

**Senate Community Affairs Committee inquiry into Gene Patents
Thursday, 20 August 2009**

Question on Notice

Senator HEFFERNAN—Should we, to give further clarification, also consider a further amendment to the act along the lines of: ‘For the purposes of this act an invention that includes or makes use of a biological material as a component will be taken to involve an inventive step when compared with the prior art base unless the incorporation and use of that biological material, regardless of whether it was known or unknown in the manner claimed in 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 anywhere in the world before the priority date of the relevant claim, whether that knowledge is considered separately or together with the information mentioned in subsection 3’? That is a pretty big mouthful and I will table it for the committee. That is too big a mouthful to think about today, but we will table it and give consideration to it.

CHAIR—Are you asking for that to be taken on notice?

Dr Moir—I would appreciate it if I could. It is very detailed.

CHAIR—Are you able and willing to do that?

Dr Moir—I am willing to take a look at it and provide a view, yes.

Response to Senator Heffernan’s question

This is a complex amendment directed to raising the height of the inventive step in respect of inventions using biological materials. The matter the Committee is enquiring into raises issues of inventiveness, patentable subject matter (including how courts have treated the current single exclusion under Section 18) and the focus in the patent system on the letter to the detriment of the spirit of the law. In my response I would like to briefly address all three issues, as they all bear on an effective solution to the problem of granting patents for genetic material identical to that found in nature.

1. Inventive step

All the evidence is that the inventiveness required for a patent monopoly is far too low in Australia—indeed it also seems far too low in the USA and Europe, with the exception of Germany. This problem applies to all inventions—monopolies are being granted in exchange for almost no inventiveness (Moir 2008). The review of the National Innovation System has strongly recommended a substantial increase in the height of the inventive step (Cutler et al. 2008: recommendation 7.2). IPAustralia issued a discussion paper on this topic earlier this year, with several minimalist proposals to raise the height of the inventive step to the very low level used in the USA. I have separately provided a copy of my response to that paper to the Committee.

The very low inventiveness standard for genetic material indicates problems in all patentable areas, as there is a single inventiveness standard (TRIPS requires no discrimination by field of technology). In my view it would be more productive for the Committee to recommend a substantial increase in the general height of the inventive

step, so that whenever a monopoly is granted for an invention there will be a genuine benefit to Australia.

Should the Committee feel its terms of reference require it to limit its recommendations to genetic material, simpler wording would be preferable. The complexity of the suggested draft is partly caused by the *legislative presumption* that any patent application is novel and inventive. This requires that the patent office show an application is not inventive rather than the applicant having to show that it is. It also requires complex double negative word forms. The heart of the proposed amendment is a global standard for “common general knowledge”. This could be clearer.

I note that the then government tried to implement a global common general knowledge standard in the *Patents Amendment Bill 2001*, which adopted a number of Ergas Review recommendations (IPCRC 2000). But this particular amendment was defeated in the Senate because of Democrat concerns (McKeough et al. 2004: 358).

Personally I consider that using a global standard for “common general knowledge” would have almost no impact on the quantum of inventiveness required for a patent monopoly. The many rules and procedures about decisions on patent grant are each slanted in favour of the applicant. As the US Federal Trade Commission said in respect of the USA a “plethora of presumptions and procedures tip the scales in favor of the ultimate issuance of a patent, once an application has been filed” (US FTC 2003: 8). Australia uses many of the same rules, but excludes even more existing knowledge from decisions on inventiveness.¹ In my view far more radical proposals are needed to set the patent system back on a path where it delivers benefits to the nation.

More radical changes are needed partly because the patent system has been heavily under-mined by those using it. It is rife with legal pretence: that software is not software, that methods of medical treatment are patentable despite longstanding traditions that they are not and that minimal difference equates with inventiveness even if that difference is in the words not the substance. Without a parallel to the anti-avoidance principles now used in the tax acts, legal drafters will simply work round this and any other amendments the Committee proposes. I provide some information on this issue in section 3 below.

The other reason why more radical change is needed is that the problem underlying the grant of patents on genetic information is IP Australia’s interpretation of some discoveries as inventions. Their approach could create further problems over time and needs to be broadly addressed. I recommend that the Committee tackle the issue of patentable subject matter more directly and with a view to the prevention of future abuses.

¹ This exclusion is not based on rules such as a national or a global standard, but on views that very narrowly define the relevant technology field. This problem exists in the USA (Bagley 2001) but is more severe in Australia. Australia seems to have particularly narrow limits on existing knowledge allowable for assessing inventiveness (see, e.g. O’Connell and Murray 2003; Monotti 2007). In *Lockwood* the High Court confirmed it was not necessarily reasonable to allow knowledge about mortice locks in assessing inventiveness for deadlocks (*Lockwood Security Products Pty Ltd v Doric Products Pty Ltd* (2005) 226 A.L.R. 70).

2. “Patentable” discoveries

The Committee might consider drawing on the essence of the excellent US Supreme Court judgement in *Diamond v Chakrabarty* (447 U.S. 303 (1980)) to develop amendments that will assist judges in determining when something identical to what is found in nature is patentable and when it is not. The Chakrabarty patent is for a micro-organism, and is often cited as the decision which allowed the patenting of “life”. The decision in fact centres on whether the micro-organism is a discovery or an invention, and is therefore extremely useful to the committee in its deliberations. The majority of the Supreme Court allowed Chakrabarty’s patent as valid because it met two criteria: it had characteristics that were *substantially different* from those found in nature and *those different characteristics had substantial utility*.

If the *Patents Act 1990* were to be amended to provide guidance to the courts and IP Australia on when a discovery is not an invention, I would recommend an amendment focusing on these combined characteristics. This would not only prevent patenting of genetic information identical to that found in nature, but would also provide sound principles for future contentious areas.

I have no experience with legislative drafting, so cannot suggest wording, but I consider that the *policy* the Committee might consider for adoption could be that:

- to be patentable an invention must be *substantially different* from anything found in nature and *the differences must contribute sufficient utility to provide a benefit* to the nation.

It is the importation of a specific meaning of the phrase “isolated and purified” that leads IP Australia to consider gene fragments and genetic information to be inventions, despite this being identical to what is found in nature. This self-deception is typical of thinking in the isolated patent community. Certainly the process for determining the information in genes and gene fragments involves isolation and purification. *But the genetic information is neither isolated nor purified*. In this, it is unlike chemical products, where naturally occurring chemicals may contain impurities which need to be removed before use. I believe the policy approach above will disallow the use of the phrase “isolated and purified” as a basis for granting patents over unchanged genetic information.

A problem in patent law is the regular use of analogy rather than cost-benefit analysis as a basis for decision-making, despite the economic objectives of patent policy. And the analogies do not seem to be subjected to any rigorous testing. In the case of the use of this chemical analogy to assess biological discoveries and inventions the analogy seems not only wrong but misleading (Thambisetty 2008).

The *Patents Act 1990* defines a patentable invention in terms of Section 6 of the *Statute of Monopolies 1623*. The ALRC, in its enquiry into gene patents, recommended review of this definition and Advisory Council on Intellectual Property (ACIP) is currently looking into this. The Committee, at the public hearings on 20 August 2009, asked some witnesses whether it should wait for the results of this review. In considering whether the Committee should wait for the “expert” opinion of ACIP, it is useful to reflect on the nature of ACIP and consider the impact this is likely to have on its advice.

The Committee will recollect that in the 1980s the then government introduced policy changes to increase public service responsiveness to stakeholders. For a regulatory body such as IPAustralia this has had an unfortunate outcome. Nowhere in its service charter does IPAustralia mention the need to protect the public interest, public knowledge, or the interests of innovating Australian firms which might be adversely affected by patent monopolies held by others. This bias flows through to ACIP. Excluding the two ex officio public service members, *only one* member is from outside “the patent community”—the group which benefits directly and financially from the patent system. Indeed the most recent advertisement calling for expressions of interest in joining ACIP (see Attachment A) makes it clear that those eligible are **only** those who *earn a living from the patent system*. ACIP has no consumer or competition representatives, and only one academic who is not an ‘intellectual property’ specialist. Advice from ACIP is thus by definition self-interested. Given ACIP membership it would be unreasonable to expect their advice to reflect the public interest in any way.

Because of these biases ACIP’s advice on patentable subject matter is unlikely to balance the interests of the public and innovating firms (most of whom do not use patents) against the interests of monopoly seekers. I draw the Committee’s attention to the ACIP report on the judicial extension of patentable subject matter to the field of “business methods”. In that report ACIP expressed the view that:

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

(ACIP 2003: 33 emphasis added)

No reasons are given for the alleged undesirability of requiring proof of national benefit for providing monopoly grants for subject matters where TRIPS does not require such grants. This view conflicts with Article 5.1 of the Competition Principles Agreement—that legislation should not restrict competition *unless it can be demonstrated* that benefits to the community as a whole outweigh costs. This principle is both economically sound and provides a major safeguard for democratic principles in ensuring that narrow sectional interests do not trump the public interest. Judicial and administrative extension of what constitutes an invention runs directly counter to this principle.

The Committee might find some of the very small number of submissions to the ACIP enquiry of use, and I have provided the Committee with a copy of my own submission. Based on previous experience it is unlikely that the ACIP report will put the public or national interest first.

If the committee recommends an amendment to the definition of a patentable invention, it may also wish to consider this in relation to the single specific exclusion to patentable subject matter. As I noted in my evidence on 20 August the courts have interpreted this single exclusion as indicating a parliamentary intent that anything else is patentable,

regardless of whether it was traditionally excluded from patentability or whether there is any need for a monopoly incentive (see also below).

The judicial interpretation of parliament's intent in the Section 18 exclusion

In Australia there have been long-standing traditions against patenting certain things, for example mathematical algorithms, ideas, discoveries and methods of medical treatment. Several of these exclusions were considered by the then Industrial Property Advisory Committee (IPAC) which undertook an 'economic' review of the patent system at the request of the Fraser government.² The review committee was divided on the issue of excluding chemical compounds, with the majority recommending against such an exclusion. The committee was unanimous in advising the government not to extend patentability to either software or business methods (IPAC 1984). IPAC also advised against adopting the EPC approach of specifying exclusions to patentable subject matter.

The government accepted all these recommendations and they are, inter alia, reflected in the *Patents Act 1990*. The Bill had bi-partisan support, but Senate negotiations with the Democrats and Independent Senator Harradine led to the introduction of a single specific exclusion (Section 18(2)).

Since 1990 Australian courts have acted to overturn some of these longstanding policies. As a result of these decisions, often made in resolving a conflict between two private parties, with no input considering the impact on the public interest, software and methods of medical treatment are now both patentable in Australia. The 1994 Federal Court decision to eliminate the exclusion for methods of medical treatment³ was because "there was no reason in principle" for the exclusion and "Parliament had an opportunity to include an exception in the *Patents Act* when it was re-enacted in 1990, and had chosen not to" (Wilcox, J. cited in ALRC 2004: 95).⁴

The decision to eliminate the software exclusion also occurred not long after passage of the *Patents Act 1990*. The two key cases are the *IBM v Smith*,⁵ and *CCOM v Jiejing*.⁶ In *IBM* the application was rejected by the Patent Office as pre-empting all uses of a mathematical algorithm. The court upheld the application on the grounds that in the context it only covered use in a computer, though it did not order rewording of the claims to clarify this limitation (Stoinaoff 1999: 505). In this case the view was expressed that "computer programs which have the effect of controlling computers to operate in a particular way, where such programs are embodied in physical form, are proper subject matter for letters patent."⁷ There was no reference to the IPAC review or the Government's response to it.

² The sole economist on the review committee, Professor Donald Lamberton, made a dissenting report, arguing that there was nothing economic about the review and that it was constrained by 'special pleading by those directly involved' (IPAC 1984: 79-80).

³ Clearly stated in *Joos v Commissioner of Patents* (1972) 126 CLR 611, 619 (ALRC 2004: 94).

⁴ As this decision was only a few years after the passage of the *Patents Act 1990* this seems an extraordinary interpretation of the events preceding the introduction of the 1989 and 1990 Patents Bills into parliament and the outcome of Senate negotiations during their passage.

⁵ (1991) 33 FCR 218.

⁶ *CCOM Pty Ltd v Jiejing Pty Ltd* (1994) 27 IPR 577; (1994) 28 IPR 481. CCOM was a petty patent

⁷ This summary of the views expressed in the *IBM* case is from the Full Federal Court consideration of the CCOM case ([1994] FCA 1168 at 119).

The CCOM ‘invention’ took a well-known linguistic technique for writing Chinese characters and used it in a computer. The initial Federal Court judgement was that the CCOM ‘invention’ simply used a computer in a conventional manner to reproduce known mental processes. Cooper J determined that this was not a manner of manufacture (27 IPR at 594). This decision seems imminently sensible from an economic and public interest perspective.

However it was overturned by the Full Federal Court, which reviewed UK law on computer program patentability in the period before the UK joined the EPC and so excluded software from patentability. The judgement in this case also referred to the 1966 US President's Commission ("To Promote The Useful Arts") which recommended against patents for software. While noting that parliament had made no such exclusion in the 1990 Act, the decision did not refer to the IPAC report on which the Act was based, and which recommended against patents for software.⁸ The CCOM case was instrumental in extending patentability to all software, with no need for any pretence that it is not software. This is perhaps because the court drew heavily on the last pre-1977 UK decision where two patent judges held that the computerisation of a known scheme was a valid patent.⁹ In summarising this decision, van Caenegem concludes that the fundamental reasoning was:

“that *more than a mental process* was involved in claiming the process of application of certain steps represented by a computer program on a standard computer, since the method as claimed was incorporated in the program and in apparatus in a physical form.”
(van Caenegem 2002: 46, emphasis added)

From an economic policy perspective it is hard to understand this. Software does not cease to be software when it does the function for which it is designed. And to define anything from which one can earn any income as a “manner of manufacture” is to eliminate almost all meaning from S.6 of the Statute of Monopolies, and certainly to discard the provisos in that Section. It is also astonishing that the courts seem never to have considered the context of the 1990 Act—amendments based on the major IPAC review. The review committee recommended no subject matter extensions, and certainly did not imply in its rejection of an EPC-style approach that they considered this would lead to major judicial changes in patent policy. The conclusion that parliament had the opportunity to introduce further limitations (which would simply have codified existing exclusions) but chose not to do so seems a wilful misreading of history.

3. The need for “anti-avoidance” provisions in the *Patents Act*

In his evidence to the Committee on 20 August Professor Drahos said “[m]ost patent attorneys will tell you that there is not an exclusion they cannot draft around.” The history of patent law across major jurisdictions is replete with examples of drafting being used to undermine the intent of patent law. In his evidence Professor Drahos referred to Markush claims. I provide below some brief evidence in respect of a range of exclusions from patentability which have been undermined by legal drafting—just as financiers crafted products to avoid the intent of tax law before the introduction of anti-avoidance provisions. Legal semantics in patent law is the parallel of crafting financial products to

⁸ [\[1994\] FCA 1168](#): 117-118.

⁹ [\[1994\] FCA 1168](#) at 116.

avoid paying tax; it involves using words to provide a veneer of inventiveness to something that would not otherwise merit a patent monopoly. This undermining of the intent of patent law could be addressed by using similar provisions to those that have successfully prevented the undermining of tax law.

In addition to the “isolated and purified” genes example, other examples of legal semantics being used to undermine patent law are in relation to chemical compounds, methods of medical treatment and software.

i). Patenting chemical compounds

When the UK government decided to remove the patent exemption in respect of chemical products it was in frustration with the use of legal drafting to get round this provision by patenting every possible production method, and thus effectively fencing off the unpatentable substance. In some ways the phrase “isolated and purified” in regard to chemical compounds is itself a convenient legal fiction adopted to give a veneer of respectability to the grant of monopolies over naturally occurring materials, presuming as it does that “isolation and purification” always occurs in fact.

ii). Methods of medical treatment

A related important exclusion is methods of medical treatment.¹⁰ This exclusion remains in most overseas jurisdictions, at least in theory. European Patent Convention (EPC) Article 53 sets out some quite clear exclusions—‘subject matter’ that cannot be granted patent monopolies. One of these is methods of medical treatment (Article 53(c)). However the European Patent Office (EPO) appears to consider that Article 56 (defining novelty) can be used to over-ride the subject matter exclusion (Ventose 2008: 11-12). “Swiss medical claims” is the name given to the style of drafting used to get round this exclusion (for an example see Thambisetty 2008). The attitude of the patent community to restrictions drafted into patent law is well illustrated in relation to this matter:

"However, the patentability of methods of treatment of humans is *as vexing an issue as ever* and in a sense it is reassuring to observe that some things never change. On the other hand, we can now use both method and Swiss style claims *to get around the problem*, or at least to pass the buck to the courts."

(Tansey and Pluck 2004: 63, emphasis added)

iii). Software

Both the US and the European legislation prohibit the patenting of software itself. In my own research I have seen examples where patent applications are rejected by the United States Patents and Trademark Office (USPTO) or the EPO on those grounds. By simply redrafting as “computer-readable medium” claims they miraculously cease to be software, becoming patentable. There is, of course, no change to the underlying ‘invention,’ which remains a software program.

¹⁰ Traditionally the professions were outside the ambit of the patent system—they were not regarded as economic activities. Indeed some (e.g. military officers, parliamentarians) could not be undertaken except by those with independent means of financial support. Inventions in the realms of the professions and the fine arts were not patentable. Only those from the realm of the useful arts—manufacturing and trade—were patentable. P This limited scope of patent policy seems to have served economic and social development well.

Miceli suggests that it is such drafting that has allowed the EPO to grant in excess of 40,000 patents despite the EPC specifically excluding software patents (Miceli 2005). The EPO would argue that these ‘inventions’ are ‘more’ than software programs. This issue of a software program becoming ‘more’ than a software program is discussed below in relation to the removal of the software exclusion in Australia.

There is some contention about this semantic myth in Europe, with UK courts in particular clearly more uncomfortable than the EPO with this legal pretence. Prescott J reviewed the reasons for the various exclusions in the EPC before rejecting a patent application on the grounds that:

“You are not allowed to get round the objection—that you are attempting to patent a computer program—by claiming it as a physical artefact, a mere change of form.”

[2005] EWHC 1589 (Pat) at 36

This decision led to a change in procedures in the UK Patent Office.

Other uses of legal semantics to introduce ‘inventiveness’

In addition to these general sets of things that policy makers and legislatures have deemed not to be patentable but which legal drafting has made patentable, there are myriad examples where “clever legal drafting” is used to make individual applications sufficiently novel or inventive to merit a monopoly grant—even though the underlying ‘invention’ seems quite obvious in the normal sense of that word. The *Patents Act 1952* introduced changes making it easier to amend patent specifications “thus allowing a meritorious invention to be maintained even though the specification may be subject to drafting defects.”¹¹

Now amendment seems the norm rather than the exception, and these often involve *trivial word changes to overcome examiner objections*. In my recent in-depth study of 72 Australian business method patents, 50 of the 72 applications were amended during negotiations with the examiner, and in many cases it was the amendment that was instrumental in allowing the grant. While the triviality of these amendments indicates the problem of “clever legal drafting”, it also points to the poverty of an inventiveness test that allows semantics to substitute for inventiveness. Approaches from tax policy can overcome this substantial deficiency in current patent policy and practice.

The change in the *Patents Act 1952* which led to most parliamentary debate was the creation of a special monopoly privilege for Patent Attorneys. It is difficult to obtain figures on the growth rates of this professional group in Australia,¹² but in respect of the USA Barton notes that the growth rate in patent attorneys substantially exceeds the growth rate in expenditure on research and development (Barton 2000).

In both the patent and the tax systems there are substantial financial incentives for parties who are well able to afford outstanding legal advice to ‘game’ the system. In discussing

¹¹ Second Reading Speech, Senator Spicer, Hansard, 22 May 1952: 687-693 at 691.

¹² My own phone calls to the Professional Standards Board for Patent and Trade Mark Attorneys received the response that retrieving data on the number of registered patent attorneys over a period of time would be too difficult!

tax law Braithwaite argues eloquently that where there are incentives to gaming behaviour it is important that statute law contain over-arching principles which trump specific rules (Braithwaite 2005). In addition he argues that it is important that there be ‘anti-avoidance’ mechanisms and that the legislature must intervene when judicial decisions undermine the purpose of the legislation.

The important principle that should be incorporated into the patent statute is its purpose—providing an incentive to *genuine* innovation and ensuring that this reward is counter-balanced by a genuine consideration passing to the nation.¹³ In other words, the statute needs to spell out the clear economic goals of the patent system, and specify that a *reasonable quantum of inventiveness* is required so that a patented invention is likely to contribute a benefit to Australia. These intertwined objectives would give judges the guidance they clearly need in interpreting the statute in a manner that is welfare-enhancing rather than welfare-reducing.

In terms of policy principles, to prevent semantics and gaming behaviour being used to undermine parliament’s intent the statute should include:

- clear specification of the objectives of patent policy
 - to induce inventions that would not otherwise occur; and
 - to provide monopolies only where the benefit to the nation will exceed the cost
- a clear statement that decisions to grant a monopoly should be based on the *substance* of the invention
 - applicants could be required to make a clear statement of the essence of their inventive contribution;
 - in granting any patent, the Patent Office should be required to confirm the inventive contribution and provide an assessment of the likely benefit to Australia;
- direction that priority be given to the over-arching principles and substance of the invention where there is a conflict with a specific decision-making rule;
- penalties for attempting to undermine the patent system through “clever drafting”;
- require input from competition and consumer protection authorities when patent cases are being considered in the courts; and
- removal of barriers to non-profit group challenges to mischievous patents.

Overall view

The proposed amendment is extremely complex. I support a substantial increase in the height of the inventive step, but preferably for all inventions. On its own, this proposed amendment will achieve little. It needs to be combined with a set of “anti-avoidance” provisions to prevent the continual undermining of the patent system. Also, given how the courts have interpreted the single subject matter exception in Section 18, parliament now needs to adopt the European approach and write into the statute all the exclusions from the patent system that were traditionally drawn from case law. The drafting must learn from the EPC experience (see Bakels and Hugenholtz 2002), and be combined with anti-avoidance provisions if it is to be effective.

¹³ “Disclosure” of the invention is inadequate as a consideration. As Machlup pointed out to the US Senate in 1958, there is no incentive to patent that which can be kept secret, so the idea that the disclosure creates a consideration for the nation is another example of simple semantics (Machlup 1958).

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Attachment B: Advertisement for ACIP members

Qualifications are stated in paragraph 3 and emphasise being a beneficiary of IP systems.

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Australian Government
Advisory Council on Intellectual Property

Expressions of interest for appointment

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

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

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

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

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

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

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

or to frances.roden@ipaustralia.gov.au

Additional information may be obtained from Kay Collins (02) 6253 2462

Source: Australian Financial Review, 2-3 May 2009: 8