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Submission to Legal and Constitutional Affairs Australian Senate On Patent Amendment (Human Genes and Biological Materials) Bill 2010

Introduction

1. I am a retired New Zealand/Australian patent attorney who maintains an active interest in intellectual property law reform using my forty plus years of experience. In 2000/01 a royal commission in New Zealand considered the broad policy issues in this country arising from genetic modification. One of the issues they considered was intellectual property policy. I led a team that prepared written submissions on behalf of the New Zealand Institute of Patent Attorneys. I also gave oral evidence as an expert witness over the course of a day to the royal commission.

2. The report of the commission[1] concluded, in respect of intellectual property rights (IPRs):

> *"The Commission sees a need to address some tensions or gaps, notably in the exemption for patenting of human being and their biological processes, and the development of an appropriate framework for the protection of traditional knowledge and taonga of Maori.* ***However, we are not persuaded that the IPR system is antithetical to the appropriate development and regulation of genetic modification***.[2] (Emphasis added)

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[1] Report of the Royal Commission on Genetic Modification, 2001, ISBN 0-477-01944-7.
[2] *Ibid.*, Chapter 10, paragraph 118, page 296.

3. The debate on gene patents in Australia (ten years after the New Zealand GM Royal Commission) is, in the words of the much quoted American baseball legend, Yogi Berra, "Deja vu all over again."

4. I urge this committee to recommend that the Patent Amendment (Human Genes and Biological Materials) Bill 2010 should go no further for the following reasons:

    - The Community Affairs Committee of the Senate investigated over two years the impacts of gene patents on healthcare, medical research and the health and wellbeing of Australians. In spite of hearing of cases of care and research being impeded, "the evidence did not show that gene patents are systematically leading to adverse impacts in these areas."[3] In other words, another committee of this senate has already concluded that the bill is not needed.
    - The Advisory Committee on Intellectual Property (ACIP), over the same time period as the Community Affairs Committee, reviewed the broader issue of what ought to be patentable subject matter, and concluded[4] that there should be no exclusion of biological materials.
    - ACIP also recommended that the "method of manufacture" test in the current Act be replaced by a codified "inherent patentability" test without the use of any of the archaic language of the 1623 Statute of Monopolies.[5]
    - The "bedrock principle" that has allegedly been the subject of a legal trick by patent attorneys for the last thirty years[6] is a myth.
    - The exclusion from patentability of biological materials as defined in the bill would exclude a large class of inventions in the field of biotechnology and would also be in violation of Australian international obligations.
    - There are other policy options besides wide subject matter exclusions for addressing perceived adverse effects of patents.
    - On occasion of Julia Gillard's recent visit to New Zealand, Prime Ministers Gillard and Key announced[7] a further step towards a single economic market, the establishment of a single patent examination system. This bill would establish a new difference between the substantive patent laws, going in the opposite direction.

Patent Systems Economics

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[3] *Report of the Community Affairs References Committee on Gene Patents*, November 2010, Commonwealth of Australia, page *xi.* (Senate Report)

[4] *Patentable Subject Matter, Final Report,* Advisory Committee on Intellectual Property, December 2010, part 4.1.2, page 60. (ACIP Report)

[5] ACIP Report, part 3.5.4, page 58.

[6] Senator Heffernan, Second reading speech, Senate Hansard, 24 November 2010, page 2000.

[7] See http://www.ipaustralia.gov.au/resources/news_new.shtml#8

5. The 2008 terms of reference of the Senate Community Affairs Committee asked it to examine the effects of gene patents on healthcare, training and accreditation of healthcare professionals, progress in medical research and the health and wellbeing of the Australian people. All those factors are potentially on the debit side of the effect of patents ledger. What the committee did not address is the broader issue of what a patent system is for, what are the positive effects of a patent system and how do the positive and negative effects balance out.

6. The theoretical basis for patent systems is economic in nature. But the precise economic theories have been a matter for debate over several centuries. One of the most comprehensive reviews of patents and economics is found in a 1958 report by an Austrian/American economist, Fritz Machlup commissioned by a subcommittee of the American senate.[8] Although the report is now more than fifty years old, the economic theories are much older and Machlup's summary and conclusions are as relevant today as they were at the time.

7. Machlup concluded that most arguments for and against patents had been made prior to the twentieth century. When one compares the arguments identified by Machlup[9] with those in the submissions made to the Community Affairs Committee, it becomes apparent the Machlup was right. Although the examples in 2010 were about gene patents, the substance of all the assertions made were the same as those itemised in Machlup's report.

8. Machlup took a radical middle view of the value of a patent system. He concluded:

> *"The literature abounds with discussions of the 'economic consequences' of the patent system, purporting to present definitive judgments, without even stating the assumptions on which the arguments are based, let alone submitting supporting evidence for the actual realization of these assumptions. No economist, on the basis of present knowledge, could possibly state with certainty that the patent system, as it now operates, confers a net benefit or a net loss upon society. The best he can do is to state assumptions and make guesses about the extent to which reality corresponds to these assumptions."*[i]

9. Machlup also had views on trying to achieve some sort of certainty in the definition of what is patentable. He said:

> *"The desire to ensure fixed and unchanging standards of patentability is probably inconsistent with the fact that, as science and technology progress, evermore can and must be demanded of the inventors' abilities. And it is after all*

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[8] Fritz Machlup, *An Economic Review of the Patent System,* Study No. 15 of the Subcommittee on Patents, Trademarks, and Copyrights of the Senate Committee on the Judiciary, 85th Cong., 2nd Session, 1958.

[9] Machlup, pages 20 to 44.

> *the "difficulty" of inventing which determines the relative scarcity of invention and, consequently, provides the rationale for the policy of creating an extra stimulus for inventive effort. This presupposes, however, as do most other problems under discussion, that it is invention rather than enterprising innovation which the patent system is supposed to encourage.* ***If society aims at stimulating innovation and at attracting venture capital into pioneering investment, then the controversies about the nature of "inventions" are beside the point. After all, the innovators' risks are not proportional to the costs and results of the inventive efforts****."* [10] (Emphasis added)

10. Machlup concluded his analysis by saying that if he had started without an existing patent system, it would be irresponsible to recommend establishing one on the basis of his understanding of how a patent system worked; but given that there have been patent systems in place for a very long time it would be equally irresponsible to recommend repealing them.[11]

11. He then added:

> *"While economic analysis does not yet provide a basis for choosing between 'all and nothing,' it does provide a sufficiently firm basis for decisions about 'a little more or a little less' of various ingredients of the patent system. Factual data of various kinds may be needed even before some of these decisions can be made with confidence. But a team of well-trained economic researchers and analysts should be able to obtain enough information to reach competent conclusions on questions of patent reform. The kind of analysis that could form the framework for such research has been indicated in the present study."*[12]

12. The policy reasons for this bill do precisely what Machlup warned against, they:

    - accept at face value assertions of the "economic consequences" of gene patents without stating the assumptions upon which they are based or providing any supportive evidence
    - seek to ensure a fixed and unchanging standard of patentability
    - proceed without the factual data needed to make the decisions with any confidence.

13. The Community Affairs Committee noted that it had received complaints of healthcare of medical research being impeded, but it did not accept at face value the assertion that gene patents were systematically leading to adverse impacts.[13] Instead, the committee expressed its frustration at "the lack of comprehensive, systematic and accessible data in relation to gene patents." Its first two

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[10] Machlup. page 9.
[11] Machlup, pages 79 and 80.
[12] Machlup, page 80.
[13] *Gene Patents,* Report of the Community Affairs References Committee, Australian Senate (November 2010), page xi.

recommendations were seek to improve the quality and availability of relevant data. But this bill is driven by assertions without supporting evidence.

14. Machlup also noted a lack of relevant data, but he recognised that while the "output restrictions based on patents are primary effects and testable; the incentive effects are secondary and more conjectural."[14] What the Community Affairs Committee heard was evidence of what costs were or might be of the exercise of the exclusive rights of patentees – the testable primary effects. What will be more difficult to determine are the incentive effects. Would the genetic test in question have been made available in Australia without the patent in question? Or, more broadly, would investors be likely to invest in innovation in biotechnology in the absence of patents for the biological materials the subject of this bill? These secondary and more conjectural effects are the critical ones, and the ones that are not possible to measure in advance. But in the view of Senator Heffernan, the submissions about these incentive effects, "Do not pass muster." [15]

15. Senator Heffernan's reference to a "bedrock principle" in his speech demonstrates that a policy goal of this bill is to achieve a fixed and unchanging standard of patentable subject matter. But, as Machlup pointed out, that approach is inconsistent with the fact that inventions, by their very nature, will always render any attempt to define "invention" obsolete. The many ways in which "manner of new manufacture" has been interpreted and reinterpreted since 1623 has been exhaustively summarised by ACIP.[16] It is not apparent from a reading of that summary which of the alternative interpretations constitutes the bedrock principle Senator Heffernan was referring to. But it is apparent that Machlup's observation about the futility of seeking a fixed and unchanging standard of patentability has been ignored.

ACIP Final Report

16. The ACIP Report is the result of a process along the lines of that recommended by Machlup, discussed above. ACIP addressed the community and social effects of the patent system while at the same time did not lose sight of the incentive effects.

17. ACIP did consider the effects of gene patents and genetic technologies within the

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[14] Machlup. page 73.

[15] [15] Senator Heffernan, 2nd reading debate on Bill. http://parlinfo.aph.gov.au/parlInfo/search/display/display.w3p;query=BillId_Phrase%3A%22s814%22%20Dataset%3Ahansardr,hansards%20Title%3A%22second%20reading%22;rec=0

[16] *Patentable Subject Matter: Issues Paper,* Advisory Council on Intellectual Property (July 2008), Chapters 6 and 7, pages 17 to 31.

broader contest of patentable subject matter. The ACIP Report endorsed the reluctance of the Community Affairs Committee to introduce a subject matter exclusion. It recognised that while the introduction of patents for genetic technologies might have effects on the provision of healthcare, these effects were not different in substance from the effects of patents for pharmaceuticals on the provision of healthcare. It pointed out that the effects on healthcare had been dealt with without at the same time removing the incentive effect of bringing the technologies from the lab to the marketplace.

18. The relevant passage reads:

> *"The Australian government has implemented programs to ensure that medical treatment is available to each individual who requires it, irrespective of the individual's financial means. This is the motivation behind the government's subsidisation of the cost of medical treatment, through the Medicare system. It is also the motivation behind the government's subsidisation of the cost of pharmaceuticals, through the Pharmaceutical Benefits Scheme (PBS). Notably, most of the top-selling pharmaceuticals subsidised by the PBS have been patented. Thus, the government has found a mechanism to support wide access to pharmaceuticals, without removing the innovators' rights to patent those pharmaceuticals. In the event that it is found that patents on other beneficial technologies (for example patents for genes, genetic materials and related technologies) are unduly restricting patient access to diagnostic tests or other medical treatment, the Australian experience with pharmaceuticals suggests that the remedy to the access problem lies with a pricing mechanism, not with removing patent protection for these inventions."*[17]

19. ACIP also recognised the futility of trying to maintain the Statute of Monopolies 1623 "manner of manufacture" test for invention. Its conclusions were:

> *" ... the problems with the 'manner of manufacture' test are not restricted to the obscurity or archaic nature of the language. The language simply does not match the practice that has been applied by Australian courts in relation to patentable subject matter for at least the last 50 years. This leads to a mismatch between the words of the legislation and the principles developed by the courts. For a person reading the legislation, there is no transparency or guidance about the nature of the test. While the legislation tends to lead the reader to the literal words of section 6 of the Statute of Monopolies 1623, the courts have indicated that this is the wrong approach."*[18]

20. Instead of recommending that Australia should remain one of the last diehards relying on a seventeenth century definition of invention to interpret twenty first century technology, ACIP has opted for a test codifying the principles of inherent patentability identified and first applied by the Australian High Court in its landmark *NRDC* decision of 1959. The test is that to be patentable, an invention

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[17] ACIP, *Final Report, Patentable Subject Matter*, December 2010, page 7. (ACIP Final Report)
[18] ACIP Final Report, pages 44 and 45.

should be an artificially created state of affairs in the field of economic endeavour.[19] The test answers many of the criticisms outlined in the ACIP Report while at the same time retaining whatever certainty can be found in the case law around the meaning of the words "manner of manufacture" over the last fifty years.

21. ACIP also considered whether there should be a "generally inconvenient" exclusion to what is patentable subject matter. ACIP were uncertain whether such an exclusion still existed in Australian law, and if it did, what it meant. It concluded that there should be no exclusion based on general inconvenience.[20]

22. In contrast, this bill recommends amending paragraphs 18 (1)(a) and (1A)(a) of the Patents Act 1990 to specify that "manner of manufacture" includes the full proviso of section 6 of the Statute of Monopolies. That means the Act would exclude manners of manufacture that are:

> *"contrary to the law … mischievous to the state by raising prices of commodities at home or hurt of trade or generally inconvenient"*

23. The criticisms in the Final ACIP Report of "generally inconvenient" are even more applicable to the complete1623 list of exclusions.

"Bedrock Principle"

24. In his second reading speech on this bill, Senator Heffernan said:

> *"The bedrock principle of patent law … has been for the past 30 years the subject of a legal trick played by clever patent attorneys. As a result, isolated biological materials … are no longer regarded as products of nature, but as inventions, the product of humankind. This legal hocus-pocus has apparently satisfied IP Australia, the sole regulator of intellectual property in this country. And without even having the legality of this legal trick tested in the Australian courts IP Australia has participated in the subversion of this principle."*

25. However, Senator Heffernan's views on patent law principles are not shared by ACIP. In its options paper,[21] ACIP set out the various interpretations of "manner of manufacture" by Australian courts up to and following 1959. The year 1959 marked a new starting point. The High Court, in its landmark *NRDC* decision,[22] said that an interpretation based on a literal reading of "manner of manufacture" was too narrow to include inventions that could not have been conceived of by the

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[19] ACIP Final Report, pages 57 and 58.
[20] ACIP Final Report, page 51
[21] ACIP*, Patentable Subject Matter: Issues Paper,* July 2008
[22] *National Research Development Corporation v Commissioner of Patents,* (1959) 102 CLR 252. *(NRDC*)

English law drafters of 1623. It advocated asking the question: "Is this a proper subject of letters patent according to the principles which has been developed for the application of s. 6 of the Statute of Monopolies?"

26. The pre-1959 interpretation would have excluded living organisms or anything else that was not a "man made device" from being patented. Under the pre-1959 interpretation, some "biological materials," as defined in this bill, might not have been considered to be patentable. However, under the post-1959 interpretation they are. What is described as a clever legal trick played by patent attorneys for the last thirty years is the legitimate application of the principles of interpretation laid down by the High Court of Australia more than fifty years ago.

27. This bill seeks to fix the standards of patentability back into its 1623 roots. What the High Court recognised in *NRDC* was what Machlup had pointed out in his report a year earlier. It is pointless to try to achieve fixed and unchanging standards of patentability because of the ever-changing advances in science and technology.

International Obligations

28. Under article 27.1 of TRIPS and the corresponding article of its free trade agreement with the US, Australia is obliged to make patent protection available for inventions in all fields of technology. The term "biological materials" in the bill encompasses many inventions in the field of biotechnology. If this bill were passed, Australia would be in violation of its obligation under article 27.1 of TRIPS.

29. Senator Heffernan asserted:

> *"The word 'invention' in both of these agreements is undefined but that does not mean that anything can be the subject of a patent. Whatever the innovation it must be an invention. Biological materials which are identical or substantially identical to what exists in nature are not inventions. They are discoveries and therefore incapable of being inventions."*[23]

30. This is a specious argument. It begs the question of what is a mere discovery. Australia would be seeking to avoid its obligations under international agreements by redefining "invention". Senator Heffernan is right in stating that Australia would be a leader in the world by excluding biological materials. But that does not mean it can avoid its international obligations under the "clever legal trick" of creating a definition of "invention" unique to Australia and not accepted by the rest of the world.

31. The patentability of biological materials was recognised by the enactment of the

[23] Senate Hansard, 24 November 2010, page 2101.

Budapest Treaty[24] over thirty years ago. The treaty provides for the establishment and maintenance of depositories of cultures of microorganisms and other biological materials in support of patents, where a written description would not be sufficient for a third party to put the invention into practice. The types of inventions contemplated are for isolated organisms themselves or their use in applications such as the production of useful metabolites. Biological materials were recognised as inventions before the Budapest treaty was signed – otherwise it would not have been needed.

32. Sections 6, 41 and 42 of the Patents Act 1990 enact Australia's obligations under the Budapest Treaty. The Australian Parliament implicitly acknowledged that biological materials are patentable inventions by including these provisions in the 1990 Act.

Alternatives to Exclusions

33. The Standing Committee on Patents of the World Intellectual Property Organisation commissioned a 2010 review comparing patent subject matter exclusions to exceptions or limitations to patent rights.[25] One of the conclusions of that review was:

> *"Where exclusions and exceptions are genuine alternatives, ... [i]n* many *ways exceptions are likely to offer greater flexibility and nuance. [C]areful thought [should] be given to broader use of exceptions, and … efforts should be made so a*s to *ensure international norms do not stifle th*is *important avenue for calibrating national patent policy."*[26]

34. The exclusion of "biological materials" proposed in this bill is exactly what the author of that report meant by "exclusion". The ACIP Report and the Community Affairs Committee report suggested the use of "exceptions". The ACIP Report suggested a scheme along the lines of the Pharmaceutical Benefits Scheme (as mentioned above) for genetic testing. The Community Affairs Committee noted that the existing crown use provisions of the Patents Act 1990 are a "genuine alternative" to the exclusion and recommended that the government develop clear policies for their use.[27]

35. The ACIP and Community Affairs Committee approaches are fully in tune with Machlup's "sufficiently firm basis for decisions about 'a little more or a little less'

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[24] Budapest Treaty on the International Recognition of the Deposit of Microorganisms for the Purposes of Patent Procedure, Done at Budapest on April 28, 1977, and amended on September 26, 1980. Australia became a treaty country in July 1987.

[25] *Exclusions from Patentability and Exceptions and Limitations to Patentees' Rights,* Prof Lionel Bently, for WIPO Standing Committee on the Law of Patents, SCP/15/3, Annex 1 (2 September 2010).

[26] *Ibid., Page 5.*

[27] Senate Report, Recommendation 11, paragraph 5.185.

of various ingredients of the patent system." This bill threatens to throw the baby out with the bathwater.

Single Economic Market

36. In 1983, New Zealand and Australia first put their respective common market big toes into opposite sides of the Tasman Sea by entering into the Australia New Zealand Closer Economic Relations Treaty (CER). In recognition of this, Julia Gillard awarded the honour of the Order of Australia to the then New Zealand champion of the treaty, Hugh Templeton, during her visit to New Zealand In February 2011.[28]

37. Enthusiasm for CER has waxed and waned over the nearly thirty years of its existence, but both current prime ministers are advocating a single economic market (SEM). Their advocacy is now being acted upon by a single body, the Trans Tasman Outcomes Implementation Group.[29] Among the initiatives being advanced at the moment are to establish a single system to regulate patent attorneys practicing in both countries, and a single patent examination system. The second of these was announced by both prime ministers during the Gillard visit to New Zealand.

38. New Zealand is slowly advancing a process (that began in the mid-1980s) of replacing its 1953 Patents Act. A Patents Bill was introduced by the then Labour-led government in 2008 before the general election that resulted in a National-led government. The 2008 version contained a regulatory part, a procedural part and a substantive law part. In 2009 John Key visited Australia and signed an SEM protocol that included the commitment to a single system for regulating patent attorneys in both countries. That meant the regulatory part of the 2008 bill, which only regulated New Zealand patent attorneys, was redundant. So when the bill was returned to parliament in March 2010, the regulatory part was carved out into a Patent Attorneys Bill. That bill came with the warning that it would be replaced by a bill instituting a trans-Tasman regime.

39. In June 2010, the TTOIG first announced that there would be a "single application process". What the process was became clear with the 18 February 2011 announcement[30] that there would be an integrated patent examination. This announcement renders redundant the New Zealand only procedural part of the 2008 original that still forms a part of the Patents Bill awaiting a second reading in the New Zealand parliament.

40. But it raises a wider question. If the economies of the two countries are

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[28] See http://www.stuff.co.nz/business/4661999/Economic-union-with-Aussie-urged
[29] See http://www.treasury.gov.au/ttoig/default.asp
[30] See http://www.ipaustralia.gov.au/resources/news_new.shtml#8

sufficiently similar that they warrant integrated regulation of patent attorneys, and integrated examination of patent applications why are they not sufficiently simlar to warrant a common substantive patent law?

41. The first two objectives of the SEM listed on the TTOIG website are:

    - Persons in Australia or New Zealand should not have to engage in the same process or provide the same information twice.
    - Measures should deliver substantively the same regulatory outcomes in both countries in the most efficient manner.

42. The first objective would be achieved by a single integrated regulatory system and a single integrated patent examination system. However, an integrated patent examination system will not achieve the second objective. There are already differences in substantive law under New Zealand's 1953 act and Australia's 1990 one. The differences would be even greater if the exclusion in this bill and the patent exclusions currently in the New Zealand Patents Bill were to be enacted.

43. The substantive patent laws of both countries are in the process of change. The New Zealand substantive changes are found in the reported Patents Bill awaiting a second reading. The Australian substantive patents law is also in a state of change. In addition to the amendment proposed in this bill there is a proposal to amend the Patents Act 1990 based on initiatives of IP Australia.[31] That proposal would increase the rigor of patent examination in Australia to be similar to the rigor of the procedures in the New Zealand Bill. The ACIP and Community Affairs proposals are also undergoing review by the Australian government.

44. In the current state of flux of the patent laws of both countries, there has never been a better opportunity to align the substantive patent laws of both countries so that an integrated examination would result in the same outcome in each country. The TTOIG should be reviewing what a common substantive patent law should be before the changes creating greater differences proceed any further.

~ Doug Calhoun
Wellington, New Zealand
24 February 2011

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[31] The Department of the Prime Minister and Cabinet announced that an Intellectual Property Laws Amendment Bill **i**n publication "Legislation Proposed for Introduction in the 2011 Autumn Sittings".