SUBMISSION

TO THE SENATE

STANDING COMMITTEE ON LEGAL AND CONSTITUTIONAL AFFAIRS

Inquiry into Patent Amendment (Human Genes and Biological Materials) Bill 2010

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The authors are members of of the Centre for Law and Genetics in the Law Faculty at the University of Tasmania. The Centre developed out of a project funded by the Australian Research Council (ARC) from 1994 to 1997. The primary focus of the project was the ethical and legal implications of advances in genetic technology. Since then, the Centre has had ongoing funding from the ARC discovery grants program and has expanded its areas of research to include broader issues associated with commercialisation of genetic technology, access to healthcare and biobanking. Professor Dianne Nicol leads the intellectual property component of the Centre's research program. Her research interests particularly focus on the interface between innovation, research and access to healthcare in biomedicine. She has undertaken ARC funded research on cooperative strategies for managing intellectual property in biotechnology with colleagues from the Australian National University.

The authors of this submission are currently in receipt of funding from the ARC for a project examining the relationship between patenting and innovation in the Australian biotechnology industry, with particular focus on the potential role of collaborative strategies, including patent, on innovation within the industry. The project is being undertaken in collaboration with colleagues from Swinburne University, Japan and Norway.

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EXECUTIVE SUMMARY

We do not support the Patent Amendment (Human Genes and Biological Materials) Bill 2010 (the Bill).

Our reasons are encapsulated in the dot points that follow. We provide more detailed explanations for our concerns in the substantive part of our submission.

- **The Bill is unclear.** Terms such as 'components', 'derivatives' and 'substantially identical' are unclear and are likely to require judicial interpretation before their meaning is settled. The definition of 'biological materials' provided in the Bill is also problematic and the title to the Bill is misleading;

- **The Bill is too broad.** Although the primary driver for this Bill is the exclusion of the so-called 'human gene patents' it also excludes other biological materials that are routinely the subject matter of research and commercial ventures in the Australian biotechnology industry. Broad exclusion of biological materials from patenting could unduly prejudice the Australian biotechnology industry;

- **The Bill is too narrow.** While the Bill seeks to exclude biological materials it does not exclude methods of using those materials. Hence, some of the most controversial aspects of patenting in the field of biotechnology are not fully addressed by this Bill, particularly methods of diagnostic testing and non-commercial research methods. The Bill also does not address problems created by broad downstream patent claims. Moreover, experience in Europe suggested that specific exclusions of this nature tend to be worked around by creative drafting;

- **The Bill is too blunt an instrument**. There are more nuanced ways for dealing with the perceived problems caused by patenting of

biological materials, which have been canvassed extensively in law reform inquiries in Australia and other countries;

- **The express inclusion of the section 6 proviso is unwarranted.** There is case law authority for the proposition that section 6 of the Statute of Monopolies is already incorporated into the *Patents Act 1990* (Cth) in its entirety, and in any case the proviso has dubious value in respect of gene patent concerns;

- **The Bill may be contrary to Australia's international obligations and international norms.** The Bill is potentially inconsistent with international patent law and domestic patent law in other jurisdictions;

- **The Bill is too late.** Many controversial patents in the field of biotechnology have already been granted and these will be untouched by this Bill as it will only have relevance to new patent applications;

- **The Bill is redundant.** The first patents in any new area of technology tend to be broad in scope, but applications for later generation patents either fail to satisfy the patent criteria or are narrowed in scope as techniques become routine and the prior art expands. It is increasingly difficult to claim right to genes and related subject matter because routine sequencing techniques and extensive databases of sequence information make the novelty and inventive step requirements hard to satisfy. Should the reforms to the patent and disclosure criteria canvassed in the recent IP Australia IP Rights Reform Consultations be implemented, then it will be even more difficult to obtain broad patents for genes and related subject matter;

- **The symbolic value of the Bill is insufficient justification for passing it.** While the symbolic step of excluding biological materials from patenting is of great importance for some members of

Australian society, it has to be weighed against other factors. One risk of taking the step of excluding biological materials is that it may be perceived as 'fixing the patent problem'. Whilst this Bill makes a valuable contribution to the discussion, our submission is that a more holistic approach to patent law reform relating to biotechnological inventions should be taken from the outset;

- **The Bill encourages genetic exceptionalism**. There are other emerging fields of technology where patent practices need to be addressed, including methods of doing business, green technology and nanotechnology. Rather than taking a piecemeal approach, it is important to address patent law reform in a more holistic fashion, taking into account the impact of patents on a wide range of emerging technologies.

Based on these concerns, we find it difficult to see how the 'simple amendment' to the *Patents Act 1990* (Cth) (*Patents Act*) provided in Schedule 1 to the Bill will, in the words of Senator Heffernan: [1]

> recalibrate Australia's patent system so that it properly and sensibly balances the needs of the medical and scientific community with the need to promote research and development for true inventions.

INTRODUCTION

This Bill raises a range of complex issues that have been the subject of numerous law reform inquiries both in Australia and in other jurisdictions, either as the primary focus of the inquiry or as matters relevant to the inquiry. Internationally, the most relevant report for the purpose of discussing the content of this Bill is the US Department of Health and Human Services, Secretary's Advisory Committee on Genetics, Health and Society,

[1] The Senate, Patent Amendment (Human Genes and Biological Materials) Bill 2010 Second Reading Speech, Wednesday, 24 November 2010

Gene Patents and Licensing Practices and Their Impact on Patient Access to Genetic Tests (May 2010) (the SACGHS Report). We also draw attention to the following Australian law reform reports and papers:

- The Australian Law Reform Commission (ALRC), Report 99 *Genes and Ingenuity: Gene Patenting and Human Health* (2004);
- The Advisory Council on Intellectual Property (ACIP), *Report on the Review of Patents and Experimental Use* (2005);
- ACIP, *Final Report on Patentable Subject Matter* (2010);
- IP Australia, 2009 Consultation Papers on IP Rights Reform, particularly *Getting the Balance Right* and *Exemptions to Patent Infringement*; and
- Senate Community Affairs Committee, *Gene Patents* (2010)

Regrettably, to date there has been little response to the recommendations arising from these inquiries. Recommendation 4 from the report of the Senate Community Affairs Committee inquiry into gene patents clearly illustrates the concern of that Committee about the lack of Government response:

> The Committee recommends that the Government provide a combined response addressing the Committee's inquiry into gene patents; the 2004 report on gene patents by the Australian Law Reform Commission; the review of patentable subject matter by the Australian Council on Intellectual Property (ACIP); and the review of Australia's patent system by IP Australia. The Committee recommends that the response be provided not later than mid-2011 or three months after the release of the findings of all reviews.

This lack of government response is disappointing, given that all but the Senate Community Affairs Committee inquiry were initiated in response to references from the government of the day. Moreover, each inquiry was the

subject of extensive public consultation and expert advice.

These inquiries all draw attention to the need for a holistic approach to the reform of patent law and patenting and licensing practices to accommodate the challenges of balancing the need to foster innovation in medical, agricultural, environmental and industrial biotechnology with the need to ensure public access to these new innovations and the need to facilitate primary research in each of these areas. Our submission is that, at best, the Bill is likely to token improvement to existing regulatory and governance frameworks in dealing with these challenges and, at worst, it may actually cause greater detriment than benefit.

THE BILL IS UNCLEAR

There are terms in the Bill that are not defined. Depending on the way they are interpreted, they could have far-reaching or limited effect. It is not at all clear what is intended by the use of these terms, nor whether they will be interpreted in a way that corresponds with the original intention.

We draw particular attention to the word 'derivatives' appearing in item 3 of the Schedule to the Bill. Whilst we acknowledge that the word 'derivative' is frequently used in the fields of genetics and genomics, it is unclear whether it has a precise technical scientific meaning when used in these contexts. In the legal context, we have been unable to find any precedent for the use of this word in patent legislation. In other legal contexts, we have found that the word does appear from time to time in connection with natural resources. The Nagoya Protocol to the Convention on Biological Diversity *on Access to Genetic Resources and the Fair and Equitable Sharing of Benefits Arising from their Utilization (ABS),* adopted by the Convention on Biological Diversity 10th Conference of the Parties on 29 November 2010. Article 2 of the Protocol defines a derivative as:

> a naturally occurring biochemical compound resulting from the genetic expression or metabolism of biological or genetic resources, even if it does not contain functional units of heredity.

The International Centre for Trade and Sustainable Development, which provides leading commentaries in the area of access to natural resources, describes this definition as 'far-reaching' and has other concerns about ambiguity relating to this and other provisions.[2] We submit that this legal definition of the word 'derivative' would at best provide only limited assistance in interpreting its ambit in the context used in the present Bill. The lack of any attempt to define the word in the Bill itself or in the Explanatory Memorandum or second reading speech creates undesirable uncertainty.

The Bill also does not provide guidance as to how the words 'components' and 'substantially identical' should be interpreted. 'Substantially identical' is particularly important in with regards to amino acid and nucleotide sequences. It is unclear whether the term is intended to refer to simple sequence identity, or to function or both. An induced mutation may have a spectrum of effects on a sequence's utility and this will always depend on its environment. The lack of a clear definition raises questions in relation to the intended scope of the provision. Is an artificially induced mutation that has not previously recorded but which has the same effect as a naturally recorded mutation elsewhere in a gene substantially identical? Naturally occurring mutations that cause non-functionality in genes have occurred all the way through evolutionary history. Moreover, evolutionary history contains millions of sequences of nucleotides and amino acids that we have never recorded. If a computer program indicates that an artificially induced mutation has almost certainly existed before, is this 'substantially identical' even when the naturally occurring mutation has not been recorded? This is a

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[2] http://ictsd.org/i/news/bridgesweekly/92903/ (accessed 17 February 2011).

particularly pertinent question in areas of research such as the development of vaccines from virus-based sequences.

The term 'biological materials' is defined in the Bill to include DNA, RNA, proteins, cells and fluids. However, other submissions have pointed to problems with this definition. In particular, the submission from the Royal College of Pathologists of Australasia notes that many naturally-occurring substances, including fats, cholesterol, vitamins. We endorse these concerns.

The explanatory memorandum associated with the Bill expressly states that 'if individual parts of a recombined and isolated gene are nothing more than a fusion of genetic parts, each of which are identical to their corresponding natural equivalents, then the recombined product is also excluded'.[3] This suggests to us that if a gene is not normally expressed in a person's body and this problem is rectified by using cutting edge gene therapy to combine the gene with another promoter and inserting them into the body, then that recombination of two naturally occurring sequences (although never observed in nature before) would be unpatentable per se. To us this appears to be an archetype example of a biological material that should be patentable.

Finally on this point, we submit that the title to this Bill does not properly reflect the subject matter of the Bill. The title refers to 'Human Genes and Biological Materials'. However, items 3 and 4 of the Schedule to the Bill make no reference to humans as such, aside from the reference to the existing exclusion of human beings and the biological processes for their generation in section 18(2) of the *Patents Act*. Rather, the Bill seeks to exclude all biological materials, including all DNA 'whether isolated or purified or not and however made, which are identical or substantially identical to such materials as they exist in nature'. In our submission, the title of the Bill is apt

[3] Explanatory Memorandum, Patent Amendment (Human Genes and Biological Materials) Bill (Cth) 4.

to mislead the casual reader into thinking that the Bill is limited in application to human genes and like subject matter, and intended to fix what can be referred to as the 'human gene patent problem'. In fact, the Bill is far broader in scope.

THE BILL IS TOO BROAD

Even if the vague and undefined term 'derivatives' is removed from this Bill, we submit that it still has the capacity to be too broad and to stifle innovation in the Australian biotechnology industry. One of us (Nicol) in collaboration with Associate Professor David Brennan of the University of Melbourne published the following hypothetical example of the potential adverse impact of the Bill on Australian industry in an opinion piece in The Age newspaper on 6 December 2010.

> A hypothetical R&D team is employed by a private company which invests heavily in developing anti-cancer drugs. The team identifies for the first time an enzyme produced naturally in a plant. It uses standard techniques to put the plant enzyme into an isolated form. It identifies the gene that encodes for the enzyme, isolates that gene, and uses the gene to genetically engineer a synthetic form of the enzyme. The team undertakes complex and lengthy testing of the enzyme. It makes the surprising finding that the enzyme has powerful anti-cancer properties. The enzyme comprises a breakthrough in treatment of leukaemia by chemotherapy.
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> The discovery of the enzyme has now served as the basis for a whole new class of anti-leukaemia drugs. The company will now try to stake a claim to what it has invented through the patent system. It will be able to do so because our patent laws has traditionally reflected a social choice that the denial of patent protection in a setting such as this to be contrary to the public interest. That is because we want the leukaemia cure. We want it as quickly as possible. We want it by companies taking private risks, rather than by the tax-payer funding of speculative research. We understand that without some way of capturing value from the private investment into the R&D that yields a cure, that R&D would not be likely undertaken.

> Therefore our current patent law accepts that a product derived from nature (such as a plant enzyme or a gene or a genetically-engineered enzyme) can be validly patented if the following conditions are satisfied:
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> 1. It is new, in the sense that it has not previously existed in that form, and
> 2. It provides an inventive solution to a problem, and
> 3. That problem is a real-world, practical matter.
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> In the scenario here presented, the isolated plant enzyme, its gene, and its synthetic form satisfy all three conditions. All are new products involved in supplying an inventive leukaemia cure.
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> However the terms of the Bill, if enacted, would appear to deny patent protection to all of these new products. They all seemingly fall within the scope of the proposed 'biological materials' exclusion. The implication of this is stark. Without the ability to appropriate value from the R&D, why would the R&D underlying the cure occur within the private sector? Most likely it would not be undertaken.

This hypothetical example is not without foundation in practice. There are many small biotechnology companies in Australia that operate in this space, and that rely on patents, not only to protect their innovations from copying, but also as a means for attracting investment and partnering opportunities. Both investment and partnering with larger (predominantly non-Australian) firms are essential for small companies wishing to bring their innovations to market.

One of the most successful medical advances in the Australian context is the human papilloma virus cancer vaccine. Professor Ian Frazer at the University of Queensland made the initial discovery of a potential target for the vaccine on the coat of the virus in 1991. Australian biotechnology company CSL, in collaboration with the multinational pharmaceutical company Merck,

commercialised the technology,[4] which is now protected by a family of patents.

Most of the claims in the more recently filed patents would not obviously offend against a provision of the nature of the new biological materials exclusion provided in Item 3 in the Schedule to the Bill. However, some of the claims in Australian patent 660954, one of the first patents to be filed by the University of Queensland in respect of this technology, clearly do. The first eleven claims in 660954 simply relate to protein sequences based on those that exist in nature, meaning that under this Bill's biological materials exclusion they would not be patentable.

In sections below we discuss how method claiming, creative drafting, and claiming amino acid and nucleotide sequences combined with other artificial research tools will allow patentees to claim the full utility of their invention as effectively as if a gene sequence itself was claimed (this can be observed with the production of Gardasil[5]). The point here is that we believe the only change the Bill will likely introduce is uncertainty.

A consistent theme of empirical research on the Australian biotechnology sector is that Australian biotechnology firms struggle to obtain adequate funds to be able to value-add to the first class research being carried out by public and private sector researchers, and that investors like certainty and are highly risk averse.[6] In a broadly based inquiry of health and medical research in Australia, the Wills Review recognised that Australia has a

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[4] For a brief overview of these developments see: Graeme O'Neill, 'CSL Celebrates Cervical Cancer Vaccine Success' (2002) *Australian Life Scientist,* available at: http://www.lifescientist.com.au/article/48933/csl_celebrates_cervical_cancer_vaccine_success/ (accessed 21 February 2011).

[5] See all 64 claims in Australian patent numbered 651727. The patentees claim antisera, VLPs, VLPs in vectors and other various uses of the sequences.

[6] Dianne Nicol and Jane Nielsen, *Patents and Medical Biotechnology: An Empirical Analysis of Issues Facing the Australian Industry* Centre for Law and Genetics Occasional Paper No. 6 (2003), available at: http://www.lawgenecentre.org/pub.php

number of strengths in this field, including world-class expertise in research. Despite this, development and commercialisation of scientific discovery tends to be weak. The Wills Review recognised that there is a need to enhance technology transfer between research and industry and to stimulate flow of medium to long-term venture capital.[7] For around 30 years now, sequence claims and other composition of biological materials have been valid. We submit that passage of this a Bill is likely to increase uncertainty in this vulnerable industry and deter investment without making significant contributions to research or the dissemination of knowledge.

It is relatively standard practice in commercialising intellectual property originating in Australia that the major market focus is not actually Australia, and that patent claims need to be tailored to the patent law of each jurisdiction. As such, even if the Bill is passed, the biological materials exclusion would not prevent patenting of those materials in other jurisdictions. One risk is that Australian innovations in biotechnology will be developed offshore. Another risk is that patents claiming innovations relating to biological materials filed with IP Australia could be subject to protracted and expensive litigation in Australia because of the uncertainties in terminology highlighted above. As such, rather than capturing the benefits of biotechnology for the community, industry and environment, as proposed in the National Biotechnology Strategy,[8] Australia could be at risk of losing those benefits.

THE BILL IS TOO NARROW

As pointed out by Senator Heffernan in his submission to the Senate Community Affairs Committee inquiry into gene patents, 'the trigger for this

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[7] Health and Medical Research Strategic Review, *The Virtuous Cycle: Working Together for Health and Medical Research: Health & Medical Research Strategic Review: Final Report* (Canberra: AGPS, 1999) (the Wills Review).

[8] Biotechnology Australia, *Australian Biotechnology: A National Strategy*, (Canberra: Commonwealth of Australia, 2000).

Inquiry was the threat of patent infringement litigation made, for a second time in six years, by the same company against publicly funded laboratories that were providing an essential diagnostic service in Australia'.[9] It is probably safe to assume that the Senator is referring to the threat that the so-called BRCA patents would be enforced by Genetic Technologies Limited, the exclusive licensee of the patents in Australia and New Zealand, against Australian diagnostic testing facilities and public research organizations. In the first paragraph of his second reading speech to this Bill the Senator raises the same issue.

We agree that the Australian Parliament should be deeply concerned about this incident and about the potential for similar incidents to occur in the future. However, we disagree that the present Bill is the appropriate response, or, indeed, that it is an adequate response. We have already noted in our summary of reasons that the Bill will not have an impact on existing patents, including the BRCA patents that triggered the Senate inquiry and the Bill. In this part of our submission we explain that in our view the Bill will not curb these types of infringement actions relating to patents granted in the future, after the Bill has entered into force (in the event that it is passed by both Houses of Parliament).

There are three components to this part of our submission. First, we address the implications of continuing to allow patents for diagnostic methods. Secondly, we consider use of genes in research tools known as vectors. And thirdly we consider the potential for creative claims drafting to be used in such a way as to create rights to subject matter not falling strictly within the definition of biological materials in the Bill, but which practically achieves this outcome.

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[9] Senator Heffernan's, Submission No 76 to the Senate Community Affairs References Committee, Inquiry into Gene Patents, 1.

Patents for methods of use

Patents have traditionally been made available both for inventive products and for inventive processes. Much of the case law on the interpretation of the manner of manufacture test in Australian patent legislation has focused on process, or method patents. The seminal case of *National Research Development Corporation v Commissioner of Patents*[10] (*NRDC*) set the ground rules for interpretation of the manner of manufacture requirement, and more specifically also clarified that a process should not be excluded from patenting simply because it is agricultural or horticultural in nature. By analogy, the same reasoning applies to diagnostic processes.

Implications of allowing method claims in the diagnostic testing context

Recently a highly-regarded research group in Belgium undertook a detailed analysis of the claims made in patents relating to 22 common genetic tests.[11] It should be noted that Professor Gert Mathijs is a member of the research group. Professor Mathijs is Head of the Molecular Diagnostic Laboratory of the University Hospital, Catholic University of Leuven and he is an outspoken opponent of gene patents. The group expressed some surprise at their results. In particular, they found that far more genetic diagnostic patents had been granted in the US than in Europe and that far more patent applications were abandoned in Europe than in the US. While there are no equivalent data in Australia, we predict from our experience and other literature that there will be even fewer granted genetic diagnostic patents in Australia and an even higher level of abandonment at the application stage. They also found that three-fifths of the patent applicants originated in the public sector. Perhaps the most alarming result was that the most problematic of the patent claims related to methods. They found that many of the method

[10] (1959) 102 CLR 252

[11] Isabelle Huys, Nele Berthels, Gert Matthijs and Geertrui Van Overwalle, Legal Uncertainty in the Area of Genetic Diagnostic Testing' (2009) 27 *Nature Biotechnology* 903-909.

claims were difficult or impossible to circumvent and that patents claiming these methods were owned by different applicants.[12] These and other findings led them to conclude: 'proposals aiming at banning patents on human genes do not provide a plausible solution, unless the ban would be on patents for broad genetic diagnostic methods as such'.[13]

While we agree with this conclusion, this should not be seen as recommending that a further exclusion should be included in s 18 of the *Patents Act* for methods of diagnosis. We believe that it would be extremely difficult to draft an appropriate and adequate provision in this regard. Rather, we endorse the recommendation of the SACGHS Report [albeit made in the US context] that patent legislation should be amended to create an exemption from liability for infringement of patent claims on genes for anyone making, using, ordering, offering for sale, or selling a test developed under the patent for patient-care purposes.[14]

Implications of allowing method claims in the non-commercial research context

Non-commercially orientated research encompasses pure academic research, research aimed at testing whether the invention performs as claimed and other research that does not have a commercially orientated intention. Government and academic researches have queried whether a research exemption covering such uses exists in Australian law. A report published by ACIP concluded that there are arguments for a type of research exemption to infringement but the law is unclear.[15]

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[12] Ibid, at 908.

[13] Ibid, at 909.

[14] US Department of Health and Human Services, Secretary's Advisory Committee on Genetics, Health and Society, *Gene Patents and Licensing Practices and Their Impact on Patient Access to Genetic Tests* (May 2010), Recommendation 1A.

[15] ACIP, *Report on the Review of Patents and Experimental Use* (2005) 36.

In practice it is widely assumed by many researchers that such an exemption does exist and researchers and patent holders alike have an unwritten rule that such research is exempt.[16] Nevertheless, there is a risk that some patent holders will choose to exercise their right to enforce their patents against non-commercial users in the future. Indeed, one patent holder has already chosen to do so. Genetic Technologies Limited publicly announced in 2005 that it had entered into research licences with Sydney University and the University of Technology Sydney in Australia in respect of its so-called 'junk DNA' patents.[17] Additionally, with regard to patents relating to mutations in the BRCA1 gene, verbal evidence given to a previous Senate inquiry demonstrates that the proprietary fetters of those patents have created a significant barrier to academic research and have delayed by two years a greater understanding of the BRCA mutations.[18]

One of the key intentions of the Bill is to avoid future obstructions to non-commercially orientated research analogous to the real BRCA scenario outlined above. Thus, if the Bill has its intended effect, future research aimed at confirming the validity of research findings that correlate genetic mutations with particular medical conditions, or testing the validity of those findings in different scenarios or identifying additional mutations in the genes that correlate with the same medical conditions could be undertaken without the risk of being exposed to demands for royalty payments or infringement proceedings. Because gene patents tend to include claims to methods of use as well as the biological material as such, these claims clearly

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[16] Dianne Nicol and Jane Nielsen, *Patents and Medical Biotechnology: An Empirical Analysis of Issues Facing the Australian Industry* Centre for Law and Genetics Occasional Paper No. 6 (2003), available at: http://www.lawgenecentre.org/pub.php at 218-222.

[17] See Dianne Nicol 'Balancing Innovation and Access to Healthcare through the Patent System - An Australian Perspective' (2005) 8 *Community Genetics* 228-234.

[18] Evidence to the Senate Community Affairs References Committee, Senate, West Melbourne, Tuesday 4 August 2009, CA 115-116 (Prof. Bowtell and Dr Mitchell).

have the ability to undermine the non-commercially orientated research intention of this Bill.

By contrast, IP Australia and legal academics have for quite some time been evaluating different types of explicit exemptions for non-commercial research. We are aware that draft of such an exemption is likely to be included within the Draft Intellectual Property Laws Amendment (Raising the Bar) Bill 2011 and its intended application can be discerned from the IP Australia document 'Exemptions to Patent Infringement'.[19] An explicit research exemption has been in development for a substantial period of time and the need for such an exemption is almost uncontroversial. What is more controversial is the exact form that the exemption might take. [20]

Downstream applied research with a commercial intent

For the purposes of this submission downstream research with commercial intent refers to research that builds upon previously patented inventions which is conducted with the intention of generating a commercial outcome.

A theoretical example of downstream research with a commercial intent that the Bill intends to relieve from proprietary fetters is the development of additional commercial tests for breast and ovarian cancer. Such research could be achieved by analysing heritable links between BRCA gene mutations claimed in Australian patent numbered 686004 with other newly identified BRCA polymorphisms.[21] In this scenario, it is quite plausible that

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[19] IP Australia, *Exemptions to Patent Infringement: Toward a Stronger and More Efficient IP Rights System*, IP Australia Consultation Paper, March 2009, 5.

[20] For a discussion of various drafting see ACIP, *Report on the Review of Patents and Experimental Use* (2005) pages 48-61 and 69-72; Australian Law Reform Commission, *Genes and Ingenuity*, Report 99 (2004) section 13,.

[21] We remind the Committee that this patent would in fact be unaffected by the proposed amendment in Item 3 in the Schedule to the Bill because it has already been granted and the Bill does not have retrospective application. We are simply using this patent as a useful model for illustrating the potential consequences of the biological materials exemption, if passed.

the 686004 patent owner would have a valid infringement claim against the researcher if this research is undetaken without their permission.

Whether or not the amendments in the Bill as drafted would achieve relief from such an infringement claim is, we believe, speculative. The biological materials exclusion proposed in the Bill expressly states that such materials are excluded 'whether isolated/purified or not'. Ostensibly this indicates that the theoretical example of commercially orientated research presented above would not be open to an infringement action, because the relevant claims would be invalid. However, almost all patent claims relating to nucleotide sequences do not only claim naturally occurring sequences, but also commonly claim sequences in research tools such as vectors. The BRCA patent, 686004, mentioned above, claims the mutations in a vector. Other controversial patents such as patent numbered 600650, relating to expression of erythropoietin (EPO) makes similar claims.[22]

The significance of vectors in biotechnology is that they enable specific types of nucleotide transference. This use sounds quite mundane but in the laboratory, it is significant. Standard, everyday laboratory techniques to clone specific DNA, sequence DNA, express genetic material in foreign cells and a variety of other techniques are dependent on the use of genetic material in a vector. While it is possible to carry out some techniques without vectors, this would restrict research as well as being expensive and/or laborious.

Claims to naturally occurring genetic material in vectors undermines the usefulness of the proposed biological materials exclusion, because it seems to us the combination of a vector and a nucleotide sequence would provide patentable subject matter that does not exist in nature. The invention would

[22] For patent 686004 see claim 5; for patent 600650 see claim 20.

not be excluded because the exclusion only applies to biological material that is 'substantially identical to such materials as they exist in nature'.

Since the use of nucleotide sequences in vectors is almost invariably applied by all laboratories conducting gene-based science and the invention of naturally occurring sequence with a vector will give such inventions unnatural properties, it is difficult to perceive how the Bill's amendments as drafted will have the desired blanket effect of relieving commercially orientated gene-based research from proprietary fetters.[23]

Creative drafting

One of the significant and essential functions that patent attorneys fulfil is drafting patent applications and, in particular, patent claims. Within the confines of the law, patent attorneys are specifically trained to draft claims as widely as possible to claim the broadest area of application for their clients' invention. While the Bill is clearly an attempt limit what may be claimed in the field of biotechnology, patent attorneys are very knowledgeable and adroit, and may well be able to draft around the exclusion.[24] We have already mentioned above that the Bill does not exclude method claims or claims to gene sequences in research tools such as vectors and this section on creative drafting should be considered in addition to them.

An example of this approach to claims drafting can be observed in Europe where 'Swiss-type claims' and 'direct second use claims'[25] have emerged to

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[23] It is worthwhile considering how inventive (under s 18(b)(ii)) putting a sequence in a vector actually is (or actually sequencing a gene for that matter). This issue is treated generally under our 'Redundancy' heading.

[24] In private conversations we have been told by patent attorneys that such exclusions can be worked around in a variety of ways.

[25] For a summary of these types of claims please see the United Kingdom's Intellectual Property Office website < http://www.ipo.gov.uk/pro-types/pro-patent/p-law/p-pn/p-pn-medical.htm>, last accessed 28 January 2011.

patent around the exclusion to methods for treatment of the human body.[26] To illustrate this point, we provide an example of an invention related to a method of treatment that was filed as an international PCT application and examined in Australia and Europe. The first claim in the original PCT filing is:

> A method for treating heterozygous familial hypercholesterolemia in a patient suffering heterozygous familial hypercholesterolemia, comprising administering to the patient (E)-7-(4-fluorophenyl)-6-isopropyl-2-[methyl(methylsulfonyl)amino]pyrimidin-5-yl] (3R,5S)-3,5-dihydroxyhept-6-enoic acid or a pharmaceutically acceptable salt thereof.[27]

The Australian grant is a replicate of the PCT filing above,[28] whereas in Europe, where methods of treatment are expressly excluded in the European Patent Convention, the granted claim reads:

> The use of (E)-7-(4-fluorophenyl)-6-isopropyl-2-[methyl(methylsulfonyl)amino]pyrimidin-5-yl] (3R,5S)-3,5-dihydroxyhept-6-enoic acid or a pharmaceutically acceptable salt thereof in the manufacture of a medicament for use in the treatment of heterozygous familial hypercholesterolemia.[29]

In essence, what this means is that for all intents and purposes the same subject matter is claimed.

Speculating on how similar types of claims relating to biological materials could be drafted in Australia, they might included methods or uses of nucleotides sequences in the design of oligos, targeted mutagenesis, gene silencing using non-coding RNA, treatment of disease, method of creating of

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[26] *European Patent Convention*, Art 53(c).

[27] See patent, PCT/GB01/05041, page 16.

[28] See Australian patent numbered 2002214165 B2, pg 16.

[29] See European patent, EP 1339409B1, pg 10.

naturally occurring nucleic acids/amino acids using cells lines, or other such uses specific to a gene or an area of research.[30]

We acknowledge that these Swiss-type claims and direct second use claims are not directly relevant to the biological materials exclusion proposed in the Bill, but the point of including this analysis is to illustrate how claims seeking to avoid the proposed exclusion could be drafted. Anti-avoidance terms have been suggested as a solution to this type of drafting[31] and this suggestion does have merit. Nevertheless, if these downstream claims are still inventive and novel, it is difficult to see how anti-avoidance clauses would achieve their aims, without invalidating what would otherwise be legitimate claims. Without intending to be ironic, what is certain is that anti-avoidance clauses would need extremely careful drafting.

Although our submission on this point is based around the argument that the Bill is too narrow, we are in no way suggesting that the ambit of the Bill should be expanded. What we are saying is that specific exclusions from patenting will rarely achieve their intended purpose because they can be worked around by creative drafting. A further difficulty is that courts and patent appeal boards tend to construe specific exclusions narrowly.[32] Hence, we are not at all confident that the Bill will achieve its purpose as drafted, nor that changing the wording would achieve a better outcome.

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[30] It is worth considering how inventive step and novelty, may apply to these generalised methods. However the point here is that as methods they will not be exempt from patentability.

[31] Evidence to Senate Community Affairs Committee, Inquiry into Gene Patents, Senate, Canberra, Thursday 20 August 2009, pgs 6-9 (Dr Peter Drahos) CA20-21 and Dr Hazel Moir, Response to Questions, Submission 20, to the Senate Community Affairs Committee, Inquiry into Gene Patents, received 19/9/09, 6-9.

[32] See, for example, *Plant Genetic Systems* T356/93 (1995) OJEPO 545 at [8].

THE BILL IS TOO BLUNT AN INSTRUMENT

In our submission to the ACIP Patentable Subject Matter Issues Paper we highlighted the dual function of the patent system in encouraging innovation and dissemination of knowledge. We expressed the viewpoint that questions relating to optimal strategies for innovation and dissemination of knowledge cannot be answered solely by imposing limitations on inherently patentable subject matter. Similarly, we doubt whether excluding specific fields of technology from patenting would solve the innovation-dissemination conundrum in those fields either. Rather, a more holistic approach is required.

The need for holistic patent law and policy reform

Each individual invention that satisfies the requirement of being an invention in a field of technology should be rigorously examined in accordance with the usual criteria of subject matter, novelty, inventive step and industrial applicability. The disclosure and claiming requirements should also be rigorously examined. The proposed amendments to the *Patents Act* canvassed in the Draft Intellectual Property Laws Amendment (Raising the Bar) Bill 2011 would increase the stringency of some of these requirements, although more perhaps needs to be done with regard to the inventive step requirement to bring it in line with other jurisdictions, particularly the US and Europe.[33] We submit that there are also strong grounds for limiting patents to use-bound claims and that this issue warrants much deeper analysis.

As noted in *Venturous Australia: Building Strength in Innovation,* which reviewed the national innovation system in Australia, patent law should be reviewed to ensure that the inventive steps required to qualify for patents

[33] For example, see *KSR v Teleflex,* 550 U.S. 398 (2007) and its effect on the biotech case *Ex parte Kubin*, 83 USPQ2d 1410.

are considerable and that resulting patents are well defined.[34] But we agree with the Report that it is not clear that a revision of patentable subject matter in isolation can address the fundamental problems. We submit that it is asking too much to expect that blanket bans on particular subject matter will address concerns about the role of the patent system in facilitating innovation and dissemination of knowledge.

It is important to acknowledge that there are other statutory tools for alleviating hold ups and anticommons risks post-grant, such as compulsory licensing, Crown use, licensing guidelines, competition law as well other initiatives such as patent pooling and clearinghouse mechanisms. We also believe that it is desirable to explore the need to create express exemptions for research and diagnostic use (we alluded to this point in our earlier discussion relating to our concern that the Bill is too narrow). It is equally important to recognize that ex-ante policy decisions must to be made by governments, funding agencies, universities and other research institutions and industry as to whether or not patenting is the optimal strategy for innovation and dissemination of knowledge, both for fields of technology and for individual inventions. These bodies should also be exploring options for creating licensing guidelines and requirements for greater transparency in licensing, as recommended in the SACGHS report.

Nevertheless, we do recognise that the patentable subject matter requirement has a legitimate role to play in facilitating innovation and dissemination of knowledge and that more guidance may need to be provided to patent examiners with regard to satisfaction of this requirement, particularly in emerging fields of technology. Satisfaction of the technicality and physicality invention requirements are particularly problematic under current Australian law. The difficulty in Australia is that there is an

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[34] Cutler & Company Pty Ltd, *Venturous Australia: Building Strengths in Innovation* (2008) Recommendation 7.2.

insufficient body of case law to guide examiners in new areas of technology. We submit that assistance could be provided in the form of guidelines rather than specific legislative exclusions. We submit that further assistance may need to be provided to patent examiners in difficult cases. For example, patent examiners could be provided with the option of sending difficult cases to an expert review panel or sending them out for peer review.

The particular problem of speculative claims and unduly broad claims

Speculative claims, for the purposes of this submission, are claims with aspects that at the time of filing cannot actually be achieved by the patentee. Unduly broad claims are claims in which each aspect of the claim can be fulfilled but the claims are drafted in such a way that they assert more uses of the invention than enabled by the description of the invention in the patent specification.

The patent numbered 324105 and titled 'NANBV Diagnostics and Vaccines'[35] has now expired. NANBV is an acronym that was replaced by the name 'hepatitis C virus' after the virus was discovered; it is now simply known as HCV. Throughout the life of the patent and into its expiration, it was exposed to criticism for including both speculative claims and unduly broad claims.[36]

Speculative claims

The initial claims in patent 324105 included a claim to 'a vaccine for treatment of HCV infection comprising an immunogenic polypeptide containing an HCV epitope wherein the immunogenic polypeptide is present in a pharmacologically effective dose in a pharmaceutically acceptable

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[35] See Australia patent numbered, AU 324105 B2.

[36] See for example, Senator Heffernan's, Submission No 76 to the Senate Community Affairs References Committee, Inquiry into Gene Patents, 13-17; Luigi Palombi, *Gene Cartels: Biotech Patents in the Age of Free Trade* (Scribe Publications, 1st ed, 2009) Chapter 9.

excipient'.[37] Construction of patent claims is a complex skill and is influenced by a number of factors. Nevertheless, a clear issue that arises from the claim for a HCV vaccine is the patent owner never had the vaccine in his or her possession when the patent was filed (nor since, for that matter).

It is worth noting that the claims were voluntarily amended in 1997, and the claim to a HCV vaccine (amongst other claims) was removed. Outwardly this makes an analysis of such claims redundant. However, since the claim was never struck out by the Commissioner of Patents or a court, it is relevant to assess how it came to exist and how the Bill's amendments or other suggested *Patents Act* amendments could cure such a specious and illogical outcome. Like the BRCA gene based claims, the removal of this type of claim is also a primary motivation for the Bill and it is regularly raised in critiques of gene patenting.[38]

A pertinent question for this Committee in its consideration of the Bill is whether the claim to a vaccine would be unpatentable if both Houses passed the Bill as drafted. Earlier in this submission, we discussed the construction of the proposed exclusion and demonstrated that its intended width is uncertain. The claim to the HCV vaccine in the 324105 patent claims an epitope. For virus vaccines, an epitope is often a specific sequence of protein on the protein coat of the virus that is capable of inducing an immune response. The protein sequence of the epitope is therefore most likely to be encoded by the virus genome and hence it is representative of a naturally occurring sequence (in much the same way as the Gardasil HPV vaccine above). This ostensibly means that the claim would be invalid under the new exclusion. However, the particular claim in issue in 324105 also includes (amid other things) an excipient, which is a substance that forms a vehicle

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[37] Australia patent numbered AU 324105 B2, claim 32

[38] See Senator Heffernan's, Submission No 76 to the Senate Community Affairs References Committee, Inquiry into Gene Patents, 13-17; Luigi Palombi, *Gene Cartels: Biotech Patents in the Age of Free Trade* (Scribe Publications, 1st ed, 2009) Chapter 9.

for a drug and often keeps the active ingredient stable. In our submission, this would mean that a future claim of this nature is not just for biological material and therefore such a claim would still be valid even if the Bill were passed.

An area of patent law that has received some attention of late, and would likely rectify such speculative claims is fair basing. Current Australian fair basing law[39] is essentially interpreted in the same way as the fair basing requirement under the *Patents Act 1952* (Cth) which applied when the HCV patent was evaluated. The requirement of fair basing has been interpreted to mean that there must be consistency between what is claimed as an invention and what is disclosed in the description. Specifically, it is a narrow question of whether the 'claim as expressed, travels beyond the matter disclosed in the specification'.[40] The High Court has held that this is assessment of form, not substance and is a simple question of whether the terms in the claims are discussed in the description.[41]

The claim for a HCV vaccine includes the following features: immunogenic polypeptides, HCV epitopes, pharmacologically effective doses and pharmaceutical excipients. Each aspect is mentioned in the specification, and as such it would appear that the fair basing requirement has been correctly applied, irrespective of the incongruous outcome. This illustrates that there is a serious problem with the fair basing test, as currently applied in Australia. We understand that the Draft Intellectual Property Laws Amendment (Raising the Bar) Bill 2011 will include changes to the fair basing requirement. Should the amendment introduce a concept of 'support',

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[39] Fair basing under the *Patents Act 1990* (Cth) s 40(3) is, 'The claim or claims must be clear and succinct and fairly based on the matter described in the specification' and under the *Patents Act 1958* (Cth) s 40(2) is 'The claim or claims shall be clear and succinct and shall be fairly based on the matter described in the specification'.

[40] *Lockwood Security v Doric Products* (2004) 217 CLR 274, 310.

[41] Kathy Bowrey, Michael Handler and Dianne Nicol, *Australian Intellectual Property Law* (Oxford University Press, 1st ed 2010) 486-494.

requiring that the disclosure in the specification supports the claim, akin to the enablement requirement in the UK as demonstrated in *Biogen Inv v Medeva Plc*[42] (*Biogen*), then we believe a different outcome would probably result.

In the UK, the support requirement, as explain in *Biogen,* may not be satisfied in a patent application in a number of ways. Most relevantly to this analysis, 'the patent might claim results which it does not enable'.[43] It is a deeper, more nuanced approach than the current Australian assessment, assessing whether the description provides adequate directions on how to put the invention into practice. A direct outcome of this is that it also has the effect of rewarding the inventor with a monopoly based squarely on what they have invented.

If this concept of support had been included in Australian patent law, than in an assessment of the claim for the HCV vaccine an examiner would have assessed each integer as mentioned above but would also look beyond this. For integers such as pharmacologically effective dose, the patent lists a range from 5 to 250 micrograms of antigen dose with a primary course of between 1 and 10 doses[44] and for excipients, it just lists a common range.[45] There is almost no guidance on issues related to human pathology, no suggestion of what works best, what has been successful or even what works. On this grounding it could therefore be envisaged that the claim for a vaccine would have been invalid for want of fair basis; it also seems to suggest that the inventor was not in possession of the vaccine when the claim was made.

Taking into account the negative effects of the Bill, as detailed above, and acknowledging that the s 18(2) amendment would not necessarily invalidate

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[42] *Biogen Inc v Medeva Plc* [1997] RPC 1.

[43] Ibid, 51.

[44] Australia patent numbered, AU 324105 B2, pg 44.

[45] Australia patent numbered, AU 324105 B2, pg 43.

the claim for a vaccine to HCV, we believe that perhaps the optimal solution for speculative claims is looking to IP Australia's fair basing amendments.

Unduly Broad Claims

Prior to 1997, the original first claim in 324105 was to 'a purified HCV polynucleotide'. It was subsequently replaced with:

> A polypeptide in substantially isolated form comprising a contiguous sequence of at least 10 amino acids encoded by the genome of hepatitis C virus (HCV) and comprising an HCV antigenic determinant, wherein HCV is characterized (sic) by:
>
> (i) a positive stranded RNA genome;
> (ii) said genome comprising an open reading frame (ORF) encoding
> (iii) said polyprotein comprising an amino acid sequence having at least 40% homology to the 859 amino acid sequence in Figure 14.'

The new claim 1 is a narrower claim, yet it can still be interpreted to be unduly broad because HCV is defined to include positive stranded genomes that encode proteins with 40% homology to the listed 859 amino acids. Using computer technology, we have estimated that 40% homology in positive stranded RNA genomes with 10 sequential amino acids from the list of 859 amino acids includes more than one protein in HCV, but also proteins in GB viruses A, B, C and D,[46] bovine viral diarrhoea virus, classical swine fever virus (not to be confused with swine flu), hog cholera virus and dengue fever virus.[47] Apart from HCV, none of these viruses is even discussed in the patent, yet because the claim is so broad, the patent owner has proprietary claims to the proteins in these other virus; a paradigm example of an unduly broad claim.

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[46] These are hepatitis-type viruses, previously known as Hepatitis G viruses.

[47] This simple piece of research was completed by BLASTing (Basic Local Alignment Search Tool) at http://blast.ncbi.nlm.nih.gov/Blast.cgi. The sequencing in figure 14 in patent 324105 was used to compare sequences in the publically available database. By BLASTing for these viruses specifically, the required level of homology can be observed.

We believe that the Bill's amendments probably do represent a solution to this specific type of unduly broad problem. In 324105's case, both the original and amended claims make reference to their peptides being encoded by the HCV genome. This clearly indicates that the sequence is identical to that occurring in nature and it therefore provides a useful example of the types of claims that, if claimed after this Bill was passed (should this outcome this eventuate), would not be patentable because they fall within the biological materials prohibition (the claim to an 'antigenic determinant' would not really effect this interpretation because the antigenic determinant would be an intrinsic product of the sequence).

In sections above we have demonstrated that it is quite likely that the Bill will have negative effects on the Australian biotechnology industry. In addition we have also demonstrated that various outcomes intended by this Bill will unlikely be achieved. Therefore, despite the fact that the Bill's amendments could result in future claims analogous to 324105 protein claims being unpatentable, we believe that there are more nuanced, logical and orthodox solutions that do not encompass such risks, with particular focus on the sufficiency requirement.

As with the requirement for fair basing under the 1990 *Patents Act*, the current requirement for 'sufficiency'[48] is effectively the same as in the *Patents Act 1952* (Cth). Sufficiency has been interpreted by the High Court to require only that the specification enables a practitioner in the art to make

[48] Sufficiency under the *Patents Act 1990* (Cth) s 40(2)(a) is, 'A complete specification must describe the invention fully, including the best method known to the applicant of performing the invention' and under the *Patents Act 1952* (Cth) s 40(1)(a) is, 'A complete specification shall fully describe the invention, including the best method of performing the invention which is known to the applicant'.

something under each claim without new inventions or prolonged study.[49] In application to the HCV peptide claims, the claim to proteins across organisms is valid as long as patent discloses how to isolate on protein from one organism.

Various commentators have called for amendments to this law[50] and the current Draft Intellectual Property Laws Amendment (Raising the Bar) Bill 2011 is likely to contain such provision. From previous IP Australia Consultation Papers, it appears likely that the provision will require that the specification enables the skilled person to be able to understand and make the inventions across the full scope of the claim, not just *something* within it. The outcome of such a change is three fold: 1. not granting a patentee a monopoly beyond knowledge that they disclose to the public; 2. removing impediments to subsequent researchers; and 3. more closely aligning our laws with other dominant trading partners and international treaties; including the European Patent Convention,[51] the Patent Cooperation Treaty[52] and UK patent legislation.[53] If this amendment to the sufficiency requirement is passed we believe that future claims similar to those in 324105 would not be granted. To be valid, the claims would have to be drafted to align them with the inventor's contribution to the art.

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[49] *Lockwood Security Products Pty Ltd v Doric Products Pty Ltd* (2004) 217 CLR 274, 297; *Kimberly-Clark Australia Pty Ltd v Arico Trading International Pty Ltd* (2001) 207 CLR 1, 17 (emphasis added).

[50] See for example, Senator Heffernan's, Submission No 76 to the Senate Community Affairs References Committee, Inquiry into Gene Patents, 29; Dr Hazel Moir, Response to Senator the Hon Heffernan's submission no 76, Submission 20, to the Senate Community Affairs Committee, Inquiry into Gene Patents, received 16/9/09, 6.

[51] *Convention on the Grant of European Patents (European Patent Convention)*, opened for signature 5 October 1973, 1065 UNTS 199 (entered into force 7 October 1977) as interpreted by European Patent Office (EPO), Board of Appeal decision T 409/91, OJ 1994, 653.

[52] *Patent Cooperation Treaty*, opened for signature 19 June 1970, [1980] ATS 6 (entered into force 24 January 1978) get specific section

[53] *Patents Act 1977* (UK), s 14(3) as interpreted by *Biogen Inc v Medeva plc* [1997] RPC 1, 50 and *Generics (UK) Ltd v H Lundbeck A/S* [2008] RPC 19, get pinpoint reference and double check this citation.

It is also worth noting that fair basing and sufficiency (with the Raising the Bar amendments) are similar in many respects and more often than not, probably rise and fall together. Indeed, UK patent law only contains sufficiency. By way of contrast in US and European legislation, written description, enablement and best method of performing the invention allow analogous arguments against for broad and speculative claims.[54] Lastly, the Raising the Bar Bill is also likely to include amendments to the standard of proof by which examiners assess patent applications. The current standard of proof for examination is the low benefit of the doubt requirement, with the benefit falling to the applicant. Current suggestions to increase the certainty of patents include increasing the required standard of proof to the 'balance of probabilities'.[55] How exactly this will affect examination remains to be seen. However, it is certainly envisioned that examiners would be expected to request amendments to speculative and broad claims.

THE EXPRESS INCLUSION OF THE SECTION 6 PROVISO IS UNWARRANTED

Items 1 and 2 of the Schedule to the Bill would amend the requirement that an invention be 'a manner of manufacture within the meaning of section 6 of the Statute of Monopolies' to read 'a manner of manufacture within the **full** meaning**, including the proviso,** of section 6 of the Statute of Monopolies' (emphasis added). We take the view that these amendments to ss 18(1)(a) and 18(1A)(a) will add nothing to the development or state of the law relating to 'manner of manufacture' and would not achieve any paradigm shift in the relevance of social and ethical dimensions to determinations of patentability. It is ambiguity as to the *scope and content* of the proviso, rather

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[54] Kathy Bowrey, Michael Handler and Dianne Nicol, *Australian Intellectual Property Law* (Oxford University Press, 1st ed 2010) 494.

[55] IP Australia, *Getting the Balance Right*, IP Australia Consultation Paper, March 2009, 15.

than its applicability, which gives rise to difficulties in this area and it is to that ambiguity which any useful reform ought to be addressed.

Proviso already incorporated into the manner of manufacture test

It appears clear from the case law that the proviso to s 6, including the question of whether the impugned invention would be 'generally inconvenient', is incorporated into determinations of validity under the *Patents Act*.[56]

In the watershed *NRDC* decision, the High Court said:[57]

> It is of the first importance to remember always that the Patents Act 1952-1955 (Cth)… defines the word 'invention', not by direct explication and in the language of its own day, not yet by carrying forward the usage of the period in which the Statute of Monopolies was passed, but by reference to the established ambit of s 6 of that Statute… The word 'manufacture' finds a place in the [*Patents Act 1952* (Cth)], not as a word intended to reduce a question of patentability to a question of verbal interpretation, but simply as the general title found in the Statute of Monopolies for the whole category under which all grants of patents which may be made in accordance with the developed principles of patent law are to be subsumed...The right question is: 'Is this a proper subject of letters patent according to the principles which have been developed for the application of s 6 of the Statute of Monopolies'?

And in *Ramset*, Brennan CJ, Gaudron, McHugh and Gummow JJ cited these passages and noted:[58]

> The Act defines the word 'invention' by reference to 'the established ambit' of s 6 of the Statute of Monopolies…This statute severely restricted the prerogative power to

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[56] *Anaesthetic Supplies Pty Ltd v Rescare Ltd* (1994) 50 FCR 1 ('*Rescare*'); *Bristol-Myers Squibb Co v F H Faulding & Co Ltd* (1998) 41 IPR 467 ('Bristol-Myers'); *National Research Development Corporation v Commissioner of Patents* (1952) 102 CLR 252 ('*NRDC*'). See also *Joos v Commissioner of Patents* (1971-1972) 126 CLR 611 at 623; *Advanced Building Systems Pty Ltd v Ramset Fasteners (Aust) Pty Ltd* (1997-1998) 194 CLR 171 at 183 [15], 190 [34]; [1998] HCA 19 ('*Ramset*').

[57] (1952) 102 CLR 252 at 269.

[58] (1997-1998) 194 CLR 171 at 183[15], 190[34]; [1998] HCA 19.

> grant monopolies but the proviso thereto contained in s 6 formed the basis of subsequent development of patent law.
>
> …
>
> What then was left to provide the doctrinal content of [the 'not an invention' ground of objection under the 1952 Act]? Section 6 of the Statute of Monopolies excluded any manner of new manufacture which was 'contrary to the Law' or 'generally inconvenient.' (footnote omitted)

These general statements support the proposition that the words 'manner of manufacture' were not simply excised from the Statute of Monopolies and 'grafted' onto Australian patent legislation with disregard for their original context.[59] Subsequent case law dealing with arguments surrounding treatment of the human body has clearly accepted the availability of 'general inconvenience' as an aspect of patentability under the *Patents Act*. In *Rescare*, Lockhart J (though not required to decide the point) accepted the availability of 'generally inconvenient' as a ground of objection under the 1952 Act,[60] and Sheppard J expressly accepted that the ground was available under both the 1952 and 1990 Act.[61] Wilcox J accepted[62] that both Acts 'left intact the principles developed by the courts in connection with the application of s 6', but was 'hesitant to introduce [a particular exclusion] by reference to those very general principles'.

In *Bristol-Myers*[63], the Full Federal Court followed the approach to medical process claims taken by the majority in *Rescare*, and implicitly accepted the availability, in an appropriate case, of the 'generally inconvenient' ground of objection. In holding that the impugned inventions could not be said to fall

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[59] See also Barwick CJ in *Joos*, in which the Court held that a 'generally inconvenient' argument was available.

[60] (1994) 50 FCR 1 at 19.

[61] (1994) 50 FCR 1 at 32-33.

[62] (1994) 50 FCR 1 at 42-43.

[63] (1998) 41 IPR 467.

within the 'generally inconvenient' ground, the joint judgment of Black CJ and Lehane J relied on the difficulty in drawing a line between products for treatment of the human body and methods for treating the human body, and the limited extent to which the Parliament addressed the issue of patents relating to the human body in the legislation[64]. As was the case in *Rescare*, it was the scope, rather than the availability of the 'generally inconvenient' ground that was considered unclear. This was expressly recognised by Finkelstein J:[65]

> In what circumstances it was intended that a patent would be invalid because it was mischievous to the State, to the hurt of trade or generally inconvenient, is far from clear…
>
> The relevance of an inquiry into the scope of operation of s 6 of the Statute of Monopolies, and in particular the effect of the proviso, is that in Australia a patentable invention is an invention that 'is a manner of manufacture within the meaning of section 6 of the Statute of Monopolies': see s 18(1)(a) of the Patent Act 1990. The result of that inquiry will determine whether a medical process is a patentable invention.[66]

What emerges from *Rescare* and *Bristol-Myers* is a reluctance by the courts to engage in debate regarding specific issues engaging ethics or social policy concerns, under the broad rubric of general inconvenience. The *Patents Office Manual* expressly recognises this, noting that:[67]

> Arguments based solely on matters of ethics or social policy are not relevant in deciding whether particular subject matter is patentable. These matters are distinct from the law relating to the subject matter of a patent, in particular, the law relating

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[64] (1998) 41 IPR 467 at 473-474.

[65] (1998) 41 IPR 467 at [107], [110].

[66] See further at [128] per Finkelstein J: 'A principled approach to the question whether a medical or surgical process is patentable requires the resolution of two separate issues. First, is such a process 'a manner of new manufacture' within s 6 of the Statute of Monopolies? Secondly, if such a process is 'a manner of new manufacture', **does it fall within the proviso so as to be excluded** from patentability?' (emphasis added)

[67] At [2.9.1.2].

to manner of manufacture. *Anaesthetic Supplies Pty Limited v Rescare Limited* (1994) AIPC 91-076, 28 IPR 383 establishes the principle that it is for Parliament, not the courts or the Patent Office, to decide whether matters of ethics or social policy are to have any impact on what is patentable.

Better options for introducing social and ethical considerations

Although we express no view on the extent to which *Rescare* and *Bristol-Myers* manifest a judicial reticence to engage fully with the potential scope of the proviso,[68] it seems clear that s 6 of the Statute of Monopolies is incorporated in its entirety into the *Patents Act*. In our view, then, the proposed amendments to ss 18(1)(a) and 18(1A)(a) simply effect an otiose legislative reminder to decision-makers of the *existence* of a largely undeveloped area of law, which already forms a part of the 'manner of manufacture' test they presently apply under s 18.

We submit that more productive reform in this area may be achieved in one of two ways. First, Parliament could provide express legislative guidance as to how specific social and ethical concerns should impact on patentability. In the alternative, Parliament could provide express legislative authorisation for the judiciary to engage with these issues. The latter would provide a more flexible and adaptive solution, albeit one which develops on a case-by-case basis. We note that the ACIP report on patentable subject matter recommended this latter approach, together with the removal of the general inconvenience proviso. We discuss this issue further in the next section of this submission, dealing with international aspects of patent law.

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[68] Compare *Rolls-Royce Ltd's Application* [1963] RPC 251, where Lloyd-Jacob J indicated (at 255) a willingness to reject an application for a method to reduce engine noise during aircraft takeoff on the basis that '[t]he responsibility of a pilot of an aircraft in flight carrying scores of passengers is already sufficiently onerous without adding to his burden the task of avoiding infringement of a statutory monopoly in the operation of his standard engine controls…'. See also *Re Eli Lilly & Cos Application* [1975] RPC 438; *Re Upjohn Co (Roberts') Application* [1977] RPC 94.

THE BILL MAY BE CONTRARY TO AUSTRALIA'S INTERNATIONAL OBLIGATIONS AND INTERNATIONAL NORMS

The Agreement on Trade-related Aspects of Intellectual Property Rights (TRIPS) and the Australia-United States Free Trade Agreement provide the most important international frameworks within which Australian intellectual property laws operate. Article 27(1) of TRIPS prescribes that 'patents shall be available for any inventions, whether products or processes, in all fields of technology …'. On one view, the exclusion of biological materials proposed in this Bill is not contrary to the requirement that patents are available for inventions in all fields because biological materials are not inventions. There is no Australian case law on point in respect of this matter. Legislation and case law from other jurisdictions also fails to provide guidance.

As noted by Senator Heffernan in his submission to the Senate Community Affairs Committee inquiry, the only patent legislation that expressly declares biological materials to be patentable inventions is the European Patent Convention (EPC) and mirror legislation of EPC signatories. Decisions of the European Patent Office Boards of Appeals relating to the BRCA patents clearly show that gene sequences are patentable subject matter in that jurisdiction.[69] Patents have issued for biological materials in Europe and many other jurisdictions, and decisions like the US Supreme Court majority judgment in *Diamond v Chakrabarty*[70] illustrate that there is nothing inherently unpatentable about biological materials per se, provided that they

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[69] *Breast and Ovarian Cancer/University of Utah Research Foundation*. 27 September 2007; *Mutation/University of Utah.* 13 November 2008; *Method for Diagnosing/University of Utah Research Foundation*, 19 November 2008. For discussion of these decisions see: Dianne Nicol, 'Are the Courts Solving the Emerging Challenges of Biotech Patents?' in: Kathy Bowrey, Michael Handler and Dianne Nicol, *Emerging Challenges in Intellectual Property* (Melbourne: Oxford University Press; in press).

[70] 447 US 303, 309 (1980).

fulfil the criteria required by the court. For example, in *Diamond v Chakrabarty,* the Supreme Court required that:[71]

> the patentee has produced a new [biological material] with markedly different characteristics from any found in nature and one having the potential for significant utility. His discovery is not nature's handiwork but his own…

There has been scant opportunity for judicial consideration of the validity of patents for biological materials that are identical or substantially identical to those existing in nature. There is litigation currently before the US courts involving a challenge to a number of the US patents relating to the BRCA genes that may provide some guidance in this regard. At first instance, Sweet J held that the claimed gene sequences do not satisfy the *Chakrabarty* test.[72] However, as the appeal to the Federal Circuit has not yet been heard, the final outcome of that litigation is uncertain.

It is clearly the case that many patents have issued for biological materials (particularly gene patents), and it is also accepted in some jurisdictions (particularly the US[73]) that there is a presumption of validity until a patent is held to be invalid. On this basis, where there is no express exclusion of biological materials that are identical or substantially identical to those existing in nature and where there is no judicial authority as to their invalidity, it could be argued that there is a presumption that they are inventions within the sense used in Article 27(1) of TRIPS. This presumption could be reversed by an express exclusion or by judicial authority to the contrary. It is quite another matter to determine whether this poses a serious risk to Australia of being exposed to a WTO dispute if the Bill is passed, and it is beyond our expertise to advise on this risk.

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[71] Extracted from *Diamond v Chakrabarty* at 301, at 117 in *AMP v USPTO.*

[72] *Association for Molecular Pathology v United States Patent and Trademark Office* 2010 U.S. Dist. LEXIS 35418 (2010).

[73] See, for example, US patent law 35 U.S.C. 282

It is not too fanciful to suppose that in the Cancer Voices litigation[74] currently before the Australian courts a finding could be made that isolated gene sequences/polymorphisms satisfy the requirements of an invention. If this situation arises then the exclusion of biological materials proposed in the Bill would be contrary to Australia's obligations TRIPs Article 27.1.

Some nations do expressly prohibit patenting of biological materials. For example, Article 10 of the Brazilian Patent Law[75] includes in its list of matter not considered to be inventions:

> natural living beings, in whole or in part, and biological material**,** including the genome or germ plasm of any natural living being, when found in nature or isolated therefrom, and natural biological processes.

Mexico, Argentina and the Andean Community have similar provisions in their patent legislation, suggesting that there is a developing international norm of exclusion of biological materials. However, it should be noted that in all of these countries concern has been expressed about access to their natural resources by foreign companies, actions often referred to as biopiracy.[76] It is probably fair to say that legislative action to exclude biological materials from patenting in these countries has been taken largely in response to the threat of biopiracy (it should also be noted that none of these countries have an exclusion as broad as the one proposed in the Bill). Australian is in a different situation from these countries. Though Australia is a mega-biodiverse country, it also has an indigenous biotechnology industry that is capable of utilizing the unique attributes of these natural

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[74] *Cancer Voices v Myriad Genetics*. Federal Court of Australia File: NSD643/2010. Current hearing date is set for 19 September 2011.

[75] Industrial Property Law N° 9279/96 of May 14, 1996, as amended by Law 10.196, of February 14, 2001.

[76] See, for example, Marcelo A.G. Bardi, Evelyn Gutie´rrez-Oppe, and Rodolfo Politano, 'Traditional Knowledge Products in Latin America and Their Misappropriation' (2010) *Journal of Intellectual Property Law & Practice* doi: 10.1093/jiplp/jpq153.

resources for the benefit of the nation. Hence, if there is an emerging norm of excluding biological materials from patenting in developing and least developed countries, this does not necessarily provide guidance to Australia as to how out patent law should develop. Rather, we should look to patent laws of other countries that have active biotechnology industries and ensure that our industry is not placed at a competitive disadvantage.

Other provisions in Article 27 of TRIPS allow certain subject matter to be excluded from patenting even though it would otherwise satisfy the requirement of being an invention. Article 27(2) is relevant when considering the extent to which matters of ethics and public policy can be raised in relation to patent validity. While there may be good reasons for dealing with ethical concerns in patent law, Article 27(2) imposes the limitation that such concerns must only relate to commercial exploitation of the invention. It is important to separate out ethical concerns relating to patenting of technology and ethical concerns relating to the technology itself. The latter should not be dealt with through the patent system but through direct regulation of research and development activities. But there will be some instances where it would be contrary to public policy or morality to allow the patent system to be used to facilitate the commercial development of certain technologies. We expect that, as a general rule, few patent applications will fall foul of an exclusion based on these grounds. Nevertheless, such an exclusion to be explicitly could be provided for in our patent legislation. Article 6 of the European Biotechnology Directive provides some useful examples of the types of subject matter that should be considered to be unpatentable on these grounds:

> (a) processes for cloning human beings;
>
> (b) processes for modifying the germ line genetic identity of human beings;
>
> (c) uses of human embryos for industrial or commercial purposes;
>
> (d) processes for modifying the genetic identity of animals which are likely to cause

them suffering without any substantial medical benefit to man or animal, and also animals resulting from such processes.

Article 27(3) allows parties to exclude diagnostic, therapeutic and surgical methods for the treatment of humans or animals and plants and animals, but not microorganisms. Although these provisions are not directly relevant to the Bill, one point to consider whether the exclusion of cells (which come within the definition of biological materials in the Bill) offends the provision in Article 27(3)(b) that microorganisms may not be excluded.

THE BILL IS TOO LATE, REDUNDANT, SYMBOLIC AND EXCEPTIONALIST

Concerns relating to these points were raised in the executive summary and we believe that these concerns speak for themselves. However, we are happy to provide further information if required by the Committee.