Patent Law and the March of Technology – Did the Productivity Commission Get It Right?

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Technology continues to march ahead at an increasingly rapid rate. As a response to the demands placed on intellectual property (IP) systems by changing technologies, there have been changes in the scope and duration of IP protection. In August 2015, the Productivity Commission (PC) was requested by the Australian Government to undertake an “inquiry into Australia’s intellectual property arrangements, including their effect on investment, competition, trade, innovation and consumer welfare”. This inquiry was to take more of a holistic view of the IP system in searching for improvements. While there has been considerable coverage of the implications of the recommendations of the PC in relation to copyright law reform, there has been surprisingly little in respect of other areas of IP law. Given the dominance of patents in influencing innovation and social welfare, this is surprising. This article appraises the recommendations of the PC in the patent law area, particularly in light of the PC’s Terms of Reference. It also considers some matters the PC omitted to consider but which are nonetheless of paramount importance as innovation rapidly progresses.

I. INTRODUCTION

Technology continues to march ahead at an increasingly rapid rate. This march significantly influences the global economy. As a response to changing technologies, there have been changes in the scope and duration of intellectual property (IP) protection. International, bilateral and regional IP instruments bind signatories to include minimal standards in their legislation, often without evaluation of the local economic consequences. One stark example was the extension of the standard copyright period for most works from life of the author plus 50 years, to life of the author plus 70 years, pursuant to the Australia-US Free Trade Agreement. It is widely recognised that this extension of term was of no economic benefit to Australia.¹ Yet Australia continues to negotiate, sign and ratify international instruments that bind us to high IP standards, with little account of economic and social consequences. The Trans-Pacific Partnership (TPP) is a case in point. Though its future is uncertain, as signed, it would have included a number of provisions that would have extended Drahos’s “IP ratchet”.²

In August 2015, the Productivity Commission (PC) was requested by the Australian Government to undertake an “inquiry into Australia’s intellectual property arrangements, including their effect on investment, competition, trade, innovation and consumer welfare”.³ Compared to other studies, this inquiry was to take more of a holistic view of the IP system in searching for improvements. The PC consulted widely with stakeholders, releasing an issues paper inviting public submissions on 7 October 2015 and undertaking a number of consultations and roundtable discussions with relevant stakeholders.

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The PC released a draft report on 29 April 2016. A total of 620 submissions (148 predraft and 472 postdraft) were received. The final report of the PC was released on 23 September 2016. The Australian Government has now responded to the PC Report and in doing so has supported a number of its recommendations, supported in principle others and noted, but not supported others.4

There has been much angst in the popular and professional media about some of the PC recommendations relating to copyright law reform, particularly the introduction of a fair use exception. In contrast, very little has been said about the recommendations of the PC in relation to the other areas of IP law.5 This is surprising, given the dominant role that patents, for instance, play in the context of innovation and social welfare. The aim of this article is to provide a short analysis of the recommendations made by the PC for reform of the patent system, focusing on those that would effect changes to substantive patent law.

The PC made a number of recommendations with regard to patent law. These include clarifying what Australians want from the patent system by including an objects clause, reforming the inventive step requirement, requiring applicants to identify the technical features of claimed invention, making administrative changes around claim and renewal fees and abolishing the innovation patent system.6 However, it is argued that many of these issues are at best indirectly relevant to innovation and development. It also argued that some recommendations are unlikely to achieve the overall goals of the PC, while others reflect misunderstandings of the purpose of the statutory framework. The report itself was largely based on an economic policy analysis, and other factors and political realities were ignored.

With regard to the issues that the PC did not address, one important omission was an analysis of the subject matter criterion following the High Court decision in D’Arcy v Myriad Genetics Inc.7 Further consideration of the utility requirement within patent law and impact of the trade secrecy regime on patent law and policy were also overlooked.

II. PC’S GUIDING PRINCIPLES

In analyzing the performance of the Australian IP system, the PC considered the overarching objective of maximizing the wellbeing of Australians. The described goal was to ensure “that the IP system provides appropriate incentives for innovation, investment and the production of creative works while ensuring it does not unreasonably impede further innovation, competition, investment and access to goods and services”.8

There were four principles that the PC ascribed to the IP system to achieve these goals: that the system is effective, efficient, adaptable and accountable. Their analysis of the current system considered these principles as the measure of a successful IP system. The principles were expanded by the PC as follows:

- Effective – The system should be effective in encouraging additional ideas and in providing incentives that ensure knowledge is disseminated through the economy and community.
- Efficient – The system should provide incentives for IP to be created at the lowest cost to society. This principle includes considering whether IP rights generate returns that are sufficient to encourage new ideas, the relative merits of public and private IP generation, and the longer-term effects on competition and innovation from granting IP rights.
- Adaptable – The system should adapt to changes in economic conditions, technology, markets and costs of innovating.

6 The Government Response supported the abolition of the innovation patent system: Response to the Productivity Commission Inquiry, n 4, 10. Although this is an important recommendation with regard to a substantive area of patent law, the rationale for the call for abolition is not discussed further in this article because this is a stand-alone issue requiring deeper analysis.
8 PC Report, n 3, 6.
There is nothing particularly controversial about any of these principles, and they received support in the Government Response.\textsuperscript{10} Although not expressly articulated in IP instruments up to this point, they have provided the primary underpinnings of the IP system for many years. The issue is how to measure the extent to which the current system satisfies these principles and what can be done to amend the system when it is not performing optimally. A critique of the way in which the PC attempted to identify and address “the patent problem” follows.

III. THE PATENT PROBLEM

There are a number of problems with the existing patent system. The PC focused on two of these – that exclusivity is granted too readily,\textsuperscript{11} and within granted patents, there are some stronger or more inventive patents than others.\textsuperscript{12} This allows for a proliferation of low-quality patents.\textsuperscript{13} The problem in such circumstances is that “IP rights can lead to IP wrongs”.\textsuperscript{14} IP rights give their holders a monopoly and the ability to prevent others from using that IP. This means there is a risk that parties may extract excessive royalties from licensing, place anticompetitive restrictions on use or not licence at all. This can affect innovation and users of IP. IP rights do not always result in additional innovation. As noted in a report by Jensen and Webster of a survey of managers of large firms between 2001 and 2006, patents were, on average, considered the least effective appropriation mechanism for both product and process innovations.\textsuperscript{15}

The finding of the PC that the bulk of Australian patents are of a relatively low value is hardly surprising for anyone with an interest in the patent system in Australia. Data from IP Australia shows that the number of patent applications filed each year continues steadily on an upward trajectory.\textsuperscript{16} It is known that applications are filed for a variety of reasons, not just for the purpose of facilitating innovation by providing a temporary zone of exclusivity around promising inventions. Attracting venture capital funding is one obvious reason for filing applications for purposes other than securing exclusivity. While not denying that there is a genuine problem with low-value patents, the market itself does have ways of ridding itself of these patents. We have seen in the area of gene patenting that despite the deluge of relevant applications in the 1990s, the majority were either never examined or allowed to lapse.\textsuperscript{17}

Implicit in these findings is the inference that patents that are not examined and not continued are of low value. While it is unlikely that self-identification by applicants and owners will rid the patent system of all low-value patents, this analysis does show that the patent environment in any given technology area is always evolving. Any recommendations for reform based on the need to respond to the perceived deleterious impact of low-value patents need to be nuanced, taking into account the potential negative

\textsuperscript{9} PC Report, n 3, 6.
\textsuperscript{10} Response to the Productivity Commission Inquiry, n 4, 3.
\textsuperscript{11} Response to the Productivity Commission Inquiry, n 4, 200–208.
\textsuperscript{12} Response to the Productivity Commission Inquiry, n 4, 208–214.
\textsuperscript{13} Response to the Productivity Commission Inquiry, n 4, 202–203.
\textsuperscript{14} Response to the Productivity Commission Inquiry, n 4, 4.
\textsuperscript{15} Paul H Jensen and Elizabeth Webster, “Knowledge Management: Does Capture Impede Creation?” (2009) 18 Industrial and Corporate Change 701.
Patents, whether of high or low value, can frustrate follow on invention and innovation, and prevent competition. After all, the whole purpose of the patent system is to provide a temporary period of exclusivity and restrict market entry. There is a long history of equivocal evidence as to whether innovation is best served by a system that grants monopoly rights or one that encourages a competitive environment. This debate is perhaps most pronounced in the patent context. An optimally functioning patent system will assist in balancing the innovation advantage provided to patent holders, with the corresponding risk of innovation blockage for follow on users. With the advent of high technology, the pace and complexity of the innovation process has increased dramatically, placing increased pressures on beleaguered IP systems. Complex webs of primary and follow-on innovators are emerging in areas of disruptive technology, making the challenge of ensuring that the patent system functions optimally, ever more demanding.

The most pronounced risks arising from broad patents claiming foundational technology are blocking effects and anticommons effects caused by patent thickets. Blocking occurs when the owner of a patent over foundational technology refuses to deal with a developer of downstream technology, while anticommons effects result from numerous overlapping property rights, particularly where reaching terms in licence agreements lead to licence and royalty stacking. The concern generated by these “patent practices” is that timely delivery of innovative products and processes might be significantly hindered, which clearly has both economic and social consequences.

Stepping back from the consumer perspective, there is genuine trepidation about the potential for patents to detrimentally impact on the primary research conducted in universities and other public research organisations, which feeds into the innovation cycle. In the university sector, in particular, patenting will rarely provide an optimal mechanism for disseminating knowledge. Concerns about hold-up and anticommons impacts on innovation must be seriously considered, despite the evidence that these are actually eventuating being mixed. However, these concerns need to be balanced against the positive role that patents can play in encouraging innovation, particularly for small, specialised firms and their licensees.

The question of whether these theoretical concerns exist in practice is yet to be fully resolved in the Australian context. In the biotechnology sector, at least, clear evidence of blocking and anticommons effects has not yet emerged, and it is clear that potentially problematic patents are often not maintained

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18 As an aside, it is noted that the PC found that the “low-value” problem was particularly pertinent with regard to innovation patents, positing that 40% of them were of relatively low value. It is recognised in this article that the innovation patent system is probably not achieving its intended purpose, but it should be noted that it was never intended to drive high-value innovation. The innovation patent system is not considered further in the article. Rather the primary focus is on the standard patent system.


20 See, eg Michele Boldrin and David K Levine, Against Intellectual Monopoly (CUP, 2008); PC Report, n 3, App D.


22 Harper et al, n 19, 102–103.


24 Heller and Eisenberg, n 23; Walsh, Arora and Cohen, n 23, 296–297.


28 Dianne Nicol and Jane Nielsen, “Patents and Medical Biotechnology: An Empirical Analysis of Issues Facing the Australian Industry” (Centre for Law and Genetics Occasional Paper No 6, Centre for Law and Genetics, Hobart, 2003).
by patent holders.\textsuperscript{29} Where blockages have occurred, this often eventuated due to “rogue players” enforcing their rights rather than any more systemic flaw with the patent system.\textsuperscript{30} This stands in contrast to the PC conclusion that overprotection can lead to reduced innovation and excessive prices.

This is not to deny that there are genuine concerns that the biotechnology environment is ripe for the emergence of strategic patent enforcement activities. The patenting of genes and other natural products and processes for using them invariably creates public ire, socially and politically. Indeed, this issue triggered a number of law reform inquiries in the early 2000s.\textsuperscript{31} In each case, fairly nuanced recommendations were made for reforming patent law, recognising that there are statutory tools for alleviating impediments to access both pregrant, through rigorous application of the patent criteria, and postgrant, through compulsory licensing, Crown use, competition law and other initiatives such as patent pooling and clearinghouse mechanisms. It is equally important to recognise the role of the ex-ante policy decisions made by governments, funding agencies, universities and other research institutions and industry as to whether or not patenting is the optimal strategy for innovation and dissemination of knowledge, both for whole fields of technology and for individual inventions.

The other primary areas of technology that have garnered community and governmental attention are software and business methods, and pharmaceuticals. In 2003, the Advisory Council on Intellectual Property was given a limited brief to examine business method patents.\textsuperscript{32} In 2012, a group of experts was tasked with reviewing the pharmaceutical patents system with assistance from IP Australia.\textsuperscript{33} Again, the recommendations for reform were quite nuanced. In contrast, the PC was given a broader licence for wide-scale and more fundamental reform of the patent system. The terms of reference required the PC to examine the entirety of the Australian IP system and recommend changes that would “improve the overall wellbeing of Australian society”.\textsuperscript{34}

**IV. UPHOT FOR PATENT LAW: WHAT DID THE PC RECOMMEND?**

As noted in the Introduction to this article, a number of broad recommendations for patent law reform were made in the PC Report. The recommendations relating to substantive patent law are considered here, namely the inclusion of an objects clause and reform of inventive step, including the requirement for applicants to identify the technical features of the claimed invention. Specific recommendations were also made with regard to particular areas of technology, namely software/business methods and pharmaceuticals. These recommendations are discussed further during the course of this examination.

**A. Objects Clause**

The PC recommended the introduction of an objects clause in the *Patents Act 1990* (Cth) and that the “objects clause should describe the purpose of the legislation as enhancing the wellbeing of Australians by promoting technological innovation and the transfer and dissemination of technology”.\textsuperscript{35} The PC’s aim for this object clause was that it would assist the patent system to balance over time “the interests of producers, owners and users of technology”.\textsuperscript{36} This wording largely mirrors that contained in the

\textsuperscript{29} Liddicoat, Whitton and Nicol, n 17.

\textsuperscript{30} Nicol and Nielsen, n 28.


\textsuperscript{34} PC Report, n 3, v.

\textsuperscript{35} PC Report, n 3, 219.

\textsuperscript{36} PC Report, n 3.
TRIPS Agreement. It also is similar to the wording proposed by IP Australia in its 2013 consultation on patentable subject matter.

It is difficult to envisage how a robust argument could be made opposing the sentiment that the objective of Australian patent law should be the enhancement of the wellbeing of Australians and the interests of Australian society. Australia is entitled to frame its IP laws in its own national interest subject only to the specific commitments it has made relating to IP rules as set out in the international legal framework. An overall objective of promoting the interests of Australian society is in no way inconsistent with Australia’s commitment to provide national treatment for inventors and rights holders from other countries.

The criteria for patentability already provide assistance in ensuring that the Patents Act 1990 (Cth) meets its objectives, especially following the amendments brought about by the IP Laws Amendment (Raising the Bar) Act 2012 (Cth) (Raising the Bar). Nevertheless, the legislation could still benefit from the inclusion of an objects clause. The inclusion may better facilitate interaction between the patent system and competition policy with regard to the benefit of society as a whole. It goes without saying that placing innovation at the forefront is critical for the effective functioning of the patent system.

Not surprisingly, the Government has indicated that it supports this recommendation in its response to the PC Report. The PC is not the first law reform body to recommend the introduction of an objects clause, and the Government has previously espoused such recommendations. As this is one of the least controversial recommendations of the PC, it seems sensible for it to be implemented without further inquiry. Having said that the Government indicated an intention to give further consideration to the precise wording of the objects clause, and IP Australia very recently commenced a consultation process to enable consideration of the form of the clause. Regardless of the form the objects clause takes, it certainly has important symbolic value even though in the long run, it may not make a great deal of practical difference to decision-making given that the Australian patent system is supposedly already designed to achieve these ends.

B. Inventive Step

The PC rejected the traditional “scintilla of invention” test for whether or not the invention claimed in the patent is obvious, preferring instead a more stringent test, taking into account the technical features of the invention. The PC also suggested that “the ‘obvious to try’ test applied in Europe would in some instances be a suitable test”. Increasing the stringency of the inventive step test is an important recommendation; alignment of Australian law with the approach adopted by the European Patent Office would not only assist in raising the threshold of the inventive step test, it would to some extent bring the


38 IP Australia, Patentable Subject Matter: Consultation on an Objects Clause and an Exclusion from Patentability (Commonwealth of Australia, Canberra, 2014).

39 TRIPS Agreement, n 37, Art 3.

40 Response to the Productivity Commission Inquiry, n 4, 8.


42 Australian Government Response to Senate Community Affairs References Committee, Gene Patents Report, November 2011, 13. This response also addressed ACIP’s recommendations in relation to the inclusion of an objects clause.


44 PC Report, n 3, Recommendation 7.2.

45 PC Report, n 3, 229.
test in line with that of major trading partners. To further strengthen this proposed change to the test for obviousness, the PC further recommended that “IP Australia should reform its patent filing processes to require applicants to identify the technical features of the invention in the set of claims”. In its response, the Government agreed and accepted both recommendations.46

Stakeholders might query whether further amendment of Australian law is needed to raise the inventive step threshold, given that changes were made relatively recently via Raising the Bar. This legislation resulted in an expansion of the information base against which an invention’s inventive step is assessed. Although these amendments make good sense, inventive step requires consideration of both the prior art base against which a patent is assessed and whether, when assessed against that base, the invention is obvious. Raising the Bar did not address this second aspect of the inventive step threshold.

The current Australian test for obviousness is not well aligned with the tests applied by our major trading partners. There was a time when the Australian position regarding inventive step was in line with that in the US regarding nonobviousness. This changed as a result of the interpretation of the nonobviousness requirement in the United States brought about by the Supreme Court’s decision in *KSR International Co v Teleflex Inc*48 as illustrated in the subsequent body of jurisprudence that built up in specific areas of technology. In biotechnology, for example the US Court of Appeals for the Federal Circuit held in *Re Kubin*50 that isolation of the claimed gene sequences was obvious to try, in line with *KSR* reasoning but in contrast to *Re Deuel*,50 which until then had been the leading case on the interpretation of the inventive step requirement for biotechnology inventions. With the closer alignment of the US position to that in Europe, it might have been timely for Australia to take a similar step when this issue was under consideration in Raising the Bar discussions in 2011. Adoption of the terminology of “obvious to try” and “reasonable expectation of success” as used in a previous Consultation Paper distributed by IP Australia51 could have provided a greater level of harmonisation in assessment of the inventive step requirement with our trading partners. Arguably, a failure to do so has led to the result that “Australia still has a materially greater propensity to grant patents when the EPO [European Patent Office] does not.”52

The problem in Australia stems from the interpretation of the obviousness test by the High Court in *Aktiebolaget Hassle v Alphapharm Pty Ltd*53 and the Court’s affirmation of this approach in *Lockwood Security Products Pty Ltd v Doric Products Pty Ltd (No 2).*54 Since Raising the Bar came into force, a series of other influential inventive step cases have been decided (albeit still mostly considering the pre-Raising the Bar requirements). One notable case is *Generic Health Pty Ltd v Bayer Pharma Aktiengesellschaft.*55 Particular attention is drawn to the last two sentences in para 71, where the unanimous Full Court of the Federal Court held that:

we think a test formulated in terms of worthwhile to try was firmly rejected by the High Court in Alphapharm (see also Pfizer [Overseas Pharmaceuticals v Eli Lilly & Co (2005) 225 ALR 416] at 476, [287], per French and Lindgren JJ). The fact (if it be the fact) that the position in the United States may have shifted does not affect the binding nature of what the plurality said in Alphapharm.

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46 PC Report, n 3, Recommendation 7.3.
47 Response to the Productivity Commission Inquiry, n 4, 8–9.
49 *Re Kubin*, 561 F 3d 1351 (Fed Cir, 2009).
50 *Re Deuel*, 51 F 3d 1552 (Fed Cir, 1995).
52 PC Report, n 3, 224.
Despite the amendments to the inventive step requirements brought about by Raising the Bar, there will continue to be circumstances where an invention will satisfy the Australian requirements even though it would not necessarily satisfy those requirements in Europe or the United States.

It is not yet clear exactly how this amendment will be incorporated in the *Patents Act 1990* (Cth): in its response, the Government indicated it would engage in further public consultation to clarify the wording of the amendment.\(^{56}\) \(^{56}\) IP Australia has subsequently released a consultation paper seeking public input into the form the amendment might take.\(^{57}\) The legislative form of the test is important: it is worth noting that none of the other jurisdictions that employ an “obvious to try” approach have enshrined this approach in legislation\(^{58}\) but have generally taken the approach of embedding a simpler test in their legislation and reserving complexity in application of the test for examination manuals.\(^{59}\) This permits the retention of simplicity and adaptability when assessing the inventiveness of emerging and challenging technologies. Accordingly, the PC recommended simplification of the inventive step test in the *Patents Act 1990* (Cth), with elaboration as to the appropriate threshold required to meet the test to be contained in the Explanatory Memorandum.\(^{60}\) The four alternatives proposed by IP Australia to implement the amendment vary in complexity and prescriptiveness, and the degree of success of any amendment hinges to some extent on which of these options is adopted.

Ultimately, the PC recommendation to amend the obviousness test seems sensible, in light of both the “low-value” problem and the desirability of harmonization. It seems inherently unlikely that change to the test will be effected judicially in the absence of legislative amendment. The PC estimates that raising the threshold would result in about 700–800 fewer low-value patents granted each year (equivalent to about 4.5% of annual patents granted).\(^{61}\) Quite whether this prediction would actually be the practical outcome of such an amendment depends on a range of factors, not least of which is judicial interpretation of the new provision.

Importantly, however, the PC was perhaps too optimistic in its view that raising the inventive step threshold is the primary (or sole) fix we are looking for to deal with the “low-value” problem. The chapter of the final report on business method patents and software patents illustrates this point. Rather than wholesale exclusion of business methods and software (as recommended in the PC’s draft report), the PC concluded that:

Raising the inventive step, requiring technical features in patent claims, and the inclusion of an objects clause would better balance the patent rights of software innovators and users.\(^{62}\)

There must be some doubt as to whether these overarching recommendations are enough, on their own, to fix the problem of granting patents that are at odds with the economic underpinnings of the patent system.

### C. The Particular Case of Pharmaceutical Patents

Producers of new chemical entities and new biologics insist that strong patent rights are vital to encourage innovation in this field because of the high research and development costs. Generic producers, conversely, argue that patent rights need to be circumscribed and of limited duration to ensure that the best treatment options are available to healthcare consumers at prices they can afford. Recognising that pharmaceutical patents raise their own distinct issues, the PC made two specific recommendations:

\(^{56}\) Response to the Productivity Commission Inquiry, n 4, 9.


\(^{59}\) PC Report, n 3, 224.

\(^{60}\) PC Report, n 3, Recommendation 7.2.

\(^{61}\) PC Report, n 3, 228.

RECOMMENDATION 10.1

The Australian Government should reform extensions of patent term for pharmaceuticals such that they are only:

(i) available for patents covering an active pharmaceutical ingredient, and

(ii) calculated based on the time taken by the Therapeutic Goods Administration for regulatory approval over and above 255 working days (one year).

The Australian Government should reform s 76A of the Patents Act 1990 (Cth) to improve data collection requirements for extensions of term, drawing on the model applied in Canada. Thereafter no extensions of term should be granted until data is received in a satisfactory form.63

RECOMMENDATION 10.2

The Australian Government should introduce a system for transparent reporting and monitoring of settlements between originator and generic pharmaceutical companies to detect potential pay-for-delay agreements. This system should be based on the model used in the United States, administered by the Australian Competition and Consumer Commission, and include guidelines on the approach to monitoring as part of the broader guidance on the application of the Competition and Consumer Act 2010 (Cth) to intellectual property (recommendation 15.1).

The monitoring should operate for a period of five years. Following this period, the Australian Government should review the regulation of pay-for-delay agreements (and other potentially anticompetitive arrangements specific to the pharmaceutical sector).64

In coming to these recommendations, the PC paid particular attention to the Pharmaceutical Patent Review Final Report (PPRFR).65 The PPRFR involved extensive economic and legal analysis, consultation with relevant government agencies, public consultations and consideration of two rounds of detailed submissions. As such, there is much useful information in the PPRFR that had not been considered in any other forum, prior to the PC inquiry. It is pertinent to note that although this inquiry was commissioned by the government of the day, by the time the final report was delivered, the government had changed and different priorities meant that there was no government response to the recommendations included therein. Even the report itself was not made public for some time after it was provided to the government.

The PPRFR included some general recommendations on transparency, international obligations, international harmonization and an objects clause for the Patents Act 1990 (Cth), which have also been picked up by the PC. However, there are other important recommendations in the PPRFR that were not addressed in the PC Report. These include the establishment of an external patent oversight committee,66 the introduction of a transparency register for therapeutic goods,67 greater involvement of the government in managing the costs to the Pharmaceutical Benefits Scheme (PBS) when a patent relating to a PBS-listed pharmaceutical is successfully challenged,68 and the establishment of a Pharmaceutical System Coordinating Committee.69 The PPRFR also included specific recommendations regarding amendments to the provisions in s 117 of the Patents Act 1990 (Cth) relating to supply infringement70 which have not been addressed by the PC.

Turning to Recommendation 10.1 of the PC report, while there is much to be said for limiting the extension of term to the actual period taken for regulatory approval (plus one year), it is not clear

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63 PC Report, n 3, 310.
64 PC Report, n 3, 329.
65 Harris, Nicol and Gruen, n 33.
66 Harris, Nicol and Gruen, n 33, Recommendation 6.1.
67 Harris, Nicol and Gruen, n 33, Recommendation 7.3.
68 Harris, Nicol and Gruen, n 33, Recommendation 7.1.
69 Harris, Nicol and Gruen, n 33, Recommendation 10.1.
70 Harris, Nicol and Gruen, n 33, Recommendation 7.2.
that this accords with our international obligations and practice in the major pharmaceutical patenting jurisdictions. In essence, the PC recommendation, if implemented, would bring an end to patent term extension, given that the Therapeutic Goods Administration would rarely, if ever, take over a year to grant regulatory approval. In contrast to the PC approach, the PPRFR included a recommendation that the effective patent life period be reduced from the current period of 15 years (noting that there was some disagreement within the pharmaceutical patent review panel as to the appropriate duration of the effective period of patent life).\(^\text{71}\)

Given that the Government, unsurprisingly, declined to accept the PC’s Recommendation 10.1,\(^\text{72}\) it might have been useful for the PC to include a recommendation of this nature as a softer alternative to Recommendation 10.1. Although Recommendation 10.1 might make sense economically, from a political perspective, the chance of implementation was inevitably low given the strength of the pharmaceutical lobby and the lack of interest on the part of the incumbent government in the softer PPRFR recommendations. Indeed, the Government Response notes Recommendation 10.1 but expresses an intention on the part of the Government to explore ways to improve the patent extension system in conjunction with the pharmaceutical sector.\(^\text{73}\)

Looking beyond pharmaceutical patents, there is no doubt that Australia’s ability in general terms to adjust its IP legislation is limited as a result of its international obligations. This is the case for every signatory to international IP agreements. For example, TRIPS constrains the ability of signatories to amend IP legislation in relation to patent criteria, the duration of patent protection and exclusions from patentability (to name just a few). Australia made a number of changes to its patent legislation in order to become TRIPS compliant, although these changes were not as significant as those required by many other signatories.

Greater impact will likely be felt due to bilateral and regional treaty obligations on Australia’s IP legislation and the impediments they pose to making further legislative changes. These obligations might not always be beneficial to Australia. The Australia – United States Free Trade Agreement (AUSFTA), for example presents a real impediment to changing the compulsory licensing provisions contained in the \textit{Patents Act 1990} (Cth). These obligations mean that the compulsory licensing provisions to which Australia is now a signatory exceed those required by TRIPS. This may directly impact on Australian innovators given that few modifications which would expedite the process of applying for a compulsory licence are now possible. A majority of Australian IP (particularly patents) is held by nonresidents, particularly in the biomedical field.\(^\text{74}\) In other words, Australian inventors are net importers of technology.

There are few mechanisms to adjust Australia’s domestic IP legislation unless these changes take place within the confines of Australia’s international and bilateral obligations. In entering future negotiations for bilateral or regional agreements, Australian negotiators should be more mindful of the effects of negotiating terms that are disadvantageous to Australian industry, bearing in mind the fact that we are primarily users of technology. This will become more important as the use of digital technologies increases in frequency, and IP rights over these technologies invariably proliferate.

\textbf{V. \textsc{WHAT DID THE PC NEGLECT TO CONSIDER?}}

Given the all-encompassing nature of the PC’s Terms of Reference, it is not altogether surprising that its coverage of issues relevant to patent law and its impact on technological development was piecemeal. There was considerable scope for much broader consideration of those issues that have the potential to play a part in advancing (or hindering) innovation. The PC’s failure to engage with a broader range of issues is disappointing, particularly given its mandate to consider IP arrangements in light of “investment,\(^\text{75}\)

\begin{footnotesize}
\begin{itemize}
\item \(^\text{71}\) Harris, Nicol and Gruen, n 33, Recommendation 4.1.
\item \(^\text{72}\) Response to the Productivity Commission Inquiry, n 4, 11–12.
\item \(^\text{73}\) Response to the Productivity Commission Inquiry, n 4, 11.
\item \(^\text{74}\) Nicol and Nielsen, n 28; IP Australia, \textit{Australian Intellectual Property Report 2015} (2015); with the exception of trademarks (see 16 of that report), most IP is held by nonresidents: during 2014, eg 18,102 patents were granted to nonresidents and just 1,199 to residents: 9. This trend is typical of the statistics in recent years.
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competition, trade, innovation and consumer welfare”. This section of the article addresses several omissions we see as being particularly pertinent.

A. The Subject Matter Requirement

Patentable subject matter is a criterion of patentability that has received extensive scrutiny in law reform inquiries, in academic commentary and in the courts over the past decade. It is, therefore, perhaps surprising that the PC did not turn its mind to considering the impact of this reform agenda, and whether it was indeed, sufficiently comprehensive. It has also been argued that further judicial developments (most notably in the shape of the D’Arcy v Myriad Genetics Inc decision) have rendered uncertain, particular aspects of the subject matter requirement. The PC was presented with a prime opportunity to address whether these claims of uncertainty are justified.

1. Subject Matter and the Increasing Importance of Method Patents

Technological advances in biotechnology in the areas of gene editing, biologics and bioprinting, and in information technology in the areas of software and bioinformatics, have been rapid. Patent applications in these areas are on the rise, and in an age of innovation typified by customization, in each of these technological areas, innovators are increasingly turning to method patents. By way of example, of nine Australian patent applications related to bioprinting filed by Organovo Inc (two of which have been granted at the time of writing this article), all include claims to methods. Genetic diagnostic testing method claims were also previously predicted to have a more pronounced impact on the availability of genetic diagnostic testing than claims over nucleotide sequences, a prediction that has to some extent been borne out by the Australian D’Arcy litigation. Method claims also have vast disruptive potential in areas such as the production of biologic medicines, and the application of business methods and computer software.

Yet the complex issue of methods as patentable subject matter received virtually no mention in the PC Report outside of its consideration of the patentability of business methods and computer software. In its draft report, the PC included a draft recommendation that business methods and software should be excluded from being patentable subject matter. Any technology specific exclusion from patenting is bound to be highly contentious. The PC canvassed a number of interjurisdictional approaches in its draft report, noting the problems being faced, for example as a result of judicial decisions in the United States attempting to define the bounds of patentable subject matter in the software area. Earlier law reform inquiries consistently recommended that a broad technology-neutral test for patentable subject matter should be retained. The manner of manufacture requirement, as interpreted in National Research Development Corp v Commissioner of Patents (NRDC) has stood the test of time. There was no suggestion in the draft report for wholesale reform of this test. As such, cherry picking certain technologies for specific exclusion seems anomalous.

75 PC Report, n 3, iv.
80 PC Report, n 3, Ch 9.
82 National Research Development Corp v Commissioner of Patents (1959) 102 CLR 252.
There were some obvious problems with the PC’s analysis of software and business method patents, and as a consequence with its draft recommendation. First, there are many different types of inventions that fall within the categories of “business methods and software”. To impose a blanket, exclusion on all these inventions from patentability would have been an extreme solution to the problems identified by the PC. Further, as the PC identified, there is no easy way to recognise when embedded software should be patentable. Finally, the PC’s difficulty with business method and software patents stems largely from their lack of physicality, a restrict requirement generated in Grant v Commissioner of Patents\(^83\) that arguably had no firm foundation in judicial precedent.\(^84\)

In making the draft recommendation, the PC also failed to recognise the difficulties the European exclusion from patentability has presented, not least of which is the large body of case law that has been generated to attempt to interpret its bounds.\(^85\) There is no guarantee a similar issue would not have arisen in the Australian context, as developers attempt to find workarounds to the exclusion. The associated uncertainty that would have been brought about by the enactment of an exclusion for software and business method patents may well have exceeded current uncertainty surrounding their patentability. The PC concluded as much in its final report, sensibly deciding not to affirm its draft recommendation.

There have been a number of recent cases in this area that have interpreted the NRDC case in the context of software and business methods. This includes Commissioner of Patents v RPL Central Pty Ltd and Research Affiliates LLC v Commissioner of Patents.\(^86\) Two Australian Patent Decisions have also considered the impact of these cases.\(^87\) This case law suggests that there is already room in the current manner of manufacture requirement to limit patent overreach in this area. However, as always, ongoing scrutiny is required to ensure that the low-value patent problem is alleviated as much as possible.

The PC did not consider more broadly the patentability of methods of medical treatment and other method patents that are set to impact directly on technological development. Case law on the patentability of methods under Australian patent law provides no consistent guidance on the inherent patentability of methods per se. Although method claims were at issue in the US Association for Molecular Pathology v Myriad Genetics decision, no such issue was raised (or required to be resolved) in D’Arcy. There was some obiter discussion in the judgment of Gageler and Nettle JJ as to whether the claims were more appropriately drafted as product or process claims, but as observed by their Honours, the process for isolating nucleotide sequences in order to conduct genetic diagnostic testing was well established and certainly not patentable.\(^88\) There was some indication that a different result might be reached if a patentee claimed a method of isolating nucleic acid sequences and examining them for specific mutations and polymorphisms for the purposes of detecting malignancy.\(^89\)

In the United States, method claims were considered along with nucleotide sequence claims. The Federal Circuit held that those diagnostic method claims which were limited to “comparing” and “analysing” sequences did not fulfil the requirements of patentability, in that they were directed

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\(^83\) Grant v Commissioner of Patents (2006) 154 FCR 62; [2006] FCAFC 120.


towards patent ineligible concepts or abstract mental processes with no transformative steps. However, a claim that “in addition to the step of comparing the cells’ growth rates … also recites the steps of growing transformed cells and determining those growth rates” was held to be sufficiently transformative and therefore patentable. This aspect of the Federal Circuit decision considering method claims was not appealed to the Supreme Court, so that the Supreme Court was ultimately only required to determine the issue of the patentability of nucleotide sequences. There remains no clear answer as to whether the same result would be reached under Australian patent law, but there is a very strong argument that the incorporation of an innovative process into a claim for isolating and analysing nucleotide sequences will render that process patentable. Given rapid developments taking place in the field of genetic diagnostic testing, particularly those incorporating next generation sequencing techniques, the outer boundaries of when methods of testing may constitute patentable subject matter are set to be tested.

Similarly, there is no clear answer to the question whether methods of medical treatment are patentable. In a case that considered only one aspect of the issue of the patentability of methods of medical treatment, the High Court recently held that a new use of a known pharmaceutical satisfied the subject matter requirement in Apotex Pty Ltd v Sanofi-Aventis Australia Pty Ltd. The import of the decision should be construed cautiously, however, as pointed out by Crennan and Kiefel JJ in their joint judgment and, separately, Gageler J. For their Honours, the question of whether or not “the activities or procedures of doctors (and other medical staff) when physically treating patients” are patentable was still to be decided. It is interesting to consider whether methods of treatment performed outside the body (eg in diagnostic testing procedures and in undertaking genome editing) might similarly be inherently unpatentable. In the absence of more clearly articulated legal principles, it is difficult to draw any conclusions on this, or even to venture to hypothesise as to the import of current legal rules on these questions. There is no doubt that a number of very open questions remain.

2. Subject Matter – How Will the D'Arcy Factors Be Applied?

Further, there was no discussion by the PC of the factors identified as relevant to subject matter inquiries for new categories of subject matter by the plurality in D'Arcy v Myriad Genetics Inc. Indeed, there was no consideration in the PC report of any aspect of this case, which has provided the most recent judicial elucidation of the tricky subject matter requirement. Despite purporting to lay down a better foundational basis on which claims at the “bounds of patentability” might be assessed, courts have struggled to know when and how to apply the High Court’s “factorial approach”.

As new technologies proliferate, the subject matter of patents becomes increasingly important. In D'Arcy v Myriad Genetics Inc, the High Court addressed the subject matter requirement head on in considering the patentability of isolated nucleotide sequences, but also the application of the statutory test for patentability for all technologies with untested subject matter at the outer bounds of patentability.
In reflecting on the two-limb NRDC test for ascertaining whether subject matter falls within the scope of patentable subject matter, the plurality in D’Arcy was at pains to reinforce the importance of applying this test as a starting point.

The plurality pointed out that often the two-limb test will be sufficient, so that the central question that must be asked in assessing patentability, is whether the subject matter establishes an “artificially created state of affairs with economic utility”. But where the claims encompass novel subject matter, a range of other factors must be applied. A number of these factors appear to put the application of this test directly within the PC’s remit. Most notably, a factor the plurality considered to be important was whether granting patentability might have a potentially chilling effect on innovation, by opening a new, broad class of patentable subject matter. Additionally, permitting patentability when that would result in other innovators infringing unknowingly was of particular concern to the plurality.

Although some have claimed the High Court has laid down a new approach to determining patentability in cases involving novel subject matter, “transformed” the law as it has stood since NRDC, the reality is that the High Court has done little more than confirm the correctness of the NRDC approach. Rather than constituting a radical departure from NRDC, the plurality’s judgment marks a shift back to the intent of the High Court in NRDC, which never claimed to be formulating a prescriptive test for manner of manufacture: quite the contrary in fact. Yet the two-limbed test extracted from NRDC (and cemented in CCOM Pty Ltd v Jiejing Pty Ltd has, over time, become the rigidly applied test for manner of manufacture, which is bound to create difficulties in its application to new technologies. Consequently, the policy factors enumerated by the High Court for use in situations at the boundaries of patentability are not altogether unfamiliar, and effectively all the plurality has done is sanction their use in these circumstances. These factors have undoubtedly been taken into account in previous decisions where patentability was at issue.

Thus far, however, there has been a marked judicial reluctance to engage with the D’Arcy factorial approach. The D’Arcy factors have not yet been explicitly applied by a court, despite several opportunities to do so. This arguably reflects the fact that the D’Arcy decision has introduced uncertainty into the subject matter requirement, which may stem from judicial apprehension with regard to the use of policy analysis in decisions on patentability. In this respect, the PC would have been well placed to provide useful guidance on the application of policy factors into decision-making on what constitutes patentable subject matter. To this end, the PC’s Terms of Reference explicitly included a mandate to:

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99 National Research Development Corp v Commissioner of Patents (1959) 102 CLR 252.
105 Ann Monotti, “The Scope of ‘Manner of Manufacture’ under the Patents Act 1990 (Cth) after Grant v Commissioner of Patents” (2006) 34 Federal Law Review 461, 478–479. For example, Monotti argued the NRDC test provided sufficient flexibility for subsequent courts to remove or redefine the requirement for physicality laid down in Grant v Commissioner of Patents (2006) 154 FCR 62; [2006] FCAFC 120, noting that the NRDC test was intended to be adaptable rather than prescriptive.
1. Examine the effect of the scope and duration of protection afforded by Australia’s intellectual property system on:
   (a) research and innovation, including freedom to build on existing innovation.

Uncertainty as to when and how the *D’Arcy* factors should be applied may lead to courts too readily finding that inventions do not fall within the purview of patentable subject matter, which would run counter to this Term of Reference. A failure on the part of the PC to clarify the import of the *D’Arcy* decision is an omission in terms of “ensuring the intellectual property system will be efficient, effective and robust through time, in light of economic and technological changes”.110 It also throws into question the PC’s assertion that:

[While the system captures [socially valuable] innovations, there is evidence that it also admits a multitude of patents that are against the public interest; the system captures not just the ‘innovative wheat’, but also the “low-quality chaff”.]111

**B. Other Patent Criteria**

The PC’s answer to this problem rested with its proposed changes to the inventive step requirement. This focus on inventive step was explained earlier in this article and stemmed primarily from the extensive reform agenda brought about by the Raising the Bar legislation. But the PC failed to address issues arising from the application of the other patent criteria, despite the fact that Raising the Bar did not implement completely comprehensive reforms and that there are many issues that remain live post-Raising the Bar. One issue dealt with by the PC was that of construction of patent claims, in response to a concern that there is an information asymmetry between patent applicants and patent examiners. This leads to poorer quality examination.112

The PC recommended that the Patent Office reform its filing procedures to require applicants to identify the technical features of the invention in the claims.113 To some extent, this recommendation seems superfluous to what is already required by s 40 of the *Patents Act 1990* (Cth), in that applicants must disclose the invention, be clear and succinct, and include claims supported by matter disclosed in the specification.

**1. Utility – Promise of the Patent?**

In any case, an issue that has the potential to be more troublesome relates to the utility criterion114 and associated specification requirements contained in s 40.115 Section 18(1)(a) of the *Patents Act 1990* (Cth) requires that an invention be “useful”. There is also an implicit utility requirement within the manner of manufacture criterion, as enunciated in the *NRDC* test. The utility requirement does not require that an invention be useful in the sense that it is worthwhile or commercially useful, only that if a particular result is claimed, it must be achieved by the invention. Utility must be demonstrated in respect of all promises made in a patent specification.116 This means that if a specification makes multiple promises of utility, they must all be achieved by the patent claims. Claims that do not fulfil each aspect of the stated advantages listed in the patent specification will fail, as reiterated in the recent case of *Ronneby Road Pty Ltd v ESCO Corp*.117 The promise of the invention (wear parts for excavating equipment) in that case

110 PC Report, n 3, Terms of Reference 3(f), (v).
111 PC Report, n 3, 201.
114 *Patents Act 1990* (Cth) ss 18(1)(a), 18(1A)(c).
115 *Patents Act 1990* (Cth) s 40(2).
117 Ronneby Road Pty Ltd v ESCO Corp (2016) 118 IPR 526; [2016] FCA 588.
were stated to be “enhanced stability, strength, durability, penetration, safety and ease of replacement”.\footnote{118 Ronneby Road Pty Ltd v ESCO Corp (2016) 118 IPR 526; [2016] FCA 588, [4], [6] (Jessup J).} While each of the patent claims (all 26 of them) delivered on at least two of these stated promises, none achieved all six. Hence the patent failed on the basis that it lacked utility.\footnote{119 Ronneby Road Pty Ltd v ESCO Corp (2016) 118 IPR 526; [2016] FCA 588, [78].}

The implications for would-be patentees of innovative technologies where anticipated benefits are speculative at best are significant, and highlight the caution that must be exercised in drafting claims in these technology areas. Perhaps more concerning is the fact that the same stringent requirement relating to multiple claims does not apply under US law,\footnote{120 E Richard Gold and Michael Shortt, “The Promise of the Patent in Canada and around the World” (2014) 30 Canadian Intellectual Property Review 35.} so that patent attorneys must be sure to be across the Australian requirements. Of major significance is the fact that the “multiple promises” requirement emanates from English law, where it exists under the guise of the false promise doctrine. The same doctrine has, until recently, also been applicable under Canadian law.

The Canadian Promise Doctrine was recently abolished in AstraZeneca Canada Inc v Apotex Inc.\footnote{121 AstraZeneca Canada Inc v Apotex Inc (2017) SCC 36.} The Canadian Supreme Court considered the Promise Doctrine to be inimical to the patent bargain, in that its effect might be to discourage full disclosure by patent applicants for fear that even one “promised” use is not “sufficiently demonstrated or soundly predicted by the filing date”.\footnote{122 AstraZeneca Canada Inc v Apotex Inc (2017) SCC 36, [50].} It also holds patent applicants to a higher standard than that laid down in patent legislation.\footnote{123 Norman Siebrasse, “The False Doctrine of False Promise” (2013) 29 Canadian Intellectual Property Review 3; Mark Summerfield, “Canada Rightly Ditches the ‘Promise Doctrine’ for Utility, Australia Should Follow Suit”, Patentology, 9 July 2017 <http://blog.patentology.com.au/2017/07/canada-rightly-ditches-promise-doctrine.html>.} On the other hand, it could impact negatively on follow on innovators if it opens the door to broad, speculative claims. Some have argued that the promise of the patent fulfils and important role in terms of ensuring patentees making good on their disclosed promises and in enforcing discipline on those drafting claims.\footnote{124 Siebrasse, n 123, Pt 4.2.} Further, the doctrine may discourage “evergreening” of pharmaceutical patents by ensuring that compounds selected and claimed to produce a “substantial advantage” will deliver the stated advantage as promised. Quite how abolition of the doctrine will play out is a matter for speculation. It is not yet clear how the balance will swing in Canada.

Given these international developments, the lack of consideration of this issue by Australian higher courts, and the fact that there has been no analysis on a policy level of utility or the multiple promise requirement, reassessment of the requirement and its role in evaluating utility is timely.\footnote{125 Richard Gold and Shortt, n 120, 38–42.} Notwithstanding, it was not an issue with which the PC chose to engage. This was likely because it was simply not on the PC’s radar, given the fact that the Canadian Supreme Court handed down its judgment so recently.\footnote{126 Summerfield, n 123.} Higher level court rulings do have a tendency to galvanise commentators and policymakers. It is difficult to see, however, how we can expect consideration of this issue any time soon given that further policy analysis of patent law as a whole is likely to be some time away. Whether or not we see any development of the law as stated in Ronneby Road in the near term is questionable. This will invariably impact on the way in which patent claims are drafted for examination in Australia.

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2. The Rise of Trade Secrecy

The PC also neglected to consider an entire IP regime, one that has an increasingly important role to play in the innovation landscape. There is a trend on the part of both industry and academic innovators to rely more on trade secrets than patents to protect their innovations. Empirical evidence on this issue is difficult to obtain, but in July 2017, the European IP Observatory published a study considering the impacts of protecting innovation through the use of patents and trade secrecy. This report was based on the Eurostat Community Innovation Survey 2012, the data set being representative firm-level data covering almost 200,000 firms operating across manufacturing and service industries in Europe. As such, the survey cohort encompassed many participants in high-technology areas. The report was premised on the notion that “trade secrets are poorly studied and their relationship with patents is often misinterpreted”.

The study found that innovating firms often use both patents and trade secrets, particularly those that engage in goods innovation. Although it was not possible to collect data at the level of individual innovation, it evidenced complementarity at the firm level. That is, firms were likely to use a mixture of patents and trade secrets possibly in relation to the same innovations. Critically, the study found that for firms engaged in process innovation, the use of trade secrets is more extensive than the use of patents.

The role of trade secrets and patents as complementary forms of protection is only just beginning to be understood, and there is now increasing recognition of the role of patents as “data-generators” or “data aggregators”. Data generated as a result of patents over genetic diagnostic testing, or the use of patented search engines, goes beyond the data generated by the normal “ordinary use” of an invention and enables patent holders to leverage big data sets by virtue of their protection under the law of trade secrecy. Myriad’s database of BRCA sequence information is a case in point, it being a compilation of information that is unlikely to be replicable. In Australia, at least, it is unlikely that there is any legal means of gaining (or compelling) access to datasets such as that possessed by Myriad. Trade secrecy provides a robust form of protection for data generated during a period of market exclusivity permitted by a patent.

The trade secrecy regime has been the subject of an extensive reform agenda in Europe, the aim being to harmonise the laws relating to protection and enforcement across the European Union. In Australia, there has been very little attention paid to the operation of the law of trade secrecy, aside from a series of proposed provisions in the ill-fated TPP that would have seen the introduction of a stronger enforcement framework for trade secrecy.

130 European Observatory on Infringements of Intellectual Property Rights, n 129, 22.
131 European Observatory on Infringements of Intellectual Property Rights, n 129, 23, Table 2.
132 European Observatory on Infringements of Intellectual Property Rights, n 129, 8.
133 European Observatory on Infringements of Intellectual Property Rights, n 129, 53.
134 European Observatory on Infringements of Intellectual Property Rights, n 129, 48, 54.
135 European Observatory on Infringements of Intellectual Property Rights, n 129, 48, 54.
138 Simon and Sichelman, n 136, 379.
140 Trans-Pacific Partnership Agreement, signed 24 February 2016 (not yet in force) Art 18.78. This strengthened protection reflected that found in the Economic Espionage Act of 1996 (US), Pub L No 104–294, 110 Stat 3488, a US statute providing strong criminal safeguards against trade secrecy theft.
A major incentive to protect data through the trade secrecy regime lies in the fact that infringement of process patents is very difficult to monitor, particularly in a field such as biotechnology where reverse engineering is inherently feasible.141 Given the increasing importance of process patents in these fields (discussed above), the significant risk that increasing numbers of process patents will result in a greater propensity to protect through trade secrecy must be contemplated. In short, trade secrecy as an important corollary of patent protection is here to stay – there are a plethora of issues the PC might have considered, all of which fell squarely within its remit. Its failure to address this increasingly important regime was, in our view, a substantial oversight.

VI. CONCLUSION

Patent law development is rarely stagnant. Constant reflection on the effectiveness of patent law for the current technological environment is imperative. Australian policymakers undoubtedly face challenges in ensuring that the provision of incentives to innovators is adequately balanced with broader societal benefit, particularly during these times of rapid technological evolution. The pace at which innovation is progressing is staggering, and there are set to be relentless challenges to the effectiveness of the patent system in sifting through the invention inundation that is fast becoming a constant.

Within the bounds of Australia’s international treaty obligations, there is some scope to tweak the patentability criteria, assuming there is a problem with the current system. The PC’s recommendations were based on the assumption that there is a “patent problem”. The first issue with the PC Report is that it is not altogether clear on the evidence available that such a problem exists. While there may be technological areas that can be perceived to be prone to innovation blockages due to low-quality patents, there is limited evidence at this point that this is occurring in actuality.

Assuming the “patent problem” is taken as a given, there are a number of questions that might be asked about the PC’s focus. Given the all-encompassing nature of the PC’s Terms of Reference, the PC Report addressed issues that are at best indirectly relevant to innovation and development, and which are unlikely to have a dramatic impact on patent quality. Introducing an objects clause may send a symbolic message, but is unlikely to have any practical import. Likewise, amending the inventive step requirement is likely to be strongly supported but will in itself be insufficient to address the low-value patent problem, particularly in those technology areas viewed as being inherently problematic, such as those involving business methods and computer software. It is also unfortunate that the PC was overly ambitious in making overarching recommendations relating to pharmaceutical patents. A more nuanced approach may have seen its recommendations given more serious consideration by the Government in its response.

Given its focus on innovation and social welfare, many other pertinent issues that will impact directly on the patent system were ignored. In particular, the subject matter inquiry which has drawn recent attention with the High Court decision in the D’Arcy v Myriad Genetics Inc continues to pose many questions. The PC considered very few of these issues. The procedure for applying the D’Arcy factors remains oblique, which has resulted in them being deemed not applicable in subsequent cases. This in turn may impact directly on decisions as to what is patentable at the boundaries of patentability. Other implications flow from the PC’s failure to consider the subject matter inquiry, not least of which is the increasingly impact of method patents on innovation. This is a live issue that warrants far greater attention than it attracted.

Another issue the PC might have considered is the utility requirement in patent law. Given its relevance in the pharmaceutical context, it had direct relevance to issues the PC undertook to investigate. Finally, trade secrecy is an under-studied area of IP law that impacts strongly on the patent regime. It is seemingly inevitable that inventions involving methods will continue to increase in importance. Raising

understanding of the relationship between patents and trade secrets is thus imperative, but the PC failed to give trade secrecy any consideration at all. This is a significant omission.

Considering the broad remit of the PC, its recommendations were cautious and based squarely on an economic rather than a practical perspective. While this in itself is not surprising, the shortcomings of the report need to be acknowledged. More intractable questions need to be contemplated, such as how we might develop a more sustainable (and less piecemeal) approach to regulating patent law given that technological advances show no immediate signs of abating.