Productivity Commission Public inquiry

into

The compulsory licensing of patents

SUBMISSION

The patent system and compulsory licensing

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Acronyms

ACIP	Advisory Council on Intellectual Property
AUSFTA	Australia-United States Free Trade Agreement
BIE	Bureau of Industry Economics (subsumed into Productivity Commission)
EPC	European Patent Convention
GTL	Genetic Technologies Limited (Australian licence holder of Myriad's BRCA1 and BRCA2 patents
IPAC	Industrial Property Advisory Committee (replaced by ACIP)
IPCRC	Intellectual Property and Competition Review Committee
IPRIA	Intellectual Property Research Institute of Australia
NOIE	National Office for the Information Economy
SCARC	Senate Community Affairs References Committee
WTO	World Trade Organization

The patent system and compulsory licensing

Overview

A fundamental principle of good policy is that it should achieve its goals. In the case of patents this is to induce investment in innovation than would not otherwise occur. The underlying assumption is that this induced innovation will produce spillover benefits greater than the costs of the loss due to grant of the monopoly. If patent policy is targeted in this way, and if spillover benefits exceed monopoly costs, then the nation is better off. One way of ensuring these assumptions are met is to limit the grant of patents to technology-based innovations. This traditional limitation has been overturned by Australia's courts and as at 18 July 2012 IP Australia has granted 1,853 patents for business methods.[1]

The assumption that patents should involve technological invention is so basic that it was rarely written down. Such shared societal understandings are rarely "fully or systematically articulated" (Hirschman 1977: 69). The assumption is implicit in the TRIPS Agreement's prohibition on discrimination between fields of technology (Article 27). It is also clear in this inquiry's terms of reference's referral to Australian *manufacturing industry*.

These major principles of patent policy – that patents are granted for induced *technological* innovation and that the spillover benefits of patents should exceed their monopoly costs – are absent from the patent system as it is administered today.

There is no requirement for inventiveness, in the ordinary meaning of the word.[2] Patents are mostly granted for trivial variations of known artefacts and for processes which recombine old systems adding no new outcomes or unexpected results in the mix. The patent system is *inefficient*. It is granting many patents where there is no benefit, but where there could well be costs.

In this context a reference on compulsory licensing is like auditing deck chairs on the Titanic.

Reviewing and improving the "safeguards" in the patent system is a dangerous activity unless it is taken in the context of a full understanding of how the patent system currently operates. This brief submission makes some comments on the context of the reference before turning to the important issue of the objectives of the patent system. It briefly addresses the political dimensions of patent policy, the historical background to compulsory licensing, availability of data on licensing in general and compulsory licensing in particular. Particular attention is paid to the issue of "alternative mechanisms deemed necessary to ensure that the balance between incentives to innovate and access to technology best reflect objectives of ensuring reasonable access to health care solutions, maximising economic growth and growing the Australian manufacturing industry" (terms of reference). Some specific issues concerning methods of medical treatment, including genetic testing, are raised in this context. This submission puts the view that the major deficiencies in patent policy need to be addressed *before* addressing arrangements for ensuring that grant of these very strong monopoly rights do not undermine other social goals.

[1] These range in "inventiveness" from linking different bank accounts (2005204292) to teaching your children about finance by having them work for their pocket money (2003203582).
[2] This is empirically demonstrated in Moir, forthcoming (2013).

Context of this inquiry

The reference came about as those who benefit substantially from the patent system argue that "safeguards" such as compulsory licensing and crown use provisions ensure that the broken patent system does not need fixing. In this instance various parties argued to the Senate Community Affairs References Committee's *Gene Patents* inquiry and the Australian Law Reform Commission's similar 2004 inquiry that these "safeguards" ensure that any "minor" problems with patenting genes can be overcome. This rhetoric that compulsory licensing and crown use provide effective safeguards is not supported by any evidence.

The complexity of the patent system means that those not familiar with it can be led to believe such "safeguards" are effective in ensuring that the worst impacts of an almost unlimited monopoly system will not eventuate. This appearance of effectiveness disappears, of course, when one enquires how often these safeguards have been used. If no-one has ever used either "safeguard" then it is disingenuous to argue that having them on the books prevents particularly negative outcomes from the patent monopoly system. It was not compulsory licensing or crown use which stopped Genetic Technologies Limited (GTL) from enforcing a demand that all BRCA1 and BRCA2 tests be done at its own laboratories – it was the strong negative publicity about its proposed action to limit testing to its own laboratories and significantly raise the price.

The futility of this reference is perhaps most evident when one considers the Australia-United States Free Trade Agreement (AUSFTA). Through this "free trade" agreement Australia appears to have already given away most uses of compulsory licensing to meet the reasonable needs of the community.

The objectives of the patent system

In the Issues paper the Commission notes the objective of the patent system as being to "encourage innovation by providing inventors with a temporary exclusive right to the patented invention." The Commission then goes on to state that the public good characteristics of ideas mean that "it may be difficult for the creators of IP to capture a sufficient portion of the benefits deriving from their invention to compensate them for the effort and risk involved in its creation" (Issues paper: 3). This superficial perspective – repeated endlessly by proponents of wide-reaching patent systems – has no basis in objective evidence. The theoretical position is clear – *only* in circumstances where there is a large lumpy investment or where followers can enter the market extremely quickly – is there any likelihood of such a "problem" (Boldrin and Levine 2004, 2008). There is substantial evidence that patents are *ineffective* in inducing additional innovation in most technologies (López 2009). And in circumstances such as Australia's – where the importation of patented goods means that spillover benefits occur overseas – there is rarely any social benefit in the award of a monopoly (NOIE 2004: 97).

For effective economic policy, patents should *only* be granted where the innovation *would not otherwise occur* – otherwise monopoly costs are incurred with no commensurate benefit. Ideally patent monopolies would be granted only where lead-time in the market is insufficient to allow the innovator to recoup the initial sunk costs of research and development *and* where there is a net social benefit from the innovation. The traditional argument for why there should be intervention to encourage innovation is that the knowledge spillovers from the innovation provide a substantial social gain to society. But the empirical evidence suggests patent policy is both ineffective and inefficient.

A full consideration of the evidence relative to the economics of patent policy is provided in the appendix. This appendix analyses the assumptions, paradoxes and evidence involved in the economics of patent policy. It is chapter 2 of my forthcoming book, an empirical analysis of the degree of inventiveness required for grant of a patent (Moir 2013).

The Commission raises the question of whether inserting an objective into the Patents Act would assist in clarifying when compulsory licenses should be granted. I have argued in a number of previous enquiries that inserting an objective into the Patents Act is essential to give guidance to our courts.[3] At present many court decisions on the patent system are highly questionable from the perspective of the economic goals of patent policy. In developing its understanding of the patent system I recommend that the Commission read a small number of court decisions to understand the very large gap between the rhetoric and practice of patent policy. I can particularly recommend the Federal Court's decision to grant a preliminary injunction to prevent manufacture of a generic version of venlafaxine despite clear evidence that the relevant patent was probably not valid;[4] the High Court decision to disallow knowledge about mortice locks to be used in challenging the inventiveness of a marginally different rim-mounted lock;[5] the Full Federal court judgement commenting that it is not up to courts to consider if an individual patent causes economic benefit or harm;[6] and the Federal court decision to grant a patent for the well-known procedure of dynamic storage.[7] None of these legal doctrines are in any way affected by recent changes to the *Patents Act 1990*. They all indicate that judges have insufficient guidance about the economic objectives of the patent system to make sound decisions in implementing this economic policy. Introduction of clear objectives into the Act will provide better guidance to these judges.

IP Australia is advised by the Advisory Council on Intellectual Property (ACIP). The principal requirement for membership of this body is that one be a beneficiary of one of the major "IP" systems. There are no consumer representatives, nor any representatives of competition interests. ACIP has recently put forward the following proposal for the wording if an objective of patent policy is inserted into the Act:

> "… to provide an environment that promotes Australia's national interest and enhances the well-being of Australians by balancing the competing interests of patent rights holders, the users of technological knowledge, and Australian society as a whole." (ACIP 2010: 5)

This very political statement reflects ACIP's composition. Its high level of generality avoids focusing on the economic objectives of the patent system, instead simply setting out the well-known jockeying between competing interests that is the hallmark of policy development in today's era of citizen disengagement. A strategy of balancing competing interests is not an objective. Australia's innovative businesses can be restricted in their

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[3] Review of the National Innovation System; ACIP review of patentable subject matter; Senate Community Affairs Committee's *Gene Patents* Inquiry.

[4] *Sigma Pharmaceuticals (Australia) Pty Ltd v Wyeth* [2009] FCA 595 (3 June 2009). Two years later the Full Federal Court found the patent to be invalid and the injunction was lifted. There are no provisions in the Patent Act for the Commonwealth to recoup the additional price paid to Wyeth for venlafaxine during this two-year period of unwarranted market exclusivity.

[5] *Lockwood Security v Doric Products* [2004] HCA 58 (18 November 2004).

[6] *Grant v Commissioner of Patents* [2006] FCAFC 120 (18 July 2006).

[7] *Welcome Real-Time SA v. Catuity Inc*, [2001] FCA 445 (17 May 2001). This decision opened the doors to business method patenting in Australia

operations by the grant of many thousands of trivial patent monopolies. They deserve better.

A proper statement of objectives for the Patent Act would indicate that patents are granted:

> "… to encourage inventions which would not otherwise occur *and* which provide sufficient new knowledge or know-how to the community to offset the cost of the monopoly to the community."

This statement indicates that providing privileges to innovators who are genuinely impeded by market failures are counterbalanced by knowledge contributions to their competitors and consumers. It also provides proper guidance to the courts. It indicates that the inventiveness requirement should be substantially higher than the current scintilla (see section below on alternative mechanisms). In the absence of this guidance courts and IP Australia have deluded themselves into thinking that the *quid pro quo* of the patent system is the publication of the patent specification. It is not. The *economic rationale* for granting a patent is to obtain knowledge spillovers that would not otherwise occur. A *condition* of grant is publication of adequate technical detail.

The *condition* of publication is not the *purpose* of patent policy. Nor does publication of documents written in legalese contribute any spillover benefits. As research commissioned by IPAC in the early 1980s demonstrated, leading inventors rarely used data in patent specifications (Mandeville et al. 1981). The main claim for a typical patent is shown in Box 1.

Figure 5.1 On Line Advertising: original and translated core claim

AU2004210528; priority date 24 September 1999

Claim 1: An on line interactive advertising system which enables viewing of advertising by a person engaged in an activity in which the person receives electronic data and/or images and at the same time and at the option of the person views said advertising; the system comprising;

[translation: someone at a computer (or similar) receives electronic information and chooses whether to look at advertising too]

a consumer station which receives electronic data or images; an information provider which delivers said electronic data or images to said consumer station, a host having a website with which said consumer station communicates and interacts, an advertising provider in communication with said host; wherein the advertising provider communicates via said host with said consumer station via the internet upon election by said consumer station responsive to an invitation from said host; wherein, without requiring software downloaded and installed into the consumer station, the consumer receives said advertising material by responding to a random invitation from the host, which appears at the consumer station wherein, when said consumer elects to view advertising from said advertising provider via said host, the consumer receives rewards, credits or benefits commensurate with the length of time advertising is viewed.

[translation: a consumer uses a computer, connected to the internet, and, in response to an invitation, can choose to access a website with advertising without downloading any software; the invitation is random and if the consumer chooses to look at the ads s/he gets rewards related to how long s/he looks at the ads].

The political dimensions of the patent system

Where regulatory intervention creates the possibility for some parties to reap substantial benefits, these parties have a strong incentive to help set up complex and arcane rules that hide the benefits from general view (Braithwaite 2005). The patent system is nothing if not complex. It is also a system where a very small number of parties reap considerable benefits. Any public interest issue in regard to the operation of the patent system therefore needs to be approached with caution. The systematic refusal to collect direct data on the operation of the patent system,[8] combined with what Professor Lamberton referred to as "special pleading by those directly involved" (IPAC 1984: 80) makes the development of sound evidence-based patent policy challenging. Nonetheless if one turns to the field of industrial economics substantial relevant data can be found – a useful summary of this compelling evidence is provided in López (2009). A third dimension making good policy outcomes in this area hard to achieve is the political context, where US policy has been captured by vested interests and the US actively pursues the narrow agendas of these few companies (Drahos 2001; Drahos 2002; Sell 2003).

Two years ago IP Australia advised the Senate Community Affairs References Committee that it was proposing to raise the inventive step test in Australia from "whether or not the skilled person in the relevant art would be led directly as a matter of course to try a particular approach with a reasonable expectation of success" to "obvious for the skilled person to try a suggested approach, alternative or method with a reasonable expectation of success" (SCARC 2010: 114).[9] This proposed change was supported by the Committee (recommendation 6). After lobbying from the patent community IP Australia backed away from making this change. Instead they said they would "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" (IP Australia 2009b: 12). This is nonsense. Examiners are required to follow precedents set in case law. More careful application of the law does not improve bad law.

Against this background it is refreshing that the *Productivity Commission Act 1988* requires the Commission to "base its assessment on what set of arrangements would give the best outcomes for the Australian community as a whole" (Issues Paper: 2).[10] In its original work addressing tariff barriers the Commission was able to draw on independent economic analysis showing the costs to the community of tariff protection. In inquiry after inquiry the Commission was able to show that the costs to the community far outweighed the benefits to the sectional interests protected by tariff walls. An approach was developed where the losers were often offered some form of compensation (such as re-training) for the reforms.

Unfortunately such robust empirical analysis has never been undertaken for the patent system. In this field almost the sole evidence of any benefit from patent monopolies is the special pleading of interested parties – those few companies with significant patent

[8] It is notable that the government has never actioned the 1984 IPAC recommendation to collect data on how patent monopolies are used. Despite this the Director General of IP Australia, Philip Noonan, is on the public record regretting the lack of data on patent use (IPRIA Pacific Rim Innovation Conference, February 2010) but has given no indication of a willingness to collect such data.

[9] Citing IP Australia, 2009a: 12-13.

[10] And of course this objective is closely aligned with Article 5.1 of the Competition Principles Agreement that competition should not be restricted unless "the benefits of the restriction to the community as a whole outweigh the costs; and the objectives … can only be achieved by restricting competition." (http://www.ncc.gov.au/images/uploads/cpa_amended_2007.pdf). The patent system of course is a massive restriction of competition.

portfolios, and the increasing ranks of patent attorneys. Patent beneficiaries seem quite effective in ensuring little direct evidence is collected about patent systems (Kahin 2003).

The market for innovation has perhaps the greatest degree of government intervention of any market. As Yale Professor John Beggs remarked in the context of the 1984 "economic"[11] review of Australia's patent system:

> "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)

This statement remains true today.

In the context of the patent system one also needs to check carefully information put forward. There is a tendency to make claims that cannot be backed up with evidence. Over-claiming is regular. For example, while the data in Box 2 of the Issues paper is referenced, there is at least one inaccuracy. The Box states that the "Raising the Bar" legislation raised the standard for inventiveness. This is incorrect. As indicated above, the government resiled from raising the standard of inventiveness; it made two minor changes to the definition of relevant existing knowledge but did not change the inventiveness test. The legal definition of inventiveness in Australia remains a "scintilla" – a trivial difference.

Historical background

As noted above the benefit which society receives to offset the costs of patent monopolies is the spillover benefits from new knowledge and know-how embodied in the new innovations. Initially these knowledge spillovers flowed through training two generations of new craftsmen – the original 14 year limit on patent monopolies. Even today new knowledge and know-how frequently flows through the movement of skilled personnel. Boldrine and Levine suggest that the far stronger economic performance of Silicon Valley compared to Route 128 is the absence of restrains on trade in Californian law (Boldrin and Levine 2008: 198-200). The original compulsory licensing provisions were designed to ensure that the spillover benefits from the new technology were actually received through the "working" of the patented invention. If the invention was not manufactured ("worked") then there were no spillover benefits. Other manufacturers could (and did) apply for compulsory licenses. Australia inherited its compulsory license provisions from the UK, just as it inherited both statute and case law.

Now that we have moved away from any requirement that patented inventions be worked in a country, compulsory licensing no longer operates to ensure the *quid pro quo* of the patent system eventuates – that there are beneficial spillover knowledge flows. As NOIE (2004: 97) pointed out, where patented goods are largely imported the spillover benefits occur overseas and *there is little or no benefit to Australia in the grant of a patent*. In this new environment, the role of compulsory licensing and crown use change.

[11] The 1984 IPAC review purported to be an economic review. The sole economist on the Committee, Professor Donald Lamberton, issued a dissenting statement that there was nothing economic about the review (IPAC, 1984: 79-80). The Committee did, however, commission two conferences and several small studies which did gather useful empirical data on aspects of the patent system (Mandeville et al. 1982a, 1982b).

It remains the case that a society (government) should not lightly grant monopolies, especially in an arena as important as innovation. Australia's definition of a patentable monopoly remains that drafted in 1623 and hedged with restrictions to ensure that monopolies were granted only for new inventions (not improvements) which did not injure trade or otherwise cause harm to society.[12] It is entirely reasonable to ensure either that monopolies are not granted where these are potentially harmful[13] or that society (the government) have the unfettered right to intervene and limit use of a granted monopoly if this is in society's interests.

A major focus of global discussion of compulsory licensing in this new environment is in implementing the Doha Agreement – that the extension of patenting to all fields of technology in all GATT signatory nations should not have too adverse an effect on public health. The terms of reference for this inquiry also raise issues about climate change mitigation, alternative energy, food security and industry standards. The strong political objections that are raised by even the threat to use compulsory licensing suggest that other mechanisms might be preferable. These are discussed below.

Data on licensing

In discussing data on the patent system it is important to note that many authors make strong assumptions about how the patent system operates. The author of the BIE study of patents assumed that the Australian patent system had an inventive step (BIE 1994). The IPCRC review assumed that the existence of an inventive step in Australia would preclude the grant of patents for business methods (IPCRC 2000). Both were wrong. Most of what is written about the patent system needs to be scrutinised for the embedded assumptions before any conclusions are accepted. This extends to the small literature on compulsory licensing – Aoki and Small, for example, *assume* that compulsory licensing will deter innovation *but produce no supporting evidence* (Aoki and Small 2004). In contrast, Chien (2003) tests this assumption. Given the dearth of compulsory licensing events, her empirical analysis covers only six incidents, but she finds no evidence of any negative impact. This replicates the results of the empirical analysis undertaken by Scherer and colleagues in 1959. Beall and Kuhn (2012) identify all pharmaceutical compulsory licensing incidents in a ten year period after signing of the Doha Agreement. They find 34 such incidents of which 24 involved both WTO members and government support for issue of the compulsory license. In this context Chien's set of six cases looks quite substantial.

Firms are notoriously reluctant to disclose any information about their patent (or other technology transfer) licenses. Brousseau and colleagues, for example, published data from a survey with a six per cent response rate on the grounds that some information – however biased – was better than none (Brousseau et al. 2005). The overall literature on licensing is thin, and little is empirical. An exception is the empirical work undertaken by Nielsen and Nicol, which is documented in their submission to this inquiry.

The first of F M Scherer's papers on the use and effect of patents was undertaken as a Harvard Business School project in 1959.[14] The question asked was whether compulsory

[12] Details are spelled out in my submission to the Senate *Gene Patents* inquiry, pp. 5-6.

[13] For example is it sensible to grant monopolies for methods of avoiding the tax one owes (Drennan 2007)? In Australia it is surprising that the *Grant* application for a method of hiding assets from legitimate creditors was not simply refused because it undermines law on bankruptcy procedures (Tyacke and Webb 2007).

[14] This study was privately published and is not available. However Scherer provides interesting material from it in his 2006 Brookings paper (Scherer 2006).

licensing rulings impacted on firms' willingness to invest in research and development. The results were surprising and were the first in a long series of empirical studies demonstrating that, in general, the existence of patents is irrelevant to industrial decisions to invest in research and development.[15]

The terms of reference ask the Commission to "[a]dvise on the frequency, and impact, of the issue of compulsory licences *in comparable markets* and the common features in such compulsory licenses" (emphasis added). The Commission choses to interpret this as referring to developed country markets. This self-imposed limitation is unfortunate. As the Commission notes, another characteristic of Australia is that it is a technology-importing nation. Comparable markets could therefore equally be determined to be markets which are technology importing.

Consideration of compulsory licensing or crown use is most frequent in regard to effective health treatments and it would be useful if the Commission investigated how such provisions have worked in all markets. The Commission will quickly see that Australia's neighbours – such as Thailand and the Philippines – have tried to use such provisions and have been subjected to considerable lobbying from overseas interests to attempt to prevent them using these "safeguards". The US Trade Representative takes an active interest in countries using such "safeguards". US interventions to prevent use of compulsory licensing procedures have attracted the interest of academics, and the Commission could consider these examples as they are among the best documented uses of compulsory licensing.

Without considering the experience of these countries the Commission will be less than fully informed about the futility of compulsory licensing and crown use as means of ensuring that the worst excesses of patents systems are held in check. A range of papers on these experiences are available (for example, Gonzales 1999; Chien 2003; Krikorian 2008; Limpananont and Kijtiwatchakul 2010; Beall and Kuhn 2012; Silverman 2012). Given the dearth of material on compulsory licensing the Commission would be well advised to consult these resources.

A further issue in identifying "comparable markets" is the combination of Australia's federal structure and the large role played by non-government organisations (both profit-making and not-for-profit) in the delivery of health services. In this (possibly unique) context crown use provisions drafted for unitary governments which have public health care provision may be inadequate to Australia's needs in any health emergency. Given that the AUSFTA severely limits Australia's ability to use compulsory licensing, attention to this is important.

Other mechanisms to achieve patent balance

The reference asks the Commission to consider "alternative mechanisms deemed necessary to ensure that the balance between incentives to innovate and access to technology best reflect objectives of ensuring reasonable access to health care solutions, maximising economic growth and growing the Australian manufacturing industry".

The limited reference in this to the public interest ("reasonable access to health care solutions") is extended somewhat by the later referral to "other areas of sensitivity". While there are indeed conflicts between the unnecessary grant of monopolies and economic growth, there are also a broad range of consumer and citizen interests in ensuring that monopolies are not lightly granted.

[15] See López (2009) for an excellent review of these many studies.

The best mechanism to ensure this appropriate balance between innovation incentives and the national interest would be to undertake a proper reform of the patent system. This should include a sound statement of economic objectives, a limitation to technology and a genuine inventive step of some height. These essential major reforms should be supported by proper audit procedures, anti-avoidance provisions to prevent undermining of the intent of the law through drafting, a requirement that examiners clearly state the reasons for grant of each patent in terms of the new knowledge or know-how contributed (in non-legal terms), and penalties for profiting from an invalid patent.

Clear objectives

The importance of inserting a clear statement of objectives into the Patent Act has been discussed above. The evidence from legal decisions shows that without this Australian courts regularly make decisions that reduce Australia's economic wellbeing (Moir 2012). The following wording is proposed:

> "… to encourage inventions which would not otherwise occur *and* which provide sufficient new knowledge or know-how to the community to offset the cost of the monopoly to the community."

Traditional exclusions from patentability

Achieving these goals would be easier if Australia's courts had not overturned the traditional exclusions from patentability – algorithms, methods of medical treatment, business processes, ideas and so on. Judicial law-making is extremely active in the patents arena, and Australia is no exception. None of these changes in policy have been based on any analysis of the economic implications. The government should return the system to the *status quo ante* and explicitly write into the Patent Act both these traditional exclusions and a limitation to fields of technology, specifically excluding mathematics from patentablity.

Before electronic computing, mathematics was a branch of science largely divorced from the world of patents, other than via its use in other branches of science or engineering. It was widely considered that mathematics as such was unpatentable. Indeed there is no consensus as to whether mathematics is an art or a science.[16]

The exclusions should be absolute. Qualified exclusions lead to "clever drafting" and the undermining of patent law. Perhaps the worst example of this is "Swiss medical claims", designed to avoid the prohibition under the European Patent Convention (EPC) of patenting second medical uses of known substances. They were designed by the Swiss Patent Office to get round the prohibition (Thambisetty 2009: 16-7). Other examples are the many grants of software patents under the EPC despite the legal exclusion of such matters from patentability (Bakels and Hugenholtz 2002; Miceli 2005).

The exclusion of ideas from patenting is also very important to get balance right between encouraging innovation and impeding it. Problems raised by the strong monopoly right provided through the patent system, in combination with new approaches tending to grant patent monopolies to upstream discoveries rather than downstream artefacts can impact significantly on technological progress and the public good. A telling example is that of "golden rice" (Beachy 2003). This type of problem can be addressed by ensuring strong prohibitions against patenting at the ideas stage and a proper height to the inventive step.

[16] http://en.wikipedia.org/wiki/Mathematics#Definitions_of_mathematics (accessed 2 August 2012).

Re-introducing an inventive step

In the Explanatory Memorandum to the Intellectual Property Laws Amendment (Raising the Bar) Bill 2011 the government stated that:

> "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." (p. 42).

This sound statement of purpose precedes a miniscule reduction in the knowledge excluded when the "inventive step" test is applied. This broadening of the allowed knowledge base might lead to the refusal of some applications, but it does nothing to address the well known fact that the quantum of inventiveness required is a scintilla, not "a significant advance over what was known".

IP Australia is well aware of the desperately low inventive step in Australia. In the first of its discussion papers leading up to this amendment bill IP Australia raised the issue of the test of "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" (IP Australia 2009a: 12). IP Australia proposed raising this very low standard by a small notch to a test based on whether 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). Had this proposal been enacted it would still have fallen far short of "a significant advance over what was known". Following lobbying, no action was taken to improve the inventiveness test. Nonetheless the government continually claims that it has raised the inventiveness standard in the 2011 amendment bill. Indeed the quotation above from the explanatory memorandum implies that the current test is "a significant advance over what was known".

As the government has advised parliament that patents should be awarded only "for things that are a significant advance over what was known", it would be nice to see this standard implemented. This could be done by replacing the current plethora of low quality rules about inventiveness with a definition that requires new knowledge or know-how. Such a definition would ensure at least some chance of spillover benefits to offset the costs of the monopolies granted. It would also eliminate a substantial amount of rent-seeking behaviour and these resources could be directed to more productive uses. Patents grant a powerful exclusive right and should not continue to be granted for every trivial variation on a theme.[17]

Other essential reforms

A number of other proposals to improve the patent system were put to the Senate Community Affairs References Committee's *Gene Patents* inquiry. Details can be seen in submissions and in their report (pp 133-151).

The patent community is well aware that "clever drafting" can introduce sufficient "inventiveness" into a patent to overcome any lack of technological inventiveness. Such semantics substantially undermine the goals of patent policy and should be dealt with in the same way as the crafting of financial schemes to avoid tax obligations. Moving IP Australia into the Treasury portfolio would partially offset the undue influence of monopoly seekers. Other audit and accountability mechanisms were proposed to the Senate committee. Finally it is the practice at the US Patents and Trade Marks Office for examiners to state the reasons

[17] Moir (2013) provides an empirical assessment of 72 granted patents showing that none contribute any knowledge or know-how.

why they grant each monopoly. In many cases these statements provide a clear insight into the alleged difference between the "invention" and previous knowledge. This discipline might do much to improve examination standards at the Australian Patent Office.

Medical treatments, including diagnostic tests and pharmaceutical products.

Prior to TRIPS, many countries did not provide patents for chemical products. When it was forced to amend this exclusion to remain a member of GATT, India required that patent monopolies be granted for pharmaceutical products only where these provide an increase in efficacy. This seems entirely reasonable – why should society grant a monopoly for a product that does not provide an improved outcome, especially in the very important area of health care. India's sensible approach to balancing innovation incentives and health goals has been subject to much criticism from major pharmaceutical companies and from the US government (Sampat et al. 2012). A leaked draft of the Trans-Pacific Partnership Agreement (TPP) suggests a general attack on the approach adopted by India.[18] Australia seems to be supporting this initiative – this unneighbourly action seems at odds with our concern to be held in sufficiently high international regard to merit a seat on the UN Security Council.

Australia's very low inventiveness standards do nothing to exclude such practices as back-door extensions to patent term through the patenting of enantiomers.[19] One example is venlafaxine, a major drug for the treatment of depression. When this reached the end of its patent life its owner Wyeth (now part of Pfizer) patented its mirror image, desvenlafaxine. The active ingredient of desvenlafaxine is venlafaxine. There seems absolutely no benefit to the nation is the grant of a monopoly for such an "invention". Further, the PBS has listed desvenlafaxine as an approved drug, even though its action is through venlafaxine which is now subject to generic competition.

Another matter that should be reviewed is the strength of the monopoly privilege granted – the "powerful exclusive right". During parliamentary consideration of the Anti-Counterfeiting Trade Agreement an example was given where a company proposing to set up export facilities for generic pharmaceuticals was inhibited in this investment as Australia allows patent owners to refuse to allow the manufacture for export of a product for which there is no valid patent in the export destination. One means of overcoming this regulatory impediment to competitive economic activity in Australia would be to provide for as-of-right licenses for production for export to any country where a parallel patent is not in force.

While Australia never refused patents for chemical compositions, there was a long standing rule that methods of medical treatment were unpatentable. This rule still operates in many countries but was overturned in Australia by the Federal Court in 1994.[20] The court argued that as parliament had written one specific exclusion into the 1990 Act, it intended to abandon all existing traditional exclusions. There is not one word to indicate any such intent in the parliamentary debates. Drawing on the longstanding exclusion, diagnostic tests used for medical treatment would not have been patentable. It is unfortunate that parliament has not yet acted to clarify to the court that this interpretation of the Harradine amendment was not intended and should be reversed.

A concerning aspect of the interaction of patents and medical testing that became evident during the Senate genes inquiry was the question of testing in a single laboratory. Such

[18] Article 8 (1) (http://keionline.org/sites/default/files/tpp-10feb2011-us-text-ipr-chapter.pdf).
[19] Pairs of chemical compounds whose molecular structures are nonsuperimposable mirror-images.
[20] *Anaesthic Supplies Pty Ltd v Rescare Ltd* (1994) 50 FCR 1.

exclusivity grants to the patent owner a wealth of valuable research data that may not be available to other parties to exploit. It goes far beyond any benefit ever intended when patent law was drafted. It excludes other researchers from using these medical data to develop improvements or investigate where alternative approaches may give better results. There is a sound public interest argument that requiring testing only at laboratories designated by the patent holder should be declared anti-competitive.

Another problem in the tension between competition and innovation in the health market is the new "intellectual property" "right" of data exclusivity. It is astonishing that data which are required by public authorities to protect the health of their citizens have been granted the status of private "property" "rights". These data should be generally available – excluding of course patient identifier variables. They were produced to meet public needs and should be available for public research. They should certainly not be used to limit competition as patent expiry approaches.

Conclusion

This reference shows that the government continues to avoid addressing the increasingly evident major problems in the patent system. Allegations that compulsory licensing and crown use provide "key safeguards" to a badly broken patent system do not make these wishes come true. For a thorough consideration of why current law on compulsory licensing cannot be expected to work the by Charles Lawson cited in the Issues Paper provide a solid and substantial analysis.

But there seems little point in tinkering with unused provisions of the Act when the overall delivery of the patent system is so very far from the goal of only granting patents "for things that are a significant advance over what was known". If the patent system were thoroughly overhauled to ensure that it provided patents only where it was likely to induce inventions and only where such inventions provided at least reasonable new knowledge or know-how (and hence spillover benefits) there would be fewer concerns about misuse of the system.

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