission provided a suggested solution:

To raise the threshold, the Patents Act should be amended by borrowing from the simpler European wording, such that an invention is taken to involve an inventive step if, having regard to the prior art base, it is not obvious to a person skilled in the relevant art. The Explanatory Memorandum should emphasise that the obvious to try test applied in Europe would in some instances be a suitable test. FICPI Australia (sub. DR581) suggested one way to ensure judicial and administrative bodies apply legislative intent to raise the threshold would be to identify case law that is no longer to be applied in determining inventive step. To this end, the Explanatory Memorandum should also state that a ‘scintilla’ of invention, or a scenario where the skilled person would not ‘directly be led as a matter of course’, are insufficient thresholds for meeting the inventive step.\(^{23}\) (emphasis added)

However, as the following analysis demonstrates, the proposed legislation itself does not even honour the above suggestion, let alone demonstrate that an “all policy options” has been considered:

1) the existing section 7(2) before the word “art” is virtually identical to the proposed section 7(2).

2) the existing section 7(2) after the word “art” together with the entirety of section 7(3) are deleted, however, the proposed deleted words and terms are merely reformulated and inserted into the proposed section 7B(2) so that:

   (i) the language deleted from existing section 7(2) is inserted in proposed section 7B(2)(d);

   (ii) the language deleted from existing section 7(3)(a) is inserted in the proposed section 7B(2)(a) and (b);

   (iii) the language deleted from existing section 7(3)(b) is inserted in the proposed section 7B(2) (c);

3) the term “information in a document that is publicly available whether in or out of the patent area” in the proposed section 7B(2)(a), merely involves inserting that same term from the existing definition of “prior art base (a)(i)” in Schedule 1 (which is deleted and replaced with the “meaning given to it by section 7B”).

4) the term “information made publicly available through the doing of an act whether in or out of the patent area” in the proposed section 7B(2)(a) merely involves inserting that same term from the existing definition of “prior art base (a)(ii)” in Schedule 1 (which is deleted and replaced with the “meaning given to it by section 7B”).

A table of the proposed section 7 amendments appears below.

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\(^{23}\) Productivity Commission Inquiry Report No 78 (September 2016), Intellectual Property Arrangements, 226-227
Inventive step

(2) For the purposes of this Act, an invention is to be taken to involve an inventive step when compared with the prior art base unless it is 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).

(3) The information for the purposes of subsection (2) is:

(a) any single piece of prior art information; or

(b) a combination of any 2 or more pieces of prior art information that the skilled person mentioned in subsection (2) could, before the priority date of the relevant claim, be reasonably expected to have combined.

Prior art base has the meaning given by section 7B, means:

(a) in relation to deciding whether an invention does or does not involve an inventive step or an innovative step;

(i) information in a document that is publicly available, whether in or out of the patent area; and

(ii) information made publicly available through doing an act, whether in or out of the patent area;

(b) in relation to deciding whether an invention is or is not novel:

(i) information of a kind mentioned in paragraph (a); and

(ii) information contained in a published specification filed in respect of a complete application where:

(A) if the information is, or were to be, the subject of a claim of the specification, the claim has, or would have, a priority date earlier than that of the claim under consideration; and

(B) the specification was published on or after the priority date of the claim under consideration; and

(C) the information was contained in the specification on its filing date.
7B - Meaning of prior art base

Inventive Step

(2) In relation to deciding whether an invention does or does not involve an inventive step, prior art base means:

(a) information in a document that is publicly available, whether in or out of the patent area; and

(b) information made publicly available through doing an act, whether in or out of the patent area; and

(c) a combination of any 2 or more pieces of information mentioned in paragraph (a) or (b) that a person skilled in the relevant art could, before the priority date of the relevant claim, be reasonably expected to have combined; and

(d) information that is common general knowledge (whether in or out of the patent area), whether that information is considered separately or together with the information mentioned in paragraph (a), (b) or (c).

While the proposed legislation is accompanied by a draft Explanatory Memorandum (the EM) and while the Acts Interpretation Act 1901 does permit extrinsic materials, such as the explanatory memorandum to a Bill, being material that is “capable of assisting in the assessment of the meaning of a provision” of a statute, the Parliamentary intent of the amendments is likely to be ascertained primarily from the provisions of the amended legislation, not the EM.

Crucially, the words contained in the key provisions, as the above analysis clearly demonstrates, are practically identical to the existing legislation. Indeed, the language before the word “art” in the proposed section 7(2) is virtually identical to the current section 7(2), while the new section 7B(2) is merely a reformulation of the current sections 7(2) and 7(3) combined with elements derived from the current definition of ‘prior art base’.

This begs the question of what the courts will do in determining what the new ‘higher’ inventive step threshold is? And even if, as the EM explains, “a ‘scintilla’ of invention, or a scenario where the skilled person would not ‘directly be led as a matter of course’” are no longer acceptable measures of this threshold, how much higher will that threshold be raised by the courts given current Australian case law?

The Commission has suggested a possible solution, namely, that “Australia should align the obviousness test with the approach in Europe, where a similar ‘problem-solution’ approach to assessing inventive step is used, but a higher threshold applies”, but whether that is the ideal solution for Australia, given that an “all policy options” approach should have been considered, is not known. Unfortunately, the proposed amendments of the Patents Act 1990 utterly fail to apply even that de minimis suggestion.

24 Section 15AB[3][e] Acts Interpretation Act, 1901

25 Productivity Commission Inquiry Report No 78 (September 2016), Intellectual Property Arrangements, 226 (emphasis added)
As to its suggestion that Australia look to the European Union for guidance, the Commission readily accepted that this was not necessarily enough.

The Commission stated:

However, even if IP Australia’s claim that its practices would ultimately align with that of Europe held true, there would be a case for further raising the inventive threshold. This is because the thresholds applied in other countries still fall short of the ideal.26

The fact of the matter is that neither the European or U.S. patent systems are perfect. And even with their much higher patent application rejection rates compared to Australia, the Commission found “the bulk of patents in the United States and Europe have a low value.”27

Furthermore, Australia’s existing case law, which has lowered the bar, is a, if not the most, significant part of the problem. The legislation itself should clearly and unequivocally, at a minimum, overrule the High Court of Australia’s decisions in both Alphapharm and Doric Products.

The Commission states:

What would a higher threshold for inventive step entail? One option canvassed by participants is requiring a significant advance on the prior art (along the lines in the Explanatory Memorandum for Raising the Bar). This sort of approach is not without precedent. China requires an advantageous technical effect compared to the prior art, while courts in Switzerland and Germany in the past adopted a similar approach (Romandini 2016). Brazil has a Bill pending that would reform its inventive step to require a significant technical advance.29

Mylan submits that while the European approach is worth considering it is, as the Commission found, not necessarily ideal for Australia. The Commission believes that an even higher threshold than currently applies in Europe should be an attainable goal.

Mylan submits that, as the Commission correctly concluded did not happen after the Raising the Bar reforms came into operation, the term ‘significant advance’ by itself and in this context is bound to fail to heighten the inventive step threshold in Australia.

Mylan submits that a bright-line formula is needed to provide a set of legislatively defined criteria that enables an objective measure requiring, as a minimum, a patentee to demonstrate an invention with a significant advance above the state of the relevant art. Absent this, no practical or meaningful change to the current inventive step threshold will result.

26 Productivity Commission Inquiry Report No 78 (September 2016), Intellectual Property Arrangements, 222 (emphasis added)
27 Productivity Commission Inquiry Report No 78 (September 2016), Intellectual Property Arrangements, 221
28 Productivity Commission Inquiry Report No 78 (September 2016), Intellectual Property Arrangements, 223
29 Productivity Commission Inquiry Report No 78 (September 2016), Intellectual Property Arrangements, 227-228 (emphasis added)
Object of the Act

An Act relating to patents of inventions

Chapter 1—Introductory

1 Short title

This Act may be cited as the Patents Act 1990.

2 Commencement

(1) Subject to subsection (2), this Act commences on a day to be fixed by Proclamation.

(2) If this Act does not commence under subsection (1) within the period of 6 months beginning on the day on which it receives the Royal Assent, it commences on the first day after the end of that period.

2A Object of this Act

The object of this Act is to provide a patent system in Australia that promotes economic wellbeing through technological innovation and the transfer and dissemination of technology. In doing so, the patent system balances over time the interests of producers, owners and users of technology and the public.

Mylan supports the insertion of an Objects Clause into the Patents Act 1990. According to the Commission:

An objects clause would provide a number of benefits. It would help to ensure that decisions in the application and design of the Patents Act are consistent over time with a well-functioning IP system. The Commission (2013a) previously found an objects clause would help clarify the context for compulsory licensing, and the considerations that should guide a court. An objects clause could also be useful in underpinning decisions on whether to grant a patent. This is important given the scope for administrative and judicial interpretation to diverge over time from the intent of policy. ... An objects clause would influence the granting of patents through the interpretation of the patent criteria, including the manner of manufacture test.30

30Productivity Commission Inquiry Report No 78 (September 2016), Intellectual Property Arrangements, 217 (emphasis added)
However, Mylan submits that the draft EM is inconsistent with the Commission’s Report and threatens to undermine this reform; one of the most significant flowing from the Commission’s Report.

Inconsistently with the above statement, the EM makes out that the Objects Clause is:

(i) only referable by the courts “in cases where the text of the legislation is uncertain or ambiguous”; and that,

(ii) “does not alter the ordinary meaning of the legislation or overturn existing case law and established precedent.”; and that,

(ii) “patent examiners” are not to use it for the purpose of introducing “a new element when considering patentable subject matter.”; and that,

(iii) “the elements to be considered are clearly set out in the Patents Act and case law, and the objects clause are not intended to alter this.”

Indeed, if the EM is to be accepted as an accurate representation of the thrust of the Commission’s recommendation, then what is the purpose of the Objects Clause?

It is clear that the Commission’s recommendation is expected to be one of a number of key reforms that have the effect of raising the bar to patentability so that the overall quality of granted patents in Australia is of a higher standard. The Objects Clause is a key aspect of raising that bar. The Commission makes this clear enough:

Given it is impossible to construct direct tests for important concepts such as additionality, an objects clause would not be a panacea for achieving effectiveness in the granting of patents. Nonetheless, at the margin, an objects clause would help to improve the likelihood that decisions align with policy objectives. In a recent case the High Court showed that it was willing to account for policy factors when considering the patentability of an invention.

It is particularly relevant in the context of the operation and functioning of the Pharmaceutical Benefits Scheme (PBS), given the Objects Clause expressly provides for Australia to have a patent system “that promotes economic wellbeing through technological innovation and the transfer and dissemination of technology” and that “balances over time the interests of producers, owners and users of technology and the public”.

Mylan acknowledges that the patent system is “primarily economic in nature”. However, one of the purposes of the Objects Clause is to provide law makers, such as courts and tribunals, with a bridge to a range of policies that apply to all Australians, such as the National Competition Policy and National Medicines Policy so as to “ensure that the appropriate balance exists between incentives for innovation and investment and the interests


32 Productivity Commission Inquiry Report No 78 (September 2016), Intellectual Property Arrangements, 217-218 (emphasis added)

33 http://ncp.ncc.gov.au/

of both individuals and businesses, including small businesses, in accessing ideas and products.” These overarching national policies are in the “interests of ... the public”. In other words, they are part of the national interest. Accordingly, the patent system is not mutually exclusive. Rather, it is mutually inclusive, being a part of the totality of the Australian economy.

The purpose of the National Medicines Policy has been acknowledged by the Commission in its earlier Compulsory Licensing Report:

The primary role of the PBS is to achieve the objective of the National Medicines Policy, endorsed by the Australian Government in 1999, to ensure the provision of timely access to the medicines that Australians need, at a cost that individuals and the community can afford. 36

Mylan strongly disagrees with the draft EM that because “patents system are primarily economic in nature” the application of the Objects Clause is limited “to only economic factors and excludes ethical and social considerations”37 for the following reasons:

First, it is inconsistent with the views expressed by the Commission in both the Compulsory Licensing38 and Intellectual Property Arrangements Reports.

Second, it is inconsistent with Australia’s international agreements expressly providing that patents may be excluded when it is “necessary to protect ordre public or morality, including to protect human, animal or plant life or health or to avoid serious prejudice to the environment”. 39

Third, it is inconsistent with the High Court of Australia which held in D’Arcy v Myriad Genetics Inc40 in regard to patentable subject matter,41 that “the decision of the Court in NRDC [does not] preclude consideration of policy factors informed by the purpose of the Act and considerations of coherence in the law”42, in view of which the decision of the Full Court of Australia in Anaesthetic Supplies Pty Limited v Rescare Limited,43 that unless the Patents Act 1990 expressly excludes “a technology” from patentability, it is to be taken to be included,44 is wrong both in law and in principle45 and must be expressly overruled in the proposed legislation.

35 Op cit 2
36 Productivity Commission Inquiry Report No 61 (March 2013), Compulsory Licensing of Patents, 210
37 Op cit 31, 17
38 Op cit 36, 127-8
39 Art. 27.2 The Agreement on Trade Related Aspects of Intellectual Property Rights, 1995. Also Art. 27.3 which provides that members may exclude from patentability “diagnostic, therapeutic and surgical methods for the treatment of humans or animals.” Also see Art. 17.9.2 Australia-U.S. Free Trade Agreement, 2004.
40 Ibid
41 Section 18(1)(a) Patents Act 1990
42 Ibid, French CJ, para 5 (emphasis added)
43 Anaesthetic Supplies Pty Limited v Rescare Limited [1994] FCA 1065
44 Ibid, para 77 [per Lockhart J]
45 D’Arcy v Myriad Genetics Inc [2015] HCA 35
Mylan submits that the *Patents Act 1990* be amended so to make it unambiguously clear that the Objects Clause provides IP Australia and the courts and tribunals with a bridge to a range of policies applicable to *all* Australians, such as the National Competition Policy\(^ {46}\) and National Medicines Policy\(^ {47}\) so that Australia’s patent system grants only high quality patents consistent with the Australian government’s mandate, to ensure an “appropriate balance exists between *incentives for innovation and investment* and the *interests of both individuals and businesses, including small businesses, in accessing ideas and products.*”

Mylan submits that the draft EM be amended so that it is consistent with the views expressed by the Commission, the law and the Australian government’s mandate.

Mylan submits for the sake of removing any doubt that *Anaesthetic Supplies Pty Limited v Rescare Limited*\(^ {48}\) be overruled in the proposed legislation.

Mylan submits that the Objects Clause should enable IP Australia and the courts and tribunals to interpret the *Patents Act 1990* so that the patent system enables the provision to generic pharmaceutical companies, such as Mylan, all information necessary to ensure the transfer and dissemination of technology so that safe, efficacious and affordable medicines can be provided to all Australians under the PBS at the expiry of the relevant patent. This should be made clear in the EM.

**Crown Use & Compulsory Licenses**

The Commission’s Compulsory Licensing Report\(^ {49}\) accepted that there are situations when it is appropriate for a government or third party to intervene directly in the exploitation of patent rights by a patent owner. The potential for such action is apparent in the provision of healthcare to Australians. The Commission acknowledged this in the case of genetic testing and personalised medicines:

> ... the Commission supports the conclusion of past reviews that there is an in-principle case for compulsory licensing and other safeguards to address concerns such as those raised by the BRCA case. While such cases are currently rare, concerns about gene patents may become more pronounced in the future if healthcare increasingly depends on emerging (newly patented) genetic technologies and personalised medicine that requires the testing of multiple genes.

Mylan agrees with and supports the proposed amendments in regard to Crown Use and Compulsory Licensing.

However, Mylan believes it is important to make it crystal clear in the legislation that the Objects Clause be taken into account by the courts in regard to interpretation of the Act in general but specifically in the case of Crown Use and Compulsory Licensing. The Commission has expressed the view that:

\(^{46}\) [http://ncp.ncc.gov.au/](http://ncp.ncc.gov.au/)


\(^{48}\) *Anaesthetic Supplies Pty Limited v Rescare Limited* [1994] FCA 1065 9

\(^{49}\) Op cit 36
... a general objects clause into the Patents Act could help clarify the role of compulsory licensing and the considerations that should guide the court in making the order. ⁵⁰

And clearly in this context the Objects Clause should not be confined “to only economic factors and excludes ethical and social considerations”. The Commission expressly cited Dr Moir’s submission in support of the Objects Clause playing an active role in directing the courts in the interpretation of the legislation so as to “make it clear that patentable inventions must also deliver a benefit to the public”, ⁵¹ which must mean that ethical and social considerations are both material and relevant because they ensure an appropriate balance exists between incentives for innovation and investment and the interests of both individuals and businesses, including small businesses, in accessing ideas and products.”

⁵⁰ Ibid, 128 (emphasis added)
⁵¹ Ibid (emphasis added)