Empirical evidence on patents and data protection

Response to the Productivity Commission's Issues Paper 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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Author information

I have an honours degree in economics from Cambridge University (1969) and a PhD from Brown University (USA) where I specialised in demography and development economics (1975). My early working experience included market research, private health insurance and development assistance. During my 19 years' service in the Australian Public Service, I spent over 5 years in the Bureau of Industry Economics (BIE). I also advised on microeconomic reform of transport and communications in the Prime Minister's department in 1989 and 1990. In 2004 I embarked on a second PhD, in public policy at the ANU. The subject of my dissertation was an economic assessment of the patent system, using data on granted business method patents to assess the height of the inventive step and identify the principal rules which caused such a very low standard for the inventiveness test. Since then I have explored a number of aspects of patent policy, including secondary pharmaceutical patents, patent policy in trade agreements and the norms that would be required to implement Article 7 of TRIPS – the Article which calls for balance in patent policy. In addition to academic papers I have made submissions to s number of government and parliamentary enquiries. I hold the position of Adjunct Associate Professor at the Centre for European Studies, College of the Arts & Social Sciences, Australian National University, where I do research on patents, data protection and geographical indications.

Contents

Acronyms

ABS	Australian Bureau of Statistics
ACIP	Advisory Council on Intellectual Property
API	Active Pharmaceutical Ingredient
ARV	antiretroviral (medicine)
AUSFTA	Australia United States Free Trade Agreement
CAFC	Court of Appeals for the Federal Circuit (US)
CGK	Common General Knowledge
EPO	European Patent Office
EPC	European Patent Convention
FICIP Australia	The Australian Federation of Intellectual Property Attorneys
FTC	Federal Trade Commission (US)
GATT	General Agreement on Tariffs and Trade
IPAC	Industrial Property Advisory Committee
IPCRC	Intellectual Property and Competition Review Committee
IP	intellectual property
IPR	intellectual property right
IPRIA	Intellectual Property Research Institute of Australia
IPTA	Institute of Patent and Trade Mark Attorneys of Australia
IT	information technology
PBAC	Pharmaceutical Benefits Advisory Committee
PBS	Pharmaceutical Benefit Scheme
PPR	Pharmaceutical Patent Review
R&D	research and development
SME	small and medium-sized enterprise
TRIPS	Agreement on Trade Related Intellectual Property Rights
PHOSITA	Person having Ordinary Skills in the Art (USA)
PPR	Pharmaceutical Patent Review
PSA	Person Skilled in the Art (Australia)
USPTO	US Patent and Trademark Office
WTO	World Trade Organization

Summary

Government intervention in markets is generally undesirable as there are substantial costs to such interference. What then is the rationale for the patent intervention? If R&D costs are high and imitation times are relatively speedy, then an innovating company may not have sufficient exclusive time in the market to recoup R&D costs through higher prices. *Where such innovation has substantial positive spillover benefits*, society would wish to provide an incentive for this to occur.

But patent systems have costs. There are well known static efficiency losses due to the right to impede competition. There is also a real risk that follow-on innovation will be held up, and plenty of historical examples of this happening.

To balance these benefits and risks a patent system needs to be *parsimonious*. Patents should be granted where they will ***induce*** inventions ***that have positive spillover benefits*** for society. Only where both conditions are met will a patent system be both effective and efficient.

There is very substantial survey evidence that, for most industries and technologies patents are not needed. Unfortunately, because of TRIPS, WTO members are required to provide patents in all fields of technology, and to treat all technologies equally. The fields where patents are least needed are those involving complex technology as this is harder to imitate. In contrast, in discrete technology fields – where products tend more to align with a single patent, patents may be necessary to induce desirable invention if the R&D costs are high.

Australia's patent system is mostly used by overseas entities. Given Australia's small market size (just 2% of the OECD market), it is unlikely that an Australian patent will act as an inducement to overseas innovators, except in other small-market countries, such as New Zealand. Overall I estimate that between 4.9 and 6.5% of granted patents are induced by our patent system. That is, between 950 and 1250 of the patents granted in 2014 might have been induced. The other 18,000 plus patents are most unlikely to have been induced by Australia's patent system.

Why does Australia grant so many – 19,304 in 2014 – patents? In 2011 parliament was advised that patents are only granted for a significant advance over what was known and what was available to the public. This is not true – Australia's standard for granting patents is one of the lowest in the world, with a minimal to non-existent inventiveness requirement.

Myriad doctrinal (policy) rules contribute to this standard: the reverse onus of proof; the decision-making rule about evidence; the definition of the hypothetical judge of obviousness; limitations on the existing knowledge used to determine novelty or inventiveness; narrowness of the technology field when identifying existing knowledge; the High Court's very low standard for inventiveness; loss of the synergy doctrine for combinations; and continual amendment of specifications during examination.

The impact of these many detailed prescriptive doctrines/policy rules creates a systematic bias towards the grant of a patent once an application is lodged. The problem is compounded by the lack of any incentives for low quality patents to be challenged.

Three recent empirical studies estimate the net welfare impact of patents, using data on patented pharmaceuticals. All find that patents operate very like tariffs. Patents lead to consumer losses that are 6-7 times the gains to producers. It would be far more efficient to subsidise pharmaceutical companies rather than to grant product patents.

By its nature patent policy is concerned with national benefit not global benefit, and most analysis of patent systems occurs within a framework of a closed economy. Within a closed economy it can be taken for granted that benefits resulting from the spillover of new

technologies will spread through the industrial base. But Australia's industrial base has little depth and spillovers from invention taking place in Australia are hard to identify. Further, as over 90% of patents are owned by overseas entities, production usually takes place overseas. So the spillover benefits for Australia from these 90+% of patents are very limited, while the costs fall fully on Australian consumers.

Over the past several decades our patent system has increased substantially in scope – both because of the fall in the inventiveness requirement and the extension in what kinds of things are granted patents. *None of these changes has been based on any evidence*. Most have been made by judges. Some derive from international trade treaties.

TRIPS creates a number of inflexibilities, limiting the opportunity to reform this important domestic tool of economic policy. Further inflexibilities are created by the AUSFTA and TPPA – both have chapters with old-fashioned detailed prescriptive rules about exactly how Australia's patent system should be administered. There are nonetheless some clear opportunities to improve the patent system, particularly by increasing the height of the inventive step and removing some new subject matters from patentability.

In considering why the continual judicial changes to the patent system have not attracted any response from parliament, one has to look to the culture of the patent community. IP Australia's advisory committees have not included representatives of consumer or competition interests. Much of the evidence from industrial and innovation economics lies outside the purview of the patent community. Indeed there is in the patent community a view that patent evaluation should only be undertaken by stakeholders – those that benefit from the system.

Over a decade ago the Cutler review of our national innovation system recommended that "IP" policy be moved from the industry to the Treasury portfolio. The move of the then Federal Trade Commission (from the AG's Department) radically improved Australia's competition infrastructure. An equivalent move for IP Australia would do much to reduce the one-sided view that IP Australia takes on most patent policy matters, opening its eyes to the equal, if not greater, importance of competition in ensuring both innovation and one of its major consequences, productivity increase.

While there is substantial empirical evidence from industry and innovation economics that patents are generally not needed to induce industrial innovation and commercialisation, there is a large gap in direct evidence on patent benefits and costs. IP Australia granted over 19,000 patents in 2014 – these all potentially allow the owner to exclude competitors from markets. Yet IP Australia *collects absolutely no data on how patents are used*, despite a 1984 recommendation that this be done. The then government accepted this recommendation in principle and it is more than time that it was implemented.

Empirical evidence on patents and data protection: Response to the Productivity Commission's *Issues Paper* on Intellectual Property Arrangements.

1. Introduction: the need for evidence and a welfare perspective

The term "intellectual property" is almost never appropriate in a rigorous analysis. This submission deals exclusively with patents and data protection. It focuses on what the empirical evidence says about how the patent system works and what it points to in terms of the need for policy change.

I then consider the evidence about patents using the Commission's proposed overarching principles of effectiveness, efficiency, adaptability and accountability. Under each of these headings I marshal the evidence of which I am aware. The sections on effectiveness and efficiency are lengthy, and are followed by Section 4 bringing together the effectiveness and efficiency evidence to address the question of the net welfare impact of the patent system. I consider enforcement issues only briefly as there is little data on this topic. I then consider data protection and how this intersects with patent privileges. I conclude with a brief section on some of the Commission's specific comments.

The Commission's framework is comprehensive, but there is one major gap in the discussion in the *Issues Paper*. While additionality is important, there is no point inducing inventions which have zero or negative spillover benefits. The objective of a well-designed patent system should thus to be *to grant patent only for induced inventions* ***which have positive spillover benefits***.

The term "intellectual property" covers so many things that its use creates confusion and can lead to logical errors. To begin with the term "intellectual property" sometimes covers inventions, creations or brands. At other times it refers to "intellectual property rights" – a range of quite different instruments. Almost the sole feature these "rights" have is that they involve government intervention in markets.

The Productivity Commission has been asked to review Australia's "intellectual property" arrangements to "ensure that the intellectual property 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" (Productivity Commission, 2015:8).[1] If the Commission succeeds in this, it will be the first time there has been a review of any type of "intellectual property right" from the perspective of achieving the economic objective of maximising the wellbeing of Australians.

Evidence based policy

When I first began studying the patent system 12 years ago I was astonished to find that most academic articles about either "intellectual property" or the patent system were devoid of data. One cause is that the field is considered to fall into the academic discipline of law, despite its clear economic objectives. But even economic articles were often "theoretical" – that is they consisted of a set of assumptions – rarely substantiated with evidence – some mathematics and then some conclusions about concepts that were often non-operationalisable. An example is the discussion between patent length and patent breadth.

Further, it was clear that policy was being made on the basis of no evidence, certainly in the field of patents. To illustrate:

[1] This paper will henceforth be referred to simply as *Issues Paper*.

> "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, yet would simply be a consequence of Australia having both national objectives and international constraints."
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> ACIP, 2003: 33 (emphasis added)

This submission considers critical issues in respect of the patent system, with a major focus on where there is evidence and where there are gaps in the evidence. Because a patent can be a mechanism to extract substantial profits from the market, there is an incentive for such users to game the system in a variety of ways. One of these is through funding research which has the appearance of academic independence and credibility but is actually funded by major winners from the patent system as currently structured. The pre-eminent example is the in the pharmaceutical field. Submissions to this enquiry from various parties cite such pharmaceutical-funded research without drawing attention to the funding source. These papers are listed in Attachment A.

Another example is through the suppression of independent studies. There are several examples from the USA, where there have been the greatest number of studies of patent systems. The American patent bar lobbied successfully to prevent the US Government Accountability Office – a highly respected research body – from undertaking a study into business method patenting. Such a study had been part of the penultimate draft of the *American Inventors Protection Act 1999* – the Congressional response to the 1998 Court of Appeals for the Federal Circuit (CAFC) case which introduced business method patenting – but it was removed in the final statute (Kahin, 2003). Kahin also reports that the White House Office of Science and Technology Policy commissioned the Science and Technology Policy Institute at RAND to undertake a study on software patent quality and business effects. He goes on to report that "it was suspended at the request of a U.S. multinational company concerned that the study would undercut efforts to secure greater international acceptance of software patents" (Kahin, 2003). Bessen and Meurer comment that the US Federal Trade Commission (FTC) recommendation most prominently rejected by the Intellectual Property Owners Association (dominated by patent lawyers from large firms) was recommendation 10 "expand consideration of economic learning and competition policy concerns in patent law decisionmaking" (Bessen and Meurer, 2008: 293-4).

Previous reviews of the patent system

There are two prior reviews of the patent system which attempted to gather empirical evidence to evaluate the operations of the patent system.

The IPAC – which reported in 1984 – held a number of seminars (Mandeville *et al.*, 1982b) and commissioned several interesting empirical studies (Mandeville *et al.*, 1982c, 1982a). During one of these seminars an economics professor from Yale warned:

> “There are general principles which are of the highest importance, that markets should be left to operate freely whenever possible, that *one must look further afield than those involved in and regulating an industry when canvassing opinions regarding changes in public policy*, and finally, if a market environment is created which can be abused or manipulated *then such a market will be abused and manipulated*.”
>
> Beggs, 1981: 44, emphasis added

One of the major empirical studies undertaken for IPAC concluded that:

> "Overall, this study suggests that the economic benefits of the patent system to the

> innovation process in Australia are not only small, but extremely subtle. They can be summarized as follows:
>
> - The patent incentive is not an important determinant of domestic IR&D activity, but has some importance for the small inventor;
> - Patents apparently play a subtle role in connection with investment expectations and the transfer of technology to Australia;
> - Patent information is a relatively unimportant source of R&D/technological information for domestic industry, small inventors, and professional engineers. However, it is regarded as having some importance by large overseas-based multinational firms.
>
> Mandeville et al., 1982a: 211

The sole economist on the IPAC review committee lodged a dissenting report (reproduced at Attachment B). In summary he stated that there was nothing economic about the review and that it was constrained by "special pleading by those directly involved" (IPAC 1984: 79-80).[2]

At least one as-yet un-actioned recommendation from this review deserves the attention of the Commission in this enquiry: the recommendation to collect use data when patents are renewed.[3] It does not seem right for the government to hand out thousands of "powerful exclusive rights" each year,[4] but to *collect absolutely no evidence* on the use or impact of these monopolies. In any other field of government endeavour such a cavalier disinterest in the impact of a major policy would be roundly condemned. Patent law is public law. **Data on patent use must be collected, reported to the public and made available for economic and policy analysis.**

The Intellectual Property and Competition Review Committee (IPCRC), reported in 2000. The report is commonly known as the Ergas Report. This committee was charged with assessing the patent system from the economic policy perspective of consistency with the principles articulated in Article 5.1 of the Competition Principles Agreement. This committee assumed that the inventiveness requirement of the patent system was of a reasonable height.[5] No data were commissioned – and indeed a feature of the patent system – not just in Australia but in most countries – is that few policy-relevant data are collected. The review lacked a sound empirical basis and made assumptions which call its findings about the patent system into question.

More than 10 years later there was a second empirical review of a particularly important part of the patent system – pharmaceutical patents (Harris *et al.*, 2013). This review did collect substantial data – particularly on patent term extensions. It was also provided with substantial

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[2] In like vein both the Institute of Patent and Trade Mark Attorneys of Australia (IPTA) and the Australian Federation of Intellectual Property Attorneys (FICIP Australia) objected to the composition of the Panel for the Pharmaceutical Patents Review as it consisted only of people independent from the patent system (though both also alleged that one member had close affiliations to the generics industry – it is my understanding that he had undertaken a single consultancy project on manufacturing for export).

[3] "We recommend that the Patent Office introduce procedures to collect more data from applicants and patentees, particularly concerning the use of patents after grant, in a form which facilitates analysis for statistical and general policy assessment purposes …" (IPAC, 1984: 78). This recommendation was accepted in principle but has not yet been actioned. Another data recommendation that was accepted in principle was to add an ASIC industry identifier to each patent. This recommendation was finally implemented 30 years after it was made, with the introduction of a much improved database, Intellectual Property Government Open Data (IPGOD) (Man, 2014).

[4] The phrase "powerful exclusive rights" is from the Explanatory Memorandum to the Intellectual Property Laws Amendment (Raising the Bar) Bill 2011 at 42.

[5] See for example the assumption that because of the inventive step requirement few business method patents would be granted in Australia. "… we believe that no additional specific recommendations for business schemes are needed since most will not pass the general tests for patent grant, particularly if these tests are modified as recommended by the Committee and stringently applied" (IPCRC, 2000: 153).

data on evergreening (low quality secondary patents usually taken out late in the like of a patent for an active pharmaceutical ingredient). The review's conclusions on effective patent life and manufacturing for export are well-based and deserve the attention of the Commission in this enquiry.

2. Effectiveness

The fundamental question here is whether the patent system[6] induces additional innovation that would not otherwise have occurred. Some 92% of granted Australian patents are owned by foreign entities.[7] From the viewpoint of maximising Australian welfare, it is clear that the patent system is indeed a very blunt instrument – the granted privileges are mostly owned by foreign entities. One could speculate as to whether the additional incentive of an Australian patent induced overseas inventions that would not otherwise have occurred. This would be likely only in countries with small markets, such as New Zealand. But the bulk of Australian patents are owned by US, Japanese, German and British entities and the Australian market is very small compared to their domestic markets.

At best, then, the Australian patent system can induce inventions for less than 10% of patented inventions.[8] But not all patented inventions are induced by the patent system. My own estimates suggest that some 4.9% to 6.4% of the 203,815 standard patents granted between 1990 and 2006 may have been induced by the patent system. In the USA, where a much larger proportion of patents are owned by domestic entities and where the size of the market creates the possibility of inducement for overseas entities, I have estimated that between 29% and 40% of the 810,487 US patents granted between 2001 and 2005 were induced by the US patent system (Moir, 2013c: 18-23).

Time in the market before imitation

If one turns to the economics of patents, the traditional argument in support of a patent system is that there will be a failure in the invention market. Once the invention is disclosed on the market other firms can imitate, and will be able to price their product lower as they will be able to "free-ride" on the initial research and development (R&D) costs. Simple scrutiny of this proposition indicates that it contains two important assumptions: that copying the knowledge in an invention is cheap if not free; and that inventions can be copied and marketed quickly.

These assumptions can be tested empirically. I have addressed this issue at length elsewhere (Moir, 2009a, 2013c). Data from the USA indicate that copying new industrial inventions takes time and money (Mansfield *et al.*, 1981; Levin *et al.*, 1987). The largest gap in the evidence on whether patents are needed to induce inventions is the fact that there are no more recent studies of the speed and cost of copying – in 2014 I searched for articles citing either of the earlier works on copying and found no such articles that presented new empirical data on imitation. There are, however, grounds for testing a hypothesis that the cost of imitation has fallen and the speed increased, and a careful empirical study of the capacity of Indian and Chinese firms to produce similar quality products would provide vital information for assessing the welfare impact of patent systems.

Any such study should usefully also address the issue of the range of incentives available for inventions. On a theoretical basis it has been shown that where R&D is subsidised and

[6] Throughout this submission the focus is on standard patents. Innovation patents are not discussed.
[7] The latest Australian Intellectual Property Report indicates that in 2014 94% of grants were to non-residents (IP Australia, 2015: 9), but the long-term figure is 92% (Moir, 2009c: 191).
[8] The proportion granted to Australian entities plus an allowance for New Zealand owned patents.

imitation takes time, welfare outcomes are higher without patents (Bonatti and Comino, 2011). Empirical testing of this hypothesis would be useful.

Survey data on inducement: the appropriability studies

Absent more recent empirical evidence on imitation, there have been a range of studies on the extent to which industrial innovations are induced by patents. These studies are largely surveys of firms to identify the factors which ensure a good return from investment in R&D and their relative importance. The most important of these are the 1984 Yale survey and the 1994 Carnegie Mellon survey (Levin et al., 1987 and Cohen *et al.*, 2000). These studies have been replicated in a number of high income countries. Again I have reviewed these detailed empirical studies elsewhere (see Moir, 2013c: 13-36). These studies have also been reviewed by López (2009). The regular innovation surveys that are conducted by many national statistical offices continue to show that most innovating firms make little use of the patent system and that most firms using patents rank it quite low in the list of factors that ensure a good return to R&D investment.

This is confirmed by ABS data. In 2004-05 the Australian National Innovation Survey showed that 34% of Australian firms were innovating (Australian Bureau of Statistics, 2007: 12). About 2,100 firms were introducing "new to the world" innovations, and about 2,800 firms "new to the Australia" innovations (respectively 8% and 10% of innovating firms). It is these firms that might be expected to own patents. Data on methods used to protect "intellectual property" are not provided by type of innovation. For all innovating firms, 74% used no method of "protection", and 3.8% used patents (21.6% for firms with more than 200 employees). If ***all*** reported patent use is among new to the world/Australia innovators, then about one in five such firms use the patent system. In other words of the about 5,000 firms which might be expected to use patents at most only 20 per cent do so. The data also show that in Australia, as in most other countries, the patent system is more used by large firms than by small firms. The more recent 2012-13 survey shows that little has changed: of the 700,000 innovating firms 20% had introduced "new or significantly improved innovations" and just 4% had used patents (Australian Bureau of Statistics, 2014).

These data give rise to what has become known as the patent paradox – why do firms take out patents when they are not needed to obtain good returns from R&D investment? Here it is extremely relevant that the nature of a patent is a "powerful exclusive right". While most firms will give as the initial reason that taking out a patent is to protect against imitation, far fewer give this as the sole reason for patenting.[9] Data from the Yale survey show that, after preventing imitation, the important reasons given for patenting were, in order of frequency, blocking rivals, preventing infringement suits, reputation and negotiating access to other firms' patented technology. Reputation was a particularly important reason for smaller firms. These data also showed that prolific patenters were particularly concerned to protect themselves against litigation, and to participate in cross-licensing negotiations. Thus very many patent applications are filed for reasons that are dysfunctional in terms of overall economic welfare (blocking rivals) or because of the very existence of the patent system (preventing infringement suits or participating in negotiations for access to complementary or overlapping technologies) (Cohen et al., 2000). Indeed it is well known that in complex technology fields – particularly electronic goods – firms amass substantial numbers of patents in order to exchange access to their patent portfolios and then get on with business without having to worry about patents (Merges and Nelson, 1990; Bessen, 2003; Cohen, 2005). This is rather like the world where the Emperor has no clothes.

[9] Oppenheim (2000), reports that while 97% of a sample of UK SMEs say a purpose of patenting is to stop copying, only 40% report this as the sole reason for patenting.

Strategic reasons for patenting are confirmed by Blind and colleagues, who review a small number of studies on this topic, and add new data from German firms which actively use the patent system (Blind *et al.*, 2006). They suggest that the motives for patenting are becoming increasingly uncoupled from the need for protection from imitation. The surveys Blind and colleagues review mainly use European data, which systematically confirm that important reasons for patenting are defensive and offensive blocking and negotiations for exchange of technologies. One of the most interesting findings reported is a survey of very large firms investigating changes in motives to patent over a ten-year period. The most important change influencing increased patenting is patenting by other market participants.[10]

Comparison of the ABS innovation data between 2004-05 and 2012-13 shows that some key information is now missing. It is no longer possible to identify firms introducing new to the world or new to Australia innovations. It would be useful if, in undertaking this enquiry, the Commission would give consideration to the data needs to support an evidence basis for patent policy and recommend their collection. This covers not only ABS data but also data collected by the Patent Office.

An interesting perspective on the data on reasons for patenting is provided by Quillen:

> "I do not recall a single instance from my thirty years [as a patent attorney] at Kodak in which we chose not to go forward with an innovation because it was not patented by Kodak. The potential reward we might reap from owning patents on our innovations was irrelevant to the decision of whether or not to commercialize the innovation. Rather, that decision depended on the robustness of the proposed innovation *and whether it was clear of the patents of others*, not whether it was patented by Kodak. I suspect that is true of most other companies whose business success depends on innovation."
>
> Quillen Jr., 2008: 61, emphasis added

Proportion of patents used

A further issue in considering the effectiveness of patents in achieving a higher net welfare outcome is the net benefit flowing from induced inventions. Here it is essential to consider how patents are used and the nature of benefits flowing from them. Again one is faced with a lack of relevant data. Some authors argue that very few (<5 %) patents are used, but they provide no empirical evidence for these claims (Lemley, 2001; Blonder, 2005). Firestone provides data on the use of UK, US and Canadian patents in the late 1960s showing that at least 30% were “worked” (used in production) and in some cases as many as 71% (Firestone, 1971, and see also Moir, 2013c: 30).

Diffusion

Under the effectiveness heading the Commission also asks whether the patent system is effective in disseminating “IP" (*Issues Paper*: 14). The question is interpreted here as whether the patent system effectively disseminates *information about new technology* embodied in patent specifications. The IPAC enquiry commissioned work on the effectiveness of the patent system in disseminating knowledge to engineers (Mandeville *et al.*, 1981). Only 14% reported using patents to track new technologies. Several commented on the difficulty of reading patent specifications due to the legalese used in drafting. Indeed, having read well

[10] Blind et al. report this as a result from a 2003 OECD survey by the Committee for Scientific and Technological Policy (Blind et al., 2006: 658). In relation to the possibility that it is the patent system itself which creates the need for patenting, Walterscheid raises this possibility as occurring as early as the late eighteenth century: "a point was reached wherein the patent system created its own logic and patents begat patents" (Walterscheid, 1996: 81).

over a hundred patent specifications myself, I can confirm that these do not convey essential information with either speed or clarity. Even searching for relevant patent data can be complex, which is why specialist firms have developed to do this. And they are able to charge high prices for this.

In previous work I have looked at the evidence concerning the value of patent data (Moir, 2009b: 40-42). Indirect evidence from surveys of innovating firms also provides convincing evidence that there are many other sources of information on new technology that are far more effective than the patent system. Customers and suppliers are important sources of information driving new product development, as are competitors (Porter, 1990). Some studies report that firms find data in patents irrelevant to their needs or available from other sources.

There are a variety of reasons why patent data provide only limited benefits about new technologies. The language in which they are written has been mentioned above, and is a major factor. In the next section (effectiveness) I provide evidence on the very low level of inventiveness of most granted patents. This means that a very large proportion of granted patents contain no information on new technology, so there is a poor cost-benefit in searching for the few patents that do contain such information. While available databases have improved searching by technology class is of limited value, as these align poorly with most information needs. Keyword searching is also of limited value as key words can be missing from a specification. Stallman provides the example of a key US patent on natural order recalculation in spreadsheets: the key terms ‘spreadsheet’, ‘natural order recalculation’ and ‘topological sorting’ did not appear in the specifications (Stallman, 2001). Labich (1988) notes that such missing key words are a matter of deliberate strategy. Murphy (2002) finds patent titles to be so obscure they are of little help in searching. On the basis of my own empirical work I would agree with Murphy and add that very often abstracts are also of little use,

The Commission asks "[w]hat scope is there to better leverage the economic benefits of patents, by taking steps to *improve the diffusion* of patent information?" (*Issues Paper*: 18). With respect, this is not the correct question at this time. Until the inventive step is increased until only genuine technological inventions are granted patents, the information in most patent specifications is not worth diffusion. It is mere noise. In 2011 there were reforms to the requirements for clarity in patent specifications. It would be useful to evaluate the impact of these – perhaps by organising several teams of independent experts to read the abstract, claims and description of the invention. If clarity has been improved, and steps are taken to substantially raise the inventive step, this question will then be worth answering. This will be about 20 plus years from now. Although when a new legal doctrine is created it takes immediate effect, there appears to be an understanding that if evidence-based reforms are legislated it is "unfair" (to the rights-holders) for these to take immediate effect. What, one asks, about fairness to the rest of the community? Particularly the 80% of Australian firms undertaking significant innovation without owning any patents.

Overall assessment of effectiveness

In my view it is not possible to address the other questions the Commission has raised under this heading until issues regarding the effectiveness of the patent system have been discussed. It will then be possible to return to such central questions as: whether patent rights encourage genuinely innovative and creative output that would not have otherwise occurred or simply reward innovation that would have occurred anyway; how the patent system could be improved to be more efficient and effective; and the evidence-basis that should be used for such re-design (*Issues Paper*: 8).

One conclusion can, however be drawn. Based on the evidence reviewed above it is clear that the assumptions underlying the traditional hypothesis that new technological information can be instantly copied at no cost are contradicted by empirical evidence. Information economics provides a much sounder basis for the development of a welfare-enhancing patent policy. It focuses on the cost and complexity of acquiring new knowledge, especially all-important tacit knowledge. Its assumptions are more consistent with the empirical evidence across all industries. Its predictions align well with the facts. Where the codified element of knowledge is high, as in the pharmaceutical industry, copying will be relatively less expensive, and some form of intervention might be necessary. But where the tacit component is high copying will be expensive, both in terms of time and resources, and the market provides adequate returns to innovation investment.[11]

It is also useful to keep in mind that at the time patent were introduced, and even at the time they came close to being abolished (Machlup and Penrose, 1950), there were no other government programs to support R&D. Now almost every high income country has an R&D tax concession program, together with a range of other government supports, from incubators, through incentives for early commercialisation funding, to the clever use of government purchasing.[12]

3. Efficiency

An efficient patent system would grant patents only for inventions which were induced by the patent system *and* which provided net positive spillover benefits. There would be no point in a policy which induced inventions which had negative or zero net spillover benefits. Article 5.1 of the Competition Principles Agreement requires that

> "legislation … should not restrict competition *unless it can be demonstrated* that: (a) the benefits of the restriction to the community as a whole outweigh the costs; and (b) the objectives of the legislation can only be achieved by restricting competition."[13]

While this is directed at the macro level – in this case the patent system as a whole – applying the principles at the micro level ensures that the aggregate of granted patents meets the Article 5.1 test (a). Patents with zero or negative spillovers fail the benefits to the community test. Both inducement and spillover benefits are addressed in this section. A third sub-section addresses the issue of patentable subject matter.

The *Issues Paper* identifies efficiency as getting the balance right such that incentives for induced new inventions incur the lowest possible cost to society. There is very little empirical academic work on the costs and benefits of patent schemes. My own work on the topic found many elements of costs and benefits where relevant data were absent (Moir, 2009b).

Given this, an alternative approach that may offer useful insights is to focus on who are the main beneficiaries of the patent system. The clearest single group benefitting from the Australian patent system are Patent Attorneys (discussed further below, see p. 44). Other beneficiaries are those holding patent rights/privileges. Patent ownership is very skewed, with a large proportion of patents owned by a small number of companies while many companies have just one or two patents. My empirical work identifying the main holders of Australian patents covers the period 1990-2006 (Moir, 2009c). The Commission might like to obtain more up-to-date information on the ownership of Australian patents.[14]

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[11] See, for example Mandeville, 1996; Saviotti, 1998; and Dempsey, 1999.

[12] Though Australia continues to be rather un-clever at using this last strategy (see Thurbon, 2015).

[13] http://www.coag.gov.au/node/52, emphasis added.

[14] Though if one's preference is to analyse patent data by filing year, as this is the point at which the invention is first sufficiently defined for business strategy assessment, there is a long lag until a full filing cohort of patent

In such a situation it is useful to return to the fundamental assumption in respect of the alleged market failure for inventions – the speed with which competitors can enter the market with a competing product. Relevant to this is the cost of the R&D investment. Where this cost is small, the inventor will need only a short period in the market before recouping the sunk invention costs. On the other hand where the cost is very large, first mover advantages may well be insufficient to recover the investment in R&D.

These factors suggest that a patent system which used these two criteria would be most likely to avoid granting patents for inventions which were not induced by the patent system. Unfortunately these variables are difficult to verify and exclusive time in the market can only be determined retrospectively. Further, TRIPS requires that three specific criteria be used to determine patent eligibility and implies that any additional criteria would not be allowed (Article 27.1). TRIPS also requires that all technologies be treated equally, though it allows certain categories of inventions to be declared non-patentable (Article 27.2). These are inventions which would contravene the *ordre public* (morality); patents for inventions needed "to protect human, animal or plant life or health or to avoid serious prejudice to the environment; diagnostic, therapeutic and surgical methods for the treatment of humans or animals; and plants and animals other than micro-organisms and essentially biological processes for their production". In the AUSFTA Australia gave away the freedom to exclude plants and animals other than micro-organisms, and essentially biological processes for their production from patentability. Further Australia specifically agreed that "any new uses or methods of using a known product" would be patentable (AUSFTA Article 17.9.1).

But still, and so fundamentally that it is rarely mentioned, patents are designed for technological inventions. It is here that R&D costs are highest and considerable trial and error can be involved in developing an innovative idea into a commercially viable product. This issue – patentable subject matter – is discussed further in Section 4 on net welfare impacts.

Over recent decades the patent system has been extended in substantial ways in Australia through judicial decision making (Moir, 2013c: 37-61). The principle extensions are to software (including business methods) and to methods of medical treatment (as distinct from products for use in methods of medical treatment). It is highly questionable whether software and business method patents are induced by the patent system – indeed for such inventions it is difficult to separate out R&D costs from production costs, hence the argument about a market failure through competitors free-riding on expensive R&D is hard to maintain.

Patents for non-induced inventions

The Commission asks whether patent rights avoid rewarding innovation that would have occurred anyway. My own work has focused on this question. Absent the capacity to use the magnitude of R&D investment as a criterion for patentability, the inventive step concept has to take on all the work of ensuring that patents are not awarded for inventions that would have occurred anyway. My initial empirical research on this issue took a sample of 72 business method patents and asked the question "how much new knowledge is embodied in these inventions"? I found no new knowledge in any of these 72 patents. Yet patents were granted for these "inventions" not only in Australia but also in the USA and Europe (Moir, 2013c; Moir, 2013b). My research confirmed the substantial anecdotal evidence about trivial patents and identified the doctrinal rules (policies) which lead to such grants. It should be noted that the grant of many trivial patents does not mean that no genuinely inventive inventions are patented. Rather it implies that the cut-off standard for patent grant has fallen well below the standard required for an economically efficient (welfare enhancing) system.

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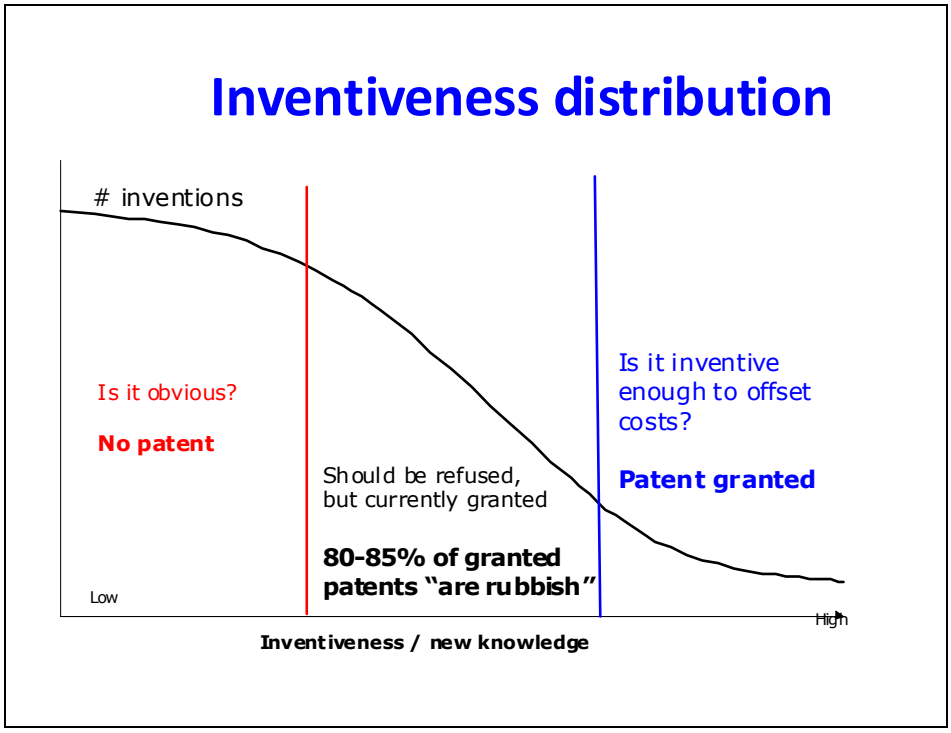
outcomes becomes available. Patents by grant year are unduly influenced by administrative factors (Griliches, 1990).

What are the doctrinal policies that give rise to this very low standard? The first problem is that the Patent Act asks the wrong question. It does not ask whether the application is sufficiently inventive to merit grant of a "powerful exclusive right." Rather it asks whether an unimaginative ordinary worker in the technology field would find the invention obvious in the light of specified knowledge at the time. The implications are shown below in Figure 1.

Figure 1: Comparison of the current and the economically efficient rules to patent grant



Notes: While the inventiveness distribution in hypothetical, there is substantial evidence that only a small proportion of inventions are radically inventive, a larger proportion are substantially inventive and very many involve only small modifications. For an interesting empirical study designed to identify the most inventive tennis racquets see Dahlin and Behrens, 2005.

The right-hand side of Figure 1 shows (in blue) the approach needed to maximise economic efficiency. The left-hand side shows (in red) the approach used by patent offices. The result is the grant of patents to a very large proportion of applications that do not meet the criteria required for economic efficiency.

Inventiveness is not a binary variable, though the grant of a patent requires that there be a point at which a patent will not be granted. It is interesting to speculate whether the scintilla of inventiveness doctrine started life as a scintilla more than the dividing line, rather than a scintilla more than no inventiveness. Perhaps the meaning of inventiveness in this doctrine was "sufficient inventiveness to merit patent grant". This would certainly make more economic sense. It would also be a first step in ensuring that patents are granted only for "a significant advance over what was known and what was available to the public" – the standard advised to the Australian Parliament in 2011.[15]

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

Even within the patent attorney profession there are views that the obviousness test is Australia is too low. Summerfield attributes this to unnecessary complexity in Section 7 of the *Patent Act 1990*:

> "Australia has an obvious problem with obviousness. For over three decades, we have been out-of-step on inventive step. The law of obviousness under the Patents Act 1952 was originally messed up by the High Court in the '*3M* Case' (*Minnesota Mining & Manufacturing Co v Beiersdorf (Australia) Ltd* [1980] HCA 9). There have since been three legislative attempts to fix it – with the original enactment of the Patents Act 1990, with the changes in the Patents Amendment Act 2001, and most recently with the passage of the Intellectual Property Laws Amendment (Raising the Bar) Act 2012.
> …
> When the laws of other countries simply direct decision-makers to assess whether the skilled person would consider the claimed invention obvious, having regard to the 'state of the art' (or equivalent), this is what they ultimately require. It is not a question of 'common general knowledge', or of 'prior art information' taken either alone or in combination. It is a matter of looking at the state of the art, and the characteristics of the skilled person, and asking 'would this person have found the claimed invention to be obvious?'
>
> Summerfield, 2015a

Beyond the initial problem of using the wrong (obviousness) test to determine eligibility for a patent, there are myriad specific doctrines which increase the likelihood that a patent will be granted for something which is uninventive in the ordinary meaning of the word.

The doctrines which contribute to the very low inventiveness requirement include:

- the reverse onus of proof;
- the decision-making rule about patentability evidence;
- the definition of the hypothetical judge of obviousness;
- limitations on the existing knowledge allowed in determining novelty or inventiveness;
- narrow technology fields for existing knowledge and the inventiveness judge;
- the High Court's very low standard for inventiveness;
- loss of the synergy doctrine for combinations;
- continual amendment of specifications during examination; and
- lack of balance in privileges and penalties.

The reverse onus of proof

Contrary to normal economic principles when there is a government intervention in the market, the onus is not on the patent applicant to demonstrate sufficient inventiveness to merit a patent. The onus is on the examiner to demonstrate that it is obvious, using a set of detailed rules that make this task hard even for the most obvious of "inventions". The Patent Act 1990 sets out the presumption that an application meets the standard required for grant of a patent (article 7), and then places the onus on the examiner to show that it fails the standards. With this un-level playing field the Australian Patent Office has, for example, granted a patent for teaching children about finance by having them work for their pocket money (AU2003203582). **The statute could usefully be amended to place the onus on the applicant to demonstrate that their application passes the threshold tests.**

The US Patent and Trademark Office (USPTO) has developed a useful practice in relation to Common General Knowledge (CGK) that declares a particular piece of knowledge to be CGK. The onus is then placed on the applicant to prove that it is not. **Australia could usefully adopt this practice.**

The decision-making rule for patentability evidence

As a consequence of the competition principles review of "intellectual property" (IPCRC, 2000) the decision making rules as to sufficiency of evidence on patentability criteria was increased from giving applicants the benefit of the doubt to deciding on the basis of balance of probabilities. It is understandable that lawyers prefer to keep the standard "beyond reasonable doubt" for criminal matters. But because of the chilling effect that unmerited patents can have on other innovators (High Court, *D'Arcy v Myriad Genetics*, 2015; at 8)[16] a very high standard of proof should be required. Further Article 5.1 requires a high standard of proof – the benefits must be clearly demonstrated. The normal economic rule for intervention in a market is that there must be clear evidence that the intervention will be welfare-enhancing. The balance of probabilities rule does not reach this standard. **I recommend that the decision-making rule for evidence of patentability be raise to "beyond reasonable doubt."**

The hypothetical person skilled in the technology

In judging whether something is obvious a hypothetical construct of an ordinary worker in the field has been developed. This person is referred to in Australia as the Person Skilled in the Art (PSA) and in the USA as the Person having Ordinary Skills in the Art (PHOSITA). Van Caenegem notes that the PSA is "an ordinary worker in the field *not endowed with any special inventive skill*" and has described this as "surreal", particularly when discussing inventions genuinely leading edge inventions "where inventiveness is a common attribute of every typical worker" (van Caenegem, 2007: 84-85, emphasis added). Until recently it was a requirement of the US PHOSITA construct that the PHOSITA have no imagination. This was overturned recently by the Supreme Court.[17] There has not, to my knowledge, been any move in Australia to review the characteristics of the PSA.

The TPPA will bind Australia to the current “is it obvious?” patentability test:

> 1.Subject to paragraphs 3 and 4, each Party shall make patents available for any invention, whether a product or process, in all fields of technology, provided that the invention is new, involves an inventive step and is capable of industrial application.[30]
>
> footnote 30: … In determinations regarding inventive step, or non-obviousness, *each Party shall consider whether the claimed invention would have been obvious to a person skilled, or having ordinary skill in the art, having regard to the prior art.*
>
> Article 18.37: Patentable Subject Matter, emphasis added.

This is unfortunate as this reverse-style test inevitably risks falling to a low standard. The key traditional elements inherited from case law – and never subjected to any form of economic evaluation – are set in concrete by the TPPA. Thus Australia, if it ratifies the TPPA will be bound to the concepts of “a person skilled, or having ordinary kill in the art, having regard to prior knowledge”. The chilling impact of this excessively prescriptive regulation could be moderated by ensuring that the key elements of “obvious” “skilled person” and “prior art” are

[16] *D'Arcy v Myriad Genetics Inc* [2015] HCA 35.
[17] *KSR v. Teleflex* [127 S.Ct. 1727 (2007). See Dreyfuss, 2008, for a discussion of this change.

defined in ways that will achieve the sufficiently stringent inventive step test advised to Parliament in 2011.

The "obvious" element is dealt with below when discussing the High Court's very low inventive test. Limitations on existing knowledge (patentese uses the term "prior art") are also discussed below. From an economic efficiency perspective it is hard to understand why existing knowledge at the priority date should be constrained in any way in assessing inventiveness.

In his submission to this inquiry Chris Dent provides interesting information on the origin of the PSA.[18] He points out that this imaginary person was originally designed to be the judge of whether the specification clearly disseminated the invention, so that a person of ordinary skills in the art could implement it. This is quite a different role from determining whether a patent is inventive or not. Dent does not advise when or how the PSA shifted from being the judge of disclosure to being the judge of inventiveness.

The completely different role for the judge of inventiveness requires that this person have the qualities of a modern research worker. Thus, for example, for pharmaceutical products, the typical skilled worker should be defined as a pharmaceutical researcher with the concomitant intelligence, imagination, ingenuity and knowledge of workers in that field. At present there is a tendency to define the relevant skilled person as a medical practitioner rather than a pharmaceutical researcher.[19] In a world where inventiveness is the norm and the average consumer is surrounded by a barrage of new products and services, it is appropriate that this high general level of inventiveness be taken into account in determining the qualities of the inventiveness judge. **The PSA must be defined in terms that ensure that the decisions s/he makes implement the "significant advance over what was known and what was available" standard advised to Parliament in 2011.**

Limitations on relevant existing knowledge

In 2011 amendments to the patent legislation removed the worst of the limits on what existing knowledge could be used in assessing inventiveness. The *Emperor Sports* decision had created a situation where knowledge in published patent documents could not be used for low technology inventions,[20] where, even when applying for a patent, the relevant PSA would not think of reading existing patent material. This doctrine was removed by the 2011 amendments.

There are different limits on what existing knowledge can be used in the separate tests for novelty and inventiveness.[21] It is not widely known outside the patent community that in testing for novelty, the invention in the application can be compared only to a single piece of evidence at a time. Given unlimited amendment opportunities it is very simple for an applicant to amend their claims to add – or even remove – a small element from the "invention" so that it is no longer identical to that in the specified document. This was a consistent feature of my own empirical work – wherever an examiner raised novelty or inventiveness objections the applicant would amend their specification in light of the examiner's report. This is discussed further below. This element of patent law derives from an 1880 English decision – *Von Heyden*.[22] It has not been subjected to any economic analysis.

[18] Submission 30 to this inquiry, p.8.
[19] *AstraZeneca AB v Apotex Pty Ltd,* [2015] HCA 30.
[20] *Commissioner of Patents v Emperor Sports* (2006) 225 ALR 407;(2006) 67 IPR 488;[2006] FCAFC 26.
[21] For a brief history, from an economists' viewpoint, of novelty and inventiveness tests see Moir, 2013c: 50-55.
[22] Von Heyden v. Neustadt (1880) 50 L.J.Ch. 126. See Bochnovic, 1982 for a fuller discussion.

In 2015, the High Court moved on the question of what existing knowledge may be considered.[23] The Court ruled that, in determining the one piece of existing knowledge ("prior art") that can be used in determining obviousness, the PSA could search through all available evidence to find the most relevant single document. Further, more than one document can be identified and used, provided each is separately combined with CGK.

The commitment to Parliament in 2011 that patents are granted only for "a significant advance over what was known and what was available to the public" implies that patent applications are assessed against the full body of existing knowledge and practice. Only if they provide a significant advance compared to this should a patent be granted. Summerfield's suggestion that Section 7 of the Act be revised to a far simpler form that does not remove any part of existing knowledge from the patentability tests merits active consideration.

All restrictions on what existing knowledge can be used in determining patentability should be removed. The sole requirement should be that the knowledge should be in existence at the priority date.

Narrowness of relevant technology field

Courts in Australia and the USA have narrowed the scope of the relevant field of technology used to determine inventiveness. In respect of the US patent system, Bagley (2001) has demonstrated how such narrowing rules as inadmissible most relevant prior knowledge in the obviousness test. In a key Australian case, *Welcome Real Time*,[24] the way in which the relevant field was construed, not as smartcard technology, but as consumer loyalty programs, was critical to the decision of validity. The heart of the invention was use of dynamic storage in a smart card. All parties to the dispute agreed that at the priority date dynamic storage was well known in the information technology (IT) field. However the "invention" was for a consumer loyalty card, and as consumer loyalty specialists had to search long and hard (about a year) for what was well known to IT workers, the patent was upheld. To an economist this seems like a reward for ignorance. It certainly falls far short of the "significant advance over what was known" standard.

Like the doctrine that combinations should not be deemed obvious unless someone has said they are (see below), this approach leans strongly in the direction of ensuring that patents are granted, regardless of whether there is any benefit to society. In part this is possible because the patent statute specifies no overall objectives. Again this issue is taken up below (p.31).

A very useful doctrine in patent law is the doctrine of analogous use. This extremely useful doctrine was developed in the English courts in 1838:

> "It would be a very extraordinary thing to say, that because all mankind have been accustomed to eat soup with a spoon, that a man could take out a patent because he says you might eat peas with a spoon. The law on this subject is this: that you cannot have a patent for applying to a well-known thing, which might be applied to 50,000 different purposes, for applying it to an operation which is exactly analogous to what was done before."
>
> (1838) 3 *Hayward's Patent Cases* 125, 141.
> (from Brennan and Christie, 1997: 29)

In my study of business methods there were a number of cases where the analogous use principle would seem to have been relevant, yet it was not applied.[25] The analogous use

[23] *AstraZeneca AB v Apotex Pty Ltd* (et al) [2015] HCA 30.
[24] *Welcome Real-Time SA v. Catuity Inc*, [2001] FCA 445.
[25] See Moir, 2013a: 250 for a three examples.

policy is important in limiting narrow interpretations of the scope of knowledge or of technology field. It needs to be applied far more rigorously.

Patent policy needs to be amended to ensure that technology fields are not narrowly circumscribed and so that the analogous use principle is rigorously applied.

The High Court's very low inventiveness standard

In 2009 IP Australia commenced a process of consultation to address some of the more obvious deficiencies in the patent system. In their initial consultation paper IP Australia said:

> "the threshold test set for inventive step … was most recently considered by the High Court in *Lockwood*,[26] where the Court affirmed that the test for lack of inventive step, or obviousness, was whether or not the skilled person would be led directly as a matter of course to try a particular approach with a reasonable expectation of success.
>
> "In contrast, in jurisdictions such as the EPC the question that is asked is: 'Would the invention have been obvious to try with a reasonable expectation of success?' This approach takes account of situations where it is routine in the art to conduct testing or combine particular approaches in order to solve a particular problem or in order to find a better way of doing things. As such it sets a lower requirement for establishing a lack of inventive step than the Australian requirement, in that it accepts that in certain circumstances some degree of routine experimentation would be standard practice for a skilled worker in the art." IP Australia, 2009a: 12

IP Australia proposed a change to:

> "revise the inventive step test to a test where the claimed invention is obvious if it was 'obvious for the skilled person to try a suggested approach, alternative or method with a reasonable expectation of success'." IP Australia, 2009a: 13

Submissions to this discussion paper were not made public. Following the consultation period IP Australia declared:

> "IP Australia's proposal was made in response to concerns that the test as restated in *Lockwood* made it harder to establish a lack of inventive step in Australia than elsewhere. While some submissions agreed with this assessment, a number of submissions argued that *IP Australia had put too much weight on* ***a particular comment*** *made by the High Court* in relation to a specific case. A number of submissions also suggested that the changes already proposed by IP Australia with respect to common general knowledge and prior art (see 1.2.1 and 1.2.2) would be sufficient to achieve the desired outcome of increasing the inventive step standard. Some submissions suggested that higher standards could also be achieved by IP Australia applying more rigorous standards during examination.
>
> After giving detailed consideration to the points raised in submissions, IP Australia proposes to address concerns through restating the guidelines for inventive step in the Examiners' Manual and through more rigorous application of the inventive step tests during examination, rather than through changes to the law - beyond the changes proposed for common general knowledge and prior art."
>
> IP Australia, 2009b: 12, emphasis added

[26] *Lockwood v. Doric* [2007] HCA 21. This is an interesting case where, for legal reasons rather obscure to an economist, the High Court declared that knowledge from mortice locks was inadmissible in determining the inventiveness of rim-mounted locks.

It is unclear just how changes to the examiner's manual could over-ride legal doctrine. The doctrine concerned was not “a particular comment”, but rather the heart of the matter.[27] After all, examiners must implement the law as it stands. The low inventiveness standard – that obviousness only happens if the PSA is "led directly as a matter of course" to the same outcome – has since been re-affirmed by the courts, most recently by the High Court in *AstraZeneca AB v Apotex Pty Ltd*.[28]

The test for the inventive step needs to be changed to achieve the outcome that patents are only granted 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."

Removal of the synergy doctrine

Prior to the 1980 *3M* decision Australia used the synergy doctrine for ensuring that obvious combinations of known things were not granted new patents. Under the synergy doctrine a combination of known elements must have either an outcome greater than the sum of the parts or an unexpected result to pass the "is it obvious?" test. The USA followed Australia's lead in eliminating the synergy test in 1983.[29] It has been replaced by the "suggestions test" where to be deemed obvious a combination of known things must have been written down. There is not a large market for writing down the obvious. The impact of moving from the synergy to the suggestions test in the USA has been particularly clearly demonstrated by Lunney (2004) though there is a vast literature on the problem of very low quality US patents.

The synergy test is still followed in Europe, and is a contender in explaining why Europe is perceived to have higher standards for patentability.

One of the strange things about patent doctrine is that the synergy test seems to apply only to things and not to processes. Certainly processes create far greater difficulties in administering patent policy than things, but there is no reason why similar principles should not apply in their evaluation.

The suggestion test must be removed and the synergy test re-established, the synergy test should apply to all forms of inventions, including processes and methods.

Limit amendments to a single instance

During my study of business method patents I observed, time after time, how an examiner would reject an application as either not novel or not inventive. The applicant – or more probably their attorney – would scrutinise the examiner's objections and then amend the specification to avoid the objection. At that time it was clear that examiners were not supported to reject business method claims and there were rarely more than two examiner's reports. One brave examiner, however, rejected an application four times for want of merit, before accepting the final amendments and granting a patent. I understand that since then the Australian Patent Office has increased the rigour with which it examines applications and, hopefully, examiners are now better supported when an application does not merit a patent.[30]

Once particularly objectionable example from my study is Westpac’s “Integrated financial service product” (AU2005204292, priority August 2005). It is a computerised system for a loan account, a credit card account and any third account selected from the bank’s product range. The loan and credit card accounts are unsecured, and have a single credit limit, but

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[27] Aktiebolaget Hässle v Alphapharm Pty Ltd (2002) 212 CLR 411 (Alphapharm). See also Lawson, 2008.
[28] *AstraZeneca AB v Apotex Pty Ltd*, [2015] HCA 30.
[29] Lunney (2004: 21) considers that the critical judgement was *ACS Hospital Sys, Inc.*, 732 F2d.
[30] Personal communication from a now-retired patent examiner.

different interest rates. There is a rewards program associated with how the customer manages transactions in and balances between the two accounts. Following a second rejection for want of inventiveness, compared to the Commonwealth's very similar Viridian product, the applicant argued that their "invention" was inventive because:

- customers *can* link credit cards to the Viridian product, but that *must* link them in the Westpac invention; and
- although Viridian provides a "benefit" in terms of reduced loan debt this benefit is not a "reward currency" and there are no "reward program rules".

This example is provided here to illustrate how narrow semantic changes are a core aspect of Australia's current approach to assessing obviousness.

Another example I have come across while studying patents for antiretroviral (ARV) medicines is a US patent (application 12/523226, priority June 2007). This is for an extended release formulation of nevirapine, an ARV used to treat HIV positive patients. The application was rejected by the USPTO in November 2011 as unclear and obvious. The applicant then deleted 23 of the 24 claims, but the single remaining claim was again rejected as obvious. The applicant then withdrew the single remaining claim and substituted a marginally different single claim. As can be seen from the changes made to the single claim (Figure 2), the major difference was a change *from a patent for a composition* to a patent ***for the use*** *of the same composition* ***to treat HIV***. The specification of the hypromellose component was also changed, but only by deleting the trademark name. By 2009 the use of nevirapine for treatment of HIV was well known – it was originally approved by the FDA in 1996 and in Europe in 1997. Nevirapine has thus been on the market for some 10 years when this particular patent application was filed. Indeed Nevirapine was added to the World Health Organization's List of Essential Medicines in 2000,[31] seven years before this patent was filed.

Figure 2 Extended release nevirapine: granted patent claim and differences from previously rejected obvious claim

Nevirapine, extended release formulation. US patent application 12/523226

Comparison of rejected claim 15 and accepted claim 24

Claim ~~15~~24

A method for treating HIV-1 infection which comprises once daily administration to a human infected by HIV-1 a ~~A~~ tablet pharmaceutical dosage from wherein each tablet comprises:

(a) 400 mg of anhydrous nevirapine;

(b) 270 mg of hypromellose 2208

~~(Methocel™ K4M Premium CR)~~

(c) 400 mg of lactose monohydrate; and

(d) 10 mg of Magnesium stearate

Wherein each tablet is compressed by a force of 10-25 kN.

Note: the editing shows the differences between the granted patent (in blue and black) and the rejected obvious claim (in black and red).

[31] See *World Health Organization, Comparative table of medicines on the WHO Essential Medicines Lists from 1977-2011*, worksheet "additions to EML", available at www.who.int/medicines/publications/essentialmedicines/EMLsChanges1977_2011.xls

The opportunity to amend a patent specification was introduced in Australia in 1952. I have not found the basis for this change, nor what evidence was brought to the question. I have not found any evidence of any evaluation of the new amendments policy. Certainly there is no mention of this issue in any of the three reviews briefly described in Section 1.

The USPTO has procedures where applicants can continually resubmit their application. In one case in my sample the US examiner rejected the application eight times.

The European Patent Office (EPO) has far more stringent procedures, at least at the examination stage. After the first examiner's report the applicant has the opportunity to amend the specification once. If that leads to a further rejection, and the applicant wishes to appeal, an oral hearing is called. Applicants can and do offer amendments at such hearings – often more than one version. If they subsequently appeal to a Technical Board, again they are allowed to introduce amendments.

The process of amendment leads to a greater emphasis on legal drafting ingenuity than on technological ingenuity. As Edwards remarked a lifetime ago:

> "As it reaches the patent office the application combines technological and legal invention, and the latter, if of superior quality, may do much to offset deficiencies in the former."
>
> (Edwards, 1949: 218)

Despite the EPO's alleged higher standards, in my empirical study I had not just one, but three cases where a European patent was rejected as not inventive but where, after amendment it was granted. In each case the amendment *simply consisted of a rearrangement of the wording* – specifically moving words from dependent claims to the independent claim. One case is where a patent was granted for a software process for checking identity prior to accessing a financial system once the words “wherein the stored fingerprint is in an encrypted format” were moved from claim 2 to claim 1.[32]

The proposed Trans-Pacific Partnership Agreement (TPPA) includes a requirement in regard to amendments. To my knowledge this is the first time such detail has been included in a trade agreement. The requirement is that an opportunity for amendment be allowed.

It would be opportune to limit the opportunity to amendment to a single instance, and I recommend that this be done as a matter of priority. This would satisfy the TPPA requirements while removing a major opportunity for semantic rather than technological ingenuity as the basis for patent grant. Based on my own empirical work, this would eliminate many uninventive patents.

Patent incentives and penalties

Privileges

TRIPS spells out the privileges which must be embodied in the patent grant. The patent owner must be allowed to prevent third parties from "making, using, offering for sale, selling, or importing" the patented invention unless permission has been granted (Article 28). This wide range of privileges dates from the period when most countries had a “local working” safeguard. Local working ensured that a useful patent need not lie unnecessarily idle. If it was not “worked” by the end of its first three years, then others could use it. While worked usually meant manufactured (which then had the advantage of knowledge and know-how spillovers), it could also mean imported.

[32] See Moir, 2013a: 25a for two cases where semantics were the key element introducing inventiveness.

The "local working" safeguard was removed by TRIPS, consistent with free trade approaches, but ignoring that TRIPS is the reverse of a free trade instrument. Without such a safeguard, a company can obtain a patent in a country, but then not supply the related good. This is most likely to occur in relation to pharmaceuticals. For example, in response to the compulsory licensing of one of its drugs Abbott withdrew seven products from the Thai drug regulatory authority application list (Krikorian, 2008). In the period 1983-2002 nearly 40 percent of all new medicines were launched in ten or fewer countries (Cockburn *et al.*, 2014). There is therefore a clear need to provide some form of protection for consumers to ensure patents are not operational in a country where the medicine they relate to is not being supplied.

Absent a local working safeguard, patent privileges do not need to be as broad as they were when the local working safeguard was in operation. Particularly objectionable in the current globalised world is the privilege to prevent the making of products that infringe a patent, when these are not intended for sale during the patent period. This prevents companies gearing up to enter the market the day after the patent expires – thereby gaining the rights-holder an additional period of market exclusivity. It also prevents companies from manufacturing for export to countries where the patent is not in force. This aspect of patent privileges has a particularly marked negative impact on the generics medicines industry.

The Commission identified the problem of the unnecessary prevention of manufacturing for export in 2003 (Productivity Commission, 2003). The Pharmaceutical Patents Review also looked into this problem, further identifying the ban on stockpiling in preparation for Australian market entry as placing domestic manufacturers at a disadvantage compared to overseas suppliers (Harris et al., 2013).

In effect, in the modern globalised world, the sole privilege needed to make the patent incentive operative is a ban on domestic sale during the patent period. All other uses should be permitted. There are a small number of highly problematic deficiencies in TRIPS.[33] The excessively wide range of privileges which must be provided for a patent should a priority for reconsideration – it is a major factor in ensuring that a TRIPS-compliant patent system fails to comply with the TRIPS Article 7 requirement for balance.

While there is nothing that can be done in the short term about the range of privileges embodied in a patent, no such limitations are attached to the practice of providing term extensions for new pharmaceutical products.

Such patent term extensions could limit the privileges they provide to that of sale in the domestic market. This would do much to offset the current problematic bans on stockpiling and manufacturing for export. The Pharmaceutical Patent Review (PPR) presented data showing that term extensions are welfare-reducing for Australia (Harris et al., 2013). Because of the AUSFTA, Australia does not have the freedom to eliminate this welfare-reducing policy. But there would seem to be no impediment to amending the range of privileges attached to the grant of a patent term extension. Providing the sole privilege of sale in the domestic market would do much to offset the current problematic bans on stockpiling and manufacturing for export.

The issue of patent term extensions, of course, raises the issue of the excessive length of the standard patent term. It was the pharmaceutical industry which pushed for both equal treatment for all technologies, and a longer term because of the specific circumstances of the pharmaceutical industry (Drahos, 2002; Sell, 2003). Since 1995, when TRIPS came into force, the pharmaceutical industry has successfully pushed for patent term extensions through

[33] The others patent deficiencies being the requirement to treat all technologies equally, the absence of chemical products from the list of allowed unpatentable subject matter, the excessively long patent term and the reverse onus of proof in infringement proceedings in respect of pharmaceutical processes.

bilateral trade agreements (Drahos, 2001; Morin, 2006; Smith *et al.*, 2009). The AUSFTA, for example, provides for extensions of up to five years, as does the TPPA. Over the longer term, if Australia wishes to design a patent system that meets the needs of domestic companies and inventors rather than the needs of large overseas corporations, Australia could take the lead in pushing for an evaluation and re-negotiation of TRIPS. Reducing the length of the patent term would be high on such a list of potential amendments.

In the meantime privileges associated with patent term extensions should be limited to the privilege of preventing sale in the domestic market.

Penalties

When it comes to penalties, these are very one-sided. Penalties for infringement are well developed in patent systems. The tension between the economic goal of disseminating new knowledge and technology and the competitive restraint provided by a patent traditionally meant that the usual penalty for infringement was payment of royalties. This simultaneously ensured a proper incentive for the inventor and the more widespread use of the technology.

In the USA, the CAFC developed a tendency to issue injunctions as a remedy for patent infringement, starting with the precedent-setting penalties in the 1986 Kodak-Polaroid case. From an economic policy perspective this seems disproportionate – injunctions involve an extremely high cost to many innocent parties, particularly those who lose their jobs. Similarly, since the Texas Instruments case in 1985-86 extraordinarily high levels of damages have been awarded in the USA.[34] Again it is hard to see how excessively high levels of damages achieve anything other than encouragement to abuse the patent system. In 2006 the Supreme Court acted to stop the use of injunctions except in exceptional circumstances.[35] This experience, and the lengthy delay between the CAFC adopting a policy of regularly using injunctions and the Supreme Court acting to constrain the use of injunctions, points to the need for clear specification of appropriate remedies for infringement in patent statutes.

The Generic and Biosimilar Medicines Association's submission to this inquiry points to the frequency with which interlocutory injunctions are granted to pharmaceutical companies in Australia. The Commission needs to consider the issue of penalties for infringement, or potential infringement, and determine the form of penalty which minimises the social cost to Australia, while providing incentives not to infringe. Clearly the courts need guidance on the least economically costly forms of penalties.

There is a major asymmetry in the incentive to challenge an invalidly granted patent compared to the incentive to sue for infringement. If a patent-holder sues for infringement and wins s/he gains all the consequent benefits (damages, costs, payment of license fees and a greater ease in obtaining license fees from other parties). Where an innovating firm finds their business path blocked by a seemingly invalid patent, s/he would bear all the costs and risks of legal action yet instantly share all the benefits of revocation (clearer market access) with all other companies competing in the field. The US has designed a means of creating appropriate incentives to challenge invalid pharmaceutical patents by providing a period of 180 days of market exclusivity for the first generic entrant who has won a validity challenge (Holovac, 2004). In the very large US market this potential reward substantially exceeds the cost of legal proceedings. A similar approach would not work in the much smaller Australian market, but alternative incentives could be investigated, such as sharing the more substantial savings gained by the Pharmaceutical Benefits Scheme (PBS).

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[34] For a discussion of the impact of this and the Kodak-Polaroid case on the salience of patents in the US business world see Hall and Ziedonis, 2001.

[35] US Supreme Court, *eBay Inc. v. MercExchange, L.L.C.*, 547 U.S. 388 (2006).

But in general the patent system has no procedures to ensure that weak patents are challenged. Where a company is sued for infringement, and counter-challenges on validity, that company will be paid compensation if the patent is revoked. But other companies kept out of the market by the invalid patent are not compensated for their forgone profits in the years the patent was used to restrict competition. When a patent is revoked, it is revoked *ab initio*, i.e. it was never valid. There are grounds for considering introduction of a clear system for repayment of all profits earned from invalidated patents. Not only would this re-balance the incentives to challenge weak and frivolous patents, thereby introducing an incentive towards greater balance in the patent system, but it would act as a disincentive for companies to seek such patents.

There is also considerable "doctrinal incoherence" (silly outcomes) in the patent system. Thambisetty notes a UK case where the failed challenger of a patent's validity had to pay damages for infringement *even after the patent had been revoked* after a successful subsequent challenge.[36] This is economic policy gone mad.

Endless amendment combines with the lack of any means of recouping profits from invalid patents to create a form of moral hazard – strong incentives to seek patents for "inventions" that fall far short of delivering any benefit to society.

When tax is erroneously under-estimated there are well-established mechanisms for repayment (including with penalties depending on the circumstances). When social security payments are made in error, these are recouped. Providing a parallel mechanism for ensuring that patent-holders do not benefit from unjustified monopolies would substantially reduce the incentive for firms to seek more and more patents for trivial "inventions". This effect could be made stronger by including a damages element. Such a policy would do much to rebalance the patent system.

In an extraordinary recent case two pharmaceutical companies disputed the right of the Commonwealth Government to seek compensation for the higher prices it had paid for PBS-listed pharmaceuticals during the period where generic entry was delayed due to injunctions and the patent was then revoked in whole or in part.[37] This attempt was unsuccessful. The case involved two medicines – clopidogrel and venlafaxine – each of which had involved use of an injunction to delay generic entry. As a consequence of this delay the Commonwealth had paid higher prices to Sanofi and Wyeth (Pfizer) than would have been the case had generic entry not been delayed. The companies had already reached settlements with the affected generic companies.

The patent system should be amended to introduce penalties for undermining the purpose of the patent system, such as attempting to patent inventions that provide no offsetting benefits, especially those contributing no new knowledge. In particular a different approach to penalties for invalidated patents is needed. But consideration should also be given to penalties for designing approaches that undermine clear patent rules. Under the European Patent Convention (EPC) the Swiss Patent Office developed a form of words to get round the rule that second methods of medical use were unpatentable (Thambisetty, 2009). Such semantic ingenuity parallels the ingenuity of financial experts in designing methods to evade tax. Approaches used to control such rorts on the tax system could be considered for preventing equivalent rorts on the patent system.

In addressing questions about efficiency in the patent system the Commission needs to address the various incentives that affect whether uninventive patents or sought and whether they are challenged or not.

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[36] *Coflexip v Stolt Comex* [2004] FSR 7 (Ch (Pat Ct)) and [2004] FSR 34 (CA) see Thambisetty, 2009: 23.
[37] *Commonwealth of Australia v Sanofi-Aventis* [2015] FCAFC 172.

Safeguards

There are a small number of safeguards in the patent system, operating to protect the interest of consumers and subsequent inventors. The most important of these is the presumption that a granted patent is not valid.[38] This allows the whole question of validity to be considered by a court *ab initio*. It is an extremely important safeguard. In the USA the CAFC has decided that granted patents have a presumption of validity and this adds substantially to the costs and risks of a third party challenger (Jaffe and Lerner, 2004). With a presumption of validity the standard of proof required for the alleged infringing party is higher ("clear and convincing evidence") than it is for the patent-holder ("preponderance of the evidence"), creating considerable imbalance between the two parties. History shows that patent offices tend to grant many patents which courts subsequently find invalid. Quillen (2006) reports on a 1980 study – prior to the creation of the pro-patent Court of Appeals for the Federal Circuit (CAFC) – by Koenig (1980) which calculated that US appeal courts found nearly two-thirds of patents challenged for validity were found to be invalid. This is an extremely high error rate. Patent offices work closely with those who seek patents and those who assist would-be patent-holders. But they have little contact with innovating firms which are harmed by the grant of invalid patents (Drahos, 2010). This builds in a tendency to favour the applicant.

The importance of Article 20 – no presumption of validity – cannot be over-emphasised. At present it is the sole element acting in favour of consumers and follow-on inventors. In 2003 the US Federal Trade Commission (FTC) found the US's patent system be one where a "plethora of presumptions and procedures tip the scales in favor of the ultimate issuance of a patent, once an application has been filed" (FTC, 2003: 8). The statutory guarantee that a granted patent cannot be presumed to be valid is the sole element of balance in Australia's patent system as it currently stands. **It should be enshrined as a key element of our patent policy.**

Other safeguards are very limited in their effect as their use is substantially constrained and hence there has been little if any use. It is interesting to note, from the submission by Chris Dent, that compulsory licenses were originally designed so that follow-on inventors could proceed without hold-up.[39] Today's compulsory licensing "safeguard" is substantially narrower in scope and effect. More recently (2011) a statutory exemption for research use was introduced. It is as yet too early to tell if this will be effective. Certainly at the time concerns were expressed that the inclusion of the adjective sole – "sole use" – might significantly weaken the protection. I note that were patent privileges less excessive, there would be no need for the research exemption. If the privilege was restricted to the key privilege of sale in the domestic market, then researchers would never risk being sued for infringement.

Other factors leading to a low inventive step.

Besides these doctrinal or statutory issues there are other administrative policies which encourage the grant of patents for uninventive inventions.

Statement of reason for grant

A particular example is the lack of any onus on the examiner to identify and declare the new knowledge or know-how contributed by the invention. This practice is part of standard

[38] "Nothing done under this Act or the PCT guarantees the granting of a patent, or that a patent is valid, in Australia or anywhere else." *Patents Act 1990*, Section 20(1). Despite this a Federal Court judge has recently qualified this express disclaimer stating that "[r]egistration of the patent is, of itself, prima facie evidence of validity" *Novartis v Hospira* [2012] FCA 1055 per Yates J, paras 51, 91-94. It is most concerning that a judge ruling on the Patent Act 1990 appears not to be aware of Article 20.

[39] Submission 30 to this inquiry, p. 9.

procedures at the USPTO. US examiners do not always confirm to the spirit of this requirement, sometimes merely reciting long pieces of esoteric claim language. But often these statements are helpful in identifying the reason for the grant. **It would be useful to introduce a requirement for Australian examiners to provide a statement to the benefit to Australia from granting the patent.** This statement should focus on the new knowledge or know-how embodied in the patent and, where there are also consumer surplus benefits, should spell out what these are expected to be. The language must be plain English. Technical language would be allowed, but not legalese. Such a requirement would be a constant reminder to examiners that the privilege they are granting carries costs, and should only be awarded where there are genuine benefits.

Performance indicators for examiners

Another issue is performance indicators for examiners. This is not a matter that I have gone into in any detail, but the design of examiner performance indicators may merit consideration.

Patents and spillover benefits

The second condition for patent grant that is required if a patent system is to be efficient is that the invention produce net positive spillover benefits. It is usual to consider that these spillovers would either involve a net increase in consumer surplus or knowledge which can be appropriated and built on by other inventors.

In a country like Australia, where most patents are owned by foreign entities, the usual closed economy analysis of spillover benefits must be interrogated. For the approximately 92% of patents which are granted to overseas entities it is likely that most if not all of any spillover benefits will occur in the country where the invention is produced. A number of analysts have noted that optimal patent policy in a technology-importing nation may well be very different from that in a technology-exporting nation (Penrose, 1951; BIE, 1994b; Gruen *et al.*, 1996). A National Office for the Information Economy (NOIE) study on productivity includes a useful appendix on the relationship between R&D expenditure and productivity growth, focusing on the role of externalities. They conclude:

> "So, while the rate of social return to R&D from a global perspective may be quite high, the domestic social rate of return in a small country *may not be much above the private return to R&D*, due to cross-border spillovers."
>
> (NOIE, 2004: 97, emphasis added)

There has been very little work on the net consumer surplus from inventions. This is not surprising as there are substantial methodological challenges. Such measurement would not only require measuring gross consumer surplus from the new invention but also identifying the consumer surplus from displaced products and subtracting that. There is one seminal article on gross consumer surplus (Mansfield *et al.*, 1977). Mansfield and colleagues studied 13 product innovations and four process innovations in the USA. This very small dataset of 17 commercialised inventions contained six with high social and private returns (i.e. they would be beneficial but would not require a patent to proceed); five which had low or negative social returns (i.e. it would be welfare-reducing to grant patents); and six with low private returns but high social returns (i.e. a patent would be needed and its grant would be welfare-enhancing).

In 1994 the then Bureau of Industry Economics published an exploratory study of spillovers from industrial innovation in Australia. The study found that spillover benefits in Australia are – as they are overseas – highly variable. It identified a number of critical factors affecting the quantum of spillover benefits: industry depth; the degree of competition; leakage of

spillover benefits overseas; diffusion processes; and learning by doing. The study concluded by saying:

> "It is evident that there is insufficient knowledge of the value and extent of spillovers in the Australian economy. This work has merely scratched the surface by pointing to some of the relevant issues. It is hoped that more detailed research would enable some of the remaining questions to be answered."
>
> BIE, 1994a: 76

Despite the policy importance of innovation – indicated by regular government statements on innovation policy – no in depth body of work on industrial innovation in Australia has yet emerged. Perhaps this should become a priority for the Australian Research Council?

There are a range of cross-sectional econometric studies on invention and spillovers, based on national accounts and other highly aggregate data. The Commission is well aware of this work. Briefly, two review articles reach somewhat different conclusions, but are useful in marshalling the available evidence.[40] Sena reviews four types of econometric studies and concludes that sizeable intra- and inter-industry spillovers exist (Sena, 2004). In contrast the US Congressional Budget Office (CBO) considers the evidence (from three different types of studies) to be relatively speculative, largely because of severe measurement difficulties (CBO, 2005). These large econometric studies give very divergent estimates of the relative value of social returns to industrial innovation.

There is one group of inventions where it is perhaps easier to identify consumer surplus – the range of medical products which can save lives and ease pain, for example, pharmaceuticals. This is discussed further under the heading of what subject matter is patentable (below p. 25). Australia has some globally competitive firms operating in the medical device area. But as the majority of their output is sold overseas, the majority of consumer surplus benefits accrue overseas.

For other products the main form of benefit that Australia will gain from Australian patents is likely to spillovers from new knowledge, particularly where there is some industry depth. A key requirement for such spillover benefits is thus *that there actually be new knowledge* contained in the patented invention and its specification.

It is often a surprise to economists that lawyers regular state that the *quid pro quo* to society for grant of a patent is the publication of the specification. Indeed this was the starting point for the Advisory Council on Intellectual Property's consideration of how objectives for the patent system should be specified (see p. 31 below). This is a substantial difference from the economist's viewpoint that the *quid pro quo* is *induced new invention* ***and*** *its associated net spillover benefits*. Of course, if the spillover takes the form of new knowledge, publication of the specification might assist in disseminating that new knowledge (subject to the problems of using patents to acquire new knowledge). But it is not, in itself, the *quid pro quo*.

As discussed above when considering the height of the inventive step, patent are regularly granted for inventions which contain no new knowledge. There is no benefit to Australia in granting any such patent, and indeed because of associated costs, such a grant might well reduce welfare. An interesting case here concerns an innovation patent application for shifting assets into a trust structure so that they cannot be claimed by legitimate creditors. While the concept might have been inventive, its application was simple computerisation. Clearly, too, there were issues about net spillover effects. This case involved four decisions before the

[40] Additionally Dempster (1994) usefully separates out the discussion of spillovers into that part of the social return which is pecuniary (producer or consumer surplus) and that part which occurs outside the market, principally flows of knowledge. This study is hard to obtain, though the library at the Australian Commonwealth Department of Innovation, Industry, Science and Research has a copy.

applicant finally accepted that no patent would be granted (Tyacke and Webb, 2007). From an economic viewpoint the most sensible decision was that of Branson J who determined:

- that given the facts of the case the NRDC decision on manner of manufacture was not relevant;
- "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";[41] and
- the invention might shield the owners from laws enacted in the public interest.

Extraordinarily the Full Federal Court rejected her analysis 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." The Full Court said "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. Parliament has already made that judgment, as its predecessor did in 1623, by rewarding innovation with time-limited monopoly".[42] This seems very poor logic. The 1623 parliamentary determination was with respect to *the patent system overall*. Many specific inventions have been refused patent monopolies because of there is no net benefit to society. Indeed the patent system *requires* courts to make judgements *with regard to specific inventions claiming a patent*. The argument as put by this decision directly overrides all the provisos in S.6 of the *Statute of Monopolies*, yet it is this section which defines a patentable invention in Australia.

As a matter of priority the doctrine spelled out by Branson J, that an invention should only enjoy a patent if the social cost of the resulting restrictions is counterbalanced by resulting social benefits, should be confirmed as a central test of balance in determining the grant of any individual patent.

Subject matter

The Commission asks whether the existing coverage of patents is optimal and whether there areas of innovation that should be included or excluded (*Issues Paper*: 18). Relevant here are the words of the US Congress in considering the 1952 patent statute. As these are frequently incompletely quoted they are worth repeating here:

> "A person may have “invented” a machine or a manufacture, which may include anything under the sun that is made by man, *but it is not necessarily patentable under section 101* unless the conditions of the title are fulfilled."
>
> H.R. Rep. No. 1923 at 6, from Menell, 2006, emphasis added

Historically, the first extension in patentability was the extension of patents from entirely new things to improvements in existing things. The currently statutory definition of what is patentable subject matter still derives from S.6 of the *Statute of Monopolies 1623*. In a series of fascinating articles Walterscheid takes apart the evidence from the time as to the meaning of each element of S.6. The Statute was drafted to make monopolies *which interfered with the common law right to carry on a trade* unlawful. This reinforces the requirement of difference from existing manufactures.[43] Walterscheid reviews Lord Coke’s 1628 discussion of the

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[41] *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.

[42] *Grant v Commissioner of Patents* (2006) FCAFC 120: at 43-45.

[43] From a policy perspective, the phrase "which others at the time of making such letters patent and grants shall not use", emphasises the quality of newness in the phrase "manner of new manufacture". But the legal interpretation can be quite different: the phrase is interpreted by some lawyers as conferring the monopoly

qualities required for a patent to be valid at law, and identifies *a strict prohibition against the patenting of improvements* ("so as also they be not contrary to the law") (Walterscheid, 1995a: 878). This prohibition was removed in 1776 (Walterscheid, 1995c: 779).

The test for newness was originally against whether an invention had been publicly worked within living memory.[44] In 1778 this test was expanded to include disclosure through publication (Walterscheid, 1995b: 849). It is interesting that the drafters of the *Statute of Monopolies* included a catchall proviso against the grant of unwarranted patents – "*so as also they be not … generally inconvenient*." Australian courts appear to be very reluctant to use this proviso.[45]

Indeed the High Court has clearly stated that the relevant definition of patentable subject matter in Australia is not the statutory definition, b*ut the subsequent interpretation developed by the courts*.[46] The invention considered in that decision was for a new use of known chemicals for a previously unknown purpose – the cheap and speedy eradication of weeds. In a country where agriculture is a major industry, this would have appeared to be a significant new benefit. This 1959 decision took place well before the introduction of a new form of statutory benefit for inventors – data protection. Data protection is discussed below (p.47). Put simply, with the introduction of TRIPS in 1994, producers of agricultural chemical products gained "protection" for their undisclosed safety and efficacy data required for marketing approval of their products (Article 39.3). The AUSFTA requires this period to be 10 years (Article 17.10.1(b)). This very lengthy period during which generic suppliers cannot use existing test data to gain marketing approval creates a very lengthy period of market exclusivity. It is far more certain than a patent as there are no avenues for challenge or appeal.

The 1959 *NRDC* decision has radically increased the scope of what is patentable in Australia. As interpreted by subsequent courts, it can mean as little as that it produces something that can be sold. There has been no economic evaluation of this or any other of the judicial extensions to patentable subject matter in Australia.

Software and business methods

The clear intent of patent policy is to encourage technological invention. Information economics, supported by the extensive empirical evidence from appropriability surveys, indicates that patents are not needed except where R&D costs are high and imitation is relatively fast. The *NRDC* decision has allowed Australian courts to extend patentability to software, an area where it is hard to distinguish between the R&D phase and the "manufacturing" phase. The issue of software patenting was considered by IPAC which unanimously held that:

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exclusion right. Walterscheid (1995a: 877) explains this as a shift in language usage and cites Coke's 1628 exposition on the validity of patents to provide an authoritative view from the time that *this was in fact a re-emphasis of the newness requirement*.

[44] The within living memory condition was adopted into statute law in the (rather ludicrous) form that patents over 50 years old did not count as "prior art". This restriction only removed from the Australian patent statute in 1990, following a recommendation by IPAC.

[45] Though in 1969 there was a very interesting Hearing Officer case where the generally inconvenient rule was used most cogently. In a case about an application for a patent for solving linear programming problems more quickly, the Hearing Officer said: "Computer programming is a relatively young art and, although many stratagems and simplifications have been devised so far, a much greater number may be expected to be devised in the future. It would certainly be mischievous to the State and generally inconvenient if, after investing a million dollars in a computer, the owner were to find himself prevented from operating it efficiently, or in any other manner he may wish, or with any degree of privacy or secrecy he may desire" (*British Petroleum Co. Ltd.'s Application* (1968) 38 AOJP 1020: 1021).

[46] *National Research Development Corp. v. Commissioner of Patents* ('*NRDC'*) (1959) 102 CLR. 252 (*NRDC*).

> "the computer software industry in Australia has been developing rapidly without relying on patent protection. This, coupled with the great practical difficulty of setting boundaries for patentable software and of conducting systematic and thorough novelty searches, convinced the Committee that it should not recommend explicit extension of the field of patentability to cover software."
>
> IPAC, 1984: 41

The committee then considered the EPC approach, where the software exclusion from patentability is codified. It did not favour adopting of this approach because of the extensive body of existing case law. IPAC recommended against extending patentability to software, but considered that *it was not necessary* to write a specific exception into statute law. The IPAC report had bi-partisan support. However during passage of the subsequent legislature, and amendment was inserted in the Senate (the Harradine amendment). This listed a specific exclusion from patentability.[47]

Ignoring IPAC, the Federal Court started granting patents for software. The key cases were IBM,[48] where the software provided the product of economic value in the form of an improved representation of a curve, and CCOM which merely involved the computerisation of a method for translating Chinese text.[49]

As noted above, the IPCRC Committee considered that few business method patents would be granted in Australia as they would be unlikely to pass the "the general tests for patent grant" – novelty, inventiveness and utility. In the 14 year period 1993 to 2006, there were 4,902 business method patent applications in Canada, 2,827 in Australia and 1,000 in New Zealand. Canada granted patents for between 2% and 6%, depending on how business method is defined. In contrast, during this same period, 23% of applications were granted in Australia and 57% in New Zealand (Moir, 2009a: 102-103).

The case which was seen as providing an authority for the grant of business method patents in Australia is *Welcome Real Time v Catuity (Catuity)*. The approval came in the form of *obiter* – words incidental to the actual decision. Heerey J simply stated, without any supporting argument, that he found the US Court of Appeals for the Federal Circuit (CAFC) *State Street Bank* decision persuasive.[50] This decision has now been clearly overturned by the Full Federal Court in the *Research Affiliates* decision. Unanimously Justices Kenny, Bennett and Nicholas found that the mere computerisation of the mental steps of a scheme or business method were not patentable subject matter.[51] In reaching this decision they reviewed European, UK and US law on the matter and considered Australian precedent in *IBM*, *CCOM*, *Grant* and *Catuity*. Some semantic contortion was required in respect of Australian precedent as many would consider the distinction between *IBM* and *CCOM* and the *Research Affiliates* "invention" to be rather like investigating the pinhead on which angels danced. In the Court's words the *IBM* "invention" for using an algorithm to produce a smoother curve was patentable because "the claimed steps are foreign to the normal use of computers, such as the production of an improved curve image" while the *CCOM* "invention" was patentable because of "the storage of data as to Chinese characters and retrieval of graphic representations to enable word processing."[52]

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[47] Human beings, and the biological processes for their generation, S.18.
[48] *International Business Machines Corporation v Smith, Commissioner of Patents* (1991) 33 FCR 218; (1991) 105 ALR 388; (1991) 22 IPR 417; (1992) AIPC 90-853.
[49] *CCOM Pty Ltd v Jiejing Pty Ltd* (1994) 28 IPR 481.
[50] *Welcome Real Time v Catuity* [2001] FCA 445 at 129.
[51] *Research Affiliates LLC v Commissioner of Patents* [2014] FCAFC 150 10 Nov 2014; re-emphasised in *Commissioner of Patents v RPL Central Pty Ltd* [2015] FCAFC 177 11 Dec 2015.
[52] *Research Affiliates* at 94.

In other fields the responsible public servants play an active role in alerting Parliament to problems introduced into statute law by particular court decisions. Since competition law has been moved from the Attorney-General's Department into the portfolio responsible for competition, officers have been proactive in monitoring emerging problems and presenting parliament with proposed legislative solutions to these. Not so the Patent Office. On the sole occasion when IP Australia actively investigated problematic legal decisions, it raised two issues – the exclusion of patent documents from existing knowledge due to the *Emperor Sports* decision and the "led directly as a matter of course" problem due to the *Alphapharm* and *Lockwood* decisions. However it rapidly backed away from reform on the inventiveness test issue and did not raise this with Parliament. When the national innovation system was reviewed in 2008, the review team took the view that:

> "It is imperative that IP policy make the transition that competition policy made over a decade ago now, from a specialist area dominated by lawyers, to an important front of micro-economic reform"
>
> Cutler *et al.*, 2008: 85

I return to this issue in Section 6 of this report, on accountability. But in regard to the extension of patentability to software, TRIPS clearly envisaged that software would be protected by copyright not patents (Article 10). This provides substantial protection – where a particular program is long and complex, but addresses similar subject matter to an existing program, companies go to great lengths to set up clean rooms to make sure that there is no copyright infringement. The consequence of this is that they incur identical production costs to the originator and hence do not "free-ride" on that product. Further, many software patents are written at such a high level of generality that they effectively patent ideas.[53]

The *NRDC* doctrine needs a thorough overall as do the decisions made in *IBM* and *CCOM*. A means has to be found to ensure that software remains outside the ambit of the patent system. This needs to draw lessons to avoid what has happened in Europe. There the EPO has granted many thousands of pure software patents despite their statutory exclusion from patentability (Miceli, 2005).

Methods of medical treatment

Australia's courts later went on to allow patents for methods of medical treatment – long considered outside the scope of patentable subject matter. Medicine was not considered either a trade or a business. It is a *profession* and as such was outside the scope of technology (the "useful arts"). Of course technology has now embraced health as a key issue where invention can provide substantial benefit is easing pain and delaying death. However there is a big distinction between a new thing – be it a pharmaceutical composition, a device or a machine – and a new method of using a known thing to treat a disease. This "new method of using a known thing" was at the heart of the *NRDC* decision. As noted above new laws on data protection now provide adequate exclusive time in the market for makers of agricultural chemicals. They also provide similar protections for new methods of using known pharmaceuticals, where the exclusivity period is five years. Given this new statutory intervention in the market it is apposite to consider whether granting a patent for what is also covered by data protection is not a kind of double-dipping.[54] Moving to exclude new methods of known things from patentability where data protection is available would clearly act to reduce social costs without affecting the incentive to innovate.

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[53] An issue also raised in submission 21 to this inquiry from Open Source Industry Australia Ltd.

[54] The patent for the compound provided strong exclusive privileges for the compound, including exclusion from all commercial uses. Thus, grant of a new patent for a specific use also constitutes double-dipping.

The AUSFTA requires Australia to grant patents for “any new uses or methods of using a known product” (Article 17.19.1). The proposed TPPA will require Australia to grant patents for "new uses of a known product, new methods of using a known product, or new processes of using a known product" (Article 18.37.2). Both also provide the safeguard that to actually be patented such "inventions" must pass the novelty, inventiveness and utility tests. As indicated elsewhere in this submission the novelty and inventiveness tests fail to exclude most uninventive inventions from patent grant.

The Australian Parliament is prevented from reforming patentable subject matter to ensure that double-dipping does not occur for new uses of known compounds where there are methods of medical treatment or agricultural chemicals. **This makes reform of the inventiveness criterion and the *NRDC* definition of patentable subject matter particularly important** as this is the only way Australia can ensure that it does not grant an excessive level of protection from competition to inventors of new methods of using old products.

Discoveries

A debate has been raging for some time on the patentability of genes and gene fragments. On the one side there are those who argue that these are discoveries and as such clearly outside the boundaries of patentable subject matter.[55] Discoveries – things that are found – are quite different from inventions – things that are made. On the other hand the biotechnology industry has a clear incentive to try and gain valuable monopolies.

In 2000 the Ergas Review considered several aspects of patentable subject matter. In regard to discoveries it took the view that competition goals

> “are well served by a patent policy that rigorously distinguishes between *discoveries* … and *inventions* … [and] only the latter should qualify for patent protection … [as] … [p]roperty rights in discoveries … could give rise to unreasonable barriers to potential competitors or to those who wished to use the "discovery" in other fields of endeavour”
>
> IPCRC, 2000: 151-2

The committee made no recommendations on the matter. But the principle enunciated—that competition goals are severely undermined if patent monopolies are granted for discoveries is important to this inquiry.

In regard to the argument that the biotechnology industry needs the financial advantage provided by the patent as an incentive to undertake this research, the story of the first Australian patent for a gene discovery is illuminating.

The isolation of the naturally occurring substance erythropoietin has potentially significant global benefits in the treatment of anaemia. Erythropoietin is the protein that initiates the production of red blood cells in bone marrow. Many parties were working in this field well before any patent was granted over naturally occurring organisms. The Supreme Court's *Chakrabarty*[56] decision in 1980 is often mis-represented as allowing for naturally occurring organisms to be patented. But in upholding *Chakrabarty* the majority emphasised that the

> "claim is not to a hitherto unknown natural phenomenon, *but to a nonnaturally occurring* manufacture or composition of matter -- a product of human ingenuity "having a distinctive name, character [and] use."
>
> *Diamond v. Chakrabarty*, 447 U.S. 303: 309-310 (emphasis added)

[55] For a very cogent discussion of this viewpoint see Palombi, 2004 and Palombi, 2009.
[56] *Diamond v. Chakrabarty*, 447 U.S. 303 (1980).

The California Institute of Technology, the Genetics Institute, Biogen, Genentech and Amgen had all commenced work on erythropoietin before the end of 1981. At that time, as indicated above, there would have been little expectation of a patent. The wording of the *Chakrabarty* decision could not have created any expectation of gaining a patent for erythropoietin, a natural substance.

In considering whether the invention was inventive in respect to knowledge at that time in Australia,[57] the Deputy Commissioner of Patents noted *the* critical factor in the successful isolation of erythropoietin was *actually obtaining sufficient supplies of erythropoietin*. From this he concluded that the invention was not obvious or all participants in the research would have invested in obtaining sufficient erythropoietin to analyse. This is an interesting perspective.

The decision does not address the issue of whether going on to derive the information claimed in the monopoly involved a "manner of new manufacture" and effectively defines the inventive element as the decision to invest heavily in purchasing erythropoietin. Nonetheless on the basis of this decision the Australian Patent Office proceeded to grant thousands of patents over genes and gene-related discoveries.[58]

One key factor in the grant of many patents for gene discoveries is the re-characterisation strategy whereby it is stated that when genes have been "isolated and purified" they are no longer identical to genes as they exist in nature. As Drahos comments:

> "One suspects that, if Mother Nature had a patent on a particular naturally occurring gene sequence, she would almost always win a patent suit brought against the alleged inventor, since typically all that happens in nonnatural gene sequences is the removal of redundant codons. In essence the sequences are the same."
>
> Drahos, 1999: 443

This re-characterisation is simply a strategy designed to enlarge the scope of the patent system, thus increasing the volume of work and quantum of income for the patent community.

The High Court has recently considered a patent on claims to gene fragments identifying the BRACA1 and BRACA2 mutations which are linked to breast cancer. For once, the Court said to extend the concept of manner of manufacture (patentable subject matter) to these claims "involves an extension of that concept, which is not appropriate for judicial determination."[59] The courts have had no qualms in extending patentable subject matter to software and methods of medical treatment, even though both involve substantial extensions in patentable subject matter. Those extensions were possible solely because of how the *NRDC* decision has been interpreted.

Given the inevitable potential for negative impacts from any patent, extensions to the patent system would seem best made after careful consideration of evidence both on whether they are genuinely needed and what their likely impact will be.[60] As the evidence in this submission demonstrates the patent system is indeed a very blunt instrument, with significant associated social costs as well as potential social benefits. The experience Australia has had

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[57] The earliest claimed priority date for the Kiren-Amgen erythropoietin patent is 13 December 1983, and the application was filed in Australia in December 1984. The decision was therefore determined under the *Patents Act 1953*, when the obviousness test was in respect only of what was obvious in Australia. The application was accepted in June 1990. The patent expired in April 2006, after a 22 year life.

[58] My recollection from the time of the 2009 Community Affairs Committee Inquiry into Gene Patents is that the work which resulted in producing sufficient quantities of natural erythropoietin was publicly funded.

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

[60] The only such review of which I am aware is the US review of the need for software patents – the 1966 President's Commission on the Patent System ('"To Promote the Progress of … Useful Arts" in an Age of Exploding Technology') (Samuelson *et al.*, 1994: 2362 and IPAC, 1984: 41).

with judicial extensions of patentability needs correction. So too does this example of patent office led extension to patentable subject matter. While the High Court has now ruled on this matter, the Patent Office has taken the narrowest possible interpretation of their decision (Summerfield, 2015b).

The issue of how to make the Australian Patent Office accountable to the whole community not just to rights-holders and facilitators of rights-holders is taken up in Section 6 below on accountability.

4. Combining effectiveness and efficiency: the net welfare impact

The Commission asks whether patent rights encourage genuinely innovative output that would not have otherwise occurred, and if not, how they could be designed to do so (*Issues Paper*: 8). Other questions raised are: what evidence is there that patents have facilitated innovations that would not have otherwise occurred; have patents imposed costs on the community, including by impeding follow-on innovation; does the patent system ensure new technology is being generated at the lowest cost (*Issues Paper*: 14 and 18).

In this section I bring the material presented earlier together to address the fundamental question of whether Australia's patent system operates to deliver an increase in net national welfare. In doing this I first address the question of the urgent need for a clear statement of patent objectives; I then look at the biases in the system that avoiding the risk of rejecting inventive inventions (type I errors) in such a way that very large numbers of patents are being granted for uninventive inventions (type II errors).

I then turn to the issue of the cost of very uninventive inventions. Usefully, data from the PBS allow the estimation of some of the costs of this. This is rare as, usually, there are little or no data available on the costs of the patent system.

Following this it is possible to turn to the question of the net welfare impact of the patent system. There are three recent studies that address this in respect of the cost of patented pharmaceuticals, finding that consequent consumer losses are 6 to 7 times greater than consequent producer gains. It would be far more efficient simply subsidise pharmaceutical companies rather than to provide them with product patents.

The objectives of patent policy

The issue of patent objectives is perhaps one of the most needed reforms to the Australian patent legislation.

When I first commenced study of the patent system in 2004 I was astonished to find that the patent act had no objectives. Nor does the EPC, except for providing a Europe-wide system. The US derives its objectives from wording in its Constitution which handed patent and copyright powers from the states to the federation. Article 1, section 8 gives Congress the power "[t]o promote the progress of science and useful arts, by securing for limited times to authors and inventors the exclusive right to their respective writings and discoveries."

The Ergas Report had to go back to 1981 to find an official statement spelling out the objectives of the Australian patent system. The report quotes from the Second Reading Speech on the Patents Amendment Bill 1981:

> "The main purpose of a patent system is to stimulate industrial invention and innovation by granting limited monopoly rights to inventors and by increasing public availability of

> information on new technology. Patent procedures must achieve a balance among competing interests while remaining administratively workable."[61]
>
> (IPCRC, 2000: 136)

The TRIPS Agreement has an objectives clause which reads as though it was designed for the patent system:

> "The protection and enforcement of intellectual property rights should contribute to the promotion of technological innovation and to the transfer and dissemination of technology, to the mutual advantage of producers and users of technological knowledge and in a manner conducive to social and economic welfare, and to a balance of rights and obligations." (TRIPS Article 7)

The Advisory Council on Intellectual Property (ACIP) reported on patentable subject matter in 2010 (ACIP, 2010). ACIP considered but side-stepped the TRIPS objectives. Instead they focused on the legal perspective that the essential bargain in the patent system is of monopoly for disclosure. This viewpoint contrasts sharply with the economists' view that the patent system should induce inventions which would not otherwise occur and which provide positive spillovers. Starting from the legal perspective, and composed as it was largely of beneficiaries of the patent system,[62] it is perhaps not surprising that ACIP's proposed objectives statement was little more than a call for competing interests to be balanced. As a result IP Australia began a "consultation process" on proposed wording for both an objectives clause and for a specific clause on exclusions from patentability (IP Australia, 2013). In this they set forward a somewhat improved objectives statement, but one which still avoided pointing out the key economic goals.

The Commission rightly points to the importance of additionality as a criterion for all "IP" systems. Modifying their words to refer only to the patent system:

> "[A patent] system is effective if it promotes the creation of genuinely new and valuable [technology] that in the absence of such a system would not have occurred. This 'additionality' is important given that the objective of the [patent] system is to improve wellbeing by correcting an under provision of [invention] that may exist in the absence of [patent] rights."
>
> *Issues Paper*: 7.

The Commission does not, in its *Issues Paper* refer to the issue of spillover benefits from industrial invention and innovation. As noted above (p.8), it would be dysfunctional to intervene with the grant of a monopoly *unless there were positive spillover benefits*. Objection to a monopoly for an invention with negative spillover benefits is a no-brainer. If there are zero spillover benefits, the deadweight losses from the intervention would also make the intervention dysfunctional. Further, intervening in the market *without clear evidence* that the benefits exceed the costs would contravene Article 5.1 of the Competition Principles Agreement.

The requirement of net positive spillovers is as important as additionality for the effective and efficient operation of a patent system. In view of the many dysfunctional legal decisions about

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[61] The Hon David Thompson, Minister for Science and Technology, April 1981 Second Reading Speech, Patents Amendment Bill 1981.

[62] Data on the membership of ACIP by year are not on IP Australia's website. An advertisement for members in the Australian Financial Review, in May 2009 states "The Government is seeking individuals with appropriate knowledge and experience in IP matters, *including obtaining, managing, exploiting and protecting IP rights*. The government is particularly interested in hearing from owners and users of IP rights within the small, medium and large business sectors, and from public and private research bodies" (Attachment E, emphasis added).

the Australian patent system, the net positive spillovers requirement needs to be included in a clear statement of patent policy's economic objectives.

Economic objectives are clear to in S.6 of the *Statute of Monopolies 1623*. The objective of this Statute was to prevent monopolies *which interfered with the common law right to carry on a trade*. There were a number of provisos which were intended to achieve a positive net welfare outcome. These included the requirement for absolute newness (see p. 25) and that any substitution of domestic for imported goods not lead to price increases (Walterscheid, 1995a: 878-9). It is notable that the drafters of the *Statute* included a catchall proviso against the unwarranted grant of patents – "*so as also they be not … generally inconvenient*.".

The TRIPS objective statement should be adopted as Australia's patent objective but the wording on net social benefit needs to be clarified to ensure that the economic objectives of the system are properly understood and implemented. The following wording is proposed:

> "The protection and enforcement of patent rights should contribute to the promotion of technological innovation and to the transfer and dissemination of technology, to the mutual advantage of producers and users of technological knowledge, such that patents are only granted for induced inventions that make a positive net benefit to society; the patent system should contribute to overall ~~and in a manner conducive to~~ social and economic welfare, and should ensure ~~to~~ a balance of rights for both rights-holders and users of patented technology ~~and obligations~~."
>
> Amended TRIPS Article 7

Type I and II errors

In assessing the effectiveness and efficiency of the patent system, one needs to consider the system biases that affect the types of errors that many be encountered. Any administrative system will make at least occasional errors. What are their nature and what are the safeguards?

The current patent administration and enforcement system gives such a strong priority to avoiding the risk of rejecting inventive inventions (type I errors) that very large numbers of patents are being granted for uninventive inventions (type II errors). The grant of invalid patents incurs high costs for the economy, through their impact on competition and invention (FTC, 2003). While design of any policy involves trade-offs, there is general agreement that a low inventive step incurs high social costs, not offset by any positive spillovers. In their useful discussion of policy design and inevitable errors Jensen and Webster (2004) suggest that there will always be some errors.

There is a considerable asymmetry in the incentive to litigate a patent between the patent-holder and alleged infringers. Litigation costs are high. In an invalidity case, the benefit of success is spread among many parties, though only one party pays the legal costs. In contrast, where a patent is deemed valid (either through litigation or because no litigation takes place), the patent holder receives the full benefit. Because of these asymmetries, the likelihood that an invalid patent will be challenged is less than would be optimal from a public good perspective.

Further, where a patent is rejected, applicants have multiple opportunities to challenge the rejection decision.[63] In such a scenario it is the potential beneficiary of the patent system who pays the costs. But where a very low quality patent is granted, it is an innocent innovating firm that bears the cost of challenge – simply to be able to continue to go about their business unimpeded by the patent system.

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[63] Tyacke and Webb (2007) provide an excellent discussion of the *Grant* case where four different rejection decisions were made.

The appeals system, then, provides a substantial safeguard against a bad rejection of an inventive invention. But there are no equivalent safeguards to prevent a non-invention being granted a patent.[64] Despite this there are a myriad of policy (doctrinal) rules tipping the system to grant of a patent for an uninventive application.

In 2014 Australia granted 19,304 patents, up 13% from 2013 (IP Australia, 2015: 9). Dahlin and Behrens, it developing metrics to identify truly radical patented inventions rejected two early estimates which identified 20% and 4% of patents as radical and ended with a measure which identified just 1% as radical (Dahlin and Behrens, 2005). But if the objective of the patent system is to grant patents for inventions which are a significant advance over what is known, then they would not be restricted to such radical breakthroughs. Dahlin and Behrens' original metric – which identified some 20% of patents as being more inventive – is a useful working estimate.[65] It suggests that over 15,000 of the patents granted in 2014 do not reach the standard advised to Parliament in 2011.

Australia's current patent system lacks balance, in common with overseas systems such as the US patent system (FTC, 2003). A myriad doctrines each favour grant of a patent once an application has been filed. There are many legal decisions upholding low quality patents as it is *the patent doctrinal rules which set this low standard*. The sole doctrine favouring the consumer/follow-on inventor is Article 20 of the Patent Act which specifies that a granted patent cannot be presumed to be valid. This ensures that, in court, the rules of evidence are equal between the two parties. I have made a number of suggestions above as to rules which should be altered to bring our patent system into better balance (see section on patents for non-induced invention.

Low quality patents create considerable noise and interference in any dissemination role the patent system might have. They also bring the patent system, and the reputational value of a patent, into disrepute. They do, however, support a vast number of patent attorneys.

The cost of low quality patents: evergreening

There are real costs attached to low-quality inventions. In a worst-case scenario they can prevent legitimate competition. Several cases where low-quality patents were upheld in court have already been mentioned (*Catuity*, *Lockwood*, *Alphapharm*). Other cases of which I am aware are one where yet another low-dose combination oral contraceptive pill was upheld for its combination with a specific release mechanism,[66] and another where the isomer of citalopram was deemed not to be novel.[67] Aside from this list being incomplete, it is very difficult to get financial data for payments resulting from patent disputes.[68]

The one area where some cost data can be obtained is in respect of evergreening patents. These are low quality secondary patents taken out late in the life of the original Active Pharmaceutical Ingredient (API) patent which underlies the medicine. Such "life-cycle

[64] The oppositions process requires innovating firms to constantly scan acceptance notices issues by the patent office. Given the effort required to translate these from patentese, this is a substantial cost. There is no evidence that many such firms do this.

[65] It also aligns with common general knowledge in the patent community (personal discussion with a senior, experienced member of the patent community).

[66] *Bayer Pharma Aktiengesellschaft v Generic Health Pty Ltd* (No 2) [2013]FCA 279.

[67] *Alphapharm v Lundbeck* [2009] FCAFC 70 (11 June 2009). At much the same time the patent for an isomer of clopidogrel was revoked for want of novelty (*Apotex v Sanofi-Aventis* [2009] FCAFC 134 (29 September 2009).

[68] IPRIA constructed a database of patent cases, which provides some evidence about litigation (Weatherall and Jensen, 2005). It does not have any data on legal costs, penalties or compensation.

management" strategies are common to originator pharmaceutical firms. Indeed Burdon and Sloper, writing in the Journal of Medical Marketing, advise that:

> "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, emphasis added

In the section above on efficiency I referred to my empirical work on Australian business method patents. More recently I have been working with data on uninventive pharmaceutical patents. The details of two of these cases are provided in the research paper at Attachment C.

Venlafaxine (marketed as **EFEXOR)**, involved the grant of a patent for the major metabolite of venlafaxine towards the end of the life of the original patent. As venlafaxine metabolises into this metabolite (desvenlafaxine) when it is ingested, it is surprising that it passed the novelty test. Not only that, it was also given an 18 month term extension. During the final 2½ years of venlafaxine's patent life, generic competition was suppressed due to an injunction in respect of a combination patent. This simple combination consisted of the known (and patented) compound venlafaxine and all methods of extended release formulation. The results of the combination were exactly as expected – there were no surprising or unexpected results so if the synergy doctrine had been in place the patent would not have been granted. The patent was eventually found invalid and the injunction lifted. In the meantime the 2½ year delay in generic entry cost Australian taxpayers between $85 and $209 million.

During the injunction period Pfizer marketed the replacement product desvenlafaxine (**PRISTIQ)** heavily. By the time generic competitors were allowed into the venlafaxine market, some 37% of scripts were being written for **PRISTIQ**. No clinical trials have been conducted comparing the two medicines, and the Pharmaceutical Benefits Advisory Committee (PBAC) found there were no enhanced outcomes from desvenlafaxine compared to venlafaxine for any patient group. The additional cost to the taxpayer from the switch to prescribing **PRISTIQ** is estimated at $A66 million. Had no patent been granted to desvenlafaxine, these costs would not have been incurred.

The second case, omeprazole (marketed as **LOSEC**), involves the patenting of its isomer, esomeprazole (marketed as **NEXIUM**). Again this is a closely related chemical to the originally patented compound (see Attachment C). In addition the owner, Astra, obtained a patent for the combination of omeprazole and an enteric coating. This combination patent – for a known and patented compound, and a known delivery technique – again demonstrates the low inventiveness standard of Australia's patent system. Notwithstanding that this was a mere combination – and one that was commercially necessary for the market success of **LOSEC** – the High Court considered that the combination was sufficiently inventive to merit patent grant. In doing so it used the "led directly as a matter of course" standard that has been criticised as substantially below the standard in other countries (see discussion above, pp. 14-15). This High Court decision cost Australian taxpayers an estimated $A1.1 billion over the seven years that generic entry was delayed.

The second case also involved a very marked prescribing switch, with 77% of the combined market being for **NEXIUM** by 2014. The additional cost to taxpayers of the switch in prescribing between **LOSEC** and **NEXIUM** has been an estimated $A1.8 billion over 12 years.

Net welfare impact

As noted above (p.4) at best the Australian patent system can induce only 10% of the 19,304 patents granted in 2014. But this is a theoretical upper limit. My own estimates of the

proportion induced in the period 1990 to 2006 were between 4.9 and 6.4%. Applying this range to the 19,304 patents granted in 2014, between 950 and 1250 patents were induced by the Australian patent system. This is a very small number of patents to carry the full weight of contributing sufficient spillover benefits to offset their own static efficiency losses as well as the costs imposed by the remaining 18,000 plus patents that were not induced.

It seems most improbable that the net outcome will be positive.

Thirty years ago studies undertaken for IPAC concluded that the benefit to Australia of its patent system was at best small, and subtle. Since then the patent system has extended in scope and patentability standards have fallen. Notwithstanding the minor improvements in the 2011 Patent Amendment Act, there is a clear need for an immediate increase in the standards. We truly need to raise the bar on inventiveness and subject matter.

Many of the changes that would have been possible in the 1980s if the IPAC review had genuinely taken an economic perspective have been ruled out by TRIPS, AUSFTA and the proposed TPPA.

The TRIPS change which has had the most severe real-world impact is the requirement that patents be granted for pharmaceutical products. Prior to TRIPS many nations did not allow patents for chemical products only for chemical processes. The story of how Germany used such a strategy to become the pre-eminent global producer of pharmaceuticals and fine chemicals has been well told elsewhere (Dutfield, 2003).[69] In the post WWII era differences remained between European countries in whether patents were allowed for chemical products or not. One country where product patents were not allowed was Italy, which became the global leader in generic pharmaceutical production. Unfortunately for the Italian generics industry the EPC took a lowest common denominator approach and required that all signatories grant pharmaceutical product patents. The Italian generics industry was wiped out (Scherer and Weisburst, 1995), and India took on this role.

In regard to pharmaceutical product patents, it is interesting to note that the IPAC review actively considered whether Australia should continue to allow such product patents or should cease granting them (IPAC, 1984: 40-41). In the end the majority concluded that there should be no change, though two of the seven members of IPAC recommended in favour of ceasing to grant such patents.[70]

Concerns are often expressed that if a country did not allow pharmaceutical product patents, then new medicines will not be available in that country. This ignores the role of an effective and efficient generics industry. Taiwan, for example, has only generics pharmaceutical companies (OECD, 2014: 10), not having adopted product patents until forced to do so to remain in GATT. Had Taiwan had problems in obtaining new pharmaceuticals this would be well known. Thailand has had some problems in accessing certain drugs, when use of compulsory licenses has led to retaliatory action by US pharmaceutical firms (Krikorian, 2008).

Because being a signatory to TRIPS is compulsory if one wants to be a signatory to the GATT, TRIPS has led to a conformity in patent laws which eliminates useful real world counterfactuals. Using historical data from the nineteenth century world fairs – when there was variation in patent systems – Moser has demonstrated that the absence of a patent system

[69] Germany actively considered the reasons for declining competitiveness in French and British chemical firms in designing its patent system to ensure that German firms focused on process improvements. Naturally German firms also took out product patents in major overseas markets such as the UK, France and the USA.

[70] In fact the IPAC Committee concluded there should be no change in most aspects of the patent system despite their commissioned research which showed that the net impact of the patent system in Australia was both small and subtle. Thirteen of their 46 recommendations were recommendations for no change.

had no impact on the relative number of inventions produced by a country. It did, however, change somewhat the fields in which this inventions occurred (Moser, 2005). The introduction of pharmaceutical product patents in India and the generic entry provisions of the Hatch-Waxman Act[71] in the USA provide current material from which the net welfare impact of pharmaceutical patents can be estimated.

Branstetter et al (2011) estimated the consumer surplus generated in the US by the paragraph IV provisions of the Hatch-Waxman Act (which facilitate generic entry to the market). Using a nested logit model they find that, over the period 1987 to 2008, consumer gains were around US$92 billion with losses to producers of some US$14 billion. With this net gain of some US$78 billion, it is clear that the net welfare gain from increasing competition in the pharmaceutical market is substantial.

Chaudhuri et al (2006) and Dutta (2011) both investigate the impact of introducing chemical product patents in the Indian market. Chaudhuri and colleagues use data on quinolones to estimate demand functions and supply elasticities in order to investigate five scenarios that might follow the introduction of pharmaceutical product patents. As with the Branstetter study, they find that consumer welfare losses substantially exceed producer gains. The total welfare loss to India from product patents on quinolone antibiotics alone is estimated at US$144 to 450 million annually, while gains to the subsidiaries of foreign firms are just US$19.6 to 53 million. With net welfare losses ranging from US$124 to 397 million annually, it is clear that product patents are an expensive proposition for any society. The large disparity between gains to producers and losses to consumers is striking.

Dutta develops a model of demand, supply and entry for a cross-section of medicines in the Indian pharmaceutical market and uses this to derive counterfactual predictions of the implementation of TRIPS in India (Dutta 2011). For the 43 medicines covered, the average price increase is 42%, and the consumer welfare loss US$378m (an average loss of $9 million per medicine). Dutta also estimates that patients covered fall by half, indicating a substantial impact on access. The benefit to patent rights holders is just $1.4 million per medicine – compared to the cost of new medicine development of some $300 to 800 million (Dutta 2011: 177).

These three studies largely replicate the well-known facts about tariff barriers, demonstrating that they apply equally to the trade distortion arising from patent monopolies. Where a domestic industry is protected by high tariff barriers, losses to consumers far exceed the gains to producers. It is therefore much more efficient to subsidise firms than to create or maintain tariff barriers. The impact of patents is similar. In effect patents operate as a form of tariff barrier leading to reduced competition and therefore high prices and high consumer welfare losses. Gains to producers are only 12 to 15 per cent of the loss to consumers. As with tariff barriers, it would be far more efficient to subsidise pharmaceutical product production than to grant product patents. It is ironic, therefore, that patent monopolies are required as part of the WTO's "free trade" suite of agreements.

It might be argued that over the longer term, there would be dynamic growth benefits to offset the immediate losses caused by pharmaceutical product patents. The experience of Italy refutes this. Prior to the introduction of pharmaceutical product patents in the 1970s, Italy was the world's major supplier of generic medicines. This thriving industry was decimated by product patents, and has not been replaced by an originator industry (Scherer and Weisburst 1995).

[71] The Drug Price Competition and Patent Term Restoration Act (Public Law 98-417), 1984.

Those lobbying for increased market intervention in respect of innovation and R&D also argue that without "intellectual property rights" (IPRs) there will be little innovation. There is no empirical support for this mantra.[72] Professor Granstrand has found that:

> "the IPR system in general, and the patent system in particular, has been neither necessary nor sufficient for technical and/or economic progress at country and company level historically."
>
> Granstrand, 1999: 44

The pharmaceutical industry is the major exception to the substantial empirical evidence that in most industries the patent system is the least useful means of ensuring good returns to innovation investment (Boldrin and Levine, 2008: Chapter 9). But even in pharmaceuticals there are many important products that were developed without patent "protection", and comparison of British, French and German experience suggests that too sweeping a patent system can inhibit rather than encourage innovation in the chemical industries (Dutfield, 2003). It is clear, then that patent policy can go too far even in the pharmaceutical industry. Monopoly "protection" for every trifling variation may assist the profit levels of global companies, but at the cost of actively undermining the vitality of the generic medicines industry.

The available empirical evidence points strongly to the conclusion that the patent system, as currently designed, reduces Australia's welfare, perhaps substantially. Action to improve the outcomes of the patent system is possible, but only if the pleadings of vested interests are set to one side.

Before moving on to discuss institutional issues and data protection, I would like to provide an example of win-win-win innovation. I have rarely come across a case that so successfully demonstrates useful innovation where all parties benefit substantially. The case involves private sector development of improved seed varieties in India. Although no patent was available, the inventor gained an excellent return on their R&D, distributors gained increased returns and farmers benefited substantially (Pray *et al.*, 1991). Australia needs the institutional and incentive arrangements that will generate this kind of mutually beneficial innovation.

5. Adaptability

The Commission states that the "[patent] system should be adaptive to change, as the impact of rigid incentives could have a strong negative impact on society" (*Issues Paper*: 8). The Commission also asks "[d]oes the [patent] system adapt as the nature of innovation, competition and broader economic conditions change?" (*Issues Paper*: 14). An important element of this issue is "how well placed is [the patent system] to adapt to [economic, commercial and technological] changes in the future?" (*Issues Paper*: 12). So too is the question of "[w]hat factors may make it harder for the IP system to adapt to change? What policy options are there to remedy any difficulties, and why might they be preferable?" (*Issues Paper*: 12). Finally the Commission asks whether "patent system [is] sufficiently flexible to accommodate changes in technology and business practices?" (*Issues Paper*: 18).

[72] There are a number of econometric studies showing an apparent relationship between IPRs and various measures of economic growth. Many of these use as their IPR variable the Park-Ginarte Index (Park and Ginarte, 1997). To say the least this is a very crude measure – so crude in fact that it calls into question the results of such studies. Similarly the fact that much of pharmaceutical R&D takes place in the USA, Europe and Japan is a matter of history, education and government support for R&D. The fact that these countries also have patent systems cannot be held to be the determining factor, especially given Germany's experience (!!! INVALID CITATION !!!).

The discussion above provides considerable evidence that the patent system has been very expansive in its coverage, reducing the quantum of inventiveness required and extending its scope to "anything under the sun made by man" without considering if it should also be patentable. There is no need to review that evidence again here. So in terms of those who own patents, or who act for those who own or seek to own patents, the system is extremely adaptive. There can be no complaints from these groups. Nonetheless, international trade negotiations show a continuing push for more and more elements to be fixed in favour of patent owners. I have reviewed at some length the patent issues in the proposed TPPA and reproduce my submission to the Department of Foreign Affairs and Trade (DFAT) at Attachment D. DFAT has radically revised its TPPA website and the public submissions made to DFAT are no longer visible.

However from the perspective of consumers and follow-on inventors, this extreme flexibility in meeting the demands of rights-holders and associated beneficiaries has had a negative impact. Because of the firm objection of the patent community to collecting data on how patents are used – note the non-implementation of IPAC's recommendation on this – the available data on the costs of this much-expanded patent system are limited. Nonetheless specific legal cases point to companies damaged by low-quality patents, and PBS data allow estimates of the cost of low-quality pharmaceutical patents to taxpayers.

What this expanding system of "powerful negative rights" does not take account of are two important new features of the global economy – network effects and the spread of low cost computing capacity. A particularly important network effects is where the learning required for an initial new product is substantial so consumers are reluctant to incur further such costs by switching products. This reinforces first mover advantages very substantially. For such products the need for patents is highly questionable.

The vast change in the price of computers from the late 1970s has created an environment where it would now be the rare business or inventor who does not have very good access to computer power. With this new platform, many processes previously carried out manually can be re-written in computer code. This can be tedious, but the simple implementation of any process through a computer merely requires a detailed analysis of every step and option then writing the relevant code. The reaction of the patent system to this new platform has been blinkered, to say the least. Determining that using a computer to translate text from one language to another (*CCOM*) is inventive ignores the reality that it is these kinds of tedious tasks for which a computer is well suited.

Looking to the future, how might one re-design the system so that changes are undertaken only where they improve net national welfare? The patent community simply does not understand this concept and certainly does not act in consistency with this objective (Drahos, 2010). The Cutler review of Australia's national innovation system concluded that it was:

> "imperative that IP policy make the transition that competition policy made over a decade ago now, from a specialist area dominated by lawyers, to an important front of micro-economic reform"
>
> Cutler et al. 2008: 85

This recommendation is repeated here as it is so important. Moving the then Trade Practices Commission from the Attorney-General's Department to the Treasury portfolio led to a marked improvement in performance. Moving IP Australia from the industry department to the Treasurer's portfolio could be expected to have an equivalent effect. Being accountable to those whose focus is on the centrally important role of competition could remove at least some of the worst elements of the inward-looking patent community. This issue is taken up further in the next section.

The Commission asks "[h]ow does Australia formulate its position on [patent] policy in the context of international agreements? What evidence and analysis informs decision-making and negotiating positions along the way and is this adequate and sufficiently transparent?" (*Issues Paper*: 27)

Australia's approach to all forms of "intellectual property" in international trade negotiations pays no attention to the net welfare increase goal of most economic policy. Australia was a "friend of intellectual property" during the Uruguay Round negotiations and played a facilitating role in the adoption of TRIPS as a compulsory part of the World Trade Organization (WTO) package. The Uruguay Round commenced in the mid-1980s – around the time the ACIP report was tabled. Other evidence that a country in Australia's situation – a net importer of technology and copyrighted goods – would benefit most with a patent system where the requirements for patent grant were stringent had been available for many years (Penrose, 1951). Becoming a signatory to TRIPS removed reform options for the patent system that had been available at the time of the ACIP review.

Since then Australia has given away further reform freedom in respect of the patent system, principally in the AUSFTA (Moir, 2015). Based on leaked versions of the "IP" chapter of the proposed TPPA – which are so close to the final that they are almost certainly accurate – Australia appears to have made few objections to proposals from the USA to further lower the quality of the patent system. If ratified, it will further constrain Australia's already constrained room for important micro-economic reform of the patent system.

The Productivity Commission has recommended against the inclusion of "IP" issues in trade agreements (Productivity Commission, 2010). The then government accepted these recommendations, but then actively proceeded to do just the opposite. In the trade agreements that Australia has with countries that also have preferential trade agreements with the USA, the "IP" provisions mirror those from the US's template. In the AUSFTA Australia participated in allowing the US to ratchet up that template by including items that in fact were non-operational.[73]

There are two concerns about "IP" provisions in "free" trade treaties. The benefits of free trade come from increased competition. But the essence of "intellectual property" laws and regulations is the restriction of competition. Secondly, ratifying detailed prescriptive regulation of major domestic policy in an international treaty reduces the sovereignty of all future governments. In a democracy this should not be lightly undertaken. It is one thing to sign up to principles for ensuring human rights. It is quite another to agree to a rule whereby:

> "In determinations regarding inventive step, or non-obviousness, *each Party shall consider whether the claimed invention would have been obvious to a person skilled, or having ordinary skill in the art, having regard to the prior art*."
>
> TPPA Article 18.37: footnote 30, emphasis added

DFAT seems not to understand the centrality of increased competition as the major source of benefits from freer trade (see, for example, their submission to this inquiry with its continual focus on exports). And governments of all political persuasions seem to be willing to pay any price for increased agricultural exports. Often, as in the case of the AUSFTA, without even bothering to estimate the price. Nor do they acknowledge the high cost to democracy of limiting the sovereignty of future governments. During the TPPA "consultations" DFAT's single position on all patent and data protection matters was that if the proposal required no change to Australian law, it was fine.

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[73] Australia agreed to text removing anti-competitive conduct as a ground for revoking a patent, but there is a side letter allowing this following a judicial proceeding (Moir, 2015: 565).

In summary no evidence or analysis informs decision-making and negotiating positions in respect of how Australia formulates its position on patent policy in international agreements. The manner in which it does this is totally non-transparent. As the Business Council of Australia noted in its submission to this inquiry, DFAT's TPPA consultations were a one way street. DFAT wasted the time of a great many people, may have listened to what they said, but took nothing on board (submission 59: 7). DFAT has dismantled its TPPA "consultation" website although public and Parliamentary debate on the TPPA text is yet to begin.

6. Accountability

In the *Issues Paper* the Commission rightly states that "[t]he policies and institutions that govern the system, and the way that changes are made to them, need to be evidence-based and transparent" and asks whether "the policies and changes made to the [patent] system evidence-based and transparent?" (*Issues Paper*: 8 and 14).

Data deficiencies

In my discussion of effectiveness, efficiency and net welfare impact I have continually pointed to the dearth of data directly measuring the effects of the patent system. While this also refers to any benefits, it is a particular concern in regard to the cost impacts of the patent system. The patent office collects no information on how the many "powerful exclusive rights" they grant are used, despite the then government having accepted IPAC's recommendation to do so in principle.

The lack of any reliable data on how patents are used is a major gap in policy-relevant evidence.

There are however independent data, largely from surveys carried out by industry and innovation economists, that do provide some sound information about the patent system. These are largely ignored by the patent community – indeed the patent community, even patent policy advisors – appear to be blithely unaware of this mass of evidence.

The Commission asks a number of detailed questions about the evidence base for patent policy:

"Ideally, what sort of information is needed to evaluate the [patent] system? In their absence, what alternative data or proxies are available? What factors have constrained transparent evaluation of [patent] rights extensions? how [did] the parameters of the [patent] system [come] to be set, and on the basis of what evidence and analysis. How were decisions to extend [patent] rights in the past assessed? Is an evidence-based approach systematically used to assess changes to the [patent] system? (*Issues Paper*: 13)

Let me address each of these questions.

Ideally, what sort of information is needed to evaluate the IP system?

To properly evaluate the impact of granted patents, specific patent data need to be linked to the owner firm, with appropriate economic variables about that firm. Some elements of that have recently been put in place with the new IPGOD database (Man, 2014). I have not yet had time to investigate this new database in any detail, but I note that it implements the 1984 IPAC recommendation on industry data – albeit at a very high level of abstraction. I also note that it builds on the firm linkage capacities developed by the ABS as a result of the experimental three-year Business Longitudinal Survey.

A number of variables about the patent need to be added, most particularly data about how the patent is used. Given the strength of the "powerful exclusive right" it seems reasonable to require the owner to advise IP Australia whenever a patent is used. This is particularly needed

for any legal uses, whether it be a simple solicitor's letter or a full-blown litigation matter. Responding to solicitor's letters takes real time and effort, diverting resources in the threatened business from their own priorities. It takes time to search for the evidence that such patents are likely invalid. Including the name of the party sued or threatened would allow researchers to link information about those who benefit and those who pay. It is improbable that a legal threat of infringement would be made against any firm but an innovating firm.

Beyond this, regular in-depth research into particular industry sectors where Australia has an apparent or potential competitive strength would not only allow a deeper understanding of innovation and commercialisation, but would also provide a basis for comparing the full range of government programs and policies which support innovating firms. Such studies would allow the role of patents to be seen in the perspective of the broader taxpayer-funded innovations incentives. If such studies were repeated at intervals a real depth of knowledge could be built. This would provide a sound basis for policy advice about the patent system and other innovation supports.

For a number of years IP Australia funded the Intellectual Property Research Institute of Australia (IPRIA), which allowed this small group of University of Melbourne researchers to develop a real depth of knowledge and systematically address a number of policy-related issues. The basis on which IP Australia withdrew this funding, in favour of internal economic expertise is unknown. Certainly it is the case that IPRIA had academic independence, while IP Australia's economists do not. One positive outcome of the move has been IPGOD, but this is a high price to pay for the lack of sound funding for independent analysis.

The national innovation surveys that first made their appearance in the 1990s have provided some limited information useful for evidence-based policies. These surveys were, however, developed by science and technology specialists (the Oslo and Frascati manuals), so paid limited attention to patents. From the Yale and Carnegie Mellon surveys we know of important questions that can and should be added to the national innovation surveys. As a priority we need to know more about when innovating firms are blocked in their R&D and commercialisation plans because of the patents held by others. We also need much clearer information as to the relative importance of a patent in inducing an innovation.

The second major gap in policy-relevant evidence is the cost and speed of copying. This needs to pay attention to the relative quality of the original and copied product as this will impact on the size of the market for the original innovator. Data on Chinese and Indian capacities in this area are particularly needed.

Measuring the height of the inventive step in terms of expert assessment of the new knowledge contributed by granted patents would be of considerable value. Proposals along these lines were made to the 2009 Senate Community Affairs Committee Inquiry into Gene Patents. Such independent audits would help IP Australia to maintain balance in their examination work.

I would also like to see at least basic annual data on the number of Patent Attorneys licensed to operate in Australia each year. I tried to obtain such data in 2007 but was told it was "too hard". Given that these professional groups have protected status – never evaluated – under the patent act, regular reporting of basic data to the public and parliament seems a minimal return.

In their absence, what alternative data or proxies are available?

For an excellent approach to developing alternative evidence in the absence of direct evidence see Boldrin and Levine (2008), particularly their chapter on the pharmaceutical industry. Moser has also been creative in identifying sources of data that allow empirical investigation

of key policy issues in regard to both patents and copyright. These are mostly historical sources and some do not accept that the lessons from these datasets apply equally today.

What factors have constrained transparent evaluation of [patent] rights extensions?

I only have clear evidence in respect of the USA, and have cited this above. The examples are chilling and bear repeating:

> The American patent bar lobbied successfully to prevent the US Government Accountability Office – a highly respected research body – from undertaking a study into business method patenting. Such a study had been part of the penultimate draft of the *American Inventors Protection Act 1999* but it was removed in the final statute (Kahin, 2003). Kahin also reports that the White House Office of Science and Technology Policy commissioned the Science and Technology Policy Institute at RAND to undertake a study on software patent quality and business effects. He goes on to report that "it was suspended at the request of a U.S. multinational company concerned that the study would undercut efforts to secure greater international acceptance of software patents" (Kahin, 2003). Bessen and Meurer comment that the FTC recommendation most prominently rejected by the Intellectual Property Owners Association (dominated by patent lawyers from large firms) was recommendation 10 "expand consideration of economic learning and competition policy concerns in patent law decisionmaking" (Bessen and Meurer, 2008: 293-4).

In respect of Australia, I have no evidence but it is reasonably logical that ACIP's recommendations on collecting use data were opposed both by patent attorneys and patent owners. In regard to the opposition to improving the "led directly as a matter of course", IP Australia could advise on this. It would be logical if this improvement had been opposed by patent attorneys – after all it would reduce the volume of their work and therefore the volume of their income.

Institutional issues

"Are there reforms to public institutions involved in defining, allocating and enforcing IP rights in Australia that would provide net benefits to the community? Are there any issues with the administrative arrangements of IP Australia for assessing and granting patents?" (18)

Drahos, who has undertaken a major study of patent offices (Drahos, 2010) as well as a variety of other studies on how patent systems operate (Drahos, 2008) and are negotiated internationally (Drahos, 2001; 2002), defines the patent community as:

> “patent attorneys and lawyers, patent administrators, and other specialists who play a part in the exploitation, administration and enforcement of the patent system. They form a community by virtue of their technical expertise and general pro-patent values. Regular users of the patent system (like the pharmaceutical companies) might also be said to be part of this community …
>
> The patent community is also an interpretive community. It is the patent community working with a shared set of assumptions, understandings, conventions and values that settles issues and problems of interpretation within the patent system. By doing so, the patent community probably exercises more influence on the direction and content of patent policy than legislatures, which in any case rely on committees of specialists to advise them on matters of patent policy.”
>
> Drahos, 1999: 441-442

Attending a conference dominated by members of this community is indeed like entering another world, though it provides opportunities for acquiring information and checking perspectives. As Drahos notes, one of its characteristics is a generally pro-patent attitude.

For many years IP Australia and its predecessor organisations operated advisory committees. ACIP was abolished in early 2015, as part of a government-wide cancellation of such bodies. I have been unable to find any evidence that ACIP – or its predecessor IPAC – has ever had a representative of consumer or competition interests among its members. Around the time of the 2009 Senate gene patent inquiry, the qualifications for ACIP membership were particularly focused on being a beneficiary of the patent or trademark system (see advertisement at Attachment E). During this period ACIP could not be said to provide independent advice, if by independent is meant a perspective which is equally representative of both creators and users of technology.

There was substantial renewal of ACIP in January 2013 with the appointment of several members who, though knowledgeable about IP, were not direct beneficiaries of the system (see Attachment E). There was still no representative of consumer or competition interests. This omission creates an imbalance in advice in respect of the patent system and patent policy.

From the publicly available evidence it is evident that IP Australia takes a very pro-patent perspective. This is evident from their evidence to the 2009 Senate gene patent inquiry; the Senate Legal and Constitutional Committee; the backing off from reform to the inventive step in 2011; and the very narrow interpretation proposed in regard to the recent High Court decision on *Myriad*. As regards the 2011 Senate Legal and Constitutional Committee hearings on the Patent Amendment (Human Genes and Biological Materials) Bill 2010 [No 2], there was a marked difference between the perspective taken by officials from IP Australia and those from the Department of Health.

The available evidence indicates clearly that, operating as it does as a central member of the patent community, IP Australia simply does not understand – or at the least substantially undervalues – the importance of the costs imposed by patents on consumers and follow-on inventors.

Further, IP Australia does not seem to understand the need for transparency. When it undertook a range of consultation exercises in the period 2009 to 2013, submissions were not made publicly available. During the Pharmaceutical Patent Review (PPR), an excellent website was established, and all except confidential submissions were made publicly available. IP Australia dismantled this as soon as an election was called despite there is nothing about caretaker government rules that would suggest the need for any such action. DFAT too does not seem to understand the importance of good public records in achieving transparency and it too dismantled its TPPA website as soon as the negotiations were finalised. Given that the main period of public discussion is yet to come this is unfortunate.

There is a simple solution to this – **IP Australia should be moved to the Treasury portfolio.** The major focus of this portfolio is on competition, and there is a culture that highly values competition as a key driver of innovation, competitive advantage and rising productivity. A patent office operating within this culture would produce far more balanced advice.

Patent Attorneys are also central and influential members of the patent community. They were granted protected profession status in 1952 when the patent act was revised. As far as I can determine there has never been an independent review of the economic impact of this protection. As noted above (p.42), there are no publicly available data on the number of patent attorneys operating in Australia. Such data must now have been produced as there is a graph – but no numbers – in the discussion paper on developing a single framework for Patent Attorneys in Australia and New Zealand (IP Australia and Ministry of Economic Development, 2011: 43). In the USA the number of patent attorneys has grown more rapidly than R&D expenditure in the period since 1970 (Barton, 2000). Members of the patent

community have no hesitation in providing advice to the governments of other countries, and any review of any aspect of the patent system attracts submissions not only from Australian patent attorneys (and their associations) but also from international patent attorney associations. Yet they do not even report to the public on the number of patent attorneys licensed to practice each year.

Making patent policy

How [did] the parameters of the [patent] system [come] to be set, and on the basis of what evidence and analysis. How were decisions to extend [patent] rights in the past assessed? Is an evidence-based approach systematically used to assess changes to the [patent] system?

The parameters of the patent system have developed incrementally over several centuries, but particularly since the mid nineteenth century. The pace of change has been particularly rapid since about 1980. I have told what I know of this story elsewhere (Moir, 2009a, 2013c). One point that bears emphasis here is that like all previous British colonies Australia inherited our patent policy a country with a completely different economic structure. We did not, like India, take steps to evaluate whether that inherited policy suited our needs.[74] There has never been a proper economic evaluation of our patent system, though Professor Donald Lamberton arranged the collection of a range of valuable data for the use of the 1984 IPAC review. This was ignored (see Attachment B).

No evidence has been used to radically extend the patent system. It seems hard on consumers and follow-on innovators if they are now required to produce substantial empirical evidence – in the face of the wilful data deficits identified above – to reverse decisions that were never made on the basis of any sound evidence.

Kingston (2004) provides a very useful review of how the patent system has developed over the period since 1950. He documents the fact that the 1952 US patent statute was developed to meet the needs of the pharmaceutical industry. But this industry is a "simple technology" industry rather than a "complex technology" industry – that is, it is characterised by one patent per product rather than electronics where there can now be literally thousands of patents for each product. Kingston argues that other advanced nations have simply copied elements of the US system, without any thorough assessment of whether it best suits their national circumstances. Kingston concludes that patent harmonisation is a Trojan horse. It suits the needs of large global companies, but may be entirely unsuitable for individual nations, particularly those with a completely different industry and innovation structure (and market size) to the USA.

How transparent have decisions to change the [patent] system been, including when it comes to legislation and international agreements? (13)

> Not at all.

Is a stronger evidence base and greater transparency in the public interest, and if so, how should this be accomplished? (13)

> As noted above the patent system has been substantially extended without any evidence base for this action. No action base should be needed to unwind these extensions – the evidence from the 1984 IPAC review is that at that time it was uncertain that the patent system created a net national benefit, and if it did, the benefit was small and subtle. The changes since then have, with a very few minor exceptions, been to further distort the

[74] Supreme Court of India, *Novartis AG v Union of India and others*, 2013, Civil Appeal Nos. 2706-2716 OF 2013 (arising out of SLP(C) Nos. 20539-20549 OF 2009), at http://judis.nic.in/supremecourt/imgs1.aspx?filename=40212.

patent system in favour of applicants. At a minimum the constraints on the height of the inventive step and the extensions in subject matter should be reversed as quickly as possible.

As to the future, yes indeed a stronger evidence base is needed and it will take substantial commitment to achieve this. I have discussed this above. A stronger evidence base can be achieved by the government deciding to require the patent office to develop good data on how patents are used and to require the ABS to consult with the Commission to develop improved metrics for measuring the effect of patents as part of its regular program on industry innovation.

As to greater transparency, the prime need is to move IP Australia to the competition portfolio.

How should a context of limited information, long legacy tails and [patent] policy irreversibility bear on the stringency of [patent] rights? In particular, if a precautionary principle is applied, should it err on the side of the consumers or on the side of the [patent] rights holder? In a global context, which approach best suits Australia? (14)

The long legacy tail for patent policy is a major problem. When a new legal doctrine is set, it has immediate impact. But when changes are made to patent policy after careful review and consideration, their implementation is delayed for a minimum of 20 years, and can be more. With the 2011 Patent Amendment Act, applicants were provided with extra time to take action that would be assessed under the old rules – rules that were overturned because they created negative outcomes for the nation. This difference in the timing of implementation has no economic justification. Micro-economic reform is a critical factor driving productivity increase and delays to the implementation of such reform need careful consideration.

The nature of the privileges granted by a patent creates a form of “property” right that can then be licensed or traded. But this does not mean that pending applications should be exempted from changes implemented to improve the economic efficiency of the system. Indeed where previous changes have provided windfall benefits – such as the fall in the height of the inventive step consequent on the *3M* decision – implementation was immediate. If the government finally agrees to require that patents are only granted for inventions that are a significant advance over what was known or used, then from a public good perspective immediate implementation would be desirable.

The economic policy implemented through patent legislation is the exchange of new technology with positive spillover effects for a "powerful exclusive right". But where such rights have been wrongly granted – in effect granted for "inventions" that contain no new knowledge or know-how – then there should be no impediment to immediate application of the proper standard to all current patents.

It is not difficult to identify a sound basis for avoiding retrospective legislation in many areas – for example what constitutes a criminal act. But patent policy is economic policy, unfortunately delivered through the economic system. No granted patent is presumed valid. Given this, at a minimum changes in the height of the inventive step should be implemented with respect to all pending applications and all currently granted patents.

7. Enforcement

The questions that the Commission asks with respect to enforcement that are relevant to the patent system are "Are IP rights too easy or hard to enforce in Australia, and if so, why? Is

Australia's enforcement system well balanced, or weighted in favour of one group? What improvements could Australia adopt from overseas approaches?" (*Issues Paper*: 28).

The fundamental problem in addressing enforcement is the almost complete lack of data. We have no good databases on what proportion of granted patents are enforced, if by enforcement we mean their use to exclude. Logically, it is likely that the number of patents where a solicitor's letter claiming infringement is sent is likely to be very much larger than the numbers involved in subsequent stages of patent dispute. At the smallest end of this spectrum – where disputes end up in court – we have limited information from the IPRIA database (Weatherall and Jensen, 2005). Unfortunately this database has no cost data.

I have commented above (Section 6 on accountability) on the need for IP Australia to collect data on how patents are used.

Another major gap in understanding enforcement and whether there are any deficiencies in current policies is that confidential settlements abound. We do not know what Amazon paid barnesandnoble.com in compensation for the injunction with respect to their one-click patent. We do know that because of this settlement this extraordinarily uninventive patent remained on the USPTO's books. We do not know what Pfizer paid to generic companies in compensation for their 2½ year injunction on their extended release venlafaxine patent. We do know they went to court to challenge the Commonwealth's right to seek compensation for the higher PBS outlays that were consequent to the injunction.[75]

Overall confidential settlements are extremely problematic when it comes to public law. They substantially limit the ability of the public to know and understand the costs and benefits of public legislation.

One thing we can do in respect of patent enforcement is learn from the experience of the USA. As Kingston has pointed out, other countries have almost sleep-walked into adopting patent law based on the 1952 US statute – a statute that was designed by and for the pharmaceutical industry.[76] A particular problem has been the CAFC and there are innumerable scholarly articles on the low standards this pro-patent court has introduced – Harris, 1989; Lunney, 2001, 2004; Quillen Jr., 2006; Dreyfuss, 1989; Jaffe and Lerner, 2004. Finally, with *KSR*, the Supreme Court started to reign in the worst excesses of the CAFC (Mojibi, 2010).[77] The Supreme Court has since addressed issues such as business method patenting, patenting of discoveries and the use of injunctions as a patent penalty.

But the behaviour of the CAFC from its establishment in 1972 to the first re-entry of the Supreme Court into patent law in 2007 warns against a specialised court for patent matters. It is too easily captured by patent interests, becoming part of the patent community. Kingston warns against this as does Quillen. Indeed Quillen provides interesting historical information on the creation of the court:

> "The Hruska Commission Report delivered in 1975 emphatically recommended against a specialist patent appeals court. ... And no one at Kodak or elsewhere expected Congress to ignore the Hruska Report and create a specialist patent appeals court that would ignore over a century of legal precedent when it began its work. … When the Federal Circuit came into existence in 1982, notwithstanding assurances to the contrary and without acknowledging it had done so, the Court almost immediately lowered the standards for patentability. … By 1985, when the district court finally decided Polaroid, the Federal Circuit had made it abundantly clear that the best way for district court

[75] *Commonwealth of Australia v Sanofi-Aventis* [2015] FCAFC 172.
[76] "The criteria of patentability in the 1952 Act were designed by patent lawyers for the pharmaceutical industry to suit that industry, but they do not suit other industries, such as engineering, nearly so well" (Kingston, 2004).
[77] *KSR v. Teleflex*, 127 S. Ct. 1717 (2007).

> judges to avoid reversal and remand in patent cases was to find patents valid and infringed. Unfortunately for Kodak, the Supreme Court did not get around to attempting to reinstate the prior law until 2007, twenty-two years after the liability decision in Polaroid." (64)
>
> Quillen Jr., 2008: 64

8. Data protection

"How does Australia's current protection of regulatory test data affect innovation and the diffusion of new products? Do data protection arrangements limit the ability of parties to understand breakthroughs and build on innovation? Could Australia's arrangements for the protection of test data be improved?" (19)

Data exclusivity is a relatively new form of government-granted monopoly. It was first introduced in 1984 in the USA as part of the Hatch-Waxman Act. That statute was motivated by the need to overturn a CAFC decision deeming that the traditional experimental use exemption to patent infringement did not apply to preparations for marketing approval of generic versions of a product.[78] This decision effectively extended the market exclusivity period substantially. It was swiftly overturned by the Congress. The Hatch-Waxman Act introduced a package of reforms to ensure that generic companies could use patent data to prepare for market entry as soon as possible after patent expiry – this exemption from patent infringement is widely known as the *Bolar exception*. The statute also included the first provisions limiting the ability of third parties to use clinical and other data required by regulatory agencies for the market approval of new medicines. Such use was precluded for 5 years. Thus the origin of the data protection/ exclusivity policy was political horse trading in the Congress.

During TRIPS negotiations the USA pushed for inclusion of a data protection policy in the treaty. Use of "undisclosed information" for "unfair commercial use" was prohibited by TRIPS Article 39. In general this is seen as referring to the data required by regulatory agencies to ensure that pharmaceuticals and agricultural chemicals are safe and effective before market approval is granted.

If one considers data protection/exclusivity dispassionately, it is puzzling as to why data required for public health and safety reasons should ever be confidential. The data are produced for a public purpose. They form important medical data and could usefully be used in wider further studies. It is often stated that the most expensive part of developing a new medicine is Phase III clinical trials where the new medicine is first used with a reasonably large group of humans.[79] But even Phase III trials do not involve sufficiently many people to develop information on, for example contra-indications. Hence post-marketing analyses – also known as Phase IV trials – are extremely importance in understanding the exact value of particular medicines. In countries where there are good databases on health use, effective Phase IV clinical trials could be set up to run off data that are readily available as administrative by-products (Goldacre, 2012). In respect of clinical trial data generally, Goldacre also documents concerns that clinical trials with negative results are suppressed. So

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[78] *Roche Products Inc. v. Bolar Pharmaceuticals Co. Inc*. 733 F.2d 858 (1984).

[79] There are significant uncertainties about the average cost of developing new medicines and the range of costs attached to different types of medicines. For a critical assessment of industry estimates of the alleged US$1.32 billion average cost of developing an NCE (see Light and Warburton, 2011b, 2011a). In summary they indicate that the original work on which these claims are based relates only to the 22% of drugs with the highest R&D costs from those first having Phase III trials in the period 1983-94, not to average drug development costs. Further, the cost elements include the opportunity cost of capital. While this is legitimate in any economic analysis, in the context in which these data are used the expectation is that the estimates are the actual outlays.

there is a very substantial public interest in moving to a situation where all clinical trial data are generally available.

As regards generic entry, the processes are, broadly, that the generic entrant has to demonstrate the equivalence of the generic product to the originator medicine, and also to meet Good Manufacturing Practice standards. The generic company is not required to replicate the earlier clinical trials – indeed this would be entirely unnecessary as the active ingredients are, by definition, identical.

In terms of both ethics and economics it is highly questionable why clinical trials should be replicated. Ethically it would be wrong to give a proportion of patients a placebo when it is known that the approved medicine has demonstrated efficacy.

The World Medical Association Declaration of Helsinki sets out ethical principles for medical research Involving humans. In the 2008 version, this included the statement:

> "Physicians may not participate in a research study involving human subjects unless they are confident that the risks involved have been adequately assessed and can be satisfactorily managed. *Physicians must immediately stop a study when* the risks are found to outweigh the potential benefits or when t*here is conclusive proof of positive and beneficial results*"
>
> (2008 Declaration of Helsinki, Article 20, emphasis added).[80]

Interestingly the second part of this guideline on clinical trials was watered down in 2013:

> "Physicians may not … can be satisfactorily managed. When the risks are found to outweigh the potential benefits or when there is conclusive proof of definitive outcomes, *physicians must assess whether to continue, modify or immediately stop* the study."
>
> (2013 Declaration of Helsinki, Article 18, emphasis added)[81]

Even with this less precise advice as to what to do when outcomes are known, it is clear that unnecessary clinical trials are ethically dubious as well as being a simple waste of resources. Why then has there ever been any suggestion that generic companies should not be able to gain marketing approval simply by demonstrating equivalence? Indeed the "use" by generic companies of earlier clinical trial data may merely be a matter of semantics (after all this is the "IP" world). The simple demonstration of equivalence *precludes any need to use any clinical trial data* as the regulatory agency already has the knowledge and proof it needs that that chemical composition is safe and has some degree of efficacy.

The whole argument for data protection/exclusivity appears to have little economic merit. It is simply a bargaining loss from international trade negotiations, like geographical indications.

It would be interesting to see data that compares original API patents and their expiry dates with data protection periods. As the average period of market exclusivity derived from a patent is 12.5 years in the USA and some 15 years in Australia, it seems probable that data protection provisions in AUSFTA may have little impact in Australia.[82]

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[80] Declaration of Helsinki 2008: Ethical Principles for Medical Research Involving Human Subjects (18th World Medical Association General Assembly, http://www.wma.net/en/30publications/10policies/b3/17c.pdf). One can presume that it is also unethical to commence such trials when there are already conclusive results.

[81] Declaration of Helsinki 2013, at http://www.wma.net/en/20activities/10ethics/10helsinki/DoH-Oct2013-JAMA.pdf.

[82] It remains to be seen what the TPPA demands. Minister Robb has said that there will be no change for Australia. But Article 18.52.2(b) seems to require the market equivalent of eight years market protection where actual market protection is only five years. This is extremely unclear but implies that Australia might well have to limit market entry for biologics for an additional three years.

The TRIPS Article 39 provision allows substantial room for countries to determine what arrangements best suit their economy and society. In particular data protection only applies where this constitutes 'unfair commercial use', and countries are free to define this.

In contrast, AUSFTA mandates a strict five-year protection for "undisclosed test or other data concerning safety or efficacy" used for marketing approval. This broadened the range of data protected and eliminated the possibility of using the TRIPS flexibilities. The wording—a new product that does not contain a chemical entity previously approved for marketing—allows more products to claim data protection than was possible before TRIPS. The relevant US industry advisory body (IFAC-3) noted this wording change as a victory.[83] AUSFTA also mandates three years of market protection where a regulatory authority requires additional data for approving a product other than a new product. This effectively extends data protection to variations to already launched drugs. AUSFTA specifically states that the data protections apply even where underlying patents have expired. As noted above the situation might not occur.

9 Other questions asked by the Commission.

"Do IP rights provide rewards that are proportional to the effort to generate IP? What evidence is there to show this? How should effort be measured? Is proportionality a desirable feature of an IP system? Are there particular elements of the current IP system that give rise to any disproportionality? (18)

For a patent system to be efficient it should provide an incentive that is just sufficient to induce the required change in behaviour and no more. In English-speaking countries the patent system has always been seen from a utilitarian perspective – it is not a reward for the effort of invention. It would be completely inappropriate to reward inventive activity in relation to the degree of effort. This would merely encourage inefficiency. Nor is it appropriate to reward inventions in relation to the net positive external benefits. Certainly the quantum of net spillover benefits is relevant to the decision whether or not to grant a patent reward. But the whole concept of efficiency is related to the lowest possible cost for the desired outcome. Which brings us back to the "just sufficient to induce the additional Inventive effort" approach.

Edwards' comments on this matter are as relevant today and in Australia as they were in 1949 in the USA:

> "If special protection [a patent] is needed at all, *the need is proportional to the probable cost of development* rather than to the profit-yielding possibilities of the patent or the size of the concern that holds it. It would be improvident to relax the protection of important public interests in the case of all patents in order to meet a problem presented by a few patents. The proper remedy is the use of special measures to encourage development at any particular points where such measures are needed." (Edwards, 1949: 247, emphasis added)

In sum, NO, it would be a retrograde step to try and make returns proportional to effort. Similarly returns should not be proportional to spillover benefits.

Should the duration of patent protection take into account how the development of [new technology] was funded? (18)

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[83] "IFAC-3 welcomes the regulatory-related definition of a "new product" contained in Article 17.10.1(d) as being a product that does not contain a chemical entity that had been previously approved in Australia as *providing an important clarification of the term "new chemical entity" found in TRIPS Article 39.3*." (IFAC, 2004:14, emphasis added).

The system for the development of genuinely new pharmaceuticals research has ended up in quite a mess. Much of the relevant research is publicly funded, so the kinds of prices charged for some in-patent products seem rather inappropriate. Really the whole system needs to be addressed. I don't quite see, given TRIPS, AUSFTA and the TPPA how we can do anything to offset the costs of granting patents for new technology that has been publicly funded. The proposed TPPA seems to preclude making most methods of medical treatment ineligible for patents.

I rather think the AUSFTA/TPPA controls on compulsory licensing would prevent their use to achieve a public return for any publicly funded component of research. Perhaps a limited form of Crown licence could be explored? But how would this apply to research funded publicly overseas rather than in Australia?

In other fields the experience of the CSIRO shows how the returns to patented publicly funded research can be achieved.

Do the criteria for patentability in the Patents Act 1990 help the patent system to meet its objectives? (18)

Not as they are currently operating

Would introducing economic criteria for patentability and/or gradually reducing the duration of patent protection substantially improve the efficiency and effectiveness of the patent system? (18)

While it would be preferable to introduce more relevant variables as criteria for patentability, this may not be possible under TRIPS. What is possible is to remove the subject matter extensions that have been judicially determined since 1980, re-define "manner of new manufacture" to be technological innovation and substantially raise the height of the inventive step. *The reform which would have the greatest impact in improving the efficiency and effectiveness of the patent system would be to raise the inventiveness requirement to "as significant advance over what was known or used" at the priority date.*

There is no freedom to change the patent term. Fees could be more rapidly increased with patent duration, though this is likely to affect small more than large owners. **Australia could follow the US example and set different fees for large and small owners.** With this type of fee differentiation, application and examination fees could be set to cover their real cost, not subsidised as at present. Further, all renewal fees after, say year seven, could be set aside for consumer awareness support including, perhaps public advocacy to challenge uninventive patents.

Do patents provide rewards that are proportional to the effort to generate IP? What evidence is there to show this? How should effort be measured? How does the balance of costs and benefits from patent protection compare across sectors and innovations? (18)

While patents are only likely to be needed for inventions with large lumpy R&D, how this could be implemented under current international treaties seems problematic.

There is some academic literature on variations in patenting by sector. Certainly the patterns are very different between simple and complex technologies. The current situation in electronics fields – where each company takes out vast portfolios of patents so that they can trade and then proceed as though the patent system does not exist seems ridiculous. My earlier work has shown that Australia's most prolific US patenter operated in the electronics field (Moir, 2011).

Is the IP system appropriately balancing the longer-run costs and benefits that stem from the system's effects on competition and innovation? (14)

We don't have good data on the patent system's short-term effects on either competition or innovation, let alone over the longer term.

Is the IP system ensuring that IP is traded so that those that can use it most effectively do so? (14) Are there obstacles in the IP system which limit the efficient trade of IP between creators and users? Are there particular areas where trade, licensing and use of IP could be more readily facilitated? (11)

There are some concerns in the USA about "patent trolls" – non-operating entities who are simply in the business of buying and selling patents. The litigious behaviour of some of these companies is exactly what the patent system, as currently designed, encourages. When the Commission is considering the issue of the forms of penalties that courts should be allowed to impose for infringement, consideration could be given to how these could be designed to limit opportunistic behaviour, both by trolls and by companies owning patents essential for a product/industry standard, an issue raised in Intel's submission to this inquiry.

There are almost no data on patent licensing. It is a highly confidential business. I have read at least one article in the journal of the Licensing Executives Society which reported data from a survey with a single-digit response rate. The authors commented that some data was better than none (Brousseau *et al.*, 2005). However biased?

What are the merits and drawbacks of using other methods to secure a return on innovation (such as trade secrets/confidentiality agreements) relative to [patent] rights? (11)

The appropriability studies discussed above (Section 3, efficiency) indicate that a very large proportion of manufacturing businesses use and value other methods compared to patents. These other methods are first mover advantages, quality and customer service, and reputation. In addition the industrial innovation literature points to complementary assets as providing substantial advantages to innovators (Teece, 1986, 2006; Winter, 2006). This last factor substantially favours large over small firms.

The value of trade secrecy is hard to measure. Certainly there are sound arguments that secrecy and patenting are not alternatives. If a new technology can be effectively protected by trade secrecy it is likely to be, as there are no time limits. This is unlikely to apply to products, which can be reverse engineered. Quillen (2008) points out that with very pro-patent courts, secrecy often needs to be reinforced by patents.

"Are there other principles that should be considered when assessing the IP rights system? Are there other factors relating to efficiency, effectiveness, adaptability and accountability that the Commission should consider as part of its inquiry?" (15)

One of the issues that IPAC made recommendations on was the rights of employees who have made inventions which are patented. The Commission may wish to review this matter.

More importantly is the issue of non-compete laws. These prevent skilled employees from taking and building on their own knowledge in their own new business. I am not sure if the Commission considers these within their remit, but they do stifle the transfer of new ideas. Boldrine and Levine claim that it is the lack of such laws in California (where they are unconstitutional) that underlies the success of Silicon Valley. They draw comparisons with Route 128, drawing on research by Gibson (Boldrin and Levine, 2008: 198-200).

Attachment A: Studies funded by the pharmaceutical industry

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Frost and Sullivan, 2014, "The Impact of Australia's Data Exclusivity Regime on Australia's Healthcare System." Unable to find; *no response from submission-author for request for more information.*

Goldman, D.P., D.N. Lakdawalla, J.D. Malkin, J. Romley, and T. Philipson, 2011, "The Benefits From Giving Makers of Conventional 'Small Molecule' Drugs Longer Exclusivity Over Clinical Trial Data," *Health Affairs* 30(1): 84-90. pharma funded

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J. A. Vernon, J. H. Golec, and J. A. DiMasi, Drug Development Costs When Financial Risk Is Measured Using the Fama-French Three-Factor Model, **Health Economics,** (20~~09~~10), No conflicts disclosed. DiMasi has links to originator pharmaceutical companies.

Some of the sources cited in the Pharmaceutical Patents Review Draft or Final Reports have similar conflicts of interest.

Attachment B: Dissenting statement, IPAC Review 1984

DISSENTING STATEMENT

BY PROFESSOR D.M. LAMBERTON

"This Report does not live up to its claim to have adopted an economic perspective and to have applied economic criteria. It has not consistently applied economic criteria; it has not made full use of available empirical evidence; and the concept of social cost, so frequently mentioned, has never really been fully grasped. The underlying idea of the process of innovation is little more than faith that more patent protection will ensure more innovation. The sensible objective is rightly declared to be "to modify the Australian patent laws, adjusting the length, strength and breadth of patent rights" to maximize the net benefit. It is unfortunate that the Report soon strays from this path.

No amount of talk about individual patent successes nor about a future in which the Australian economy has magically become progressive, innovation-oriented, and competitive on the world scene, can hide the facts that Australia exports little in the way of manufactured goods and has few inventions for sale. M[o]st patents are granted to overseas firms. To make the most of this situation, Australia needs to reduce social costs to the extent possible without inhibiting innovation and without provoking international retaliation. As a small nation, there is scope for such action. The constraints of the Convention are largely myth.

A policy exercise such as this Report should look to the dimensions that can serve as the basis of effective action. Abdication in favour of competition law does not hold good prospects in a small domestic market with highly concentrated industries often dominated by foreign investment. This approach is even less promising because patents operate as effective non-tariff barriers to import competition. In these circumstances the thrust of the Report should have been designed to f[o]ster and capitalize on the capability to respond dynamically to change, to imitate, and to innovate competitively and not to preserve the profits of protected stability.

To acknowledge the circumstances of the Australian economy and to seek such a balancing of social cost and dynamic benefits is to reject much of this Report. In particular, it points to:

(a) reduction of standard patent term to 10 years;

(b) some freeing of import competition from the restrictions patents permit (If permitting import competition would be tantamount to abandonment of the patent system, the case for exposing the protection afforded to public scrutiny, as is done with tariffs, is a strong one.);

(c) implementation of a comprehensive system of employee rights in inventions;

(d) making sure that provisions such as compulsory licensing and reexamination can function effectively;

(e) ensuring that patent legislation facilitates the monitoring and control of the conditions under which technology is acquired from overseas;

(f) avoiding the restrictive consequences and additional social costs that can arise if the scope of the patent system is extended unnecessarily in the development of the information economy;

(g) weakening the professional patent attorney monopoly of costly advice;

(h) significantly improving the educational requirements for those working within the patent system; and

(i) clarifying the extent to which Patent Office operations are to be subsidized.

Some important matters have been addressed inadequately, eg.:

(i) the nature and extent of restrictive practices;
(ii) co-ordination with other industrial and economic policy measures;
(iii) co-ordination of availability of patent information with other sources of technological and business information; and
(iv) the administrative efficiency of the Patent Office.

The Report is not an imaginative one. It is constrained by the very "haze of assumptions about rights and rewards for inventors, special pleading by those directly involved, and a plethora of legal procedures and criteria in the Patents Act" that it deplores. Many of its recommendations are for no change; and when change is implemented it is all too often merely procedural or has little prospect of being effective. A good opportunity to adjust an ancient institution to the current needs of the Australian economy has been missed."

Source: Industrial Property Advisory Committee, **Patents, Innovation and Competition in Australia**, report to the Hon Barry O Jones, MP, Minister for Science and Technology, 29 August 1984, pp79-80.

The report is available at
https://web.archive.org/web/20120227072854/http://www.acip.gov.au/library/Patents,%20Innovation%20and%20Competition%20in%20Australia.pdf

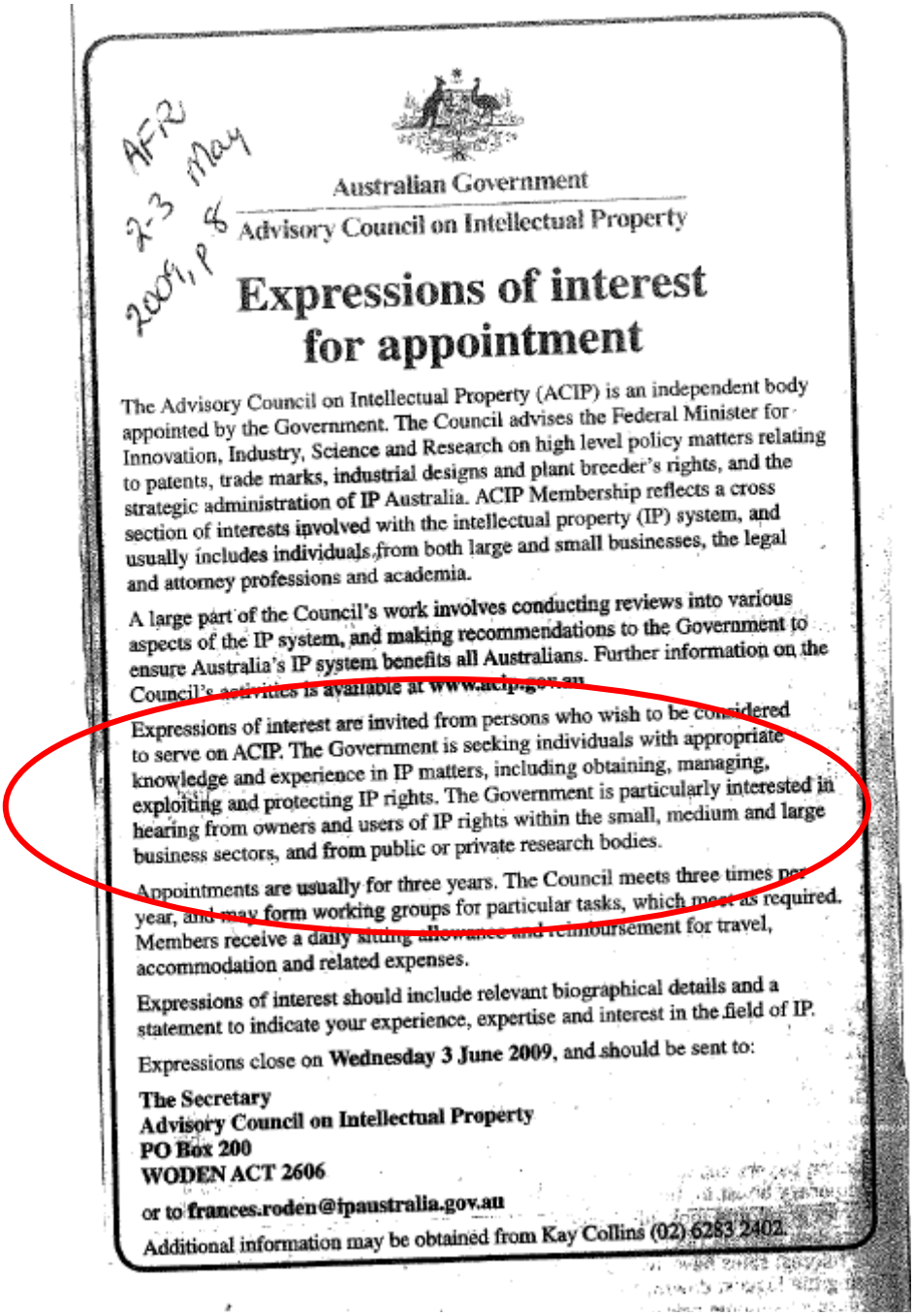
Attachment C: Evergreening – insights into patent costs

This is attached as a separate document

Attachment D: TPPA submission to DFAT

This is attached as a separate document

Attachment E: ACIP membership, 2009 and 2013



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Australian Government

Advisory Council on Intellectual Property

Expressions of interest for appointment

The Advisory Council on Intellectual Property (ACIP) is an independent body appointed by the Government. The Council advises the Federal Minister for Innovation, Industry, Science and Research on high level policy matters relating to patents, trade marks, industrial designs and plant breeder's rights, and the strategic administration of IP Australia. ACIP Membership reflects a cross section of interests involved with the intellectual property (IP) system, and usually includes individuals from both large and small businesses, the legal and attorney professions and academia.

A large part of the Council's work involves conducting reviews into various aspects of the IP system, and making recommendations to the Government to ensure Australia's IP system benefits all Australians. Further information on the Council's activities is available at www.acip.gov.au

Expressions of interest are invited from persons who wish to be considered to serve on ACIP. The Government is seeking individuals with appropriate knowledge and experience in IP matters, including obtaining, managing, exploiting and protecting IP rights. The Government is particularly interested in hearing from owners and users of IP rights within the small, medium and large business sectors, and from public or private research bodies.

Appointments are usually for three years. The Council meets three times per year, and may form working groups for particular tasks, which meet as required. Members receive a daily sitting allowance and reimbursement for travel, accommodation and related expenses.

Expressions of interest should include relevant biographical details and a statement to indicate your experience, expertise and interest in the field of IP.

Expressions close on **Wednesday 3 June 2009**, and should be sent to:

The Secretary
Advisory Council on Intellectual Property
PO Box 200
WODEN ACT 2606

or to **frances.roden@ipaustralia.gov.au**

Additional information may be obtained from Kay Collins (02) 6283 2402.

Members of ACIP [http://www.acip.gov.au/members.html, 21 April 2013]

Chair **Professor Jim Butler** **(**health economist, ANU)

Members

Dr Noel Chambers
Director of Centuris Pty Ltd a boutique consulting and contract management company assisting with the translation and commercialisation of research and innovations.

Professor Mark Davison
Professor of Law, Monash University; part-time IP legal practitioner, Knightsbridge Lawyers; members of the Law Council of Australia IP sub-committee since 2006; appointed to ACIP in January 2013.

Mr Adam Liberman
Director Intellectual Property at Brand Finance; Professorial Visiting Fellow at the University of NSW Law Faculty since 2009; over 30 years' experience as an IP lawyer; past President Licensing Executives Society International; member of ACIP since January 2009.

Mr Greg Munt
Registered patent and trade mark attorney and worked in field for nearly 30 years, particularly patents; actively involved in the Asian Patent Attorney Association and currently is a member of their Advisory Board; appointed to ACIP in January 2013.

Professor Mary O'Kane
Executive Chair, Mary O'Kane & Associates; NSW Chief Scientist and Engineer; various company directorships; Vice-Chancellor, University of Adelaide 1996-2001; former member CSIRO Board and Board of F.H. Faulding; appointed to ACIP in January 2013.

Dr Tracie Ramsdale
PhD in Biochemistry from the University of Queensland; co-founder Alchemia, an ASX-listed biotechnology company, specialising in drug discovery and development; member of ACIP since January 2009.

Associate Professor Kimberlee Weatherall
Associate Professor of Law, Sydney University; teaches and researches in IP law; member of the Law Council of Australia IP Subcommittee since 2006; appointed to ACIP January 2013.

Professor Beth Webster
Director of the Intellectual Property Research Institute of Australia; PhD economics (Cambridge); has published widely on the economics of innovation and IP; member of ACIP since January 2009.

Ex-Officio Members

Mr Philip Noonan
Director General of IP Australia, B.Sci and B.Law, admitted to practice as a solicitor and barrister in Victoria; served on ACIP since January 2008.

Mr Ken Pettifer
Head, Innovation Division, Department of Industry, Innovation, Science, Research and Tertiary Education. B. Econ (hons), ANU; served on ACIP since July 2009.

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