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Submission to Advisory Council On Intellectual Property: Patentable subject Matter

Personal

1. I am a retired patent attorney and IP lawyer. Prior to my retirement at the end of March 2006 I was for 26 years a partner with the firm of AJ Park in Wellington, New Zealand. I was a registered Australian patent attorney under the provisions of the Trans Tasman Mutual Recognition Act.
2. In the course of my career at AJ Park I was active through the New Zealand Institute of Patent Attorneys (NZIPA) and AIPPI in the process of law reform. I was commissioned to do a chapter in the 1990 Ministry of Commerce two-volume study of options for patent law reform. I was an expert witness for NZIPA on the topic of patent law before the Royal Commission on Genetic Modification (GM Commission) in 2000/2001. I have also appeared before many select committees of the New Zealand parliament making submissions on bills relating to various aspects of intellectual property.
3. I have been on the editorial board of the LexisNexis New Zealand Intellectual Property Journal since it began in 1995. In this capacity I have written a number of editorials on patent law reform in New Zealand.
4. The issue of what should be patentable subject matter has been at the core of most debates about the form of any new patent law. The landmark *NRDC* High Court decision in Australia was followed in New Zealand and its principles have been at the forefront of numerous submissions I have made over the years in support of the patentability of my clients' inventions.
5. In short, I have a wealth of experience and a keen interest in sharing my views on this topic with ACIP. I would be happy to participate in further discussions with ACIP if they were considering coming to New Zealand.

Objectives of System

6. There are probably as many economic theories about the bases for patent systems as there are economists who have written on the topic. Part 3 of this discussion paper is a testament to this. The Lampe and Niblett paper mentioned in footnote 6 on page 8 reviews the extensive literature on optimising a patent system. There are a large number of parameters that can be manipulated to achieve any particular outcome. But it seems to me that the key question is, what is the outcome you are seeking to achieve?
7. It was my submission to the GM Commission that New Zealand patent system is based on the social contract theory – in return for exclusive rights to exploit their patented invention for a limited term the inventor has to make the invention available to the public. To ensure that both the Crown and the inventor have maintained their sides of the bargain there is a multitude of checks and balances built into the system. For example, patents in New Zealand are subject to three possible checks to ensure a patentee is entitled to a patent: each application is examined before acceptance; each accepted application is open to opposition by an interested party; and the validity of every granted patent can be challenged in the court.
8. By focussing on the single question of what is the appropriate subject matter, ACIP risks making recommendations that could change the current equilibrium of checks and balances without considering whether or not the current equilibrium is optimal and how the equilibrium would change.
9. A concern of the biotechnology industry is the overlap and interdependency of subject matter of granted patents – the tragedy of the anti-commons. A subject matter approach to solving this problem is to ban patents for gene sequences. It might solve the immediate overlap problem, but it would also seriously undermine investor confidence in the industry.¹
10. There are other ways of adjusting the existing checks and balances in the system. One is to tighten up the scope of what is fairly based on the disclosure. The US Patent and Trademark Office did this with their tightened written description requirements. Another way of dealing with the overlap problem is by providing for dependency licences. Under TRIPS article 31(l), member countries may authorise “ ... the exploitation of a patent ... which cannot be exploited without infringing another patent ... “ under certain conditions. In cases where patentees cannot voluntarily agree on dependency licences such a provision can force a settlement to allow exploitation by both.

TRIPS Agreement

11. The discussion paper suggests that one answer to the rhetorical question I asked in paragraph 6 is a balance between the costs of limiting competition and the

¹ When President Clinton and Prime Minister Blair, during the HUGO human genome mapping research, offered the opinion that undifferentiated gene sequences should not be patentable the biotech stocks on the Nasdaq exchange lost large amounts of value.

- benefits of the availability of new inventions. Those costs are apparently to be quantified within Australia. But that is too narrow an economic outlook. Australia is a trader in a global economy. To enjoy the economic benefits of trading agreements that it has entered into Australia must give effect to the responsibilities it has taken on.
12. When Australia entered into the WTO (Marrakesh) Agreement of 1994 it agreed to have intellectual property laws that conformed to the TRIPS agreement. Indeed, article 7 of TRIPS sets out an economic rationale and a checks and balances basis for the treaty.² Similarly, the Free Trade Agreement with the United States now forms an integral part of the economic considerations in determining the balance.
 13. The discussion paper considers international treaty obligations almost as an afterthought in part 8, rather than as an integral part of the economic considerations and this, in my submission, diminishes their importance.

Section 6 – Statute of Monopolies

14. Before embarking on a consideration of whether a definition of patentable subject matter should be based on section 6 of the Statute of Monopolies, ACIP should be satisfied that section 6 would comply with both TRIPS and the AUSFTA. In my submission, it does not.
15. Section 6 of Statute of Monopolies provides that letters patent may be granted for all "matters of new manufactures" provided that the granting is:
" ... not contrary to the law, nor mischievous to the State, by raising prices at home, or hurt of trade, or generally inconvenient ..."
Section 6 does not define what is a "manner of new manufacture" as such. It only defines the grounds under which patents can be denied for matters of new manufacture.
16. Professor Susy Frankel has argued that the section 6, "...is a legitimate method of domestic law enacting a permitted exclusion under the TRIPS Agreement."³ But the risk in relying on section 6 is that it might be used as a back door way of enacting exclusions beyond what is permitted under TRIPS and under AUSFTA.
17. The generally inconvenient exclusion in section 6 was considered in a 2004 New Zealand Court of Appeal decision on whether a method of medical treatment of humans was patentable.⁴ The majority of the court expressed the opinion that the whole of section 6 forms a part of the definition of invention.⁵ But it qualified this general statement with the acknowledgement⁶ "that a generalised exception to

² *Article 7; The protection and enforcement of intellectual property rights should contribute to the promotion of technological innovation and to the transfer and dissemination of technology, to the mutual advantage of producers and users of technological knowledge and in a manner conducive to social and economic welfare, and to a balance of rights and obligations.*

³ "Lord Cooke and Patents: The Scope of "Invention", Prof. Susy Frankel, Victoria University of Wellington Law Review, Vol. 39, No. 1, 73, at page 80.

⁴ *Pfizer Inc v Commissioner of Patents* [2005] 1 NZLR 362.

⁵ *Ibidem*, paragraph [52].

⁶ *Ibidem*, paragraph [57].

- patentability based on inconvenience could, if broadly interpreted, create a wider exception to patentability than would be permitted under article 27.” It concluded that Parliament would have made it clear if the exception needed to be limited to comply with TRIPS.
18. In a minority opinion in the same case, Anderson P. was not so sure that the New Zealand Parliament was all that prescient. Anderson P. added a caveat that he saw little, if any, scope for excluding inventions on the ground of inconvenience other than inventions for methods of medical treatment of humans.⁷
 19. It is submitted that Anderson P.’s caveat is the correct interpretation and that the New Zealand Parliament did not take into account in 1994 whether the mischievous to the state and generally inconvenient exceptions in the section 6 went beyond what is permitted in articles 27.2 and 27.3 of TRIPS.
 20. The following parts of this submission will consider whether or not the proviso in section 6 of the Statute of Monopolies is compliant with both TRIPS and AUSFTA.

Contrary to Law

21. Although article 27.2 of TRIPS states that member countries may exclude from patentability inventions whose commercial exploitation is contrary to morality or *ordre public*, article 27.2 has a very precise proviso:
“ ... provided that such exclusion is not made merely because the exploitation is prohibited by their law.”
22. Section 50 (1) (a) of the Patents Act 1990, which permits the commissioner to refuse a patent application for inventions the use of which would be contrary to law, does not appear to be in compliance with this proviso of TRIPS.
23. This view is supported by the position taken in New Zealand. In 1994 the New Zealand Patents Act 1953 was amended to comply with TRIPS. Among the changes was the repeal of clause 17 (2) that was the equivalent to section 50 (1) (a).⁸
24. To underline the point, clause 14 (2) of the Patents Bill currently before the New Zealand Parliament, provides:
“For the purposes of subsection (1), commercial exploitation must not be regarded as contrary to public order or morality only because it is prohibited by any law in force in New Zealand.”
25. Article 17.9, paragraph 2 (a) of the AUSFTA has the same proviso as article 27.2 of TRIPS.
26. In the light of the New Zealand interpretation ACIP may well wish to recommend that section 50 (1) (a) ought to be repealed.
27. There would be no point in adding an equivalent to the New Zealand clause 14 (2) into the Australian legislation because the Australian legislation does not have an exclusion of inventions the commercial exploitation of which is contrary to public

⁷ *Ibidem*, paragraph [7].

⁸ The New Zealand Parliament was addressing the express wording section 17 (2) of the 1953 Act rather than section 6 of the Statute of Monopolies in making this change.

order or morality.⁹

Mischievous to the State

28. Examples given in section 6 of manners of new manufacture that are mischievous to the state are those that raise prices at home or hurt trade. Each of these examples goes beyond any exception permitted under articles 27.2 or 27.3 of TRIPS. The immediate fall in the price of a patented medicine once its patent has expired demonstrates that permitting patents for medicines will raise prices at home. But it would be a clear breach of article 27.1 to exclude medicines from being patentable on this ground.
29. It is a bit more difficult to give an example of a patent for a manner of manufacture that would hurt trade, but if a country were permitted to use this as a ground of exclusion it could allow the creation of new non-tariff barriers to trade. A main aim of the Uruguay Round that led to the TRIPS Agreement was to eliminate barriers to trade, not to create new ones or to perpetuate existing ones.

Generally Inconvenient

30. In New Zealand, the Court of Appeal did consider that in the absence of an express exclusion in the Patents Act 1953 of patents for methods of medical treatment of humans, the generally inconvenient exclusion, at least as far as it extended to methods of medical treatment of humans, was permitted under article 27.3 of TRIPS.¹⁰ However, if this ground of exclusion were to be used more broadly to refuse patents for DNA sequences, for example, the exclusion would be discriminating against a particular technology and run afoul of article 27.1 of TRIPS.
31. Professor Frankel suggests¹¹ that an exclusion based on general inconvenience may be equivalent to an exclusion based on *ordre public* or morality. But that suggestion overlooks a very important difference between section 6 of the Statute of Monopolies and article 27.2 of TRIPS. In section 6 the proviso is that if the *granting of a patent* for a manner of new manufacture is generally inconvenient it may be excluded; in contrast, the exclusion under article 27.2 only applies if the *commercial exploitation* of an invention would be contrary to *ordre public* or morality. While there may be some examples where the exclusions are equivalent there will be many others where they are not.

Conclusion on TRIPS and AUSFTA Compliance

32. It will be apparent from the discussion above that there is considerable doubt that the exclusions in the proviso to section 6 of the Statute of Monopolies comply with the exclusions permitted under TRIPS and AUSFTA. There appear to be

⁹ That exclusion is in clause 14 (1) of the New Zealand Bill.

¹⁰ See paragraphs 17 to 19 above.

¹¹ On page 82 in the article noted in footnote 3 above.

- two legislative possibilities to remove this doubt. One is to remove all references to the Statute of Monopolies. The other is to insert a proviso into section 18 (1) (a) of the Patents Act 1990 analogous to clause 14 (2) of the New Zealand Patents Bill 2008. This proviso would state that nothing in section 6 of the Statute of Monopolies would permit the Commissioner of Patents to refuse a patent application on any ground other than one permitted under article 27 of TRIPS and article 17.9 of AUSFTA.
33. The first possibility has the advantage of simplicity because it would eliminate arguments over whether an alleged invention is a manner of manufacture or not and whether it falls within the grounds of exclusion. It has the disadvantage that it leaves behind the body of case law dating back to 1623 of what is a manner of new manufacture. Any patent attorney looking objectively at arguments they have submitted over the years in support of the patentability of an alleged invention would have to say that their clients would have been better off financially without the manner of manufacture exclusions. It is difficult to see how the public have benefited from patent office examiners engaging in such arguments on their behalf. While there is a large legacy, the diverse conclusions various courts have reached over the years would indicate that there is precious little certainty.
34. The second possibility would, by reference, comply with both TRIPS and AUSFTA. But it would leave open the question of what is the area of overlap between the exclusions permitted in section 6 of the Statute of Monopolies and those in article 27 of TRIPS and article 17.9 of AUSFTA. Dancing on the head of a pin would not become a lost art among patent practitioners if this possibility were adopted.

Double Threshold

35. In a paper¹² cited in footnote 153 on page 66 of the issues paper, Jeremy Blum makes out a cogent case that by including a reference to the Statute of Monopolies in section 18 (1) (a), the Australian Patents Act has established a double threshold for novelty and inventiveness. First the patent applicant has to satisfy the commissioner that the invention is a manner of *new*¹³ manufacture, creating a first novelty and inventiveness threshold; and then the applicant has to satisfy the commissioner that the alleged invention meets the requirements of novelty and inventiveness under section 18 (1) (b), creating a second threshold.
36. Blum counsels against this approach in New Zealand, but his observation that the double threshold is an unsatisfactory approach applies, in my submission, in Australia too.

¹² *Why "Invention" Should be Removed from New Zealand Patent Law*, Jeremy Blum, Intellectual Property Forum, Issue 64, March 2006, 22.

¹³ Although the word "new" is not included in section 18 (1) (a), it has been read into the section by the *Mirabella* High Court decision (See page 27 of the Blum article).

37. Blum speculates that the Australian approach was made to compensate for the relatively low threshold of novelty and inventiveness in Australia.¹⁴ Returning to the theme of checks and balances,¹⁵ it is submitted that a better way of addressing the low threshold of novelty and inventiveness is to do so directly. The Patents Bill 2008 has done this in New Zealand by defining¹⁶ the prior art base to be considered in assessing novelty and inventiveness as:
- “ ... all matter (whether a product, a process, information about a product or process, or anything else) that has at any time before the priority date of that claim been made available to the public (whether in New Zealand or elsewhere) by written or oral description, by use, or in any other way.”*
38. It is suggested that the same approach might be followed in Australia rather than continuing with the current section 18 (1) (a), if ACIP considers that the current novelty and inventiveness threshold is too low.
39. Blum’s suggestion to the New Zealand legislators is to remove the possibility of creating a double threshold by adopting the Canadian definition of “invention”, by substituting the term “subject matter” for “invention” where “invention” was used in clause 13 of the then draft New Zealand Bill, and by removing all reference to the Statute of Monopolies.¹⁷ Adopting that suggestion in Australia would address both the threshold issue and the issue of the compliance of section 6 of the Statute of Monopolies with TRIPS and AUSFTA.

Exceptions to Patentability

40. Apart from the exclusions implicit from reference to section 6 of the Statute of Monopolies and the contrary to law exclusion already discussed,¹⁸ the Patents Act 1990 also contains exclusions for mere admixtures of foodstuffs and medicines¹⁹ and the very curious exclusion of claims containing names.²⁰
41. The mere admixture exclusion clearly discriminates against foodstuff and medicine technologies. It does not appear to comply with article 27.1 of TRIPS. The equivalent provision²¹ was repealed in New Zealand in 1994 when the New Zealand patents Act 1953 was amended to comply with TRIPS.
42. The name exclusion does not appear to fall easily into any of the TRIPS article 27 exceptions, but why would one bother to do anything about it?

¹⁴ See page 32 of the Blum article.

¹⁵ See paragraphs 6 to 10 above.

¹⁶ In Patents Bill 2008, clause 8 (1).

¹⁷ See pages 33 and 34 of the Blum article.

¹⁸ See paragraphs 21 to 27 above.

¹⁹ Patents Act 1990, section 50 (1) (b).

²⁰ Patents Act 1990, section 50(2). One wonders whether some self-important inventor insisted on having his name immortalised in a claim and a frustrated examiner could not find any other way to remove it – so the law was changed.

²¹ Patents Act 1953 (New Zealand), section 17 (3). Both the New Zealand and Australian sections were derived from the UK Patents Act 1949.

43. ACIP should be slow to recommend the introduction of any new exclusion to patentability in the absence of any evidence that the equilibrium resulting from the existing checks and balances is not appropriate. If it finds that the current equilibrium is not appropriate it should only look at all the checks and balances and decide which, if any, could be changed to achieve a more desirable equilibrium.
44. There are three main exclusions permitted under both TRIPS and AUSFTA: inventions the commercial exploitation of which is contrary to morality or to *ordre public*, and methods of treatment of humans. Adapting any one of these would change the existing equilibrium to the detriment of patent applicants and owners. Unless there is an identifiable corresponding public benefit, introducing any such change would be contrary to the intent of the TRIPS agreement²² even if it were within the wording of the article 27.
45. There are several reasons why exclusion on the ground that exploitation would be contrary to *ordre public* or morality is not of benefit to anyone. There is great uncertainty in what either of the expressions means, and their subjective nature means that their interpretation could be arbitrary and unpredictable. Secondly, if the intent is to discourage socially unacceptable activities, discouraging those activities by banning patents is ineffective. A patent gives the patentee the right to exclude others from unauthorised use of a patented invention. It does not give the patentee the right to exploit that invention. The absence of a patent for an invention does not mean that the invention cannot be exploited. Other laws control the exploitation of patented inventions directly and are a much more effective way of doing so than exclusions from patenting.
46. A patent right is a property right. Laws governing real property and other forms of intellectual property do not exclude ownership because of what the putative owner might use that property for. A film might be obscene under obscenity laws, and a house might be used as a brothel, but there is nothing in copyright law that prohibits the film from having copyright or in property law that prohibits the owner having title to the house. The morality of the activities is judged under the laws that deal directly with the activity, not the laws that deal with ownership of property associated with the activity. It is difficult to see why an exclusion based on *ordre public* or morality should be applicable only to patent rights.
47. The rationale for excluding patents for methods of medical treatment of humans in New Zealand given by Hammond J. in the *Pfizer* decision.²³ “It would be unthinkable ... by virtue of a patent grant, to prevent a health professional from performing his or her role to the best of that person’s knowledge and ability.”
48. With respect, that rationale is specious. Patents for medicines per se include the right to exclude health professionals from any protected activity, such as formulating or inducing others to use patented medicines. Doctors are much more constrained in what they can do for their patients by funding limitations. This is evidenced by long waiting lists of patients whose doctors have recommended surgery, but who lack the funding. Doctors are constrained in what they can

²² See article 7 of TRIPS in footnote 2 above.

²³ *Pfizer Inc v Commissioner of Patents*, [2005] 1 NZLR 362, at paragraph [119].

- prescribe not by patents, but by what medicines are funded by the public health authorities. Pharmaceutical companies have been heavily criticised for the money that their representatives allegedly spend in courting doctors to use their medicines. It would be marketing suicide for a drug company to sue a doctor for an infringing use of a patented method of medical treatment.
49. On the other side of the ledger, continuing to have patent protection available for methods of medical treatment would encourage investment in medical research directed to the application of the most recent and ongoing discoveries in molecular biology. These discoveries allow medicine delivery to be tailored to patients with genes that are receptive to a particular medicine.
 50. Patent applications claim methods of medical treatment when the invention lies in the discovery of a new use of a known medicine or when the invention lies in the discovery of a more effective treatment regime. Patentees would, of course, prefer to be able to claim compositions of matter, but such claims would not be novel. A method of medical treatment claim is the most direct way of protecting those types of invention.
 51. In considering what effect the prohibition of patents for methods of medical treatment would have on the equilibrium of checks and balances of the Australian patent system, ACIP needs to weigh up the considerations in paragraphs 47 and 48 against those in paragraphs 49 and 50. It is submitted that the public interest is best served by not introducing such a prohibition.

Summary of Submissions

- The Australian patent system is based on the social contract theory. In return for a time limited exclusive right to exclude others from practicing the patented invention the patentee makes the invention available to the public.
- The integrity of the social contract is maintained by a system of checks and balances that has established an equilibrium. Any patent law reform process should begin by considering whether the current equilibrium is desirable in the public interest. If it is considered that a different equilibrium would be more desirable, the effect of change in each relevant check and balance should be assessed to determine what the resulting new equilibrium would be.
- ACIP risks achieving an undesirable new equilibrium by focussing solely on the issue of patentable subject matter.
- The economic basis considered in the discussion paper is limited to economic effects within Australia. Australia is a participant in a global economy. A primary consideration in assessing what ought to be patentable subject matter should be whether any proposal complies with Australia international obligations.
- Section 6 of the Statute of Monopolies permits the granting of letters patent for manners of new manufactures except where the grant would be contrary to law, mischievous to the state or generally inconvenient. All three of these exclusions go beyond what is permitted under article 27 of TRIPS and Article 17.9 of AUSFTA.
- To comply with TRIPS and AUSFTA, section 18(1) of the patents Act 1990 either needs to be repealed or qualified with a proviso that no patent application

- may be refused on any exclusion ground beyond that permitted under TRIPS and AUSFTA.
- Section 18 (1) of the Patents Act 1990 establishes a double threshold of novelty and inventiveness. Adopting the Jeremy Blum proposal of incorporating a definition of invention from the Canadian legislation and substituting “subject matter” for “invention” would eliminate the double threshold and would be compliant with TRIPS and AUSFTA.
 - If ACIP considers the existing threshold of novelty and inventiveness to be too narrow because of the scope of the prior art base against which novelty and inventiveness are to be assessed, it could recommend expanding the prior art base.
 - Both grounds for exclusion under section 50 (1) of the Patents Act 1990 go beyond what is permitted under TRIPS and AUSFTA. Section 50 (1) should be repealed.
 - The Australian public interest would not benefit by a prohibition on patents for methods of medical treatment of humans, nor a prohibition of patents for inventions the commercial exploitation of which would be contrary to *ordre public* or morality.

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