Response to
the Productivity Commission's Draft Report
on Intellectual Property Arrangements.

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The views presented in this submission are my own and should not be taken to represent the views of any institution with which I am affiliated.

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1. Framework

While the variety of forms of ingenuity and creativity considered in the report – and the various regulatory interventions designed to create specific legal privileges – are very different, the Commission's framework works well for each different type of market regulation.

Draft recommendation 2.1 **SUPPORT**
Policy should be based on robust evidence and have regard to the principles of effectiveness, efficiency, adaptability and accountability.

2. Patents

The Commission's report breaks new ground in producing an *evidence-based* analysis of the impact of patents on invention. As this policy area has, to date, been devoid of any evidence-based analysis, the Commission is to be commended for marshalling the large array of data that can be used to ensure that patent policy is well designed to achieve the objective of enhancing the net well-being of all Australians.

If the government adopts the Commission's key recommendations with respect to patent policy Australia will have a somewhat improved environment better encouraging invention, innovation and commercialisation. The Commission's recommendations do not, however, go far enough. This response not only comments on the draft findings and recommendations but also points to important areas not yet addressed by the Commission. A particular omission is the lack of analysis of the factors affecting overall balance, particularly the vey one-sided nature of incentives and penalties.

1.1 Patent policy objectives

Draft recommendation 6.2 **NEEDS MORE FOCUS**
Incorporate an objects clause into the *Patents Act 1990*.

The Commission recommends an objects clause describing:

> "the purposes of the legislation as being to enhance the wellbeing of Australians by providing patent protection to ***socially valuable innovations that would not have otherwise occurred*** and by promoting the dissemination of technology. In doing so, the patent system should balance the interests of patent applicants and patent owners, the users of technology — including follow–on innovators and researchers — and Australian society as a whole."

This lengthy statement distracts attention from the key objective – to encourage ***socially valuable innovations that would not have otherwise occurred.***

The draft report repeatedly emphasises the importance of granting patents only for induced inventions – inventions that would not take place absent patents – that are socially valuable. Only by striving to achieve this goal will the patent system be efficient and effective and conform to Article 5.1 of the Competition Principles Agreement.

While the report emphasises the importance of additionality, it does not directly point to the very low proportion of inventions induced by Australia's patent system. It is not credible that the small Australian market provides sufficient additional incentive to induce inventions from firms in the world's large markets. As around three-quarters of Australian patents are owned from entities from the USA, Japan, Germany, the UK and France (Moir, 2009: 191), the share of Australian patents that relate to additional (induced) inventions is small. My own estimates put this at between 4.9 and 6.4% of granted Australian patents might cover induced inventions

(Moir, 2013c: 27). This extremely low impact factor suggests the need for **very substantial** reform to make the patent system both effective and efficient.

Technological **invention**

One of the unspoken assumptions behind patent policy is that it is to encourage ***technological*** invention. This presumption is so basic that it has rarely been written down. Legal decisions over recent decades suggest that if this basic presumption had been written down it would have saved everyone a lot of wasted time and effort and assisted in ensuring soundly based decisions in respect of individual legal disputes.

The limitation to technological innovation was previously achieved through the "new manner of manufacture" definition, but the wide interpretation of the High Court's 1959 *NRDC* decision has substantially undermined this decision. While such interpretations of the *NRDC* decision are often criticised within the legal community, it remains the fact that the current definition of a patentable invention in Australia is simply something artificial from which an economic return can be made. This radically extends the boundaries of the patent system beyond technology. Yet it is in technological areas that substantial investments may be required to bring an invention to a commercial stage. It is such high up-front investment that is the reason for intervening in the market and granting a monopoly.

I strongly recommend adding the word technological to the objects statement.

The patent *quid pro quo*.

Society benefits from encouraging socially valuable induced inventions ***because of the spillover benefits of such inventions***. These can take the form of higher net consumer surplus or new knowledge that can be used for yet further technological developments. If these spillover benefits outweigh the static efficiency losses caused by patents, then society is better off with a patent system, achieving what are commonly known as dynamic efficiency gains.

It goes without saying that it is important for any new technological knowledge embedded in a patent to flow through the community. But the dissemination of patented knowledge is a second-order objective. While some have argued that, without patents, new technological knowledge will be kept secret, this is generally not possible. If it were, there would be a clear preference to use secrecy as there is no time limit. There is little evidence of this.

During the 12 years I have been studying patent policy, I have been amazed to find that most legally trained actors in the patent arena believe that the *quid pro quo* for society from the patent system is the simple publication of the patent specification. This is wrong – indeed the misleading nature of this perspective has been one factor encouraging the fall in the inventiveness requirement. Presuming that dissemination is the *quid pro quo* draws attention away from the key requirements of **additionality** and **socially valuable** and thus underplays the importance of the inventive step as a gatekeeper for effective patent policy. To include dissemination conditions in the objects clause will lead to a continuation of the problems that derive from this erroneous perspective.

The objects clause in the Patents Act should simply focus on the key economic objective of technological invention and should read:

> "the purpose of the legislation is to provide patent protection to socially valuable technological innovations that would not have otherwise occurred."

Such a simple clear objective statement will focus the minds of judges on ensuring that patents are only granted where they are merited.

Certainly dissemination is important but it is a second-order issue. Once a patent is granted – granted because it is for additional socially valuable technology – **then** a condition imposed

on the patent-holder is publication of the specification. This might create a channel through which some of the spillover benefits will flow.[1] Originally this channel was training two generations of skilled craftsmen (14 years). As the industrial revolution progressed this channel was re-framed as publication of the patent specification (Walterscheid, 1995).

During the so-called Raising the Bar reforms, there were improvements to the disclosure requirements – a clear and full description of the patented invention.[2] Any additional need for statutory specification of dissemination belongs in s.40(2) of the Patents Act, not in the objects clause. A dissemination objective could be added to s.40(2).

It would also be useful to clarify, in the Explanatory Memorandum, that the grant condition of publication is a channel for the flow of technological information not the reason for the grant. The reason for the grant is induced technological invention with net spillover benefits.

The other aspects of the Commission's proposed objects clause – overall net welfare impact and balancing competing interests – also more properly belong in the Explanatory Memorandum.

The recommendation that the Act also be amended to instruct the Commissioner, or her delegates, to have regard to the object of the Act in making decisions under the Act is sensible and I support it.

1.2 The inventiveness requirement

The single most important reform needed in patent policy is to raise the inventiveness requirement from "a scintilla". After considering the 2011 "Raising the Bar" reforms, the Commission concluded that:

> "While these reforms raised the overall inventive step threshold, they did not address the minimum quantum of advance over [existing knowledge] required to meet the obviousness test. Yet in many cases patentability will turn on this quantum of advance. Indeed, this element of the inventive step is central to ensuring that only socially valuable inventions — which must entail some advance in human knowledge — receive patent protection." (182)

The Commission went on to observe that "[t]he case for raising the obviousness threshold for meeting the inventive step is compelling" (183). It is surprising then that the Commission merely concluded that "the inventive step should at least be set at the highest level applied in larger markets for technology" (184). There is a large academic literature drawing attention to the low inventiveness requirement in the USA and the negative outcomes from this.[3] Nor does the European standard impress as being one that optimises balance in the patent system.

It has long been clear that a technology-importing nation will benefit more from a higher than a lower inventive step (Penrose, 1951). A high inventive step will not affect the patenting of genuine inventions – inventions such as those by the CSL, Cochlear, Resmed and other globally competitive innovative firms. These and other firms are developing genuinely innovative new products.

Draft recommendation 6.1 **SUPPORT BUT STRENGTHEN**

Increase the height of the inventive step by amending ss. 7(2) and 7(3) of the *Patents Act 1990* (Cth) 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.

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[1] Though this is arguable. See my earlier submission (# 130) for the evidence that patent specifications are hard to search and rarely used as a source of leading technological information.

[2] See pp46-48 of the Explanatory Memorandum.

[3] See, for example, Dreyfuss, 1989; Harris, 1989; Jaffe, 2000; Lunney, 2001, 2004; Quillen Jr., 2006.

This change simplifies the inventiveness requirement by removing much old-fashioned detailed from the article *and by removing the presumption of inventiveness*. I support both these changes.

I do, however strongly recommend replacing the phrase "the prior art base" with the phrase "the state of existing knowledge" (see Summerfield, 2015a). The continual use of extremely dated terminology in the patent system encourages dysfunctional decisions. Were technology referred to as technology in the patent world, then it seems unlikely that patenting business methods would have been so easily possible. It is credible to see business processes as an art, but not as a technology. Further, referring to existing knowledge rather than to "prior art" makes excisions from the current state of knowledge both more obvious and less credible, thus assisting in achieving a sounder policy basis.[4]

If the proposed Trans-Pacific Partnership Agreement (TPPA) fails to be ratified – as suggested by policy statements from leading contenders in the 2016 Presidential race – then Australia would have the opportunity to improve on this proposed wording.[5] In this case the inventiveness criterion could be phrased positively rather than negatively – for example:

> "an invention is taken to involve an inventive step if, having regard to the state of existing knowledge, it provides a significant advance over what is known or used."

This position is compliant with TRIPS and with the AUSFTA, though not with the TPPA.

I recommend that the Commission develop such an alternative wording, given the likelihood that the TPPA may not be ratified.

The Commission also recommends two specific sets of words for the Explanatory Memorandum. The first – that the intent of this change is to better target socially valuable inventions – is unexceptionable. It will, of course, need to be explained that this refers to socially valuable ***spillovers***, not just inventions with high private returns which will occur absent the patent incentive. The second, however, falls into the trap of being over-specific.[6]

As noted in my original submission and demonstrated in my empirical analyses of business method and evergreening patents (Moir, 2013b; Moir, 2013c; Moir, forthcoming),[7] there are a multitude of doctrinal rules which have led to the current abysmally low inventive step (see Box 1). *To focus on just the one doctrine mentioned in this recommendation will not raise the standard in Australia to that used in Europe*, let alone to that which would be optimal for Australia.

It is essential that other doctrines, *particularly the suggestions test for combinations*, the requirement that the relevant skilled person be unimaginative, and the failure to apply analogous use doctrines to processes are also overturned. This can best be done by ensuring clear advice to judges and those administering the Patents Act, that s. 7 is designed to limit patent grant to "things that are a significant advance over what was known and what was available to the public at the priority date of the patent."[8] This is the standard that was advised

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[4] Indeed the patent world is one of the few where words often do not take their ordinary meaning, contrary to normal legal practice. In *Welcome Real-Time SA v Catuity Inc* [2001] FCA 445, Justice Heerey discounted expert evidence on the grounds that the witnesses did not understand the meaning of the word obvious as used in patent law!

[5] The conditions in the TPPA on ratification mean that if it is not ratified either by the USA or Japan, then it will not take effect.

[6] "the test should be applied by asking whether a course of action required to arrive at the invention or solution to the problem would have been obvious for a person skilled in the art to try with a reasonable expectation of success."

[7] A revised version of Attachment C to my submission is now forthcoming in the Australian Economic Review.

[8] Explanatory Memorandum, Intellectual Property Laws Amendment (Raising the Bar) Bill 2011: 42. The full text is "A key principle of the patent system is that *protection is only given* for things that are *a significant advance over what was known and what was available to the public* at the priority date of the patent. A granted

to Parliament when it considered the Raising the Bar Bill in 2011. The rationale for this high standard in unexceptionable – a granted patent can be a powerful exclusive right.

Giving a narrow specific doctrine as the new standard for inventiveness falls into the trap of the current system. Instead of a modern regulatory approach focusing on the desired outcome, it specifies a detailed approach which will fail to be adaptable into the future.

Box 1 Procedures and doctrinal rules creating a low inventiveness requirement

- Reverse onus of proof
- Limitations on existing knowledge used in testing novelty and inventiveness
- Suggestions test for combinations (rather than synergy test)
- Non-use of combinations tests for processes
- Failure to use the analogous use doctrine for processes
- Qualities of the skilled person, especially ordinary skills and lack of imagination
- Narrowly defined prior art, so well known "inventions" are defined as inventive
- Continual amendment of specifications
- Decision-making rules
- No requirement for examiners to state reasons for grant
- No penalties for gaming the system

Source: Based on detailed analysis of granted business method patents (Moir, 2013c) and confirmed by analysis of evergreening pharmaceutical patents (Moir and Palombi, 2013; Moir, forthcoming).

There are two issues here. The one the Commission raises in the draft report is a possible risk that if the inventive step is raised to an optimal level Australians may be denied access to certain new goods supported by such patents. The other is the old-fashioned over-prescriptive regulatory nature of the proposed wording for the Explanatory Memorandum.

Today's economy and society is highly inventive – competition ensures a continuous stream of new products and services. A high standard of inventiveness is therefore essential if the system is to reward only *induced* inventions.

Risks from a high inventive step over-emphasised

In its Issues Paper (pp13-14), the Commission recognised the need to assess the relative risks (and net benefits) of over- and under-protecting IP. It also recognised the long legacy of IPR rules. Given that only a very small proportion of Australian patents are for inventions induced by the patent system (well under 10%), and the high cost of evergreening patents, the evidence clearly points to lower inventiveness standards being a riskier policy for position for Australia than higher inventiveness standards. Further, the position of the international actors who drive patent policy in trade treaties calls for increasingly lower standards of inventiveness. Reforming patent policy now to institute standards as near to optimal as

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patent can be a powerful exclusive right: as such, it is appropriate that the inventive step requirement be sufficiently stringent" (emphasis added).

possible is a more flexible position than making the meagre improvement recommended by the Commission.

The kinds of "inventions" supported by an inventiveness requirement that is below optimum but higher than "obvious for a person skilled in the art to try with a reasonable expectation of success" are likely to be far from leading edge technology. As such, there would be no disadvantage to Australian consumers from their absence from the market. Should there be a demand for such products and this was not being supplied from overseas, this would create new opportunities for Australian producers. To the extent that such opportunities emerge for domestic business this would be a real win for Australia's innovation economy – many innovations which do not merit patents still contribute to the creation of an innovation culture.

In respect of evergreening combination patents – such as extended release venlafaxine and enteric coated omeprazole – it is highly unlikely that the producers would refrain from selling these products. These low-quality additional patents are an essential part of the process of commercialisation of the original API medicine – a lengthy process that led directly to a four-year extension in the duration of standard patents plus possible five-year patent term extensions (Moir, forthcoming). Refraining from marketing these versions of the medicines would reduce the income the originator companies would receive from their much larger investment in the API development. Such an action would be unlikely, except as a political (bullying) tactic. As was the case in South Africa in 1999, it is probable that public opinion would quickly lead to a reversal of this position. Australia has a generics industry that is better developed than its originator industry. Generic firms would be able to fill any void left by strategic behaviour by global pharmaceutical companies.

Detailed over-prescription

The Commission recommends specifying a narrow legalistic approach in discussing the new height of the required inventive step in the Explanatory Memorandum, adopting a standard from the European Patent Office (EPO). The Commission notes that this may not be the optimum standard, and that there may be benefits to raising the threshold further. But in order to achieve an appropriate inventiveness standard the Commission recommends international collaboration.

Peter Drahos has published meticulous research demonstrating that patent offices around the world are strongly biased towards the interests of those seeking patent privileges (Drahos, 2010). It is the practices of these offices – together with an unwillingness to draw poor legal decisions to the attention of parliamentarians so ensuring statutory correction of inappropriate decisions – which has led to the continual decline in what society gets back for increasingly strong patent privileges. The EPO is not excluded from these practices.

The role of global pharmaceutical companies in defining and changing patent policy is well documented,[9] and these companies appear to determine national patent policies in major markets (USA, European Union (EU), Japan). Suggesting that these major trading blocks will be willing to change their agenda on a low inventive step is totally unrealistic. Just as there is a strong argument for unilateral tariff reform, so there is a strong argument for unilaterally introducing a high inventive step into the patent system. After all, patents operate very like tariffs, creating far higher costs for consumers than the benefits they confer on patent owners.[10]

The High Court case that is widely seen as requiring a very low standard to Australia's inventiveness test is instructive. In particular I draw the Commission's attention to the dissenting opinions by Justices McHugh and Kirby. These, particularly the dissent by Justice

[9] In respect of TRIPS see Drahos and Braithwaite, 2002; Sell, 2003. In respect of domestic US patent policy see Kingston, 2004. For the TPPA see Gleeson et al., 2016.

[10] For estimates of the welfare losses from delayed generic entry to the pharmaceutical market see Branstetter et al., 2011; Chaudhuri et al., 2006; Dutta, 2011.

Kirby, draw attention to the issue of whether specific “doctrines” are in fact policy rules or simple explanations of reasoning appropriate in specific cases. If Justice Kirby's interpretation is correct, this suggests that a long list of policy rules/doctrines need to be removed from the Patent Examiners' Manual. If Kirby is right, the “obvious for a person skilled in the art to try with a reasonable expectation of success” standard is simply a line of reasoning. Such an interpretation is consistent with IP Australia's reasoning in deciding not to change the inventiveness standard as part of the "Raising the Bar" reforms. However this position would have required IP Australia to remove all such "doctrines" from the Examiners' Manual. This has not been done.

So it seems that in practice, if not in theory, these lines of reasoning are treated as policy/legal doctrines.

Relevant here is the reasoning put forward in the *Grant* case by Branson J, where she found that "an invention should only enjoy the protection of a patent if the social cost of the resulting restrictions upon the use of the invention is counterbalanced by resulting social benefits".[11] From an economic policy perspective, this is one of the most sensible statements from a Federal Court judge. The Full Federal Court however appeared not to understand this principle, confounding parliament's decision to operate a patent system with the issue of whether an individual patent provided a net benefit.[12] How can the overall system deliver a net benefit to Australia if there is no attempt is to ensure that this principle applies to each individual grant?

A broader specification in the Explanatory Memorandum – an explanation focusing on the desired outcome from the patent intervention and a warning not to grant patents too lightly – would better ensure that the Patents Act would be fit for purpose in the current highly inventive and innovative age.

The EPO grants patents for semantic rather than technological invention, as demonstrated by "Swiss patent claims" – claims for second medical uses at a time when these were specifically declared unpatentable by the European Patent Convention (Thambisetty, 2009). In my own research dataset I have three cases where applications were deemed uninventive by the EPO – *until words were moved* between clauses in the patent claims (Moir, 2013a). This is hardly a standard to aspire to in any country, let alone one where innovation is a major plank in government policy as a priority for future economic prosperity.

Leaving the inventive step at the "obvious for a person skilled in the art to try with a reasonable expectation of success" standard will continue to allow the grant of evergreening pharmaceutical patents, whose cost to Australian taxpayers can be in the billions (Moir, forthcoming). At a minimum, standards for combinations and patentability for methods of medical treatment must also be addressed.

As the Commission notes, Australia's inventive firms patent extensively overseas. Given the small relative size of Australia's market (2% of the OECD total), firms such as ResMed, Cochlear, Aristocrat and CSL regularly patent overseas, particularly in the US market (Moir, 2011). These firms produce genuine high-quality inventions which would easily meet a "significant advance over what is known or used" standard. These firms are – indeed need to be – highly conversant both with domestic and key overseas patent law. Having a higher patenting standard in Australia than overseas will in no way penalise Australia's genuinely

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[11] *Grant v Commissioner of Patents* (2005) FCA 1100: at 20. This view derives from Section 6 of the *Statute of Monopolies* to define invention. S.6 includes various provisos including not being contrary to law, not hurting trade, and not being generally inconvenient.

[12] "We do not find it necessary to discuss the requisite economic benefits of the alleged invention. … Nor is the Court in a position to determine the balance between social cost and public benefit (*Grant v Commissioner of Patents* (2006) FCAFC 120: at 43-45).

inventive firms. And it will significantly benefit Australian taxpayers, consumers and follow-on innovators.

In reforming the inventiveness threshold, the step must be set at a suitably high standard – a significant advance over what is known. This will remove from the system a very large number of patent grants for "inventions" that in fact contribute little if any new knowledge. This will remove potential obstacles to innovating Australian firms. Indeed if a consequence is that products supported by these low quality patents are no longer imported into Australia, then new business opportunities will be created for Australian business.

The Commission has recommended abolishing the innovation patent system. I refer to this here as setting the inventive step for standard patents an appropriately high standard to prevent inappropriate use of this powerful exclusionary right will create new space for innovative Australian firms, offsetting any losses from abolition of the innovation patent option. This leaves patent attorneys as the only losers from such a policy change.

Draft recommendation 7.1 **STRONGLY SUPPORT**
Abolish the innovation patent system.

1.3 Patentable inventions

Draft recommendation 8.1 **SUPPORT; NEEDS TO GO FURTHER**
s.18 of the *Patents Act 1990* (Cth) should be amended to explicitly *exclude* business methods and software from being patentable subject matter.

If the objects clause in an amended Patents Act refers to technological inventions this will assist in ensuring that these completely unnecessary patents are not granted.

But this is not the only area where courts have broadened the subject matter reach of the patent system without any assessment of evidence. Other important extensions are methods of medical treatment and aspects of discoveries.

In effect, when the Harradine amendment led to the introduction of s.18(2), the Federal Court interpreted this as meaning that parliament had decided to remove all tradition exemptions from patentable subject matter.[13] In fact there is no evidence that parliament intended this at all. However the Australian Patent Office did not alert the parliamentary draftsman to the need to add these traditional exemptions to the newly inserted exemption. This oversight has not yet been corrected.

Australia is out of line with most other countries in allowing methods of medical treatment to be patented (Summerfield, 2015b). Providing patents for methods of medical treatment has traditionally been seen as impeding the ability of medical practitioners to provide treatment, and there are cogent reasons for excluding medical treatment methods from patentability (Frankel, 2008). The exclusion has been codified in New Zealand's new Patents Act. Such an exclusion is permitted both by TRIPS (Article 27(3)(a)) and by AUSFTA (Article 17.9.2(b)).

A particular concern here is with respect to not just double-dipping but triple-dipping by the pharmaceutical industry. An original patent on a new Active Pharmaceutical Ingredient (API) provides privileges which prevent **all** commercial uses of the compound over the 20-25 year patent term. There is little argument about this, though as noted in my earlier submission it would be more efficient to provide a simple subsidy rather than to grant a pharmaceutical product patent.[14]

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[13] *Anaesthetic Supplies Pty Ltd v Rescare Ltd* (Rescare) [1994] 50 FCR 1. Methods of medical treatment were not considered by the High Court until *Apotex Pty Ltd v Sanofi-Aventis Australia Pty Ltd* [2013] HCA 50.

[14] p. 37. Briefly, three recent studies demonstrate that, in respect of pharmaceutical product patents, the gains to producers are only 12-15% of the losses to consumers (Branstetter et al., 2011; Chaudhuri et al., 2006; Dutta,

The insertion of the requirement that patents be granted for *new uses of a known product* in AUSFTA (Article 17.9.1) appears to allow a further patent on the API, albeit with narrower scope – limited to a specific new use of the compound. The TPPA will introduce a requirement for three years of data protection where additional clinical data are required for marketing approval of use of a medicine for a new indication (Article 18.50.2(a)). Any costs associated with the marketing of a known drug for a new indication relate strictly to safety and efficacy data, required for regulatory purposes, some of which will already have emerged from Phase IV data on the API. Providing both a second (narrower) patent and a three year data exclusivity privilege effectively provides for a second and third set of monopoly privileges for the API.

This excessive restriction of competition could be handled simply by returning the traditional exclusion from patentability for methods of medical treatment. Such an exclusion would in no way contravene existing or proposed treaty obligations. Originator companies would have a guaranteed period of exactly three years of market exclusivity[15] to gain a return on the costs of the new clinical trials. Generic companies could gear up for entry on day one after the data exclusivity period ended.

Australia is significantly out of line with global standards in providing patents for methods of medical treatment.

As regards incentives, three years of market exclusivity provided by the TPPA data protection provisions seems more than adequate to ensure the appropriate regulatory data are provided. If this is inadequate in particular cases, there is no reason why a company cannot make a special case, based on data as to costs and financial returns. The Pharmaceutical Patent Review report cogently argued that special cases should be dealt with through special treatment rather than through the blunt instrument of patent policy (Harris et al., 2013).

The sorry story of granting patents for genetic discoveries has been told elsewhere.[16] The initial decision to grant a patent over an "isolated and purified" gene sequence was made by a Deputy Commissioner of Patents. Only in 2015 did the High Court consider the matter. It ruled that patenting genes was a policy issue and as such a matter for government not the courts.[17] This decision has been very narrowly interpreted by the Patent Office (Summerfield, 2015c).

This inquiry provides the opportunity for an evidence-based consideration of patentable subject matter. At a minimum the traditional exclusions, inadvertently lost because of Patent Office inattention during the passage of the Patents Bill 1990, should be re-instated. Given recent court decisions the only way to return these traditional exclusions is by specifically listing them.

Subject matter specifically excluded from patentability should be:

- discoveries (things identical to things found in nature), whether purified or not;
- methods of medical treatment;
- algorithms and mathematics generally, including all software; and
- methods of doing business, including schemes and arrangements.

2011). It would therefore be far more efficient to provide pharmaceutical companies with a direct subsidy than to grant them product patents.

[15] Provided data protection is changed to allow TGA processing during the protection period. Otherwise this period of market exclusivity will be longer.

[16] See Palombi, 2009, the Senate Community Affairs References Committee's report on gene patents (*http://www.aph.gov.au/Parliamentary_Business/Committees/Senate/Community_Affairs/Completed_inquiries/2010-13/genepatents43/report/index*) and the debate on the private member's bill on gene patents.

[17] *D'Arcy v Myriad Genetics Inc* [2015] HCA 35 at 94.

The Commission asks whether a distinction should be drawn between software per se and embedded software. The European Patent Convention shows the difficulties created because of the limitation of the software exclusion to software per se. Tens of thousands of software patents have been granted (Miceli, 2005). Work by Drahos (2010) and Quillen (2006) demonstrates that patent offices tend to be much more inclined to grant than reject a patent application. Given this tendency an absolute prohibition on patents for software would provide a better net welfare outcome.

1.4 Reform of patent term extensions

Draft recommendation 9.1 **SUPPORT, GO FURTHER**

Reform extensions of patent term for pharmaceuticals such that they are calculated based only on the time taken for regulatory approval by the Therapeutic Goods Administration over and above one year (9.1)

Draft recommendation 9.2 **SUPPORT, SHOULD GO FURTHER**

Tailor the term extension system to explicitly allow manufacture for export in the extension period (9.2)

The World Trade Organization has heard a dispute that bears directly on this issue.[18] In this dispute the EU claimed that Canada's policy of allowing manufacturing and stockpiling of pharmaceutical products without the consent of the patent holder during the six months immediately prior to the expiration of the 20-year patent term contravened the TRIPS Agreement. The dispute resolution panel's decision hinged on whether the Canadian regulations conformed to the "limited exceptions" allowed by Article 30. "The Panel agreed with the EC interpretation that "limited" is to be measured by the extent to which the exclusive rights of the patent owner have been curtailed."[19] In considering the curtailment of patent rights, the panel took the view that the broad patent privileges granted in Article 28, particularly the rights of "making" and "using", was an affirmation of the intent to extend patent monopolies beyond the 20 year term.[20]

Many would dispute this conclusion.

A single decision by a panel that is not a properly constituted court should not set international norms.

The next thing to note about term extensions is that the cause and effect are mis-aligned. It is not Australian taxpayers who are responsible for any delay in marketing approval processes. Yet it is taxpayers and health consumers who pay the price of any such delay. It would be far more efficient to simply provide a cash offset, rather than a patent term extension. This far more proportionate penalty is, unfortunately, prevented by AUSFTA Article 17.9.8(b). Australia should attempt to re-negotiate this provision with the USA. In the meantime further reforms to term extensions are needed. Recommendation 9.1 should be strengthened to include over-ruling the judicial extensions to eligibility for term extensions. Further, term extensions should be limited to the patent covering the original API.

Given the removal of the local working safeguard from TRIPS, privileges that go beyond the right to prevent sale in the domestic market are excessive. Patent policy, by its nature, is domestic policy. The incentive provided is the right to charge high prices during the patent period. It is unreasonable and unjustifiable to then extend this patent term beyond the already excessive 20 years by additional rights that prevent competitors from gearing up to enter the market the day after the patent expires. This issue relates to all technology fields. The

[18] WT/DS114/R of 17 March 2000 Canada – patent protection of pharmaceutical products.
[19] Ibid, para 7.31.
[20] Ibid, para 7.35.

Commission has suggested that Australia should develop a model agreement for the various IPR fields. With respect to patent policy a high priority is to re-negotiate Article 28, to limit the privilege to the right of sale into the market where the patent is valid. At a minimum it should be clearly specified that actions to allow market entry on day one after patent expiry are TRIPS-compliant.

With this in mind recommendation 9.2 should go further. The tailored term extension system should be limited to preventing the right of sale in the domestic market. This right should not extend to the right to prevent parallel importation. Such a provision would not only allow Australian companies to manufacture for export. It would also allow generic companies to gear up to enter the Australian market very quickly after patent expiry.

1.5 Data protection

Draft recommendation 9.3 **STRONGLY SUPPORT**

There should be no extension of the period of data protection, including that applicable to biologics. Further, in the context of international negotiations, the Australian Government should work with other nations towards a system of eventual publication of clinical trial data in exchange for statutory data protection.

This is a priority area.

It is hard to see any justification for treating clinical trial data as confidential – apart that is from normal research protocols to protect individual privacy. Indeed the whole system of clinical trials needs urgent improvement to ensure that ***all*** clinical trial data are made available both to regulatory authorities and to all researchers. The Commission finds no evidence that patents are not providing the required incentives for pharmaceutical R&D and notes various drawbacks in data protection systems.

Claims that these data are commercial in confidence do not hold water. They are produced to meet public regulatory needs and firms undertaking the trials are well compensated for the cost through strong patent privileges. Indeed it is arguable whether data protection is also needed to create adequate incentives for the development of new medicines.

Currently the European Medicines Agency is progressing a staged implementation of improved access to clinical trial data, though commercial interests appear to have ensured that access is limited to read on screen only.[21] While unilateral action on making these data public does not appear possible at present, Australia should push, in international fora, for maximum access, subject only to non-disclosure of patient information. Australia should take a principled approach that these data are public not private data.

The current system of data protection in Australia means that the Therapeutic Goods Administration (TGA) cannot commence its market approval process until the day after the data protection period has ended (draft report: 276). Like the WTO dispute panel on Canadian pharmaceutical regulations, this procedure effectively extends the market exclusivity period beyond the agreed period of data protection.[22] Australia should push for regulatory approval to be undertaken before the expiry of the data protection period and that marketing approval for generic products should date from the day after the expiry of the protection period.

One could however approach the whole issue differently. Once a drug approval authority has received data showing that a particular chemical is safe and efficacious, then that chemical is approved for sale. Once a particular chemical is approved for sale there is no need to refer

[21] See http://www.ema.europa.eu/ema/index.jsp?curl=pages/special_topics/general/general_content_000556.jsp and http://www.ema.europa.eu/docs/en_GB/document_library/Report/2014/09/WC500174226.pdf, pp 4-5.

[22] And this extension occurs in what can only be called an under-hand matter.

back to the clinical trial data – merely to demonstrate chemical equivalence. It should be possible to side-step the whole issue of data protection.

Data protection can prove very expensive for consumers and taxpayers. It is a favourite item in preferential trade agreements made between large powerful actors and small states. In the earliest TRIPS-Plus preferential trade agreement, Jordan experienced delayed generic entry for 79% of medicines newly launched between 2000 and 2006 (Oxfam International, 2007: 7). Similarly in Guatemala, data protection has led both to higher prices and delayed generic entry (Shaffer and Brenner, 2009).

1.6 Accountability

A critical issue not discussed at all in the draft report is the range of incentives and biases built into current policy settings. With respect to patent policy virtually every incentive element and procedural/decision-making rule favours the grant and retention of patent privileges. Some of these are administrative rules which are regularly exercised in a one-sided manner. Others are policy rules, which again strongly favour only rights applicants and rights holders. Particularly important here is the one-sided nature of penalties. These two sets of evidence are discussed in the next section.

Another problem that arises with accountability is major gaps in available data and consequently understandings of the impact of current policy settings. These issues are discussed in the section after next.

Governance: Outcomes from current arrangements

This section of the report is as yet rather weak. The wide range of evidence about the biases in the current system are neither fully reported nor assessed. Here I point to evidence as to IP Australia's administrative and policy actions which demonstrate both:

- a complete lack of understanding of the important role of competition in driving innovation; and
- a consistent failure to apply TRIPS Article 7, which calls for balance between the rights of creators and users of new technology.

This evidence covers approaches to administering regulated time limits, a willingness to accept semantic innovation rather than requiring technological invention, an extremely biased approach to stakeholder identification, a failure to monitor judicial changes to patent policy and ensure corrective action and issues around understanding the importance of transparency. Beyond this there is a lack of balance in penalties, which characterises not only Australian patent policy, but patent policy around the world. Such imbalance in penalties shores up the tendency of the patent system to favour rights holders and applicants. Its effect is magnified by the lack of any incentive to challenge invalid patents unless facing a charge of infringement.

Regulatory time limits for specified events

The patent regulations set a range of deadlines by which certain actions should be taken. There also procedures for allowing applications after deadlines have expired. All such procedures for late applications should be removed. In particular IP Australia should cease to allow late applications for enhanced rights. The Lundbeck case is particularly shocking. IP Australia granted an extension of time for an application for a patent term extension to Lundbeck *more than ten years after the deadline for such applications*.[23] Such actions mean

[23] Lundbeck applied for a term extension on patent 623144 one day prior to the expiry of the 20 year patent term, and more than 10 years after the deadline for applying for term extensions. Their request was granted. A

that no innovating firm can ever trust the patent system and no potential competitor can presume that IP Australia will not accept back payment of fees to revive ceased patents.

Given that the Commissioner of Patents always acts in favour of rights applicants and rights holders, all such discretionary powers need to be removed from the Patents Act and its regulations. Specified deadlines should always be respected, and the Commissioner should have no leeway to allow late applications in respect of any part of patent administration. Most patent applications are made and managed through a patent attorney. Members of this protected occupation know the rules very well. There are no justifiable reasons for not making these rules completely inflexible. Given the biases demonstrated to date, this is the **only** way to ensure proper balance in this part of the system.

Semantics not technology

The Australian Patent Office (APO) has been a strong supporter of the legal fiction that applications for patents over genes and gene fragments are patentable subject matter.[24] It has long been absolutely clear that discoveries are not patentable subject matter. Yet the Commissioner of Patents strongly supports the view that "isolation and purification" turns such discoveries into inventions. Isolation and purification appears to mean nothing more than removing unwanted pieces from the identified gene fragment. I provided information on this matter in my original submission to the Commission (p. 30). In summary, it is hard to interpret the APO's stance as anything other than a willingness to use semantics to enlarge the subject matter scope of the patent system.

The APO is so wedded to this legal/semantic fiction that it has adopted the narrowest possible interpretation of the 2015 High Court's *Myriad* decision[25] on patenting genetic discoveries (Summerfield, 2015c).

The stories around the process of examination ("patent prosecution") have been littered with examples where narrow differences in wording were sufficient to gain a patent grant for "inventions" that had been judged to be obvious.[26] I provided a clear example of such "semantic inventiveness" in my submission to the Commission (p. 17). This involved amendments that narrowed a claim for the medicine nevirapine. Although the claim had been judged by the USPTO to be obvious, the narrowing of scope led to its grant. This type of case – where inventiveness in acquired by making something that is uninventive narrower – is frequent in the surreal patent world.

Both at the policy level (its response to the High Court' Myriad decision) and at the administrative level (regular grant of patents following semantic changes that are unrelated to any underlying technology), the APO demonstrates its clear preference to grant a patent rather than to protect the public from an undeserved grant. At a minimum patent examiners should be required to make a clear statement of the reason for any patent grant. This should identify the essence of the new knowledge contributed in the patented invention, using clear non-legal language.

The Commission asks (information request 6.1) about requiring that applicants be required, in their applications, to articulate why their invention merits a patent (why their invention is non-obvious). Consistent with the proposed change in wording of ss. 7(2) and 7(3), the onus

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consequence has been that generic firms who entered the market thinking it was clear of patents will now be faced with substantial damages costs.

[24] See, for example their evidence to the Senate Community Affairs Committee's 2009 inquiry into gene patents.

[25] *D'Arcy v Myriad Genetics Inc* [2015] HCA 35.

[26] There were numerous examples in my dataset on business method patents. Such practices were evident not only in the APO but also in the USPTO and the EPO. They are also evident in pharmaceutical evergreening patents.

should be on the applicant to specify in non-legalese, what is the core inventive contribution of their "invention".

Stakeholder identification

Nowhere in IP Australia's strategic plan is there any mention of consumers, competition, follow-on innovation or the public interest.[27] IP Australia sees potential users of the rights it administers as the sole relevant stakeholders. This very one-sided view also dominated the range of interests represented on the then Advisory Council on Industrial Property (ACIP). At no point has there ever been a representative of consumer or competition interests on this advisory council. I wonder if generic pharmaceutical interests have ever been represented on ACIP?

I note that some submissions have called for such a body to be re-instated. Unless any such body adequately represented all interests – particularly those interests that IP Australia fails to understand – then it will be a further waste of taxpayer resources.

The Department of Foreign Affairs and Trade (DFAT) consistently advised people with whom it "consulted" about the IP chapter of the proposed TPPA that Australia would resist including anything inconsistent with current policy settings. With respect to patents it has failed in this objective. It does not identify this failure in the national interest analysis provided to the Joint Standing Committee on Treaties (JSCOT). The ultimate responsibility for not identifying this change to current policy settings presumably lies with IP Australia as the organisation responsible for advising DFAT on IP matters.

Article 18.72.3 of the TPPA introduces a presumption of validity for the claims of a granted patent. This is the sole current feature of Australia's patent policy that preferences the public interest over patent-holders' rights. DFAT has earlier agreed to such a presumption of validity in our preferential agreement with Malaysia (Moir, 2015: 568). Although this treaty came into force in 2013, this provision has not, thankfully, been implemented. We will not be so lucky with the TPPA. The US Trade Representative monitors implementation of IP commitments with an eagle eye.

These examples demonstrate clearly that IP Australia has strong built-in biases – the sole interests to which it caters adequately are those of entities seeking the products it administers. Neither IP Australia nor DFAT has yet demonstrated any proper understanding of the concept of enhancing the wellbeing of Australians. Both focus only on selected interest groups – not always Australian interest groups – and fail to recognise the costs paid by other segments of our economy and society.

Failure to advise corrective action

One responsibility of agencies which administer statutory law is to monitor how that law is applied in the court and to advise, through their Ministers, when corrective action needs to be taken through an amendment bill. Such actions are evident, for example, in the area of competition law – certainly since competition law moved to the Treasury portfolio.

IP Australia does not appear to understand this. With few exceptions, amendments have focused on details that benefit applicants, rights-holders and the patent attorney profession. The two exceptions were the amendments following the Ergas report and the so-called raising the bar amendments.

But there is a long list of judicial decisions, either reducing the threshold for grant of a patent, or broadening the scope of patentability, where no corrective action has yet been taken. The cases listed below have all had a negative net welfare impact on Australia:

[27] https://www.ipaustralia.gov.au/sites/g/files/net856/f/ipa_strategic_plan_external_web.pdf.

- *Minnesota Mining & Manufacturing v Beiersdorf* (High Court, 1980)
  → removed the synergy doctrine. This continues to allow many low-quality patents in all fields including pharmaceuticals
- *IBM v Commissioner of Patents* (Federal Court, 1991-92) and *CCOM v Jiejing* (Federal Court, 1994)
  → made software patentable, despite the bi-partisan acceptance of Industrial Property Advisory Committee's recommendation that patentability not be extended to software (IPAC, 1984). Continues to allow software patents
- *Anaesthic Supplies v Rescare* (Federal Court, 1994)
  → removed the traditional exclusion of methods of medical treatment. This has now been extended substantially allowing second and third method of use patents for already patented compounds
- *Hässle v Alphapharm* (High Court, 2002) (also *Doric*)
  → required a very low standard of obviousness, at an estimated cost to Australian taxpayers of $A1.1billion over 8 years (Moir, forthcoming).

With the exception of the *Alphapharm* case IP Australia has shown no evidence that it understands the major negative impact of these decisions on net welfare. There is no evidence of any action to take corrective action.[28] One case not listed above – as the judicial system has finally taken steps to overrule it – is the *Welcome Real Time v Catuity* (Federal Court, 2001) case which endorsed the grant of business method patents with the single statement "[t]he State Street decision is persuasive."[29] However the courts have taken 13 years to correct the consequences of this unfortunate aside.[30]

Understanding the importance of transparency

In 2009 IP Australia commenced a major reform process. While it issued a discussion paper, and invited submissions, it made no effort to make these submissions public. It then stepped back from the major proposed reform because of responses from unknown parties. Similarly it dismantled the website for the Pharmaceutical Patent Review instantly on the announcement of a Federal election on the extraordinary grounds that such action was a norm of a caretaker period! It has does nothing since then to re-establish access to these documents. Some have been captured by the wayback machine, but unfortunately there is no wayback snapshot for the period between the receipt of all submissions on the draft report and the dismantling of the site.

In the past IP Australia took the step of loading past advisory council reports on the ACIP website, including the important 1984 IPAC report. With the demise of ACIP, IPAC documents are now rather hard to find. More recently, IP Australia has started to make improvements in transparency. There are now a number of reviews, including past reviews, where submissions are available.[31] These improvements are a good sign. They need to be reinforced and extended.

[28] IP Australia did, however, address the negative impacts of the 2006 E*mperor Sports* (Commissioner of Patents v Emperor Sports (2006) 225 ALR 407; (2006) 67 IPR 488; [2006] FCAFC 26) decision in the 2011 "Raising the Bar" bill.
[29] *Welcome Real Time v Catuity* [2001] FCA 445 at 129.
[30] *Research Affiliates LLC v Commissioner of Patents* [2014] FCAFC 150.
[31] See https://www.ipaustralia.gov.au/about-us/public-consultations.

Penalties

Patent policy is well developed in respect of policies for infringement – there are strong penalties, usually in the form of financial compensation.[32] Little consideration has yet been paid to incentives to prevent abuse of the patent system,[33] for example by seeking to drive down standards of patentability or for attempting to gain patents for "inventions" where the only inventiveness is in the legal drafting. Because there are no such clear and certain penalties, firms regularly apply for very low quality patents. There is a strong case for developing policy rules in respect of patents which are revoked. There is also a strong argument of the need for penalties to prevent gaming of the system.

When an innovating firm is sued for infringement, it will normally counter-sue for invalidity. If successful, the firm challenging validity will receive costs **but no compensation**. But there is no rule that *all profits based on an invalid patent should be repaid*. An invalidated patent is invalidated *ab initio*. That is, it should never have been in force. At present it appears that the owners of such revoked patents are *allowed to retain all the monopoly profits* they have earned from that patent. The lack of such a penalty reinforces incentives for firms to try to game the patent system by seeking low quality patents.

In respect of pharmaceutical evergreening patents, firms are actively advised to seek and defend low quality patents as this will create substantial financial rewards for them:

> "Even where the final outcome of proceedings is that the patent is held invalid, the effect of the litigation will have been to delay the generics' entry to the market. Fighting the litigation may also have 'warned off' other generic competition. In any event, for a successful product, the benefit of even a short time of additional proprietary sales may easily outweigh the costs of patent litigation."
>
> Burdon and Sloper, 2003: 238

In many ways the patent system is like the tax system – it is complex and the complexities are exploited to gain major financial advantages. Drahos has likened the patent system to a system of private taxation (Drahos, 2010). The patent system can provide very substantial financial advantages, and there is naturally a strong incentive to seek such outcomes. A range of pharmaceutical patenting strategies have been identified which lead to long additional monopoly periods. These strategies are entirely legal. They are possible because of major weaknesses and imbalances in the patent system – imbalances and weaknesses at least partly attributable to lobbying by pharmaceutical companies.

Unless more balanced penalties are introduced, such welfare-reducing behaviour will continue unrestrained. Allowing firms to retain profits from revoked patents is like allowing tax cheats to retain the money that should have been paid in tax. Introducing a blanket requirement for repayment of all profits from products or services covered by revoked patents would begin to provide more balance to the incentive structures of the patent system.

When bottom of the harbour tax evasion schemes were addressed some years ago, penalties for deliberately trying to evade tax were important in reducing leakage from revenue (Braithwaite, 2005). Even today the provision against schemes largely designed to reduce tax is important in reining in the worst abuses among those who actively decide how much tax to pay. This suggests there should also be clear penalties for behaviour designed to undermine the objectives of the patent system. Such penalties would assist in re-balancing the system and would protect the public from the worst excesses that are currently evident.

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[32] Unfortunately there is a dearth of information as to the penalties paid following legal disputes as to patent infringement or invalidity. The fact that this important aspect of public law can be allowed to be subject to commercial-in-confidence provisions is questionable.

[33] Such issues were, however, raised in evidence to the 2009 Senate inquiry into gene patents and the 2012-13 Pharmaceutical Patent Review.

Without such penalties for gaming the system there will be strong incentives for firms to continue to file applications for very low quality patents. Any improvements adopted now will be quickly eroded.

Because of the way in which low patent standards and expanded patentable subject matter have advantaged originator pharmaceutical companies at the expense of health users and taxpayers, the generics and biosimilars industries are a well-placed litmus test of balance in the patent system. The evidence such companies and their associations have provided to the Commission is a strong indicator of areas of imbalance in the system.

In the attachment to its submission to this inquiry the Generic and Biosimilar Medicines Association (GBMA) has pointed to the frequency with which interlocutory injunctions are issued in Australia. Indeed the GBMA points out that not issuing an injunction is the exception not the rule, pointing out that:

> "In interlocutory injunction applications, the balance of convenience has fallen persistently against generic sponsors."[34]

The whole Australian patent system mirrors that in the USA with a plethora of detailed rules giving rise to a strong probability of grant once an application has been lodged. This lack of balance is made worse but one-sided penalties. Further the organisations responsible for patent administration and policy have demonstrated over and over again that they do not understand the importance of balance and the need to ensure that the whole system acts in the overall interests of Australians.

In its report the Commission discusses the Department of Industry, Innovation and Science's (DIIS) role in patent policy. DIIS has always had a problem attracting staff with a good understanding of innovation. This is at least in part due to the fact that industry and innovation do not feature strongly in the curricula of university economics departments. As a result **the** major source of recruitment for this part of DIIS has always been the APO. Patent examiners who want to move on find this an easy route out of examination. Unfortunately, while skilled in a science and aspects of law, they do not usually have any economics or policy training, and they bring with them the bounded patent office view of the central role of patents in innovation. As the Commission has noted in the evidence reviewed in the draft report, it is competition that is a prime driver of innovation and innovative firms have many strategies for ensuring a return from their innovative activities. Patents rarely feature high on that list. The consequence of this is that DIIS has a poor understanding of patent policy.

Summary on governance arrangements

Overall, while IP Australia has made some recent improvements in demonstrating an improved commitment to accountability, it is clear that its fundamental culture stands in need of a substantial re-orientation. The most important element that needs to be introduced is a profound understanding of the importance of competition as a driver of innovation. A second important element is the impact of market interventions on customers, including other Australian businesses. Ensuring this cultural transition is a far more important issue than fragmentation[35] or separation of administration and policy advice.[36] Without this Australia's

[34] GMBA submission, attachment, p.32.

[35] The fact that firms use trademarks and copyrights as well as patents does not necessarily mean that administrative arrangements need to be consolidated. At present each form of "IPR" is so far out of balance that the priority must be restoring balance to each system. Naturally this should be done in the context of the whole range of supports, including not just other "IPRs" but also other innovation support programs such as R&D tax credits. The two "IPRs" that must always be considered in close conjunction are patents and data protection as both are primarily designed to meet the needs of originator pharmaceutical companies.

[36] Again this is not in itself the problem. The key problem is the biases and lack of evidence in developing policy. This derives from the isolated and self-reinforcing nature of the patent community, reflected in IP

patent policy decisions will not reflect the "objective, impartial and consistent basis, without conflict of interest, bias or improper influence" that the OECD recommends.[37] Nor will it ever approach meeting the requirements of Article 5.1 of the Competition Principles Agreement.

The draft report notes that the Australian Public Service Commission (APSC) "found that IP Australia's stakeholders … viewed the agency as impartial and as operating without agenda or bias" (p. 437). The APSC report accepts as a given IP Australia's unbalanced statements about its role and objectives and its identification of stakeholders as its customers. Although the APSC consulted stakeholders, their report does not list the entities and individuals they consulted (Australian Public Service Commission, 2014). There is no evidence that any representatives of competition or consumer interests were consulted.

The draft report provides a table on statements about objectives and outcomes for various agencies (Table 16.1). It is notable that the only agency that reports a goal of advice "based on an objective and thorough understanding of issues" is Treasury. The word evidence does not appear in this table. The word objective only appears as "objectives of IP" and in the Treasury entry.

The draft report notes (p.439) that previous reviews had recommended external oversight of IP Australia's regulatory decisions, particularly in order to ensure a high quality in granted patents. The Senate gene patent report, in particular, saw such oversight as being necessary to mitigate the undue influence of particular interest groups. My own view is that, although such oversight is essential, it will not, alone, be sufficient to develop a proper balance in IP Australia's culture and thus advisory and decision-making capacities.

In order to achieve a more balanced patent system it is essential that:

- IP Australia be moved to the Treasury portfolio; and
- expert groups be established to review patent grants, particularly in the pharmaceuticals and other sensitive areas.

The government's response to the Senate's proposals noted existing measures to ensure the quality of individual patents. With respect, ISO quality procedures simply review the steps in a process. They do not touch upon the issue of a set of rules that ensures a minimal inventiveness requirement. They simply ensure that the low standards are delivered consistently. The mechanisms for third-party challenges are extremely costly to those parties and simply cannot generate the range or volume of challenges needed to control the proliferation of low-quality patents.

The draft report notes how policy and administrative roles are split in respect of Treasury agencies responsible for tax and competition policy. Given the similarities with patents – overly complex systems that provide large rewards for gaming the system – such arrangements would also be suitable for IP Australia. The proposed expert group should also review the Examiners' Manual to ensure that examiners are not improperly restrained from rejecting low quality applications.

Governance: developing an evidence base

There is little evidence that past patent policy decisions have been made on the basis of any evidence. Many extensions to patent policy have been made by judges in dealing with individual disputes, often between two private parties. These are by definition devoid of any evidence as to their net welfare impact. Others have been made in trade negotiations where

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Australia's culture. In the past IP Australia operated in a more balanced manner as evidenced by a variety of past decisions, such as *British Petroleum Co. Ltd.'s Application* (1968) 38 AOJP 1020.

[37] Cited in draft report, p. 424. From OECD Regulatory Policy Committee, 2012, *Recommendation of the Council of the OECD on Regulatory Policy and Governance*, OECD: 4.

small increases in agricultural access have been traded for domestic policy inflexibility. Indeed the presumption by rights-holders that no evidence should be required is so strong that the "independent, expert"[38] advisory body ACIP considered that:

> "Previous decisions on the patentability of other controversial areas, such as software, genes, bioinformatics and the treatment of humans, *have not been based on assessments of whether patent protection is necessary* in order to encourage innovation in those particular fields. *To require such assessments* for all inventions which are not in a field of technology would result in Australian law having different criteria of patentability for different areas of innovation. This *appears to be undesirable*… "
>
> (ACIP, 2003: 33, emphasis added)

The draft report indicates that some submissions suggest a recent improvement in the quality of evidence used for patent policy making. I would be interested to know what that evidence is. The simple creation of an Office of the Chief Economist needs to be seen in historical context. Prior to this IP Australia provided substantial funding to the Intellectual Property Research Institute of Australia (IPRIA) at Melbourne University. This was a genuinely independent group with substantial expertise in both innovation and patent policy. Their track record in producing useful new evidence-based research was excellent. Although the Office of the Chief Economist has now been operating for some years, its main useful output has been the IPGOD database.

Overall, however the establishment of the Office of the Chief Economist is no substitute for the withdrawal of financial support from IPRIA. There is a good case that a percentage of patent revenues should be hypothecated for genuinely independent evidence-based research, perhaps administered through the Australian Research Council.

Evidence and data

The Commission notes the problems in using so-called IP indices. I agree. These indices are more measures of IP-friendliness than IP quality (van Pottelsberghe, 2011). Box 16.3 on data and research gaps addresses – at a very high level – research gaps for different types of "IPRs". It does not identify the data gaps. The only recommendation the Commission makes about data is with respect to term extensions and s.76A.

Draft recommendation 9.5

The Australian Government should reform s. 76A of the *Patents Act 1990* (Cth) to improve data collection requirements. Thereafter, extensions of term should not be granted until data is received in a satisfactory form. After five years of data has been collected, it should be used as part of a review to consider the ongoing costs and benefits of maintaining the extension of term system.

In regard to term extensions, the principle data that would be useful for public policy purposes are data on the costs of R&D and commercialisation and revenues received to date. This would allow the question of whether term extensions were needed to ensure an adequate return on development expenses to be answered.

IPAC recommended that data on patent use be collected when patents were renewed. This recommendation was accepted in principle, but has not yet been implemented. It is time it was. The Commission has recommended changes to fees,[39] but more important are other

[38] The draft report characterises ACIP as an "independent, expert body" (p.426). As the quotation above shows this is not an accurate description. ACIP is better characterised as representing the interests of patent and trademark rights-holders.

[39] Draft recommendations 6.3 seems sensible. However more steeply rising renewal fees will have no impact on evergreening patents. It is unclear why the Commission considers claim fees would reduce patent breadth, unless by this it means the number of claims. A single-claim patent can have considerable breadth in terms of the technology area covered. The Commission should also consider recommending introducing differential fees by

actions that could and should be undertaken when patents are renewed. Principal among these is reporting on any uses of the patent during the past 12 months. For certain types of patent – those relating to biological substances – there is a continual development in the underlying patented invention. This challenges the principles of disclosure as the disclosures made at the time of application quickly become outdated. For such patents continual update of disclosure, including best method, should be a pre-requisite of renewal. This requirement should be identified during examination and be a condition of renewal.

The ABS innovation survey previously identified firms that were making new to Australia/new to the world innovations. This classification seems to have been dropped. As such firms are likely to be the principal users of the patent system this is unfortunate. The innovation survey has not yet asked the key Yale and Carnegie Mellon survey questions on the role of patents on appropriability. It is more than time they did so. At the same time it would also be useful to ask innovating firms if they have ever had to change their behaviour because of patents owned by other firms.[40]

I have not yet had time to test the range of questions that can be asked with the new IPGOD database, or whether it can be linked with ABS data to provide a more solid basis for research on industrial innovation. As Commission staff have done some very useful analysis using IPGOD data they are perhaps well placed to check this out.

The most important question of all for patent policy is "what is the speed and cost of copying"? We have US data on this issue – and the answers are that for more significant innovations the speed is slow and the cost high. But these data are old. Since then both China and India have developed substantial capacities in copying new products. Empirical work on the speed and cost of different types of copying in these two countries would be invaluable for policy makers.

In the post-AUSFTA environment, with the introduction of changed data protection and patent linkage provisions, there is one striking gap in data. Originator companies are not yet required to provide a list of all patents relevant to a medicine on the Australian Register of Therapeutic Goods (ARTG). This is a critical omission and needs urgent correction. The absence of such a requirement is another example of how strongly the overall system is designed to meet the needs only of originator companies. Generic producers are strongly disadvantaged by the absence of such a register.

3. Overall balance: towards a model patent agreement

During the next stage in the inquiry many persons and entities with vested interests will, naturally, attempt to persuade the Commission that its recommendations for reform should be watered down rather than improved. But unless these actors place genuine new evidence on the table, there is no case for resiling from the Commission's central finding (p.3) that:

> "Australia's patent system grants protection too easily, allowing a proliferation of low-quality patents, frustrating the efforts of follow-on innovators, stymieing competition and raising costs to the community."

Because of the importance of innovation to Australia's future growth and prosperity, it is essential that all policies that bear on innovation are as well designed as possible. Current patent policy is well below optimum on a number of counts. The preceding sections of this submission discuss a range of patent policy reforms that are treaty-compliant.

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enterprise size. This approach is used in the USA. Lower fees for SMEs would to some extent offset any discontent from abolition of the innovation patent system.

[40] Also the lack of any separation between use of a trademark and use of copyright is a problem for researchers and policy advisers. These are two completely different things and should not be presented in the one category.

Other bad design features cannot be immediately addressed because of treaties designed to promote the interests of originator pharmaceutical companies. With its small market size Australia's needs from patent policy are substantially different from those of trading partners such as the USA, Japan and the EU. The Commission has sensibly recommended that these constraints be addressed by designing model agreements to guide international negotiations on various aspects of "intellectual property".

Australia has a track record in promoting welfare-enhancing international economic policy through its leadership role in the 1990s on agricultural reform. As a medium economy with a highly skilled workforce that has areas of global excellence in some areas of technology and creative content, but being a net technology and content importer, Australia is well placed to develop sound evidence-based models for the various forms of "intellectual property rights". At present, however, it lacks the institutional capacity to do so.

The need for a more balanced patent policy is urgent. A model patent policy should be based on TRIPS Article 7 and the available evidence on industrial innovation and commercialisation. Such a model would appeal to many current and future trading partners, particularly emerging new global powers such as China and India.

Such a model should focus on identifying those features of TRIPS which undermine the balance required by Article 7 and thus stand in need of amendment. It should also address the range of parameters that lie within the TRIPS flexibilities and demonstrate how these can be used to maximise balance in the patent system.

Key elements of TRIPS and the Doha Agreement are in need of urgent revision.

TRIPS Articles needing amendment

- The range of privileges granted by a patent (Article 28)
  - → privileges should be pared back to the right to domestic sale (but excluding the right to prevent parallel importing).
  - → This would:
    - : allow immediate market entry by competitors after patent expiry
    - : allow manufacturing for export at any time during the domestic patent life
- Remove the requirement for technological neutrality (Article 27(1))
  - → this requirement effectively requires all WTO members to have bad patent policy. Technologies are different, especially with regard to whether there is any evidence of the need for a patent intervention.
  - → the requirement to provide patents for pharmaceutical products should be removed. There is now substantial evidence that pharmaceutical products are welfare-reducing (Branstetter et al., 2011; Chaudhuri et al., 2006; Dutta, 2011). Given the human right to life, allowing policies which actively prevent available life-saving technologies from being used to save lives cannot be countenanced.
- Remove Article 34 specifying a presumption of guilt.
  - → This is contrary to normal legal presumptions.

The Doha Agreement: the paragraph 6 non-solution

The negotiated Paragraph 6 agreement on the basis for countries with no domestic pharmaceutical production capacity is so complex that is has hardly been used.[41] The paragraph 6 "solution" thus undermines rather than implements the Doha Agreement (Drahos, 2007). These procedures need to be withdrawn, and replaced with procedures that are no less

[41] "However, since the acceptance of the Paragraph 6 Waiver, the implementation of compulsory licensing by developing countries has been almost nonexistent" (Champagne, 2012: 92).

complex than the already complex Article 31 procedures for compulsory licenses where there is domestic production capacity.

TRIPS flexibilities

The TRIPS flexibilities that could be used to maximise balance in a patent system are:

- Defining patentable subject matter in such a way as to maximise exclusions where there is no evidence of any need for the patent incentive:
  - → when the 1952 US patent statute was debated it was famously said that "A person may have "invented" a machine or a manufacture, which may include anything under the sun that is made by man…" The second half of this sentence is often dropped. But the sentence went on "but it is not necessarily patentable" (Menell, 2006). Throughout patent history there have been limits placed on what kinds of inventions are not patentable.
    - the most fundamental limitation is that patents are only for technological inventions;
    - discoveries are not patentable as they are not inventions. This means that patents over genes and gene fragments, including proteins, are not patentable;
    - a longstanding traditional exclusion is methods of medical treatment, and this exclusion is specifically allowed by Article 27(3)(a) (Davis, 2014;
    - another longstanding set of exclusions is algorithms, ideas and mental models and methods of doing business.
- Maximising the use of exclusions from patentability allowed by TRIPS Article 27(3). In particular it is important to fully utilise the Article 27(3)(a) exclusion of "diagnostic, therapeutic and surgical methods for the treatment of humans or animals". The pharmaceutical industry has, over recent decades, managed to persuade most patent offices to grant second and third patents over specific uses of already known, and often previously patented, substances. But patents for new indications (uses) of known pharmaceuticals clearly fall into the definition of a method of therapeutic treatment (Davis, 2014).
- Setting the inventive step at a height that properly balances the rights of inventors and users of new technology. Given that TRIPS does not allow discrimination on the basis of whether products are imported or locally produced, there is no guarantee that the spillover benefits will occur in the location where the static efficiency losses are incurred. Where dynamic gains (spillover benefits) occur overseas but costs impact locally, a balanced patent system will be one that sets the inventive step at a high level. The proposed "significant advance over what is known" level would seem about right in these circumstances. The elements for the inventive step test that are important are:
  - → The inventiveness judge. Dent (submission 30) indicates that the "person skilled in the art" was designed as the judge for the adequacy of the disclosure. When it comes to inventiveness, it is appropriate that the judge be a leading researcher in the field. After all, we now live in a very inventive world, so it is appropriate that the standard for a patent be commensurately high
  - → The required quantum of inventiveness should be a significant advance over what is known
  - → Relevant existing knowledge should be all knowledge at the time the application is filed – "the state of existing knowledge"
- Maximise the use of parallel importing (Article 6) as this provides a degree of control over excessive prices.
- Actively use compulsory licenses (Article 31) where pharmaceutical costs are excessive, as is the case with many new biologic drugs.

- Use a clear objects clause in the legislation to ensure that attention is focused on the twin requirements of additionality and net spillover benefits when judging patent validity.
- As well as penalties for infringement, ensure that profits made from invalidated or revoked patents are repaid. Consider including penalties for actions which are designed to obtain low quality patents or patents where the main inventiveness is in the legal drafting.

The most important of the above changes is paring back patent privileges (TRIPS Article 28). As the Commission notes (p.200) strong patent privileges compound the negative effect of granting patents too easily (false positives). Further, if the privileges were scaled back to the essential and central reward of sale in the domestic market, problems around how the experimental use exception is drafted would not arise (information request 6.2).

4. Other "IPRs"

I have not had time to consider the other parts of the draft report in such detail, but I offer the following comments.

The copyright recommendations look sensible and I support them all, including draft recommendation 18.1 on implementing the AUSFTA safe harbour provisions across all suppliers. It is past time these issues were properly dealt with. They simply do not go far enough. At a minimum I would suggest addition of a recommendation on priority areas for evidence-based research. There are key research questions with respect to the terms and conditions of contracts for different categories of copyrighted material. Perhaps a start could be made with academic writing. In particular the cost of materials for legal studies is exorbitant. An empirical research project in this area would be invaluable. It could also be designed to provide a methodology for further studies in other academic fields.

The Commission has called for further evidence on copyright contracts. Evidence is not required to support a legislative change to the effect that copyright contracts should not override copyright law. Clauses in copyright contracts that purport to over-rise normal access provisions, whether fair dealing or fair use, should simply be void in all circumstances.

The trademarks recommendations also look sound and I support them. I would however, prefer a return to the 1955 Act procedures on mandatory disclaimers. I note that IP Australia's argument (on p 341 of the draft report) that labelling laws are sufficient reason for the Trade Mark Registrar to cease raising objections to geographical references. This is very poor reasoning.[42] Given the likelihood of negotiations with the European Union over a preferential trade agreement, it is essential that Australian producers not be allowed to fall into the trap of using geographic names in their trade marks.

The draft does not, in my view, deal adequately with the misleading outcomes from excessive branding. It is moot whether a government should intervene strongly to restrain trade simply to support a particular business model. It is even more moot where that business model substantially undercuts one of the most fundamental assumptions of economic analysis – that tastes are given and not manipulated by the market. Research is urgently needed to develop an evidence base for trademark policy, in particular on the proliferation of brands and the extent to which this confuses customers.

The recommendations on the intersection of "IP" law and competition law and with respect to publicly funded research look sensible and I support them.

I consider international harmonisation to be a Trojan horse (Kingston, 2004). The sole beneficiary is large global business. Given that Australia has few such businesses, it is not in Australia's interests to increase harmonisation. Ever since the Paris Convention these treaties

[42] Or simply another example of IP Australia's biases in favour of its customers.

have been driven by business interests with little evidence-based assessment by governments. A telling example is the continuation in the Berne Convention of the requirement for no formalities. This dates form an age where such formalities were onerous. Today they are not.[43] But it is the absence of the formalities requirement that creates orphan works and increases the costs for users of copyrighted material.

With regard to enforcement, penalties are generally disproportionate to offences. This is particularly true in copyright where unauthorised use has been criminalised in some circumstances. This is an outmoded penalty dating from a time where religious beliefs could be construed as treason. It is more than time such penalties were removed from the system. Instead of this happening the distributors of copyrighted material are pushing for stronger and wider penalties. And in the TPPA there is a push for criminal penalties for trade secret breaches. A most important principle in the rule of law is that penalties should be proportionate. Throughout the "IPR" areas they are not.

There needs to be a thorough overhaul of penalties to ensure that they act effectively to maintain a quality system. That is they need to be in place to limit bad behaviour both by creators and by users. They need to be designed to act as deterrents while achieving the best possible net welfare outcome.

[43] I completed my PhD in the USA prior to the USA joining the Berne Convention. Registering my copyright in my dissertation was a very simple matter.

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