Comments on the Productivity Commission's Draft Report on Compulsory Licensing of Patents

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The views presented in this submission are my own and do not represent the views of any other person or organisation

The patent system and compulsory licensing

Adequately assessing compulsory licensing and crown use provisions as "safeguards" against abuse of the patent system requires a sound understanding of the system that these "safeguards" are designed to protect against. Such an understanding is not yet evident in the draft report. The Commission appears to have accepted as being correct a number of assumptions which are contradicted by the available evidence.

Patent systems: justification

There is no sustainable economic argument for providing monopolies for minor inventions which involve no major impediments to their development. The draft report contains a lengthy repetition of the uninterrogated set of assumptions about rivalry and exclusion that underlie arguments for patent monopoly systems (pp 33-44). But these assumptions have been shown not to hold for most technology classes.[1] Indeed simple first principles show that it is **only where development costs are large and lumpy** that there might be any problem in the market for the development of inventions (Arrow 1962; Boldrin and Levine 2004). It is disappointing that the Commission has ignored the substantial empirical evidence in favour of repetition of unsubstantiated and uninterrogated assumptions.

In particular, the draft report cites several authors to caution against equating the "powerful exclusive right" granted by a patent with market power.[2] For it is a negative "right" – the "right" to prevent others from using the "technology" covered in the patented claims. Indeed Quillen (2008) has pointed out that it is not the patents you own that promote innovation and commercialisation – it is the patents which *others* own which prevent it. Nonetheless it is true that many patents provide little market power – largely because the inventiveness requirement is so low (see below). However if most patents provide little market power, then these many patents are unlikely to induce invention which would not otherwise have occurred. Commentators like Gans, Williams and Briggs (2004) simultaneously argue that patents are an essential inducement mechanism and that they grant no monopoly power. Either one or the other can hold – but not both simultaneously.

Ex ante protections: worthwhile inventions that would not otherwise occur

In the draft report the Commission supports the view that "patents should only be granted where they lead to worthwhile innovations that would not otherwise occur" (p 44). Indeed the report lists the inventiveness requirement as an important ex ante safeguard to limit the potential shortcomings of patent systems.

The inventiveness test

Economists tend to assume that the patent system requires genuine invention before a patent is granted. The Ergas review, for example, assumed that few business method patents would be granted as they would not pass the inventiveness test (IPCRC 2000, p.

[1] See López (2009) for a summary of the extensive empirical evidence which refutes the general applicability of these assumptions.

[2] The phrase "powerful exclusive right" is from the Explanatory Memorandum to the Intellectual Property Laws Amendment (Raising the Bar) Bill 2011, p.42.

153). They were wrong.[3] The quantum of inventiveness required for grant of a standard patent in Australia is "trivial difference".

The Commission falls into the same trap as other studies in assuming that the inventiveness test ensures patents are granted only for "worthwhile innovations that would not otherwise occur".[4] The sole evidence presented to support this statement is the "Raising the Bar" amendments which the draft report claims will result in "a tougher threshold test" (p.45) or "increasing the threshold for inventiveness" (p.55).

As background to the "Raising the Bar" amendments, the Commission needs to understand that the tests in the patent system have been refined, by decades of legal argument, into very detailed and legalistic tests. The first shock to the economist new to the patent system is that much existing knowledge is excluded before tests are applied. The novelty test was entirely emasculated when an English judge ruled in 1880 that existing knowledge could be considered only one document at a time.[5] What the "Raising the Bar" amendments did was to finally remove two substantial exclusions from the knowledge considered in the inventiveness test. Removal of the common general knowledge outside Australia exclusion was also recommended by IPAC (1984, p.5) and the IPCRC (IPCRC 2000, p. 16).

But the "Raising the Bar" bill did not address the very low test used to determine inventiveness in comparison to allowable existing knowledge.

IP Australia recommended a small increase in the inventiveness test in its 2009 consultation paper (IP Australia 2009a: 11-13). It proposed increasing the test from "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" to "obvious for the skilled person to try a suggested approach, alternative or method with a reasonable expectation of success" (IP Australia 2009a: 12-13).[6] As can be seen both tests are quite low, and either well represents the "scintilla" of inventiveness that is all that is required by our patent law.

But IP Australia did not proceed with this very modest amendment, despite its commitment to the Senate Community Affairs References Committee during its gene patenting inquiry.

In reporting on the outcomes of its consultations, IP Australia reported that "a number of submissions" disagreed with the proposal.[7] The final outcome was that:

> "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 [existing knowledge]."
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> (IP Australia 2009b, p.12 emphasis added)

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[3] As at 18 July 2012 IP Australia had granted 1,853 patents for business methods (my original submission, p.8).

[4] See for example BIE (1994); and the Ergas Report (IPCRC 2000).

[5] Von Heyden v. Neustadt (1880) 50 L.J.Ch. 126. Indeed a footnote reference in one document to a second document does not automatically permit that second document to be used together with the first document for assessing novelty.

[6] This proposed change effectively followed the findings of the Supreme Court in the 2007 *KSR* decision and would have raised the Australian inventiveness test to the very low standard used in the USA.

[7] Reviews and inquiries by IP Australia and its advisory body, ACIP, frequently involve confidential submissions, and even the identities of those making such submissions are not made public. They would most likely be those benefiting from the current system – holders of substantial numbers of patents and patent attorneys.

In other words no action was taken to reform the legal tests for inventiveness. Examiners are required to apply the law. In a common law country such as Australia case law forms part of the body of law unless it is changed by statute or over-ruled by a higher court. As the "led directly as a matter of course" test was used by the High Court,[8] it is hard to see just how more rigorous examination can in any way lift the quantum of inventiveness required to pass this test.

It is therefore wrong in fact to conclude that the 2012 amendments will result in a tougher inventiveness test.

The amendments do reduce the amount of existing knowledge excluded before applying the test. But the test itself remains very low. Three sets of evidence in support of this are presented below. One relates to evergreening patents in the pharmaceuticals area; one relates to the types of "inventions" granted in the business methods area; and the third relates to case law and the examiners' manual.

The many evergreening patents surrounding genuinely new chemical entities confirm the low quantum of inventiveness required for a standard patent in Australia (Box 1). While the example given (des/venlafaxine) has only a small number of evergreen patents – compared for example to es/omeprazole with 53 evergreen patents – these have been highly effective in providing Pfizer ***with nearly 40 years "protection" from full generic competition.*** In respect of granting patents for desvenlafaxine, as Drahos has said:

> "The real question that society wants an answer to is not whether this is inventive as a matter of patent law jurisprudence, a jurisprudence that has been paid for by decades of pharmaceutical company litigation, but rather whether it is innovative as judged by the community of experimental pharmacologists, a community which tends to look for genuine leaps in therapeutic benefits rather than clever marketing strategies."
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> (Drahos 2007, p.6)

The low height of the inventive step is also confirmed by consideration of the many business method patents granted in Australia (Box 2). Indeed examiners can find several "inventive" concepts where the ordinary person would find none. For example application AU2006202244 – for early repayment of a home equity loan - was split into three because the examiner found three inventive concepts, depending on how the repayment amount was calculated. These three "inventions" were for repayments based on (a) the current value of the asset if the value has increased, but not if it has decreased; (b) a proportion of the change in property value (AU2007201104); and (c) the elapsed time and a later valuation (AU2007201087). Such "inventions" have been fairly standard throughout the financial services industry for many decades.

Alternatively a browse through the patent examiners' manual will quickly indicate that the grounds for grant of a patent in Australia is failure to prove it is not obvious rather than that it is "worthwhile" or that it represents " a significant advance over what was known".[9] But "obvious" in patent law has a particularly narrow meaning (Box 3). Patent law also falls into the trap of assuming that that which is not obvious (in narrow patent law terms) is sufficiently inventive to merit a monopoly grant. But inventiveness is a continuum, like

[8] Indeed this was the case (*Aktiebolaget Hässle v Alphapharm Pty Ltd* (2002) 212 CLR 411) that led Lawson to conclude that the quantum of inventiveness in Australia had been "lowered … to almost a per se rule so that the quality of obviousness will almost never be relevant in assessing patentability." (Lawson 2008, p. 44).

[9] Explanatory Memorandum to the Intellectual Property Laws Amendment (Raising the Bar) Bill 2011, p.42.

beauty. That which is not ugly is not necessarily beautiful. There is a large set of "inventions" which fall between "obvious" (in patent law) and "a significant advance over what is known." Patent law desperately needs reform to exclude these so-called inventions from being patented. Without statutory reform this will not happen.

Box 1: evergreen patents - venlafaxine/desvenlafaxine

The original patent for venlafaxine expired on 6 December 2008, after a 5-year term extension. It has a small (but highly effective) number of evergreen patents: two for methods of treatment, two for extended release (XR) versions and three for its major metabolite, desvenlafaxine. One of the XR patents is the "divisional grand-child" of the other. This "grandchild" patent (2003259586) held up generic entry to the venlafaxine market from February 2009 to November 2011 when it was declared invalid. In the meantime three patents had been granted for desvenlafaxine.* Desvenlafaxine has the same effect in human bodies as venlafaxine – indeed the European Medicines Agency concluded that it had little clinical value compared to venlafaxine and Pfizer withdrew its application for marketing approval in Europe. In Australia it has been so effectively marketed to GPs that its market share has reached 37%. While this drug has only a small number of evergreen patents, it has effectively been granted patent protection from December 1983 to August 2023 – a massive 39+ years.[10]

Because desvenlafaxine is listed on the PBS as an F1 drug, the cost to the taxpayer each time it is prescribed instead of venlafaxine is between $5.60 and $6.32. As at June 2012 over 250,000 scrips were written monthly for the two drugs. The additional impost on the taxpayer from desvenlafaxine is $0.57m ***each month***.

* The desvenlafaxine patents are 767835 for ethers of O-desmethylvenlafaxine, granted March 2004, now ceased; 2002357049 for methods for preparing O-desmethylvenlafaxine, granted October 2009, expires December 2022; and 2002250058 for a succinate salt of O-desmethylvenlafaxine, granted December 2007, expires August 2023 (5-year term extension granted).

The Commission might wish to review the statements it makes about the changes implemented in the "Raising the Bar" Act to ensure they are consistent with the legislative changes actually made. The Explanatory Memorandum is not a particularly useful guide as it includes such statements as:

> "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).

There is no evidence to substantiate this statement and considerable evidence to refute it.[11]

[10] For further details, and other examples, see my submission to IP Australia's pharmaceutical patents review (http://pharmapatentsreview.govspace.gov.au/files/2013/01/2013-01-26-Hazel-Moir-Moir-the-Promise-to-the-Public-Submission.pdf).

[11] The fact that some granted patents are genuinely inventive throws no light on the height of the inventive step. In the only systematic sample of patents where the quantum of inventiveness was measured in terms of new knowledge contributed, my own work shows that the height of the inventive step is very low (Moir 2013).

Box 2: business method patents granted by IP Australia

- Real estate website where icons on a map can be clicked to show the view from that point (AU2003250595);
- System for assessing organisational performance by storing a user-defined organisational structure, importing productivity data, and mapping this to the organisational structure using a configuration table (2003268607);
- System for providing lottery winnings to purchasers of the magazines (all the elements of the claim are identical to lottery ticket processes, except that the initiating purchase is a magazine not a lottery ticket) (AU2004203807);
- Computerisation of the steps involved in a major IT business systems upgrade (for example SAP implementation) (AU2003255356);
- Computerisation of standard methods for valuing buildings (AU 2005203023);
- Process for delivering goods to a container with an electronic lock (none of the claims are about the electronic lock operations) (AU2003262357);
- Wholesaling system where goods are reserved while credit is checked, then either returned to stock or shipped – the "inventive" feature is that shippers are used for credit checking (AU2003231594);
- Benchmarking the environmental sustainability of residential construction projects (AU2004200942);
- Pre-qualifying suppliers then using an automated auction process to choose the best value (AU2003204278);
- Combining the features of a store card and a credit card, including data migration and user initiation (AU2003262344);
- Linking two loan accounts with any third bank account and providing rewards for moving money between the loan accounts (AU2004201587);
- Computerised project management system to predict work end points (AU2003204420);
- Automating the process of applying for a patent through the Patent Cooperation Treaty system (AU2003244578);
- System for assessing organisational risks by listing key factors in business performance and assigning risk levels, threats and probabilities in order to calculate an aggregate risk-weighted score (AU2003200483) and
- Using audit techniques to monitor the use of chemicals in agricultural products (AU2004233489).

For further information see Moir 2013.

Box 3: "obvious" in patent law

While the general approach in law is that words should have their ordinary meanings, this is rarely the case in patent law. In the case that is credited with allowing the patenting of business methods in Australia, Justice Heerey drew attention to the dictum that evidence on obviousness "ought not to be received unless it is first demonstrated that the expert understands *the concept of obviousness as explained in the 1990 Act and the authorities*."[a] On these grounds he reduced the weight he gave to the defence experts: "Dr Brookes speaks of claim 1 of the Patent being "obvious or a 'routine next step'". Likewise Dr Clarke identifies as the question of whether the invention of the Patent was "obvious to, or a natural next step for, persons skilled in the relevant art in the light of the knowledge readily available at the time". However, neither witness expounded his understanding of this concept. Since the Full Court speaks of this deficiency as a matter of admissibility and no objection was taken I do not reject the evidence on this ground, but it affects weight."[b]

Section 7 of the *Patent Act 1990* states that an application for a patent "is to be taken to involve an inventive step when compared with the prior art base unless the invention would have been obvious to a person skilled in the relevant art in the light of the common general knowledge as it existed in the patent area before the priority date of the relevant claim, whether that knowledge is considered separately or together with the information mentioned in subsection(3)" (Article 7(2)). Subsection (3) specifies allowable knowledge – this subsection was amended in 2012.

In addition to the statute ***presuming inventiveness*** unless it can be disproved, case law adds several features, in particular that the skilled person must be "an ordinary worker in the field *not endowed with any special inventive skills*" (van Caenegem 2007: 84, emphasis added). In the US this limitation was overturned in 2007 when the Supreme Court determined that a "person of ordinary skill is also a person of ordinary creativity, not an automaton."[c]

The "invention" being discussed in *Welcome* was dynamic storage on a smart chip card. All parties to the dispute agreed that dynamic storage was well-known in the information technology field. However it was applied here in the business field of consumer loyalty schemes. In concluding that there was an inventive step Justice Heerey stated: "It took the respondents themselves twelve months to progress from their Wizard/Transcard to CiT/Transcard system. As is recounted above ([9] to [18]), the applicant's parent in its work with Carte Jeunes encountered obstacles and went down blind alleys. It is hard to ignore the comment that if what the inventors did was all that obvious, somebody else would have done it."[d] Others might conclude that they should have consulted IT experts earlier – the judgement seems to reward ignorance rather than inventiveness.

a *Welcome Real-Time SA v. Catuity Inc*, [2001] FCA 445 (17 May 2001) at 153 (emphasis added) citing *Aktiebolaget Hassle v Alphapharm Pty Ltd* (2000) AIPC 91-636 at 69.

b *Welcome* at 154.

c *KSR v. Teleflex* 127 S.Ct. 1727 (2007) p 723.

d *Welcome* at 158.

Inducement and restriction to technological inventions

The issue of limiting the patent system to inventions "which would not otherwise occur" (p.44) is challenging. The report is silent on this issue. The historical limitation of patentability to technology would, if combined with a high inventive step, do much to constrain patents to inventions which required some substantial investment and would therefore be more likely not to occur, absent patents. This issue goes substantially beyond the Commission's terms of reference, but the Commission might note that our courts have overturned the traditional limitation to technology. This radical change in policy – undertaken with no economic (or other) analysis of its impact – will be enshrined in statute law if ACIP's recommendations on patentable subject matter are implemented. This seems a step fraught with dangers for Australia's innovative firms.

Economists tend to assume that patents are only for technological inventions – indeed this view is encouraged by the language of the TRIPS Agreement that patents must be available for "any inventions … without discrimination as to … the field of technology" (TRIPS, Article 27 (1)). The objective of TRIPS is to "contribute to the promotion of technological innovation" (TRIPS, Article 7). At the time TRIPS was agreed the general view was that software was not a "field of technology" and TRIPS specifically requires that copyright cover computer programs.

But Australia's judges have removed any requirement for technology from Australia's patent system – though they have drawn the line at patenting "inventions" in their own field of law. Anything else goes – no technology base is required. In the *Grant* case, the Full Federal Court referred to an opinion of the Patent Office (in the *Szabo* case) that an "artificially created state of affairs" required some material application of science or technology. The Court said "[w]e are not sure that this is correct".[12] The Court also questioned the Deputy Commissioner's view that patentable inventions should lie within the area of science and technology.

The recent ACIP report on patentable subject matter recommends enshrining this judicial view in statute law. After rejecting the TRIPS focus on technology as dangerous, the report focuses on the interpretation of the watershed NRDC case that extends patentability to any "an artificially created state of affairs in the field of economic endeavour" (ACIP 2010, p.14). In other words if you can make a dollar out of it, it should be patentable. The report includes no economic analysis yet its recommendations have been accepted by government. Implementation of these recommendations would set in concrete a series of legal decisions – taken in the context of private disputes and with no assessment of their effect on the public good – which are highly questionable from an economic perspective.

The real test for "that would not otherwise occur" would be that the development costs are large and lumpy and that the initial period of market exclusivity will be too short to recoup these. A good proxy for this requirement is the combination of a requirement for technology with a high inventive step.

In the discussion of subject matter exclusions in Chapter 3 and in the Appendix the whole history of traditional exclusions in Australia is ignored. The Commission seems unaware that our courts have ignored reports and government responses to these in radically extending

[12] *Grant v Commissioner of Patents* [2006] FCAFC 120 (18 July 2006) at 38

patent scope. IPAC recommended not extending patentability to software, and there is evidence that this recommendation had bi-partisan support. Yet in extending patentability to software, the courts did not mention this report or the government response. Unfortunately those charged with administering the patent system did not respond with a statutory amendment. Similarly the Federal Court, on the dubious grounds of the Harradine amendment to the 1990 patent bill, took the view that parliament had decided to abandon all traditional exclusions from patentability, particularly the exclusion of methods of medical treatment. Drawing on the same body of legal precedent Lord Cooke concluded that such an major policy change was a matter for the New Zealand parliament, not for its courts (Frankel 2008). Patents are probably the greatest area of judge-made law, yet an understanding of this is nowhere evident in the report.

Patent "quality"

The discussion of so-called patent "quality" in the appendix (B.2) is better than that in the text (p.54). The text discussion suggests that the Park and Ginarte paper is worth citing in the context of patent quality, which it is not.

As van Pottelsberghe shows in a series of inter-linked papers (van Pottelsberghe 2010, 2011, forthcoming) the Park and Ginarte (1997) paper is about patent-friendliness not patent quality. Indeed the well-cited Park and Ginarte piece is best used as an example to poor input data and poor output analysis. But while van Pottelsberghe does come closer to looking at issues of patent "quality" most of his measures focus on the quality of patent **processing** – in relation to the standards set by patent offices – not quality in the sense of whether patents are granted for "worthwhile innovations that would not otherwise occur". Indeed the central issue in patent quality – how inventive must a granted patent be – is not amenable to quantitative analysis. This is one reason why it is such a neglected topic.[13]

Social benefits and local working

Another aspect of the overall patent system that the draft report does not consider is just how the public is recompensed for the grant of patent monopolies. A critical reason why patents were accepted as an albeit crude economic policy is the evidence that the social returns to innovation are substantially greater than the private returns. A major avenue for spillover benefits is through the flow of new knowledge to rival firms. This underlay the old requirement for "local working". If a patent was not locally worked there were no local channels for these knowledge spillovers and thus no benefits in granting the monopoly. The report dismisses the local working requirement as protectionism, following the IPCRC in this flawed understanding. But with 92% of standard patents owned by overseas-based entities there are real questions as to what benefits Australia now gets from her patent system. Beyond, that is, that patent monopolies are now a threshold entry requirement to GATT.

Patent utilisation

The analysis of patent data in Section 4.1 is by grant year. This simply reflects the allocation of administrative resources and consequently is **misleading** with respect to overall patenting trends (Griliches 1990). All grant data should be re-run by filing year. This will produce a reliable set of comparative statistics. Thus, for example, Figure 4.1 should be re-run showing

[13] Though there is a very interesting paper using the low USPTO standards to assess the quality of granted US software patents. See (Campbell-Kelly and Valduriez 2005). All 50 assessed "inventions" are found to be only incrementally inventive, yet they were selected as the 50 "best" patents in the software field.

applications by year of application and the number of each cohort of applications which have been granted. **The data as presented provide a misleading view of patent grant rates.**

In Section 4.5 a critical point about patent pools and cross-licensing it that this simply allows participants to proceed as though the patent system did not exist. This outcome lies very much in the realm where the emperor has no clothes. It also does nothing to encourage new entry – a critical factor in Schumpeterian dynamic innovation.

The esp@cenet database is not a clearing house. It is a simple database. Any search has a limit of 500 cases, and provides data only on applications. *To find out which applications have been granted requires looking up each case individually.* The European Patent Register allows search without the 500 case limit, but again requires checking each hit individually to find the current legal status of the application. *Basically innovating companies in Europe cannot easily find out what patents are in force in any particular technology field in the country in which they are operating.* Such was also the case in Australia until the recent introduction of AusPat. A remaining problem for Australian innovating companies who wish to avoid others' patents is that ceased patents can be revived on back payment of renewal fees.

As far as I am aware there are no patent clearing houses – at least none operating at a national level. There is one US company which regularly holds auctions to publicise the patents it has available for sale (Ocean Tomo).

Implications of the low standards and broad reach

In considering the issues of compulsory licensing and crown use the Commission needs to understand that the patent system in practice has almost no boundaries beyond legal inventions and the fine arts, and has an inventive step that is so low that a patent can (and has) been granted for teaching your children about finance by working for their pocket money (2003203582).

In the context of such an unbalanced system, careful consideration needs to be given to just what are the "abuses" that compulsory licensing and crown use are designed to ameliorate.

The first consideration is the nature of patent policy. It is an economic tool designed to induce a higher level of invention than would otherwise occur at a price that creates a net benefit for Australia. There have been decades of propaganda designed to change the popular understanding of such state-sanctioned monopolies.[14] These include changes in language – for example the overall organisation within which the Australian Patent office lies changed its name from the Australian Industrial Property Organisation to Intellectual Property Australia in the late 1990s/early 2000s. As google's ngram facility shows, this phrase came into existence in the late 1970s just as the major lobbying to include these monopolies in the "free" trade agenda was developing.[15] A very strong push has also taken place in renaming these "powerful exclusive rights" as property not privileges. A particularly nasty line of argument is that **all** free-riding should be suppressed (Lemley 2005) – that is that there should be no spillovers from new patented technology. Yet it is these spillovers

[14] "Patent protection" means protection from competition, ie grant of a monopoly. The privileges granted with a patent are referred to as "rights" then conflated with the kinds of ownership rights over physical property. Indeed including these state-granted monopolies within a system that is still referred to as a "free" trade system requires considerable mental agility.

[15] http://books.google.com/ngrams/graph and enter the phrase "intellectual property".

that are a major driving force for productivity growth and hence economic growth. The patent system is not designed to appropriate 100% of the return to the inventor – merely enough to induce the invention. Arguments against free-riding on innovation are quite different to those in respect of free-riding with respect to, say, public security.

The real abuse of the social contract underlying the patent system is the very low inventiveness standard and the removal of the limitation to technology. There is substantial evidence that the pharmaceutical industry has been gaming the system in Europe (European Commission 2009) and such behaviour is probably also occurring here. **Against this background the government should retain a strong right to use patented technology for the good of the Australia people with as few hurdles and limitations as possible.**

Proposed objectives for the patent system

The Commission finds (draft finding 6.2) that the planned introduction of an objectives statement into the *Patent Act 1990* "could assist in clarifying the context for compulsory licensing and the considerations that should guide a court" (p.21). The objectives statement proposed by ACIP is reflective of its membership – composed of beneficiaries of patent, trade mark and plant rights system but not representatives of those who pay the costs. It is a vague statement of "national interest" combined with the goal of mediating competing interests. It will do nothing to improve the quality of economic outcomes from legal decisions as it does not clearly state the economic goals, including cost considerations.

Certainly an objectives statement is desperately needed in the Patent Act but is needs careful consideration. It should be clear and specific about the goal of inducing technological innovation. It should also make it clear that patentable inventions must also deliver a benefit to the public. The simplest clear requirement of such a benefit is new knowledge ("a significant advance over what is known").[16] Courts need to understand clearly that granting patents for every trifling invention will impede innovation not promote it. Further the social contract with the public is not met if there is no net social benefit.[17]

The Patent Act and international treaties

International treaties have substantially weakened whatever "protections" lay in compulsory licensing. Certainly the Commission is right to question the overhang from the historical requirement for national working, and to re-focus this on a public interest test. Given the state of the patent system, this test needs to lean towards the public interest and not be overly concerned with the so-called rights of those who have been so leniently granted a monopoly.

Draft recommendation 6.3 I support draft recommendation 6.3 to repeal S.136. It is very poor practice in a democracy to import international agreements in this manner. Any new legal practices agreed in international agreements should be considered by parliament and specifically and clearly incorporated into Australian law.

[16] Current processing procedures do not consider what new knowledge is delivered. They simply look for difference then assess this against the narrow patent law definition of "obvious".

[17] In *Grant* (see footnote 12) the Full Federal Court took the view that it was not up to them to determine if an invention might lead to any benefit to the public. But if each individual patent provides no benefit – or indeed is simply not assessed for the likelihood of benefits – how can the overall system provide a net benefit?

Draft recommendation 6.2 The proposals in draft recommendation 6.2 lean heavily towards the interests of the patent holder. They are unlikely to produce many applications for such licenses.

There are two public interest issues underlying compulsory licensing. Is the product being marketed at all in Australia? And is it being marketed at a reasonable price?

There should be a fast-track compulsory license system if patented goods or services are simply not available. And in these circumstances a standard percentage of production costs (say 2%) would be an appropriate royalty. There should be an extremely short (if any) "tried for a reasonable period" requirement. And there should be a fast and efficient process to grant such licenses. If such administrative capacity does not exist it should be created (though resources would be better spent reforming the broken patent system).

If a product or service is available, but at an excessive price, a whole different set of considerations come into play. The patent system works by allowing patent-holders to charge high prices. But it has become a lottery. Once the patentee has achieved a return on their investment including a risk-adjusted profit margin, then consumer and competition considerations become more important. But if the patent-holder has not yet achieved such a return the policy sense in allowing a compulsory licensing is questionable. The demonstrated finances of the invention are therefore central to compulsory licensing considerations. But if a reasonable return has already been achieved, then there should also be an efficient and streamlined process to permit such licenses. In the pharmaceutical field so-called "dependent patents" are rife and should be encompassed within the terms of any compulsory license.

In practice, however, compulsory licensing is difficult to implement. It is clearly most likely to be needed in the health field. Yet it is precisely in this field that substantial trade sanctions are threatened when a State decides to place the health of its people ahead of foreign profits (see for example Krikorian 2008).

Crown Use

Crown use is a far more interesting issue. What is the point in a society providing a private monopoly to the detriment of other social and economic goals for its citizens? Such goals should naturally trump the narrower considerations of rewarding (mostly overseas) invention. For example if an important health treatment is overly expensive or if a major breakthrough in mitigating climate change is insufficiently used due to an excessive price, then serious consideration needs to be given to over-riding a granted monopoly. This can be done far more readily through the crown use provisions than the compulsory licensing provisions.

Draft recommendation 7.1 Given Australia's complex and idiosyncratic approach to service provision, particularly in the community services and health fields, the clarification that crown use extends wherever an Australian Government effectively pays for the service is helpful.

But just a few decades ago we lived in a far more mixed economy. Since then substantial services which are essential to daily living have been privatised. For example both cases cited in Box 7.1 are in industries that are now "private" in at least some States. The provisions for crown use need to be drafted to cover those industries such as communications, transport and utilities which are vital to the effective operation of society and consequently are heavily regulated in the public interest.

Draft recommendation 7.2 As drafted this recommendation overly constrains our sovereign governments when they need to balance the public interest against narrow corporate interests. It is clear that governments these days are extremely sensitive to criticisms from corporations. There need be no fear that they will lightly invoke crown use provisions. Indeed there would instantly be heavy-handed representations from major global corporations and likely also from the USTR. Indeed, as in the case of plain packaging of cigarettes, challenges in the WTO could be expected. There is therefore no need to make crown use other than easy and straightforward. Crown use is likely **only** in emergencies. And any remuneration should be determined (ex post) on the basis of audited financial data on returns to the investment. As drafted this recommendation does not adequately protect the public interest – it leans over backwards to protect the interests of those who have sought and gained a monopoly.

Some minor points

Technological neutrality One of the worst features to emerge from international bargaining about patent systems is so-called "technological neutrality", raised on p.171 of the draft report. Such bargaining has never yet been based on sound economic analysis. And as the Commission would well know from its substantial earlier studies on specific product lines, the characteristics of different industries and technologies vary substantially. Technological neutrality first entered patent law in the bargaining surrounding the European Patent Convention, giving rise to compulsion to provide patents for chemical compositions (and as one consequence ruining Italy's flourishing generics pharmaceuticals industry, see Scherer and Weisburst 1995). Careful consideration and historical evidence suggests that the type of patent system which best promotes innovation in chemicals and pharmaceuticals is one where patent monopolies are available for processes not products (Dutfield 2003). In other technologies product patents are more important. The only advantage of so-called technological neutrality is that reduces costs for those seeking grant of patent monopolies across different technology fields.

The lack of legal parallels On p 142 the draft report raises the lack of legal parallels as a problem. The number of systems for state-granted monopolies has been expanding (over recent decades to printed circuits, plant breeding and data exclusivity) but is so far still countable. One would expect few legal parallels to its more minor features. But this is not a sound argument for not considering an option on its merits.

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