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Ms Naomi Bleeser
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Dear Ms Bleeser

Inquiry into Gene Patents: comments on Senator Heffernan's submission

Thank you for your email of 7 April referring me to Senator Heffernan's submission to this committee. You advised that he "disputes the evidence of some submissions and witnesses to the inquiry" as well as making recommendations. You offered me the opportunity to consider this submission, and asked that I respond to this 73 page submission by Friday 30 April. Thank you also for the extension to Sunday 2 May.

My response focuses in two areas: (i) whether evidence presented to the committee is reliable; and (ii) the recommendations.

Reliability of evidence provided to the Committee

It is an unfortunate fact that most of what is written about the benefits of the patent system is opinion and is not based on any empirical evidence. This is despite the fact that since 1980 a substantial body of empirical evidence has been produced showing that the alleged basis for patent policy (to provide an incentive for invention) is problematic. This view is supported by leading US scholars of industrial innovation such as Professors Richard Nelson and F M Scherer. Both these highly regarded scholars have expressed concern that despite the mounting evidence that patents are not generally important as an incentive to industrial innovation, patent policy has been extending its reach. I cited this research in my submission to the Committee, and for summaries by these experts refer you to two articles included in the references to that submission (Mazzoleni, R. and R.R. Nelson, (1998), 'The Benefits and Costs of Strong Patent Protection: A Contribution to the Current Debate', *Research Policy*, 27, 273-284; and Scherer, F.M., (2006), *The Political Economy of Patent Policy Reform in the United States*, Washington, D.C.: AEI-Brookings Joint Center for Regulatory Studies Working Paper 06-22).

Given the lack of any evidence base for most of the opinions expressed about the patent system, it does not surprise me that Senator Heffernan has disputed the evidence of some submissions and witnesses to the inquiry. Indeed it would be surprising if intelligent interrogation of the opinions expressed to the Committee did not question at least some of the

"evidence". Use of the term "evidence" for *opinions* can unfortunately lead to the erroneous impression that such opinions are based on genuine empirical evidence. In determining its findings and recommendations it is important that the opinions expressed to the Committee be sifted to search for those that are based on substantial and objective evidence and those that are mere opinion or the views of those who benefit financially from the grant of gene patents.

As an example of the lack of any substantive evidence to support opinions as to the benefits or harm caused by the patent system in general or gene patents in particular, in the preliminary briefing of the Committee (Canberra, 19 March 2009), Senator Heffernan asked the Deputy Director-General of IP Australia "What data can you present to the committee that the benefits of allowing patent monopolies on human and microbial genes and non-coding sequences, proteins and their derivatives, including those materials in an isolated form, outweigh the costs?" (CA13) Mrs Beattie replied "—I do not have that information. I am not aware of any study that has done that sort of evaluation." (CA13) Later in her evidence she added "But in terms of harm, I am not aware of any studies that have been done to reflect it." (CA14)

Senator Heffernan then asked "Have any studies been done to show there is a benefit?" Mrs Beattie responded in generalities, citing no empirical evidence. The "benefits" she cited were disclosure of information that would otherwise be kept secret, facilitating international research collaboration and facilitating access to overseas technology. Calling publication of patent specifications a benefit is to ignore the evidence of the 1984 IPAC review of the Australian patent system, which found that there was negligible use of patent data by leading-edge researchers. It also ignores the advice provided by Professor Fritz Machlup in his 1958 report to the US Senate enquiry into the patent system. Professor Machlup referred to strong evidence that only those inventions which could not be kept secret would be patented, so the alleged benefit of disseminating information simply does not exist.[1] The other two "benefits" were investigated by the 1984 IPAC Review, whose overall conclusion was that the benefit of the then patent system (then much narrower in scope, with a higher inventive step and excluding software and gene patents) was likely negative.[2]

In reviewing Senator Heffernan's submission to the committee, the "evidence" which he might be considered to "dispute" falls into this realm of unsubstantiated opinion. The *possible* areas of disputed opinion, as far as I can determine, are:

1. Mr Slattery's opinion that GTL's letter of 7 July 2008 was a "warning shot" aimed at opening negotiations (Mr Slattery is a patent attorney and former partner of Davies Collison Cave) rather than being a pre-emptive move (pp19-22);
2. Advice from the NH&MRC that it was not aware of any specific examples where patenting practices have had a negative impact on research in Australia (p28);
3. IPAustralia's view that the current patent system is functioning effectively in achieving its objectives of encouraging innovation…" (p.28);
4. Unspecified views that the Crown Use provisions are functioning as an adequate safeguard; (p.29);
5. Unspecified views that the compulsory licensing provisions are operating as an adequate safeguard (p.29);
6. Unspecified views that an express research exemption will address any concerns about the impact of granting patents on genes per se (p.29);

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[1] Machlup, F., (1958), *An Economic Review of the Patent System*, Washington, D.C.: US Government Printing Office, Study No. 15 of the U.S. Senate Subcommittee on Patents, Trademarks and Copyrights.

[2] IPAC, (1984), *Patents, Innovation and Competition in Australia*, Canberra: Industrial Property Advisory Committee (now available at http://www.acip.gov.au/library/).

7. Views from a number of interests that the "isolation" of the information in a gene or the "purification" of a protein constitutes an invention not a discovery (p.36);
8. Dr Kwang Lin's views that gene technology is "too new" for there to be a reliable policy assessment on appropriate patent policy (42);
9. Views expressed by Mr Richard Harmer (partner in Allens Arthur Robinson and a patent attorney) that there is no future problem and that isolated biological material is different chemically when it is separated from other elements (pp42-42);
10. Views from Professor Weisbrot (ALRC) that the issue of gene patents is "yesterday's battle" (p.43);
11. Views from the ALRC; Department of Innovation, Industry, Science and Research; IP Australia; Medicines Australia; Davies Collison Cave; the Institute of Patent and Trade Mark Attorneys of Australia; Pfizer Australia; Intellectual Property Committee of the Business Law Section of the Law Council of Australia; the Chartered Institute of Patent Attorney's and AusBiotech that amending the Patent Act to restrict or prohibit the patenting of biological materials would breach TRIPS or AUSFTA agreements (p.53); and
12. Views (unspecified) that the Australian court system provides an adequate system of checks and balances in patent policy (p.70)

In relation items 2, 3, 6 and 8 above there is unfortunately no systematic effort, whether by IP Australia, the Australian Bureau of Statistics, the Department of Innovation, Industry, Science and Research or any academic to collect evidence on the positive and negative impacts of the patent system. This is despite the 1984 IPAC Review recommendation to at least collect information on patent use at the time of patent renewal. Although patent monopolies are granted by the Commonwealth government, there is no requirement to inform the Commonwealth government when these monopolies are used to restrain the activities of any researcher or any innovating firm. It is therefore entirely possible that the NH&MRC may be in ignorance of the negative impact of these monopolies (item 2 above). But for the same reasons it is hard to see what basis IP Australia has for concluding that the current patent system is effectively promoting innovation (item 3 above) – there are no data collected on innovation which is suppressed by patent monopolies, nor whether the patent system is a critical factor encouraging innovation in Australian-based firms. Dr Lin is correct in saying there are no data addressing the gross and net impacts of gene patents on innovation (item 8 above), but there are data on the relationship between industrial innovation and the patent system which raise serious questions as to the need for patent monopolies. Given this lack of systematic data, it seems surprising that the view could be put that clarifying the research exemption will solve any problem (item 6). This view is especially surprising in view of the letter by GTL which indicated a direct effect of gene monopolies on the price of health-care for those facing a life-threatening condition.

In relation to items 4, 5 and 6 the view that Crown Use and compulsory licensing provisions are effective safeguards against abuse of patent monopolies is surprising given the rarity of their use. In one of the rare uses of compulsory licensing (in Thailand in 2006 for HIV/AIDS drugs) significant international pressure was brought to bear by patent owners to try and prevent this action.[3] In regard to the opinion that the current court system provides an adequate check and balance (item 12), this seems to run directly counter to the available evidence. This includes the courts' misinterpretation of Senator Harradine's amendment to the *Patents Act 1990* to read into this the intent of parliament to abandon all traditional exclusions

[3] See Gaëlle Krikorian, "The politics of patents: conditions of implementation of public health policy in Thailand", pp 29-55 in Sebastian Haunss and Kenneth C. Shadlen, Politics of Intellectual property: Contestation over the Ownership, Use and Control of Knowledge and Information, Cheltenham: Edward Elgar, 2009.

from the patent system. Courts also seem not to understand that they are required under the *Patents Act* to determine the validity of grants in relation to Section 6 of the Statute of Monopolies and have recently argued that it is not their role to determine whether a specific patented "invention" is likely to bring a benefit as parliament has already determined this through the existence of the *Patents Act* (see page 8 below).

Items 1, 7, 9 and 10 above are all opinions. It may well be that a patent lawyer reads a letter asking for a response the next day and advising that papers have been prepared to commence court action as an opening position in a negotiation (item 1). To anyone else it sounds like advice of immediate legal action, and in this case a substantial threat. The view that the isolation of a gene is an invention not a discovery is at the heart of the matter being considered by this Committee and there are strong views from both sides. In assessing this view it must be remembered that patent policy is an area where semantics, not substance, is playing a very large role. I have previously drawn the Committee's attention to the actions of the European patent offices and patent attorney profession allowing semantic redrafting to undermine the legislative exclusion of patents for methods of medical treatment (so-called "Swiss medical claims"). Certainly there are circumstances where it is difficult to distinguish between a discovery and an invention, but in regard to chemical and biological materials it is simple to ask whether the claimed invention differs in any way from what is found in nature.

The IPCRC enquiry in 2000 (under the Competition Principles Agreement) noted the scientific and economic importance of not granting patent monopolies for discoveries. This is a central issue in relation to gene patents. Some have argued that the issue of patents on genes, gene fragments and related proteins is "yesterday's problem" (items 9 and 10 above). Medical evidence suggests a continuing emphasis on new genetic technologies and the importance of investigating multiple genetic elements in assessing a health issue. This suggests that whether monopolies on genes and genetic material *per se* can be granted will have a major impact on health treatment in the future and on the cost of that treatment. There has as yet been no legal case on the issue in Australia and it cannot be assumed that those patents that have been granted are valid. Indeed there is substantial legal opinion that they are not. For example a recent US federal court decision (*Association for Molecular Pathology and Others v United States Patent and Trademark Office and Others*, handed down 29 March 2010) determined that the isolated BRCA 1 and 2 human genes linked to breast and ovarian cancer were "unpatentable subject matter" under US patent law "because the claimed isolated DNA is not markedly different from native DNA as it exists in nature" (at p.135). Gene patenting is also not "yesterday's problem" for another reason: while the issue today may be genes, we do not know what the future areas of technology breakthrough will be. But for those as yet unknown areas, the principle of not patenting basic materials is equally important both for scientific research and for sound economic policy.

A number of organisations, particularly those benefiting from or administering the patent system, express the view that denying patents to genetic materials would breach TRIPS and the AUSFTA (item 11 above). This would seem to be an opinion based on a view that such materials can be defined as "inventions". There is nothing in TRIPS nor the AUSFTA that requires patenting discoveries – though the AUSFTA does require the grant of monopolies for new uses of known materials provide these meet the other criteria for patentability.

Senator Heffernan's recommendations

Curing the many ills of the patent system, whether in general or in regard to gene patents alone, requires a multi-faceted approach. This is because of the gaming behaviour of those who benefit so substantially from the current system at the cost of Australian innovating firms and Australian consumers. When considering reforms to address the problem of granting

patents on genes, gene fragments and proteins those consumers who fund the profits of (largely overseas) corporations are also those facing major health difficulties. Senator Heffernan's recommendations seem to me to be very well considered and to recognise that apparently simple solutions will not work in the face of intransigent behaviour from the system's intermediaries. I offer comments on each recommendation below and conclude with an overall comment on the recommendations as a set.

Proposed Recommendations

1.1 Amend the *Patents Act, 1990* so that a condition to the grant of a patent monopoly be the public disclosure of information sufficient to enable, without undue experimentation:

(a) the replication of the invention to the same or higher standard as its closest commercially available equivalent at the time of grant, and,

(b) to the extent that the scope of the monopoly covers more than one embodiment of the invention, the disclosure in (a) include each and every embodiment.

1.2 Amend the *Patents Act, 1990* so that a condition of the patent registration renewal be the public disclosure of information sufficient to enable, without undue experimentation:

(a) the replication of the invention to the same or higher standard as its closest commercially available equivalent at the time of renewal, and,

(b) to the extent that the scope of the monopoly covers more than one embodiment of the invention, the disclosure in (a) include each and every embodiment.

I support recommendations 1.1 and 1.2. I note that these complement recommendations in the *venturousaustralia* report on Australia's National Innovation System that patent claims be clear. These recommendations, that there must be adequate disclosure for a patent to be valid, are an essential part of ensuring balance in the patent system. IP Australia, in its evidence to the Committee, advised that disclosure is a major benefit of the patent system. But it is clear that the current system is more about non-disclosure than about disclosure. There is a large literature on this issue: currently the vast majority of patent specifications do not provide sufficient disclosure of technical information to allow replication. Many even hide the cental aspect of the "invention". Requiring such disclosure as a condition of a grant being valid is a minimal response to restoring balance in the patent system and ensuring that the "invention" granted a monopoly is fully disseminated. The US system, requiring disclosure of a "best method" would certainly be worth adopting in Australia.

1.3 Devise and implement a set of coherent and national policies to facilitate the exercise of Crown Use powers by Commonwealth and State agencies;

1.4 Devise and implement a set of coherent and national policies to facilitate compulsory licensing so that it will encourage the working of the invention in Australia;

I support recommendations 1.3 and 1.4. I note that Crown Use and compulsory licensing provisions are often referred to as providing an appropriate check on patent monopoly excesses. I also note that these provisions have almost never been used, indicating how ineffective they are in their current form. The Committee may also wish to note that use of either provision is very strongly resisted by major patenting companies, backed up by their governments. An example of this is the fuss in Thailand when, in 2006 and after a long period of internal debate about access to reasonably priced HIV/AIDS medicines, the government moved to issue three compulsory licenses. In her in-depth analysis of the conditions for and responses to this action, Krikorian details the various parties which participated in the domestic debate.[4] These included the European Commission and the US government.

1.5 Devise and implement an administrative licensing system to facilitate and regulate the conduct of experiments which will be exempt from patent infringement.

I support this recommendation.

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[4] See Krikorian, 2009, op.cit.

In my response to IP Australia's IP Rights Reform paper on this issue (*Exemptions to Patent Infringement*) I expressed concern about IP Australia's proposed inclusion of the word "solely" in the proposed legislative amendment. As I said in May 2009 I thought this would completely undermine the objective of establishing a clear and strong research exemption. It is essential that the exclusion to the patent monopoly cover *all forms of research* whether these are carried out in the public domain or by profit-making companies. As is well known, new knowledge is cumulative. We need an environment where new knowledge can freely cumulate so that it can be used in the development of new artefacts embodying the new knowledge. The patent system was never designed to monopolise knowledge, only specific artefacts embodying that knowledge.

In their research exemption proposal IP Australia proposed a wide interpretation of the research exemption by listing a range of research purposes, including the purpose of meeting regulatory requirements. At the time I strongly recommended that a catch-all also be included along the lines of "or any other research purpose". Our imaginations tend to be limited to what we can conceive of today. But the directions and uses of future research may move in ways that would surprise us. The research exemption must be so broadly worded that researchers and research organisations cannot be in any way limited in their research work by the patent monopoly system. Indeed it may be preferable to make this an exemption which covers *any non-commercial use* in Australia.

Whatever research exemption is adopted must be as strong as possible. Otherwise the immediate goal of the patent system – to encourage more innovation – is undermined.

1.6 Amend the *Patents Act, 1990* so that an injunction cannot be granted if the effect is to restrict access to an essential service or product.

I support this recommendation, though I would like to see it go further. In my view there is not a strong case for considering injunctions in cases of patent infringement, given the objective of patent policy to increase the level of innovation. Alternative remedies can be found that do not so disadvantage the public. I am unaware of any evidence of a demonstrated case for granting injunctions as a remedy for infringement even for non-essential goods or services.

Issuing injunctions as a penalty for patent monopoly infringement was, in the USA, rarely used before 1982.[5] I have not studied injunctions in any depth, but was shocked last year to read our Federal Court's judgement in *Sigma Pharmaceuticals (Australia) Pty Ltd v Wyeth* ([2009] FCA 595). In a 3 June 2009 judgement Sundberg J issued an injunction to prevent Sigma supplying a generic modified release formulation of venlafaxine hydrochloride (the leading antidepressant in our market). This was despite his findings: (i) that "Sigma has satisfied me that there is a prima facie case that the invention would have been obvious to a person skilled in the relevant art" (i.e. Wyeth's patent is invalid for want of sufficient inventiveness) (para 27); and (ii) that Sigma had made a prima facie case that the patented "invention" is not a "new manner of manufacture" (i.e. that it is unpatentable) (para 34). In other words the judge effectively found a prima facie case that, on two grounds, the Wyeth patent was invalid. Nonetheless he went on to issue an injunction preventing Sigma from marketing a generic version of a product that currently has no generic competitor and thus creates significant additional costs to Australians suffering from depression. The current market size for non-healthcare card holders in over $50 million a year.

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[5] Jaffe, A.B. and J. Lerner, 2004, *Innovation and its Discontents: How Our Broken Patents System is Endangering Innovation and Progress, and What to Do About It*, Princeton: Princeton University Press: 112.

In presenting the key facts influencing this judgement there was no mention of the impact of the injunction on the costs of pharmaceuticals for Australians suffering from depression. This contrasts with the situation in the USA where the Supreme Court, in *EBay Inv et al v Mercexhange LLC* (handed down on 15 May 2006) spelled out a 4-point test for issuing injunctions in cases of patent infringement. The fourth of these is "that the public interest would not be disserved by a permanent injunction". While the injunction in the Sigma case is temporary – pending resolution of the invalidity/infringement case – the requirement that the public interest be considered in considering injunctions for patent infringement is a sound policy principle.

2.1 Amend the *Patents Act, 1990* to overrule *Rescare* and *Bristol Myers* in so far as the issue of patentable subject matter is concerned;

I support this recommendation. In my original submission to the Committee, and in response to Senator Heffernan's question on notice of 20 August 2009, I criticised the Australian legal decisions overturning the long-standing exception that methods of medical treatment are not patentable. The rationale for our courts over-turning this long-standing exception is unpersuasive – that parliament intended them to do so when it accepted Senator Harradine's motion to amend the *Patents Bill 1990* by adding Section 18(2). There is no such evidence in Hansard and such an interpretation of Senate negotiations where the government does not have a Senate majority is to seriously misunderstand parliamentary procedure and intent.

I draw the Committee's attention to the far more robust judgement of Lord Cooke on the same matter in New Zealand. New Zealand of course draws on the same body of law as Australia. In *Wellcome v Commissioner of Patents* ([1983] NZLR 385 (CA)) Cooke J concluded that changes to exclusions from patentability are a matter for parliament to determine, not courts. He specifically disagreed that parliament had left such matters open to the courts. One of his reasons for drawing this conclusion was that parliament had available to it a breadth of evidence on economic and social impacts that was not available in a legal case about patent validity. Another was "a deep-seated sense that the art of the physician or the surgeon in alleviating human suffering does not belong in the area of economic endeavour or trade and commerce" (ibid, 388).[6]

2.2 Amend the *Patents Act, 1990* to include a set of economic and social objectives;

I support this recommendation. I have made similar recommendations in my submission to the ACIP enquiry into patentable subject matter. At present judges have no clear guidance as to the purpose of patent law, so it is not surprising that they seem to make many decisions within this field that appear to reduce Australia's well-being. The stated objectives need to cover both the overall objective of achieving a higher level of innovative investment and the strategic objective that this should be done in a way that makes Australia preferably better off but certainly not worse off.

Unless each granted patent is likely to contribute a social benefit equal to or greater than the social cost of restrictions on use, then it is probable that the overall system will operate to the disadvantage of Australia. While perfect foresight is not possible, there should be at least some attention paid to the likelihood of the invention creating a benefit to Australia as suggested by Branson J:

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[6] For a useful discussion of the New Zealand approach to patenting methods of medical treatment see Susy Frankel, 2008, "Lord Cooke and Patents: The Scope of 'Invention'", *Victorian University of Wellington Law Review*, 39, pp. 73-98.

> "The principle which has been developed for the application of s 6 of the Statute of Monopolies that seems to me to be critical in this case is the principle 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. This principle is derived from the theoretical justification for the grant of a patent; that is, the assumed value of inventive ingenuity to the economy of the country." (*Grant v Commissioner of Patents* [2005] FCA 1100, 13, 20).

Unfortunately Justices Heerey, Kiefel and Bennett (on appeal) held that:

> "It is not relevant, in our view, that some may think that a method or product will not advance the public interest. Once a product or process has been patented, its use is subject to the laws of the land, such as (to take but a few examples) those concerned with environmental protection, pharmaceutical product approval and occupational health and safety. "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*." (*Grant v Commissioner of Patents* [2006] FCAFC 120, 44-45 (emphasis added))

This latter view seems to call for urgent advice from parliament to the judicial system about the purpose of the patent system. The purpose is indeed to deliver a social benefit to the country and it is the role of the courts, in each individual case, to determine that this criterion is met before a patent is held to be valid.

2.3 Amend the *Patents Act, 1990* so that the patentability thresholds are consistent those economic and social objectives;

I support this recommendation. In order to achieve a test that ensures a reasonable chance that each granted monopoly will deliver a benefit greater than the costs it imposes there will need to be a substantial change to the inventive step. It may be necessary to develop a completely new test. The details of "novelty" and "inventiveness" written into current legislation have been so undermined over time that they may not be capable of rescue. In the early days of patent law courts started from the clear principles set out in Section 6 of the Statute of Monopolies. It may be necessary to set out such principles to provide clear guidance to courts.

It would also be useful to require examiners to specify the basis on which they consider an application should be approved. This occurs to some extent in other jurisdictions, and provides very useful information on how the rules are being applied. For example, at the United States Patent and Trademarks Office (USPTO), where an application is initially rejected and is subsequently granted, the examiners specify the reasons why the grant is then made. This correspondence is in the public domain,

2.4 Amend the *Patents Act, 1990* to expressly prohibit the patenting of:
(a) biological materials that exist in nature, including their derivatives, however derived, and whether isolated or purified or not, and
(b) diagnostic, therapeutic and surgical methods for the treatment of humans or animals;

I support this recommendation. As noted above and in my submission to the Committee I consider that the court decisions to extend the reach of patent law by abandoning traditional exclusions as a matter that parliament should have addressed and corrected more than a decade ago. While I support recommendation 2.4 I am fearful that it will encourage courts to believe that the extension of patents to software, mathematical algorithms and business methods are sound decisions. IPAC recommended unanimously against any such extensions and the lack of any comment to the contrary in the parliamentary debate on the *Patents Bill 1989* and the *Patents Bill 1990* suggests this had bi-partisan support. In support of this view is the action by the then government in 1984 to amend the *Copyright Act 1968* to extend its

reach to software. Similarly in adopting the WTO Treaties in 1994, parliament concurred with the provision that appropriate "protection" for software was through the copyright not the patent system (Article 10 of TRIPS). While this is beyond the reach of the Committee's terms of reference, I would recommend that the committee note this likely problem and recommend that all the traditional exclusions be re-instated unless there is clear and substantial evidence that their removal would create a net economic benefit to Australia.

2.5 Require the Productivity Commission to monitor the impact on the Australian economy of the express prohibitions and present a report to the Australian government within 3 years of their taking effect.

I support this recommendation, but would like to see such reports presented to the parliament every 3 years. These reports should also cover the principle underlying Clause 5(1) of the Competition Principles Agreement – that the benefits of the system should outweigh the costs. I note that the Productivity Commission will be very challenged in making such a report prior to implementation of recommendation 3.4 and/or the inclusion of more targeted questions in the ABS National Innovation Survey.

2.6 Amend the *Patents Act, 1990* to insert general anti-avoidance provisions that give effect to a policy to strike down patents claims which are a blatant, artificial or contrived attempt to undermine the economic and social objectives set out in the legislation;

I strongly support this recommendation. This recommendation is critical to the effectiveness of all other recommendations. I have made similar recommendations in my submission to the ACIP enquiry into patentable subject matter. In my response to Senator Heffernan's question on notice on August 2009 I drew attention to the attitude of the patent attorney community that any exclusion in law was merely a challenge in coming up with a form of words to undermine the parliament's intent in drafting that exclusion. Senator Heffernan has also drawn attention to the impact of this behaviour on an important policy goal in UK patent law – the exclusion of chemical compositions from the patent system. This exclusion was abandoned only because it was undermined by semantics. Now, however, major reforms in tax legislation have shown how anti-avoidance provisions can be applied.[7] It is time parliament stopped gaming of the patent monopoly system.

2.7 Amend the *Patents Act, 1990* so that patent claims define products, processes or methods that are (a) inventions within the full meaning of the Act, (b) novel, (c) contain an inventive step and (d) commercially practical and useful across the full breadth of the scope of the monopoly and not requiring undue experimentation based on the information disclosed in the patent specification;

I support this recommendation. I note there is overlap with the *venturousaustralia* (report on Australia's National Innovation System) recommendation that patent claims be clear.

2.8 Immediately have IP Australia establish a free and publicly accessible, user friendly and searchable database that will enable anyone to determine the effective legal boundaries of all patented technology in Australia and provide useful and meaningful statistics that will aid in the maintenance and development of economic and social policy in Australia.

I support this recommendation.

I have found IP Australia to be very helpful in providing available data in excel format to assist my work as a researcher. But their databases are not set up to meet the needs of other than examiners and patent attorneys. They exclude much material relevant to policy analysis. IP Australia did take a major step forward with its *AusPat* database, released in April 2008, which allows one to ask for all current patent monopolies in a technology field (such a search – for currently operating patent monopolies in a specific technology field – is still not possible in the United Kingdom or at the European Patent Office (EPO)). In Australia there is no

[7] Braithwaite, J., 2005, *Markets in Vice, Markets in Virtue*, Sydney: The Federation Press.

requirement for examiners to publicly justify grant, nor is correspondence between applicant and examiner made available to the public as it is at the USPTO and the EPO. Such information is of great use in determining how the eligibility rules are being applied. While IP Australia does grant free access to files for research purposes, the processes for access are very cumbersome due to the poor underlying systems for their virtual files.

I have been trying to address the issue of the net benefit to Australia of the patent system for the past 6 years. This question can only be addressed indirectly because of the lack of concrete data on the operation of the patent system. It is not helpful that the National Innovation Survey asks few useful questions on patenting behaviour from innovating companies. Nor is it helpful that IP Australia has no information on how the many monopolies it grants are used. In 1984 IPAC recommended that patent holders provide information on how they are using their patents at the time of renewal. This recommendation is long overdue for implementation. It would also be entirely reasonable for the government to require advice of use of a patent, prior to its use, as it is the government which has granted the monopoly. It seems irresponsible to hand out so many monopolies without having any knowledge of the impact of their use.

Given the initiatives the Australian Bureau of Statistics has made in linking its economic databases through the use of ABNs, it would be of great value to link in patent data in the same way. This would allow researchers to link behaviour in patenting with data on economic size and innovative activity, for example. It would be entirely reasonable to require companies registered in Australia to provide their ABN as part of their patent application. For overseas based companies with no legal presence in Australia, unique identifiers should also be provided. This might take further thought and require liaison with overseas patent offices so that the same companies could be tracked through all the major patent offices. Perhaps overseas equivalents of ABNs could be used together with the country identifier.

3.1 Immediately commission a broad and multidisciplinary Inquiry into the workings of the Australian patent system;

I support this recommendation. This commission should be adequately resourced to collect data (as was the IPAC enquiry in 1984). Otherwise it will simply have to spell out the critical and important gaps in knowledge that need filling in, rather than being able to reach conclusions on how the system operates and how it might best be improved.

3.2 Immediately transfer to the Treasurer of Australia all responsibility for the administration and regulation of the Australian patent system;

I support this recommendation. The *venturousaustralia* report on Australia's National Innovation System also suggested that it was time the patent system became the leading edge of micro-economic reform in Australia and suggested a portfolio move. Without transfer to a portfolio that has a deep understanding of the role of effective competition in creating and maintaining a healthy competitive economy, the patent system will continue to be managed by vested interests and to the detriment of Australia.

3.3 Abolish ACIP forthwith and replace it with an independent, multidisciplinary and well-funded intellectual property regulator which will have the power to (a) audit IP Australia, patent attorneys and patent lawyers to ensure their compliance with Australia's patent law (b) investigate abuses of the Australian patent system (c) instigate civil and criminal proceedings in Australian courts against those that are alleged, on reasonable grounds and after a thorough investigation, to have abused the Australian patent system (d) oversee the regulation and discipline of patent attorneys, patent lawyers and patent bureaucrats and (e) provide regular advice and reports to the Australian government on the workings of the Australian patent system.

I support this recommendation. Advisory bodies composed almost entirely of beneficiaries of the system on which they advise bring democratic institutions into disrepute. Professor Drahos' suggestions to establish an independent auditor of the patent system offers hope that

the essence of the patent system can be retrieved from the current abuses. Unless penalties are introduced to prevent gaming of the system, and to recover monies made wrongfully from the system, it will be very difficult to re-institute an effective patent system delivering on its goals of encouraging innovation in the most cost-effective manner. As noted earlier, courts in Australia have tended to made decisions on patent law which undermine the public good objectives of the legislation. It would be useful for parliament to receive regular reports on key legal cases, including assessment of their economic and social costs and benefits.

3.4 Immediately have IP Australia establish a patent transparency register that will:
(a) track and publish the patent portfolios of patent owners, especially those with large patent holdings; and
(b) develop databases in co-operation with user groups or other interested government agencies so that the degree of concentration of ownership of crucial technologies associated with that portfolio, and information about the licensing and assignment of those technologies are easily and publicly available.

I strongly support this recommendation. I undertook some research in early 2008 trying to identify the main beneficiaries of the Australian patent system and, given the available data, this was extraordinarily labour intensive, despite IP Australia's assistance in providing data in excel form. The concentration of patent ownership among a remarkably small number of companies is well known. But there are no good data to support more quantitative work in this area, to isolate technology areas where there is almost no global competition, or to track changes over time.

Overall comment

Thank you for giving me the opportunity to comment on this submission. The recommendations are impressive and hang together as a well thought out set of recommendations to prevent the problems which the wholesale grant of patents on genetic material have given rise to. The recommendations appear on the surface to go further than the terms of reference. However narrower recommendations would be ineffective, giving the gaming behaviour that is rife in the patent system. In my view this set of recommendations should deal effectively with the problems that the grant of monopolies on genetic material have raised and can raise. If implemented, they would substantially benefit Australia.

I do trust that the final Committee report is of the same calibre. The ALRC report in this area remains a great disappointment. It hardly addressed the issue it was established to assess and seemed to consider that the views presented in submissions to it constituted objective "evidence" that could be drawn on in reaching its conclusions. The ALRC's conclusion that the problem had passed and that the issue of granting patents for discoveries need not be addressed let the community down. As we have seen the problem did not go away. The issue of the grant of monopolies for discoveries remains a central challenge to effective innovation policy now and into the future. It will certainly affect almost every future new technology.

As I have previously advised the committee, the views I present are my own and should not be taken to represent the views of any institution or organisation with which I may be associated.

If you require any further information please contact me on 02 6251 4951 or at hazel.moir@anu.edu.au.

Yours sincerely

Hazel V J Moir
2 May 2010