Ministry of Economic Development

Manatū Ōhanga

Review of the Patents Act 1953: Boundaries to Patentability

A Discussion Paper

March 2002

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Foreword

In putting forward the government's innovation strategy, the Prime Minister has stressed the need to enhance the innovation system. As the Prime Minister noted, an important element of this is enhancing New Zealand's intellectual property framework. This review of the Patents Act 1953 will contribute to the government's goal of growing an innovative New Zealand and will help to ensure that New Zealand gains the greatest value from its innovations.

A modern patent system is essential if New Zealand innovators are to have the incentive to invest in research and development. A modern patent system is also necessary to encourage the transfer of technology to New Zealand by overseas innovators, so that New Zealand businesses have access to the technology and know-how needed to compete effectively in international markets.

The Patents Act 1953 is nearly fifty years old and is in need of a substantial overhaul. In August 2000, the government agreed to a three-stage review of the Act to take account of the social and technological changes since the Act was passed. Stages 1 and 2 of the review, which have already been completed, dealt with technical and operational changes to the Act for which substantial agreement has already been reached.

Stage 3 of the review considers a number of issues that have arisen since the Act was passed and that it does not adequately address. These include the Act's definition of invention and its ability to deal with new technologies, whether or not there should be exclusions to patentability, and the patentability of medical treatments, computer software and business methods.

The concerns of Māori and others regarding the granting of patents for plants and animals, and for inventions involving genetic material and genetic modification also need to be considered. Māori concerns regarding the granting of patents for inventions involving traditional knowledge will be explored.

These issues have been the subject of considerable public debate, both in New Zealand and overseas. The government has therefore decided to release this discussion document seeking public input before making any final decision on these matters.

We would welcome your submissions on the matters discussed in the document as a first step in the government's consideration of these issues.

Laila Harré

Hon Laila Harré
Associate Minister of Commerce

Hon Paul Swain
Minister of Commerce

Information for Persons Making Submissions

Submissions in relation to this discussion paper are invited from inventors, scientists, patent owners, users of patented inventions, and members of the public. Submissions will be considered in the development of policy recommendations to the government on possible legislative reform. Readers should note that a discussion of the plant variety rights system in New Zealand appears in *Review of the Plant Variety Rights Act 1987: A Discussion Paper*.

To aid respondents in making submissions, questions for discussion can be found at the end of sections 3 – 8.

Submissions should be sent to:

Patents Act Review Submissions
Attention: Warren Hassett
Regulatory and Competition Policy Branch
Ministry of Economic Development
PO Box 1473
WELLINGTON

Emailed submissions are also welcome. They should be addressed to:
warren.hassett@med.govt.nz

Submissions may be subject to disclosure under the Official Information Act 1982. Persons making submissions that include commercially or otherwise sensitive material that they wish the Ministry to withhold under the Act should clearly identify the relevant information and the applicable grounds under which the Ministry could withhold the information.

The closing date for submissions is **Friday 26 July 2002**.

1. The Present Patent System and Its Rationale

What Is a Patent?

1. The Patents Act 1953 is one of several New Zealand statutes providing rights in "intellectual property", that is, products of the mind. The other statutes include the Designs Act 1953, the Trade Marks Act 1953, the Plant Variety Rights Act 1987, and the Copyright Act 1994.

2. Under the Patents Act 1953, a patent may be granted for any invention that is a "manner of new manufacture". The grant of a patent for an invention provides the patent owner with a right to exclude others from making, using or selling the patented invention during the term of the patent. A New Zealand patent can have a maximum term of twenty years from the date of filing of the patent application. In return for the grant of a patent, the owner must make public a complete description of the invention. Patents are granted after an examination process by the Intellectual Property Office of New Zealand (IPONZ, the business name of the New Zealand Patent Office).

3. Effectively, a patent is a limited form of monopoly right. In other spheres, monopolies may not be in the public interest because of the reduced choice and higher prices that may result. These factors impose economic costs on society. The grant of a patent, however, is considered to be justified, because, in return for granting this temporary monopoly, society benefits from something that it did not have before: the disclosure of an invention that is new and innovative.

4. This does not mean that the costs associated with monopolistic behaviour are not present, rather a well designed patent system should maximise the net benefits that society achieves from innovations that are occurring both inside and outside that society.

Why Should Patents Be Granted?

5. If there were no patent system, it would be possible for anyone to copy a new invention and profit from it without having to bear the costs of developing the invention. Since the costs of copying many inventions can be substantially less than the development costs, this would allow the copier to sell the invention at a lower price than the original inventor, which may make it difficult or impossible for the inventor to profit from the invention. This could mean that businesses or individuals would have little incentive to invest in research and development, or would only invest in those inventions that could be kept secret. If businesses are not provided with adequate incentive to invest in research and development, economic growth may be inhibited.

6. The grant of a patent, by providing the owner with a limited monopoly, gives the owner an opportunity to make a profit from the invention. The possibility of a return on the patent owner's investment in developing the invention provides the incentive that is the main justification for the granting of patents. It is this incentive for research and development that is the main justification for the patent system.

7. In most countries, an invention will be considered to be a "genuine innovation" which may be eligible for patent protection if it meets the following criteria:

- it is new – an invention is considered to be new if a description of the invention has not been published, or the invention has not been publicly used before the filing date of an application to patent the invention;

- it involves an inventive step – an invention is considered to involve an inventive step if the invention would not have been obvious to an appropriately skilled person;

- it has to be "useful"[1] – an invention is considered to be useful if the inventor has identified a practical use for the invention.

These three criteria are now recognised internationally to be the minimum requirements for the grant of a patent.

8. If patents are granted for inventions that are not genuine innovations, society is giving away a valuable property right without receiving anything of comparable value in return. That is, the cost to society of such patents would exceed the benefits.

9. The grant of patents for inventions that are not innovations could also mean that technologies that would otherwise be free for anyone to use and exploit would no longer be freely available. This could discourage research and development in those technologies, as it would not be possible to commercially exploit any new developments arising from the research and development without infringing a patent. This could severely limit the ability of New Zealand researchers to develop new products and technologies, which would impose a further cost on New Zealand.

10. This is particularly important as New Zealand is a net importer of technology, with most New Zealand patents being granted to non-residents, as the table below shows:

Grants of New Zealand Patents (2001)

Residents	Non-residents	Total
376	4351	4727

11. The grant of a patent gives the patent owner an opportunity to charge a higher price for the patented invention than would be the case if a patent had not been granted. As most New Zealand patents are granted to non-residents, much of any extra revenue that patent owners might earn would flow overseas. This would increase the economic cost to New Zealand of granting patents for things that are not innovations.

12. Since most of the benefits of New Zealand's patent system flow overseas, or would occur even if New Zealand did not have a patent system, the patent system may provide little net benefit to New Zealand. This makes it all the more important that patents are only granted for inventions that are real innovations. This suggests that the criteria for granting a patent should be as strict as possible, and applied rigorously by IPONZ.

[1] Some countries use the term "capable of industrial application" rather than "useful."

13. If, however, New Zealand does not provide adequate levels of patent protection, innovators in other countries may be unwilling to allow their inventions to be exploited here. This means that New Zealand businesses may not have access to new technologies that they need to become internationally competitive. Lack of adequate protection in New Zealand may also mean that other countries may be unwilling to provide protection for inventions developed by New Zealanders.

14. As discussed previously, the main benefits to society of granting patents are the incentive to innovate, and the incentive to disclose new inventions. As most New Zealand patents are granted to non-residents, most of these benefits will flow overseas. Further, New Zealand patents granted to non-residents will also be the subject of patent applications overseas. As a consequence, details of the inventions involved will be published by overseas patent offices. New Zealand will get the benefit of the disclosure of the inventions even if no patent is granted (or applied for) in New Zealand.

International Obligations

15. New Zealand is a party to the Paris Convention for the Protection of Industrial Property and the WTO TRIPS[2] agreement, which require New Zealand to have a patent system that provides certain minimum levels of patent protection. Both the Paris Convention and the TRIPS agreement require parties to provide the same level of patent protection to residents of other parties as they provide for their own nationals. This means that New Zealand cannot discriminate against non-residents, for example by making it easier for New Zealand applicants to be granted patents than for non-residents. Conversely, other countries cannot discriminate against New Zealand applicants.

16. New Zealand has signed a Memorandum of Understanding with Australia on Business Law Co-ordination. This recognises that co-ordination of business law may help to minimise impediments to trans-Tasman business activity. The Work Programme for Co-ordination of Business Law listed in the Annex to the Memorandum includes:

> Exploring the potential for more closely co-ordinating the granting and recognition of registered intellectual property rights.

This does not mean that New Zealand and Australia are required to adopt identical laws. Nevertheless, when considering changes to the Patents Act 1953, the possibility of harmonising New Zealand's law with that of Australia should be borne in mind.

17. The World Intellectual Property Organisation (WIPO), of which New Zealand is a member, has begun work on drafting a Substantive Patent Law Treaty. The aim is to harmonise substantive patent law world-wide (substantive patent law deals with such things as the threshold tests for patentability, rather than administrative requirements for filing applications).

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[2] *Agreement on Trade Related Aspects of Intellectual Property Rights*, Annex 1C to the Agreement establishing the World Trade Organisation.

18. The justification for harmonising substantive patent law is that this will make it easier and cheaper for innovators in one country to obtain patents in other countries. The negotiations on this draft Treaty are still in their early stages, and no final text has been decided. New Zealand would be under no obligation to ratify any Treaty that might eventually be concluded. There may, however, be benefits to New Zealand applicants from harmonising New Zealand's substantive patent law with that of New Zealand's major trading partners, whether or not New Zealand ratifies any Substantive Patent Law Treaty.

2. Reform of the Patents Act 1953

Is Reform Necessary?

19. As discussed in section 1, if the patent system is to benefit New Zealand, it must ensure that patents are only granted when the benefits to society of a patent exceed the costs that it imposes on society. This will occur if patents are only granted for inventions that are genuine innovations. The criteria for granting a patent, as provided in the patents legislation, must be sufficiently strict to maximise the likelihood that patents are only granted for real innovations. Are the criteria for granting a patent contained in the New Zealand Patents Act 1953 sufficiently strict to ensure that this object is met?

20. The two main criteria for grant of a patent in New Zealand are that the invention be:

- new, and that
- it be a "manner of manufacture."

21. Under the Patents Act 1953, an invention is considered to be new if a description of the invention has not been published in New Zealand before the filing date of the application. No notice is taken of information published outside New Zealand but not publicly available within New Zealand. That is, an invention would be considered "new" even though details of it were well known outside New Zealand, just as long as these details were not publicly available in New Zealand.

22. The term "manner of manufacture" has been interpreted by the Courts to exclude such things as "products of nature", mathematical operations, bare principles, mathematical algorithms, schemes or plans, and methods of medical treatment of humans.

23. There is no requirement in the Patents Act 1953 that inventions must involve an inventive step, or be useful, in order to be granted a patent. Lack of inventive step and lack of usefulness are however, reasons for revoking a patent after it has been granted but will not normally prevent a patent being granted in the first place. Third parties may oppose the grant of a patent on grounds that include clear lack of inventive step. The costs and uncertainty involved in revoking a patent, or opposing its grant, mean that relatively few patents are revoked or refused grant on these grounds.

24. The Courts, in decisions relating to the United Kingdom Patents Act 1949, and the Australian Patents Act 1952 have ruled that the Commissioner of Patents may only refuse to grant a patent if it was "practically certain" that if a patent was granted it would be held to be invalid. If there is any dispute, the applicant is to be given the benefit of any doubt.

25. These Acts are very similar to the New Zealand Patents Act 1953, and the New Zealand Courts have followed decisions relating to them. As a result, the Commissioner of Patents may be required to grant patents for inventions that might not meet all of the requirements for patentability set out in the Patents Act. The United Kingdom and Australian patent legislation has since been amended to so that the Commissioner of Patents is no longer required to give applicants the benefit of the doubt.

26. It can be seen then, that the criteria for granting a patent in New Zealand are such that patents can be granted for things that are not genuinely new, that do not involve an

inventive step, and that may not be useful. As a result, it is possible that some patents are being granted for things that are not genuine innovations. As described in Section 1, the grant of such patents will provide no benefits to New Zealand, and may in fact cause a loss.

27. The criteria for granting a patent in New Zealand are less strict than those applied in most other countries, including New Zealand's major trading partners. In these countries a patent can only be granted for an invention if the invention is new, involves an inventive step, and is useful. These countries would refuse to grant a patent on inventions that would be granted a patent in New Zealand. This means that it is easier for applicants from other countries to obtain a New Zealand patent than it is for New Zealand applicants to obtain a patent in those other countries. This situation does not provide any benefits for New Zealand.

28. It is also possible that the requirement in the Patents Act 1953 that an invention be a "manner of manufacture" may not be flexible enough to take account of new technologies. This means that patent protection may be being denied to some inventions that are genuine innovations.

29. Since the Patents Act 1953 was passed other issues have arisen that the Act does not adequately address. The moral and cultural issues involved in some technologies, such as genetic engineering or genetic modification, are not dealt with explicitly.

30. Calls have been made to limit the patenting of life form inventions on ethical grounds, including animal welfare and the risk of reduced respect for human and animal life. Many people, including Māori, have questioned the morality of granting ownership rights such as patents over living things. Māori also consider that it is immoral to interfere with the integrity of plant and animal species. There are concerns that the possibility of obtaining a patent on life form inventions may encourage investment, research and development in ethically dubious areas.

31. On the other hand, however, it might be considered to be unethical not to grant patents for some inventions. Refusing to grant a patent might mean that morally positive outcomes such as the development of new drugs or vaccines would be impeded, as the lack of patent protection could discourage research. The refusal to grant a patent for such things could be considered unethical, on the grounds that failure to encourage these developments would show disrespect for human life.

32. In response to concerns expressed about the possible social and environmental effects of genetic modification, a Royal Commission on Genetic Modification was established in May 2000. The Commission's brief, as stated in its Warrant was to:

> receive representations upon, inquire into, investigate, and report upon the following matters:
>
> (i) the strategic options available to enable New Zealand to address, now and in the future, genetic modification, genetically modified organisms, and products; and

(ii) any changes considered desirable to the current legislative, regulatory, policy, or institutional arrangements for addressing, in New Zealand, genetic modification, genetically modified organisms, and products.

33. After extensive public consultation, the Commission presented its report[3] to the Governor General on 27 July 2001. Chapter 10 of the Commission's Report deals with intellectual property issues. Two of these recommendations are directly relevant to the current review of the Patents Act 1953. These are:

- Recommendation 10.2:

  That the Patents Act 1953 be amended by adding a specific exclusion of the patentability of human beings and the biological processes for their generation, in line with s18 of the Patents Act 1990 (Commonwealth).

- Recommendation 10.3:

  That a Māori consultative committee be established by the Intellectual Property Office of New Zealand to develop procedures for assessing applications, and to facilitate consultation with the Māori community where appropriate.

34. These recommendations will be discussed later in this document. The government's response to the recommendations in Chapter 10 of the Commission's report can be found at: http://www.mfe.govt.nz/issues/genetic_modification/intellectual_property.htm.

35. The Act also does not address the issue of the protection of the cultural property and traditional knowledge of Māori. There is currently a claim before the Waitangi Tribunal ("Wai 262") which alleges that the Crown has breached its obligation under the Treaty of Waitangi to provide such protection. The patenting of inventions using indigenous flora and fauna or of inventions based on traditional knowledge is a concern for Māori and for other indigenous peoples around the world.

36. It is important to note however, that modifications to the patent system to restrict the patentability of certain types of inventions will not prevent the development and use of such inventions. Conversely, the fact that a patent has been granted for an invention does not mean that the invention can be commercially exploited. The grant of a patent does not over-ride any other legislation that might regulate the use of the invention. For example, a new pharmaceutical cannot be marketed until the Minister of Health has given approval, even though the pharmaceutical has been patented.

37. It can be seen then, that the criteria for granting a patent as laid down in the Patents Act 1953 are not strict enough to ensure that patents are only granted for real innovations, and are out of step with the criteria applied internationally. The Patents Act 1953 also does not address the moral or Treaty issues that have arisen since the Act was passed. Reform of the Patents Act is considered necessary to ensure that New Zealand's patent legislation:

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[3] http://www.gmcommission.govt.nz/RCGM/index.html

- ensures that patents are only granted for things that are genuine innovations;
- makes a positive contribution to New Zealand's economic development and contributes to the government's objectives of developing a "knowledge economy" by providing adequate incentives for New Zealand businesses to innovate;
- provide adequate incentives for overseas innovators to transfer their technology to New Zealand;
- deals appropriately with the concerns expressed by Māori regarding the patenting of inventions involving traditional knowledge and indigenous plants and animals;
- takes account of moral and cultural concerns relating to the patenting of living organisms, and genetic material, and takes into account the recommendations of the Royal Commission on Genetic Modification.

38. In putting forward the innovation strategy, the Prime Minister has stressed the need to enhance the innovation system. As the Prime Minister noted, an important element of this is improving New Zealand's intellectual property framework. This review of the Patents Act 1953 will contribute towards the government's goal of growing an innovative New Zealand and help to ensure that New Zealand is able to gain full value from its innovations.

History of Reform

39. In 1989 the then Ministry of Commerce commenced a review of the Patents Act, as part of a general review of New Zealand's intellectual property legislation. The review of the Patents Act culminated in the release of a discussion paper in 1992[4] ("the 1992 paper").

40. Submissions received in response to the 1992 paper indicated general agreement with its recommendations. Some sections of the community, however, including a number of Māori commentators, expressed concerns about the proposed reforms. There were two main concerns:

- that the proposed reforms did not address the issue of the patentability of biotechnological or "life-form" inventions, and
- that they did not address the issue of the protection of traditional remedies and the patenting of inventions based on traditional knowledge.

As a result, the proposed overhaul of the Patents Act was postponed while further consultations with Māori and other stakeholders took place. As part of the consultation process, the Ministry convened a Māori focus group to consider and report on the issues relating to the patenting of life forms, and a series of hui was held in 1999 which discussed

[4] *Reform of the Patents Act 1953, Proposed Recommendations*, copies available from the Ministry of Economic Development.

the focus group's report and an accompanying Ministry publication, "Patenting of Biotechnological Inventions"[5].

41. Since the release of the 1992 paper the only changes to the Patents Act 1953 were made in 1992 and 1994, to take account of New Zealand's accession to the Patents Co-operation Treaty, and the TRIPS agreement, respectively.

42. In August 2000, the Government decided to re-start the reform process, and agreed to a three-stage review of the Act. In Stages 1 and 2, Cabinet has agreed to a number of operational amendments to the Act which were based largely on the recommendations in the 1992 paper. The focus of these amendments is to update and improve the Act with the aim of providing greater certainty that when a patent is granted there will be a net social benefit to New Zealand.

43. To achieve this, the amendments proposed in Stage 1 and 2 included a change to the novelty requirements, so that an invention would be only considered "new" if no description of the invention has been published **anywhere in the world** before the date of filing of a patent application. Also included is a proposal to require that an invention must be shown to involve an inventive step **before** a patent can be granted. A new Patents Bill incorporating the changes proposed in Stage 1 and 2 is currently being drafted.

44. These proposals did not seek to address the moral, cultural and Treaty issues identified earlier. The question of the definition of invention was not addressed either. These issues have been the subject of considerable public debate, both in New Zealand and overseas. The Government has therefore decided to seek public input before making any final decision on these matters.

45. This discussion paper is being released as part of Stage Three of the review. In addition to the issues identified above, this discussion paper will also deal with the following issues:

- the interface between the Patents Act and the Plant Variety Rights Act 1987.
- the patentability of business methods and computer software related inventions;
- the patentability of methods of medical treatment of humans;
- the stringency of the tests used to determine whether a patent should be granted.

[5] Copies of this publication and the report of the Māori Focus group can be obtained from the Ministry of Economic Development. It is also available on the Ministry's website www.med.govt.nz

3. Definition of Invention

What Is Meant by "Definition of Invention"?

46. The patent laws of some countries, including New Zealand, incorporate a definition of what constitutes an invention. Anything that does not fall within the definition is not considered to be an invention and will not be granted a patent, even though it otherwise meets all the other criteria for grant of a patent.

47. The reasons for having a definition of invention, at least in those countries that based their legislation on that of the United Kingdom, date back to the Statute of Monopolies. This statute was enacted in 1623 for the purposes of declaring all monopolies void. An exception, though, was made for "patents for invention" with the intention of encouraging national economic development. By providing a definition of invention, the monopoly rights conferred by the grant of a patent could be given only to those things that were seen to give real economic benefits to society. Things that were not considered to provide such benefits would not be considered inventions and would not be granted a patent.

48. The definition of invention is subject to interpretation by courts and patent offices. In general though, the sorts of things that have not been considered to be inventions include mere discoveries, scientific theories, mathematical algorithms, and purely aesthetic creations.

49. It is not absolutely necessary to have a definition of invention. Some countries do not include a definition of invention as such in their patent legislation. Instead, the legislation provides a list of those things which are not considered to be inventions, and not eligible for the grant of a patent.

50. Many countries also exclude certain types of invention from patent protection, even though they otherwise meet all the criteria for the grant of a patent. The inventions that are excluded from patent protection are usually those where there may be moral or cultural objections to granting patent protection.

51. Most countries are parties to the WTO TRIPS Agreement. Any exclusions from patent protection must be consistent with this agreement. Article 27 of the TRIPS agreement deals with patentable subject matter and permits some specific exclusions to patentability. The Patents Act 1953 is consistent with Article 27. Any changes to New Zealand's patent laws must be also be consistent with this Article.

52. Article 27 states:

> 1. Subject to the provisions of paragraphs 2 and 3, patents shall be available for any inventions, whether products or processes, in all fields of technology, provided that they are new, involve an inventive step and are capable of industrial application.[6] Subject to paragraph 4 of Article 65, paragraph 8 of Article 70 and paragraph 3 of this Article, patents shall be available and patent rights enjoyable without discrimination as to the place of invention, the field of technology and whether products are imported or locally produced.
>
> 2. Members may exclude from patentability inventions, the prevention within their territory of the commercial exploitation of which is necessary to protect *ordre public* or morality, including to protect human, animal or plant life or health or to avoid serious prejudice to the environment, provided that such exclusion is not made merely because the exploitation is prohibited by their law.
>
> 3. Members may also exclude from patentability:
>
> (a) diagnostic, therapeutic and surgical methods for the treatment of humans or animals;
>
> (b) plants and animals other than micro-organisms, and essentially biological processes for the production of plants or animals other than non-biological and microbiological processes. However, Members shall provide for the protection of plant varieties either by patents or by an effective *sui generis* system or by any combination thereof. The provisions of this subparagraph shall be reviewed four years after the date of entry into force of the WTO Agreement."

The Definition of Invention in New Zealand

53. Section 2(1) The Patents Act 1953 defines an invention as:

> any manner of new manufacture the subject of letters patent and grant of privilege within section 6 of the Statute of Monopolies[7] and any method or process of testing applicable to the improvement or control of manufacture; and includes an alleged invention

54. This definition of invention is essentially the same as that used in United Kingdom patent laws until the passage of the United Kingdom Patents Act 1977. Consequently there is an extensive body of case law from the United Kingdom courts concerning the interpretation of this definition. This case law has generally been followed in New Zealand. Where the courts have decided that something does not fall within the definition of invention, this is effectively an exclusion from patentability. These "judicial" exclusions (as

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[6] A footnote to Article 27 states "For the purposes of this Article, the terms 'inventive step' and 'capable of industrial application' may be deemed by a Member to be synonymous with the terms 'non-obvious' and 'useful' respectively."

[7] The Act of the 21st year of the reign of King James the First, Chapter 3, intituled "An Act concerning monopolies and dispensations with penal laws and the forfeiture thereof" – s2 Patents Act 1953.

opposed to “statutory” exclusions) include “products of nature”, mathematical algorithms, bare principles, mathematical algorithms, mere schemes or plans, and methods of medical treatment of humans.

55. Section 17 of the Patents Act also allows the Commissioner of Patents to refuse to grant a patent for an invention on the grounds that the use of the invention is “contrary to morality”. This provision has rarely, if ever, been applied.

56. New technologies have tested the limits of the current definition, and raised questions about the ability of the current definition to deal with inventions in areas such as biotechnology, medical treatments, computer software and business methods. Another issue is whether the Act should specifically state that some inventions should be excluded from patent protection.

57. It was recommended in the 1992 paper that the current definition of invention be repealed, and that the decision on whether to grant a patent should be made on the basis of what are now the three internationally recognised criteria of novelty, inventive step, and industrial applicability or usefulness. The paper stated that this would have the following advantages:

- A clear break from the present approach which would limit the restrictions imposed by previous practice;
- Greater certainty and potentially lower costs;
- Consistency with other jurisdictions.

58. The 1992 paper also recommended that there should be no specific exclusions from patentability, on the basis that existing exclusions could be dealt with by other means in the Patents Act or in the general law. The paper noted that exclusions reflect historical precedent and differing national perspectives on the impact of the patent system on economic development. On the basis of overseas experience, however, and following some strong objections to that recommendation, the government considers that this issue should be revisited.

59. Possible options for change to the definition of a patentable invention are described below. While mention is made of possible exclusions to patentability, it is not intended, in discussing the options for change, to determine what these exclusions (if any) might be. The question of whether there should be exclusions to patentability is explored later on in this document.

Option 1: No Change

60. Under this option the definition of a patentable invention as currently provided in s2 of the Act would remain. This would retain the present “judicial exclusions”, while leaving the Courts free to interpret the definition of invention on a case by case basis, as has occurred in the past. The Commissioner of Patents would still have the power to refuse patents where the use of the invention would be “contrary to morality”.

61. A possible disadvantage of retaining the present definition of invention is that it may lead to uncertainty as to the eligibility of some new technologies for patent protection. On the other hand, it has been argued[8] that the current definition has demonstrated sufficient flexibility to meet the challenges of technological change, while adequately protecting society's interests.

62. Retaining the current definition of invention would not address such issues as whether or not life forms, or inventions related to genetic modification or engineering, should be the subject of patent protection. Neither would it address the question of the granting of patents to inventions that make use of Māori traditional knowledge and cultural intellectual property.

63. The Royal Commission on Genetic Modification has recommended (Recommendation 10.2) that the Patents Act 1953 include a specific exclusion of the patentability of human beings and biological processes for their generation. As the government has accepted this recommendation, this option (no change to the definition of invention) is not viable.

Option 2: Retain Current Definition, with Specific Exclusions

64. This approach would involve keeping the current definition of invention, while incorporating into the Act a list of things which, although they might satisfy the definition of "invention", were not considered suitable subject matter for a patent. Such exclusions would have to be consistent with Article 27.3 of the TRIPS agreement (see above). This may go some way towards meeting the concerns of those who feel that some things should not be granted a patent on moral or cultural grounds.

65. There may be others, however, who would oppose the addition of specific exclusions on the grounds that they would find such exclusions morally or culturally unacceptable. They may consider that such exclusions would discourage research in areas that would benefit society, such as the development of new medical therapies or labour-saving technologies.

66. The use of specific exclusions, however, may not be sufficient to deal with patents for inventions using Māori traditional knowledge and cultural property.

67. An advantage of this option is that it would retain the present judicial exclusions, while allowing the Courts the freedom to re-interpret the definition of invention as they consider necessary. It would also leave the Courts free to revisit the existing judicial exclusions. One risk with this approach is that it is possible that the Courts may consider that if one of the existing judicial exclusions was not specifically included as an exclusion in any new legislation this might indicate that Parliament did not wish to retain the exclusion.

68. This was the approach taken by the Australian Federal Court in *Anaesthetic Supplies Pty Ltd v Rescare Ltd*.[9] In that case, methods of medical treatment of humans, previously

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[8] See p148, *Review of Intellectual Property Legislation under the Competition Principles Agreement: Final Report by the Intellectual Property and Competition Review Committee*, Australia, September 2000.

[9] (1994) 122 ALR 141.

unpatentable, were found to be proper subject matter for a patent. One of the grounds for this finding was that if Parliament had intended to continue to exclude such methods from patentability, it would have enacted a specific exclusion into the Australian Patents Act 1990. As no such exclusion was enacted, the Court concluded that Parliament did not wish the exclusion to continue.

69. If it is considered desirable that the present "judicial" exclusions remain, it may be necessary to provide for specific exclusions relating to them.

70. If New Zealand were to exclude certain technologies, for example gene technologies, from patent protection using Article 27.2 of TRIPS, this would not prevent the use of such technologies, nor would it prevent such technologies from being patented in other countries. It is also possible that other parties to the TRIPS agreement might challenge New Zealand's use of Article 27.2 in this way. The exclusion of some technologies from patent protection might act as a disincentive to research in those technologies in New Zealand, and result in a loss of New Zealand researchers to countries with a more liberal patent regime.

Option 3: No Definition of Invention

71. Under this option, the Act would contain no definition of invention. Anything that met the criteria of novelty, inventiveness and usefulness as specified in the TRIPS agreement would be granted a patent. Certain things that otherwise might meet these criteria could be specifically excluded from patent protection. The main advantage of this approach would be that patentability would not be restricted by previous practice. Other advantages and disadvantages are as for Option 2.

72. This approach is used in the European Patent Convention, and therefore also used in the United Kingdom Patents Act 1977.[10]

Option 4: Keep Current Definition, with Additional Criteria, with or without Specific Exclusions

73. The definition of invention would retain the requirement that an invention be "a manner of manufacture", with the definition of invention additionally including the specific criteria of novelty, inventiveness, and industrial applicability. Specific exclusions could be introduced. This is essentially the same approach as used in the Australian Patents Act 1990. The only specific exclusion from patentability in the Australian Act is for human beings, and biological processes for their generation. The advantages and disadvantages of this approach are the same as for option 2, with the additional advantage of harmonising New Zealand patent law more closely with that of Australia.

[10] See s1(2) and (3), also s4(2).

Option 5: Repeal Current Definition, Replace It with an Alternative Definition, with or without Specific Exclusions

74. Given the doubts that have been expressed about the current definition of invention, some alternative definition could be provided that could be more easily adapted to new technologies. Any new definition though, would still be subject to interpretation by the Courts, and there is no guarantee that any new definition would produce fewer problems than the present one. Any new definition could, of course, be accompanied by specific exclusions.

Questions

1. Which of the options identified above should be adopted. Why?
2. Should there be any specific exclusions from patentability? If not, why not?
3. If there were to be specific exclusions, what should they be? Why?
4. Should the power currently given to the Commissioner of Patents to refuse to grant patents for inventions whose use would be "contrary to morality" be retained? If not, why not?

4. Māori and the Patenting of Biotechnological Inventions

Background

75. As discussed in section 2, in 1989 the then Ministry of Commerce began a review of the Patents Act 1953 as part of a general review of New Zealand's intellectual property legislation. Submissions received in response to a 1992 discussion document indicated concern within the Māori community that the proposed reforms did not address the following issues: the patentability of biotechnological or "life-form" inventions, and the protection of traditional remedies and other inventions based on traditional knowledge. As a result the review of the Patents Act was postponed to allow further consultation with Māori to occur.

76. Submissions to the then Ministry of Commerce from Māori in 1994 and 1999 indicated that Māori are in general opposed to any reform of the Patents Act that might either “extend” patentability in the area of biotechnology, or that might not prevent the granting of patent rights to inventions based upon living organisms.

77. Many Māori are concerned about the application of patent rights to life forms, including indigenous flora and fauna. These concerns are wide ranging. First, there is concern that a patent for an invention derived from indigenous flora and fauna may, through the grant of exclusive rights in relation to the invention, infringe what Māori consider to be their rights under the Treaty of Waitangi to maintain control over their resources, and may also limit the rights of Māori themselves to develop new uses of those resources. Second, there is concern about the cultural and spiritual implications of the alteration of life forms, and the encouragement given through the patents system to continue innovation in this field.

78. Māori have also raised concerns about the application of the patents system to inventions based on traditional knowledge. There is a concern that traditional remedies, or their active ingredients, may be patented by individuals from outside the iwi from which the knowledge is obtained, and that Iwi would then be denied access to their traditional remedies during the patent term without either informed consent or arrangements for benefit sharing. Conversely, the requirement for inventions to be “novel” and to involve an “inventive step” may prevent Māori themselves from obtaining patent protection for traditional knowledge (which is typically passed on from generation to generation and evolves incrementally).

79. Another concern is that, while the Patents Act permits some collective ownership of patent rights, the system does not as a whole sit well with the concept of collective ownership of knowledge. It is also argued that the patents system allows and promotes the commercial exploitation of knowledge, whereas the objective for Māori is more often the protection of traditional knowledge against inappropriate use and possible loss. In many instances the commercial exploitation of traditional knowledge is culturally offensive.

80. In addition, many Māori share the same concerns as other New Zealanders about the possible social and environmental effects of genetic modification, and oppose the patenting of genetically modified products and processes on these grounds. Others, however, welcome genetic modification as a means of ensuring reliable supplies of valuable medical supplies such as insulin. In any event, it is important to note that patents,

while they may provide an incentive to further research and development in this field, will not operate to prevent research and development in that area. The Patents Act essentially deals with the granting of rights over the “end product” of what is often a long process of research and development.

Consultations to Date

81. Four consultation hui were held in 1994 to discuss Māori concerns raised about proposed changes to intellectual property legislation. In 1995, in response to Māori concerns, the then Ministry of Commerce established the Patenting of Life Forms Focus Group ("the Focus Group"). Its purpose was to identify for the Ministry some issues of probable concern to Māori in relation to the patenting of life forms. The Focus Group engaged in wide consultations in developing its report.

82. The Focus Group’s report and the Ministry’s discussion paper on the Patenting of Biotechnological Inventions [link] were released for public discussion in February 1999. Consultation hui and workshops on these papers took place between April and June 1999. Submissions were also received on both papers from New Zealand scientific and research organisations and the patent attorney profession.

83. Responses to the Focus Group's report and the Ministry's discussion paper included a wide range of views. Some respondents were against any exclusions to patentability, or any amendments to the Patents Act to accommodate specific Māori concerns. Others argued strongly that Māori should be consulted when decisions are being made on the patenting of life form inventions, and that the Act should be amended to ensure that Māori have standing to raise issues of concern to them in patent opposition or revocation proceedings.

Issues to Be Considered

84. This document does not seek to re-examine the issues raised comprehensively in the report of the Focus Group and the Ministry’s discussion paper. Rather, its purpose is to assist in exploring the extent to which Māori concerns about the patents system might be accommodated within the existing regime while still permitting the system to function effectively in promoting innovation, competition and New Zealand’s overall economic interests. There is a broader set of concerns relating to the protection of traditional knowledge and cultural heritage which conventional intellectual property mechanisms, such as the Patents Act, do not address because of the underlying objectives and values on which they are based. These concerns could be addressed by the development of a stand-alone system to protect traditional knowledge (this issue is discussed further below in paragraphs 107 - 112).

85. The Focus Group also noted that many of the concerns raised by Māori, although seen as very much related to the discussion of Patents Act reforms, were more appropriately dealt with in some other forum. These concerns included:

- the use of the research material involved, including indigenous flora and fauna;
- controlling access to such resources; and
- the exercise of rangatiratanga over indigenous life forms.

86. As mentioned in section 2, there is a currently a claim before the Waitangi Tribunal ("WAI 262") which alleges that the Crown has breached its obligation to protect the cultural and intellectual property of Māori. This claim arises from Article II of the Treaty.

87. Article II of the Treaty of Waitangi preserves the rights of Māori to exercise te tino rangatiratanga ("their full chiefly authority") over their taonga (literally "treasures"- rendered in the English version of the Treaty as natural resources including lands, forests, fisheries and other properties).

88. The Wai 262 claim may be seen, at least in part, as a response to the tension between what are understood by Māori to be Article II rights and obligations, and the proprietary rights granted under intellectual property rights legislation, including the Patents Act 1953. The claim asserts that the Treaty guarantees rights of ownership, control, and authority over the genetic resources of indigenous flora and fauna, and cultural and intellectual heritage and traditional knowledge. The concept of "ownership" would cast Māori in the role of guardians of their heritage, while "control" suggests the possibility of commercial exploitation. The claim also asserts that the Crown is in breach of Article II of the Treaty through the enactment of legislation, including the Patents Act, which is inconsistent with those rights.

89. The Wai 262 inquiry is some way from completion. Meanwhile the government is proceeding with legislative reform that may go some way towards addressing the issues raised by the claim. For example, the new Trade Marks Bill introduced in June 2001, will, once enacted, require the Commissioner of Trade Marks to refuse to register a trade mark where the Commissioner considers that its use or registration would be likely to offend a significant section of the community, including Māori. The Bill goes some way towards addressing some of the concerns raised in the Wai 262 claim by ensuring that the Crown is not inappropriately registering trade marks containing Māori text and imagery.

Māori Concerns and the Review of the Patents Act

90. In considering potential changes to the Patents Act it is necessary to take account of the implications for Māori in granting intellectual property rights to inventions which may be perceived to conflict with Māori rights and interests in traditional knowledge, native plants and animals. The Crown also has an obligation to consult with Māori on matters affecting their interests under the Treaty.

91. Traditional knowledge, and Māori interests in indigenous flora and fauna, could be given some protection through amendments to the Patents Act while continuing to comply with New Zealand's international obligations.

92. These might include, for example, providing for consultation with Māori when making decisions on patents based on traditional knowledge or indigenous genetic material (see below paragraphs 98 - 106). The Act might also be amended to provide that Māori will have standing to seek revocation or re-examination of a patent.

93. Some Māori also assert a special interest in the genetic integrity of non-indigenous flora and fauna (in the context of genetic modification) on the basis of their spiritual connection to all living things. Māori concerns in this regard could be examined along with other similar claims based on religious or cultural grounds. These might not be the subject of specific consultation with Māori, but could be considered in the context of any public morality type exceptions to patentability.

94. Māori may be concerned that a patent, through its grant of an exclusive right to use and commercially exploit an invention, may both prevent Māori from continuing to use their own traditional knowledge, and may not result in any appropriate compensation for the knowledge contributed. It is important to note however, that a patent gives rights only in respect of the specific invention being claimed and nothing more. A patent on an invention derived from traditional knowledge does not prevent the continued use of that knowledge by the relevant community (but it may affect the future patentability of traditional knowledge based inventions by the owners of that knowledge). It should also be noted that before a patent can be granted for a traditional knowledge based invention, the examining office, in this instance IPONZ, must be confident that the invention is new, that is, that details of the invention have not been previously published.

95. In Stage 2 of the review of the Patents Act, a change is proposed that which would require that an invention involve an inventive step (not be obvious) before a patent can be granted. This would also reduce the likelihood of a patent being granted for an invention based on traditional knowledge. Whether an invention involves an inventive step is determined having regard to the information already known and used in the relevant field - the invention must not simply be a natural consequence of something already known.

96. Where traditional knowledge has contributed to the development of a new invention, ideally questions of benefit sharing would be managed by the parties concerned and would not be a matter for legislation. In the absence of legislative requirements, it is possible that this may not occur equitably or at all. The issue of access to genetic resources and benefit sharing for indigenous peoples is currently being considered at the international level by organisations such as the World Intellectual Property Organisation and the Convention on Biological Diversity. New Zealand has signalled its intention to participate actively in these discussions.

97. Providing for Māori input into the patent process could assist in addressing inequalities that may result from the situations described above.

Māori Input into the Patent Process

98. The Patents Act could be amended to ensure that consultation with Māori occurred when applications are made for patents for inventions based on traditional knowledge or indigenous genetic material. Such consultation could take place on examination of the patent application, or in the course of revocation or re-examination proceedings.

99. Proposals to require consultation have been criticised by stakeholders for imposing uncertainty on the patent process. Patents, however, should not be granted without rigorous examination and will always be subject to challenge at any time during the patent term. In this respect, the system could already be said to be “uncertain” and the introduction of possible mechanisms to, in effect, reduce future uncertainty, can only contribute to its over-all soundness.

100. The nature of any consultation process would need to be carefully determined to ensure both its effectiveness and over-all fairness to all interested parties. It would be advisable to impose some time limits on any proposed consultation process to ensure it did not result in undue delays for users of the system. One proposal that has been put forward by Māori groups is that patent applicants be required to provide clear evidence of the source of any genetic material concerned or, in the case of inventions which may be based on traditional knowledge, of “prior informed consent” of the owners that knowledge.

101. Even if patent applicants were required to provide evidence of the source of genetic material and obtain "prior informed consent", it will still be important to ensure that patent examiners are able to recognise patents based on traditional knowledge or indigenous genetic resources, independently of information provided by the applicant. The ability to recognise traditional knowledge is important to enable patent examiners to determine whether an invention is new and is eligible to be patented.

102. It is difficult to identify how and what consultation should take place at the examination stage, when examiners become aware that a patent is based on traditional knowledge or indigenous genetic resources. One option could be the formation of a committee to represent Māori interests in this context, and to advise the Commissioner of Patents as to the nature of the interest and the particular communities or persons with whom the Commissioner should consult. Alternatively, the patent applicant could be directed to undertake consultation. It may be difficult, however, for applicants to arrange adequate consultation before filing a patent application, particularly if the applicant is from outside New Zealand.

103. The Royal Commission on Genetic Modification has recommended (recommendation 10.4) that a Māori Consultative Committee be established to develop procedures for assessing applications, and to facilitate consultation with the Māori community where appropriate. In its response to the Royal Commission's recommendations, the government agreed that:

> a Māori consultative committee be established, but that its scope and role be confirmed following public consultation as part of Stage 3 of the review of the Patents Act 1953.

104. The functions of this committee in relation to "assessing applications" would be limited by New Zealand's international obligations in respect of Article 27 of the TRIPS agreement, which deals with patentable subject matter and permits limited specific exclusions to patentability. The exclusions are set out in section 3 of this discussion document, and include exclusions necessary to protect *ordre public* or morality, to protect human, animal or plant life or health or to avoid serious prejudice to the environment. Article 27 does not expressly allow parties to refuse the grant of a patent on cultural grounds, although such a refusal may fit within the *ordre public* and morality exception.

105. The Royal Commission on Genetic Modification also recommended (recommendation 10.5) that New Zealand pursue an amendment of the TRIPS agreement which would allow the avoidance of cultural offence as a specific ground of exclusion. In its response to the Royal Commission's recommendation, the Government has directed officials from the Ministry of Economic Development, Te Puni Kōkiri and the Ministry of Foreign Affairs and Trade to:

- support the concept of exclusion or reservation on the basis of cultural offence through work currently being progressed through the World Intellectual Property Organisation, and the development of a new system for the protection of Māori "cultural and intellectual property"

- be alert for opportunities which may arise in the World Trade Organisation TRIPS context.

106. Another possibility might be to include provision in the legislation for Māori to participate in the application process as interested parties. For example applications for

re-examination (both pre and post grant) or revocation of particular patents could be made by Māori groups or individuals where they considered their interests had in some way been contravened.

Sui Generis Mechanisms of Protection of Traditional Knowledge

107. An alternative to adapting existing intellectual property legislation to protect traditional knowledge is to develop a "*sui generis*" (stand alone) system. The development of a *sui generis* system will address the broader concerns raised about the protection of traditional knowledge which cannot be adequately achieved by adapting existing intellectual property mechanisms.

108. The importance of developing mechanisms to protect traditional knowledge has been recognised internationally. Work is being undertaken in a number of international fora including the World Intellectual Property Organisation, which has recently established an Intergovernmental Committee on Intellectual Property and Genetic Resources, Traditional Knowledge and Folklore. New Zealand has signalled its support for work by the Committee on *sui generis* systems to protect elements of traditional knowledge not covered by existing intellectual property systems. This is consistent with recommendation 10.4 of the Royal Commission on Genetic Modification, that:

> New Zealand be proactive in pursuing cultural and intellectual rights for indigenous peoples internationally.

The government has agreed with this recommendation, and has directed officials ot implement it. New Zealand has also stated that this approach should not preclude the development of country or region-specific alternative approaches to protecting the knowledge and practices of indigenous communities.

109. *Sui generis* protection for traditional knowledge could be developed in conjunction with mechanisms governing access to genetic resources and benefit-sharing, as well as other measures such as registries of traditional knowledge, which would be used by patent examiners when considering patent applications. Such protection might include registers recording traditional knowledge and prior informed consent.

110. The development of registers of traditional knowledge is a contentious issue. Such registers would to some extent prevent the commercial exploitation of traditional knowledge by preventing third parties from obtaining patents for traditional knowledge based inventions where it could be shown that the invention was not new or obvious. There is, however, considerable concern among indigenous peoples about the public disclosure of traditional knowledge in this way.

111. Some countries, including the members of the Andean[11] community and the Philippines, have already introduced *sui generis* systems at the national level. International agreement on a *sui generis* system is, however, likely to take some time, as

[11] Bolivia, Columbia, Ecuador, Peru, Venezuela.

is the development of any *sui generis* system within New Zealand. Meanwhile it is appropriate to explore ways in which the existing regimes for intellectual property rights, including patents, can be adapted to address some Māori concerns while still meeting its overall objective to promote innovation and competition.

112. The New Zealand Biodiversity Strategy, released in February 2000, acknowledged the need to encourage Māori participation in managing biodiversity and in developing a framework for the retention and promotion of Matauranga Māori.[12] It also recognised the need to take Māori interests into account in developing access to and use of New Zealand's indigenous genetic resources and the sharing of benefits of their use. Implementation of the Strategy (which is the responsibility of several government departments, including the Department of Conservation and the Ministry of the Environment) will complement any amendments to the Patents Act to take account of Māori interests in these areas.

Questions for Consideration in Relation to the Review of the Patents Act 1953

5. Should applicants for patents be required to provide evidence of the source of any genetic material? If so, what sort of evidence would be required?

6. Where inventions are based on traditional knowledge, should applicants be required to provide evidence of the prior informed consent of the holders of that knowledge. If so, what form should that evidence take? What process would be required?

7. How might patent examiners be made aware that patent applications are based on Māori traditional knowledge or indigenous flora and fauna?

8. Should there be specific consultation with Māori during the patent examination process?

9. If so, what sorts of applications should Māori be consulted about? Applications based on Māori traditional knowledge and indigenous flora and fauna? Anything else? Why?

10. What should the role of the Māori consultative committee be? How would it be constituted? Should applicants be required to consult with Māori, or should the onus be on the Crown, or a combination of both?

11. How else might Māori interests be taken into account in the patent process?

[12] Matauranga Māori: Māori traditional knowledge, which includes knowledge about traditional medicines, fishing, weaving, and other aspects of everyday life.

Other Questions You May Wish to Consider (Although They Are Outside the Scope of the Patents Review)

1. Is a *sui generis* (stand alone) system for the protection of traditional knowledge and cultural heritage needed? Is international protection of traditional knowledge necessary? Why?

2. If so, what should a *sui generis* system protect, and how?

3. Should a *sui generis* system be limited to the protection of traditional knowledge, or should it also provide for the commercial exploitation of the knowledge by the holders of that knowledge?

4. Should registers of traditional knowledge, to assist patent examiners in the search of prior art, be developed? What are the advantages and disadvantages? What sort of information might be contained on registers? Who would be responsible for the compilation and maintenance of such registers?

5. New Issues in Patentability 1: Biotechnological Patents

What is Biotechnology?

113. Biotechnology is essentially about the study or manipulation of one or more of the basic components of living things, including tissues, cells, proteins, genes or DNA, to create new products or technologies. Biotechnology is employed in the development of many everyday products, from the processing of foods, to the development of vaccines and other medical treatments. Early uses of biotechnology include traditional breeding techniques used to improve plants, livestock and other food products.

114. Genetic engineering or genetic modification is an aspect of biotechnology that involves the manipulation or movement of DNA material, including between species.

Why Is it an Issue?

115. Biotechnology, (including genetic modification) has a well-established presence in New Zealand. Potential applications of biotechnology are wide with new applications constantly being developed. New Zealand has an excellent reputation for high quality research and research facilities and is a world leader in agricultural and horticultural research, a great deal of which involves some form of biotechnological activity. Biotechnological inventions have also had a major impact on a number of other New Zealand industries, including medical research, agriculture, animal production, dairy, food and beverages and waste processing.

116. Because of the importance of the primary production sector in our economy, and in our external trade (with around half our exports comprising food products and two thirds derived from agriculture, forestry and fisheries), the implications of biotechnology for primary sector production are particularly important for New Zealand. Parts of our primary sector, including organic producers, oppose the use of a number of biotechnological applications, and particularly those which involve genetic modification.

117. Medical uses of biotechnology are also becoming increasingly important, both in terms of a growing range of diagnostic tests and new pharmaceuticals now available to New Zealanders, and also in the area of medical research where an ever-increasing number of professionals are using biotechnology applications to study and prevent diseases.

118. It has been suggested that research (and subsequent product development) in the field of genetic modification and other biotechnological applications has the potential to be a valuable source of intellectual property for New Zealand, and one which can be sold on world markets. In recent years increasing numbers of patent applications have been filed around the world (including New Zealand) for inventions involving biotechnology.

119. There has, however, been some opposition to the commercial exploitation of inventions involving biotechnology, particularly those involving genetic modification. Although in many instances it is the activity involved or the possible end result of that activity which generates concern, concerns have also been expressed that the availability of patent protection for such inventions encourages their creation.

Royal Commission on Genetic Modification

120. Public concern about the possible adverse effects on society of genetic modification lead to the establishment of the Royal Commission on Genetic Modification. The Commission presented its report on 27 July 2001. The report made two recommendations regarding the patenting of biotechnological inventions. These recommendations are discussed later in this section.

121. Questions have also been raised as to the appropriateness of allowing proprietary rights to inventions which include living matter, and in particular to inventions which relate to, or include what are often called "higher life forms" such as animals or human beings.

122. Many countries have laws that regulate the exploitation of certain inventions for moral, ethical or environmental reasons. As noted previously, arguments against patenting of biotechnological and genetically modified inventions, particularly those involving "higher life forms" appear to focus on the activity involved. For example, there is concern that genetic modification may interfere with the integrity of species and as such is inherently wrong. Questions have been raised over the morality of assigning economic value to biological material and the implications this has in terms of distribution and concentration of wealth.

123. A 1994 paper prepared by the Westminster Institute for Ethics and Human Values at the McGill Centre for Medicine and Law (Canada*): Ethical Issues Associated with the Patenting of Higher Life Forms* noted that if genetic engineering and its applications are regarded as ethically concerning to begin with, patenting becomes ethically suspect in direct proportion to the strength of the incentive it provides for such research and development.

124. While there are many people, including Māori who see genetic modification as being in some way immoral, there is another point of view. This alternative view sees interventions such as genetic modification as a proper extension of society's enquiries into nature. Failure to pursue such research can be seen as a dereliction of duty in caring for other human beings, as the research may provide major health benefits. On this basis it would be considered immoral to take any action which discouraged research in these areas.

Biotechnology Patents in New Zealand

125. The definition of a patentable invention contained in s2 of the Patents Act 1953 does not specifically exclude biotechnological inventions, although IPONZ does have a practice of refusing patents that would include human beings within their scope. Non-human animals, however, may be patented, and such patents have been granted by IPONZ. For example, New Zealand patent 243908[13] claims a transgenic mouse.

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[13]"Gene encoding mutant l3t4 protein which facilitates HIV infection and transgenic mouse expressing such protein."

Treatment of Biotechnological Inventions in Other Countries

126. Attitudes to the patenting of biotechnological or "life form" inventions in different jurisdictions tend to reflect the extent to which biotechnological activity impacts on the economy in question. Developing countries have tended to focus on issues such as the availability of products including food and medicines at prices which make them accessible to consumers. These countries may be reluctant to implement patent systems that conflict with these objectives.

European Union

127. The European Patent Convention (EPC)[14] reflects the TRIPS Agreement in excluding from patentability inventions which are contrary to public order or morality. Article 53 of the EPC states that: "European patents shall not be granted in respect of inventions the publication or exploitation of which would be contrary to '*ordre public*' or morality…..[and shall not be granted] in respect of plant or animal varieties or essentially biological processes for the production of plants or animals….."

128. The European Union Directive 98/44/EC sets out rules for patent offices in EPC member states regarding biotechnological inventions. Member states are required to convert such directives into domestic law. It allows inventions to be excluded from patentability if they are considered to be against "*ordre public*" or morality and provides examples of the types of inventions that would fit this criteria including:

- processes for cloning human beings;
- processes for modifying the germ line identity of human beings;
- uses of human embryos for industrial or commercial purposes; and
- 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.

129. The treatment of the patent application for the Harvard "Oncomouse" in 1995[15] can be seen to reflect this approach. A patent was granted on the Oncomouse on the basis that the benefits (the study of cancer) were considered to outweigh the disadvantages (cruelty to animals). Accordingly, the European Patent Office refused a similar type of patent on a mouse developed to study hair growth as the subject matter was not considered important enough to outweigh animal suffering.

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[14] The members of the European Patent Convention are: Austria, Belgium, Switzerland, Cyprus, Germany, Denmark, Spain, Finland, France, Turkey, Greece, Ireland, Italy, Liechtenstein, Luxembourg, Monaco, The Netherlands, Portugal, Sweden, United Kingdom.

[15] A mouse genetically engineered to be susceptible to cancer, European Patent No 169672.

130. The Directive states that gene sequences without an indication of a function do not contain any technical information, and are not patentable inventions as they are not capable of "industrial application" as required by Article 52(1) of the European Patent Convention. Biological material which is isolated from its natural environment however, or produced by means of a technical process and which is capable of industrial application, may be the subject of a patentable invention even if it previously occurred in nature.

United States

131. United States Patent law has no specific exclusions to patentability. In 1980, the United States Supreme Court ruled that a live, human-made micro-organism is patentable subject matter.[16] This lead to the United States Patent and Trademark Office (USPTO) conferring patentable status on plants, seeds, and plant tissues in 1985, and two years later on "multi-cellular living organisms, including animals". The Harvard "Oncomouse" (referred to above) was granted a patent (No 4736866) under this policy. However, the United States Patent Office will reject an application if the broadest reasonable interpretation of the claimed invention as a whole encompasses a human being. Such an invention would be considered contrary to the 13th Amendment to the United States Constitution, which forbids slavery.

132. In January 2001, the USPTO introduced revised "utility examination guidelines" to be used by patent examiners is assessing whether an invention is "useful" as required by the s101 of the United States Patents Act (Title 101 US Code). These guidelines, although applicable to all patent applications, were introduced in response to concerns that gene sequences or DNA fragments were being patented even though their inventors had not described any particular use for them. The guidelines require that the utility of an invention be:

- Specific - that is specific to the subject matter claimed;
- Substantial - that is that a real world use is defined rather than one which requires further research to identify it; and
- Credible – is the utility believable to a person skilled in the field?

The effect of these guidelines would be to prevent the patenting of mere discoveries for which a specific, substantial, and credible use has not been described.

South America

133. Latin American countries have some of the greatest biological and cultural diversity in the world and, (it is argued), this characteristic makes an ideal location for bioprospecting activity – the practice of exploring potential commercial uses of natural resources and related traditional knowledge. This has caused considerable concern amongst Latin American communities that knowledge and resources are being appropriated with little or

[16] *Diamond vs. Chakrabarty*, 447 U.S. 303 (1980)

no benefit to the peoples concerned, and whose cultural beliefs may also be being ignored in the process.

134. In response to this problem, the Andean Community[17] has introduced a Common Intellectual Property Regime.[18] Article 3 of this regime states:

> The Member Countries shall ensure that the protection granted to intellectual property elements shall be accorded while safeguarding and respecting their biological and genetic heritage, together with the traditional knowledge of their indigenous, African American, or local communities. As a result, the granting of patents on inventions that have been developed on the basis of material obtained from that heritage or that knowledge shall be subordinated to the acquisition of that material in accordance with international, Andean Community, and national law.

The regime also restricts the patentability of living things and genetic material (Articles 15(b) and 20(c)). Where inventions are developed or obtained from genetic material originating in one of the member countries, or make use of traditional knowledge, applicants must show that they have permission to use the genetic material or traditional knowledge (Articles 26(h) and (i)).

How Should New Zealand Approach Biotechnology Patents?

135. The 1992 paper recommended the repeal of section 17[19] of the Patents Act 1953, on the grounds that patent law is not the appropriate mechanism to control the development and use of certain inventions, and that refusing to provide patent protection would not affect the development or subsequent use of inventions considered ethically concerning. It was also considered inappropriate that the Commissioner of Patents be required to determine ethical questions.

136. Since that time however, there has been a growing body of interest in both intellectual property law reform and issues related to genetic modification and associated technologies. It has become apparent that there is a sufficient degree of concern and in some instances opposition to any reform of the Act which might either extend patentability in these areas, or which may in turn result in the granting of patent rights to inventions based upon living organisms.

137. Submissions to the Royal Commission on Genetic Modification, developing countries' interventions to the TRIPS Council on issues related to Article 27.3(b) of the WTO TRIPS agreement, and a growing body of academic and other work in this area suggest it is timely for New Zealand to consider its position on these matters again. The areas of greatest concern are the patenting of genes or gene sequences, and the patenting of living

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[17] Bolivia, Columbia, Ecuador, Peru, Venezuela.

[18] The text of this agreement can be found at http://www.comunidadandina.org/ingles/treaties/dec/D486e.htm.

[19] S17: "If it appears to the Commissioner in the case of any application for a patent that the use of the invention in respect of which the application is made would be contrary to morality, the Commissioner may refuse the application."

organisms, particularly plants and animals. Both gene sequences and non-human living organisms are patentable in New Zealand.

138. It has been argued that genes should not be patentable on the grounds that they do not meet the requirements for a patentable invention. Reasons that are advanced in support of this argument include:

- if a gene exists in nature, it is not novel and therefore not patentable;
- an inventor who isolates a gene does not actually invent or discover anything and should not be entitled to a patent;
- determining the structure of a gene is, at most, a discovery rather than an invention;
- sequencing a gene has become such a routine automated process that it cannot be regarded as inventive.

139. Those who support the patenting of genes point out that it has long been possible to obtain patents for chemical substances that occur in nature. The rationale for this, confirmed by judicial decisions, is such patents only cover the substance when isolated and purified, and that it does not exist in nature in an isolated purified form. Once purified and isolated, the substance is in a useful form. As a gene is a chemical substance, that is, a DNA molecule, then an isolated and purified DNA molecule that has the same sequence as a naturally occurring gene is considered patentable because the DNA molecule does not exist in nature in an isolated and purified form.

140. The grant of a patent on a gene or gene sequence does not mean that the patent owner also "owns" any organism containing that gene. A gene is simply a DNA[20] molecule, that is, it is a chemical substance, which can be purified and isolated. A patent covering a gene only covers the isolated and purified DNA molecule that forms the gene, but does not cover the gene as it is found in nature. So, for example, a person whose body contained a patented gene or gene sequence would not infringe the patent, and the patent owner would not have any "rights" over that person.

141. If a gene, whether or not it is patented, is inserted into a living organism, such as a plant or an animal, the living organism could be patented. This would allow the patent owner to control the commercial exploitation of the plant or animal. Commercial exploitation of plants and animals, such as buying and selling them, is widely accepted in our society. The idea that someone can own plants or animals is also widely accepted. The buying and selling of human beings, or the idea that a person can be someone else's "property" is, however, considered to be morally repugnant. Because of this, patents that might include human beings within their coverage are not granted, either in New Zealand or in other countries.

142. The Patents Act 1953 contains no specific ban on the granting of patents for human beings. Any patent application that might include human beings within its coverage would

[20] "DNA" stands for deoxyribonucleic acid.

be refused by IPONZ on the grounds that it does not constitute a “manner of manufacture” and it is unlikely that such a patent would be granted. The Royal Commission on Genetic Modification considered that the issue should be put beyond doubt and recommended (recommendation 10.2) that the Patents Act 1953 be amended by adding a specific exclusion from patentability of human beings and the biological processes for their generation, in line with section 18(2) of the Australian Patents Act 1990. The government has agreed that this amendment should be made. It should be emphasised that such an exclusion would not prevent research taking place in this area. If it was intended to regulate such research, specific legislation would be required.

143. A problem that has arisen in other countries, particularly the United States, is that some applicants have obtained patents for large numbers of gene sequences without describing any use for them, in the hope that anyone who does discover a use will have to pay a royalty. There is no explicit requirement in the Patents Act 1953 that an invention be “useful” before being granted a patent, although grant of a patent could be refused if the patent applicant had not identified any use at all for the invention.[21] In such a case, the invention would considered to be a discovery rather than a patentable invention. But if the applicant identifies some use for the invention, however insubstantial, the grant of a patent could not be refused. Lack of usefulness is, however, a ground for revoking a patent.

144. If there was a formal requirement for an invention to be “useful” before a patent is granted, this would discourage, for example, the patenting of large numbers of gene sequences with no known use. In light of the developments in Europe and the United States described earlier, should New Zealand introduce a requirement that an invention be shown to be “useful” before a patent is granted?

145. The patenting of living organisms, particularly animals, raises ethical concerns where animal welfare is concerned. The European Union Biotechnology Directive (referred to earlier) provides that where genetic modification of an animal may cause suffering without any substantial benefit to humans or animals, patents may be refused for the animal or a process for producing it on the grounds that such inventions would be against public order or morality. Should IPONZ adopt similar guidelines? Animal ethics committees in New Zealand already monitor animal research applications in these terms.

146. Any restrictions on the patentability of biotechnological inventions, for example to restrict the patenting of genetic material or living organisms, would need to be consistent with the exclusions to patentability permitted by the WTO TRIPS Agreement. Articles 27.2 and 27.3 allow parties to TRIPS to exclude from patentability:

- inventions whose commercial exploitation must be prevented for the protection or *ordre public* or morality, including the protection human animal or plant life or health or to avoid serious harm to the environment;

- diagnostic, therapeutic, and surgical methods for the treatment of humans or animals; and

[21] *General Electric Co Ltd's Application* (Patent) [1961] RPC 21.

- plants and animals (other than micro-organisms) and biological processes for the production of plants or animals.

147. Among the issues to consider in reviewing the current provisions under the Act is New Zealand's status as a net importer of technology and products subject to intellectual property rights. Most of our pharmaceutical and technological products are imported. Essentially New Zealand is on the receiving end of "technology transfer" and consideration would need to be given to the potential effects a less liberal patent system might have on our continued ability to access such goods, and the extent to which New Zealand might miss out on the benefits provided by an expanding biotechnology sector.

Plants and Patents

148. New Zealand provides protection to new plant varieties[22] through the provisions of the Plant Variety Rights Act 1987, and, since 1981 has been a member of UPOV, the International Union for the Protection of New Varieties of Plants. A plant variety right will be granted if the variety is "new, distinct, homogeneous, and stable" (s10(2)(d) of the Plant Variety Rights Act 1987).

149. The grant of a plant variety right under the Plant Variety Rights Act 1987 gives the owner of the right the exclusive right to produce for sale, and to sell, reproductive material of the variety concerned (S17(1)(a) of the Plant Variety Rights Act 1987). Where the variety is a plant that is a vegetatively propagated fruit or vegetable producing plant, or a vegetatively propagated ornamental plant, the owner of the right also has the exclusive right to propagate the variety for the purposes of the commercial production of fruit, flowers or other products of the variety.[23]

150. It is also possible for plants to be granted a patent under the Patents Act 1953. Where a plant variety is protected by a patent, the rights of the patent owner are greater than those conferred by the grant of a plant variety right under the Plant Variety Rights Act 1987, as shown in the table below. For example, the owner of a plant variety right cannot prevent other breeders exploiting another variety bred from the protected variety. A plant variety right owner cannot prevent farmers from saving seed from a previous crop in order to sow a new crop. The grant of a patent, however, would prevent the exploitation of "essentially derived" varieties and would also prevent farmers from saving seed for their own use.

[22] S2 of the Plant Variety Rights Act 1987 defines a "variety" as a cultivar, or cultivated variety, of a plant, and includes any clone, hybrid, stock, or line of a plant; but does not include a botanical variety of a plant.

[23] S17(1)(b) Plant Variety Rights Act 1987, and Plant Variety Rights (Grantees' Rights) Order 1997.

Comparison of Rights Conferred by the Plant Variety Rights Act 1987 and the Patents Act 1953:

	Plant Variety Rights Act 1987	Patents Act 1953
Right to prevent others from producing for sale reproductive material of the protected variety:	Yes	Yes
Right to prevent others from selling reproductive material of the protect variety:	Yes	Yes
Right to prevent others from producing and selling bred from the protected variety:	No	Yes
Right to prevent farmers from sowing saved seed:	No	Yes

151. New Zealand patents have been granted for plants. Patent Nos. 330335 and 330495 claim varieties of olive plants, while patent No. 217113 claims plants that have been made resistant to glyphosate herbicide by genetic engineering.

152. Article 2(1) of the 1978 revision of the UPOV Convention[24], (to which New Zealand is a party), states that member states may recognise the rights of plant breeders by the grant either of a special title of protection or of a patent. The Article goes on to state that member states whose national law allows both forms of protection can provide only one of them for one and the same botanical genus or species. Despite this provision, the present New Zealand legislation does not prevent plant breeders from seeking both patent and plant variety right protection for the same genus or species. That is, if a new plant variety meets the criteria for protection under the Plant Variety Rights Act 1987, and is similarly eligible under the Patents Act – (that is, it falls within the definition of invention), it can essentially receive dual protection.

153. Amendment of the Patents Act would be required to ensure consistency with the 1978 UPOV Convention. This is because the existence of a granted patent (or a patent application) for the same genus or variety is not a ground for refusal of a plant variety right under the Convention. Alternatively, New Zealand could consider ratifying the 1991 UPOV convention, which does not contain any provision equivalent to Article 2(1) of the 1978 Convention. This would require amendment of the Plant Variety Rights Act 1987.

[24] The text of the UPOV Conventions can be found at http://www.upov.int/eng/convntns/index.htm.

The Situation in Other Countries

Australia

154. Protection for new varieties of plants is available under the Plant Breeder's Rights Act 1994. Australia has ratified the 1991 UPOV Convention, which allows for a level of protection for plant breeders that is similar to that provided by a patent. Australia also allows plants, including new plant varieties, to be granted a patent under the Patents Act 1990.

European Community

155. Article 53(b) of the European Patent Convention states that:

> European Patents shall not be granted in respect of plant or animal varieties or essentially biological processes for the production of plants or animals; this provision does not apply to microbiological processes or the products thereof.

Article 4(2) of the European Biotechnology Directive (Directive 98/44), however, states that inventions which concern plants or animals shall be patentable if the invention is not confined to a specific plant or animal variety.

United States

156. In the United States, protection for asexually reproduced new plant varieties is available under Chapter 15 of the United States Patents Act (Title 35, United States Code). Sexually reproduced varieties are protected under the Plant Variety Protection Act (Chapter 57, Title 7 of the United States Code). Following the decision of the US Board of Patent Appeals and Interferences in *Ex Parte Hibberd*,[25] which held that seeds, plants, and plant tissue were eligible for the grant of a patent, the United States Patent Office also grants patents for plants under Chapter 10 of the United States Patents Act. Chapter 10 deals with the granting of patents for inventions in general.

International Obligations

157. Article 27.3(b) of the TRIPS agreement provides that members may exclude certain matters from patentability, including plants or animals. The Agreement requires, however, that members shall provide for the protection of plant *varieties* (as opposed to plants themselves) either by way of patents or by an effective *sui generis* system, that is, by way of legislation especially intended for this purpose.

Should Plants Be Eligible for Two Forms of Protection?

158. The availability, in New Zealand of two forms of protection for plant varieties raises two questions

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[25] 227 USPQ 443

- should plant varieties be eligible for two forms of protection? and
- are patents an appropriate form of protection for plants?

159. It is not clear why plant varieties should be eligible for two forms of protection, when inventions that do not involve plants are only eligible for one. As discussed earlier, a patent gives a greater level of protection than a plant variety right. If, however, New Zealand were to ratify the 1991 UPOV Convention, new plant varieties would be entitled to a level of protection similar to, although not necessarily the same as, that provided by a patent.

160. Article 14 of the 1991 UPOV Convention extends the protection provided by a plant variety right to cover varieties that are "essentially derived" [26] from a protected variety. Ratification by New Zealand of the 1991 UPOV Convention would be in line with Recommendation 10.1 of the Royal Commission on Genetic Modification which recommended that the Plant Variety Rights Act 1987 be amended to introduce the concept of essentially derived varieties. The government has agreed in principle with this recommendation, subject to the outcome of the review of the Plant Variety Rights Act 1987 being undertaken in tandem with Stage 3 of the the review of the Patents Act 1953. Article 15(2) of the 1991 UPOV Convention also allows member countries to provide that the use by farmers of their saved seed would not infringe a plant variety right.

161. If it were decided that plants should be eligible for only one form of protection what form should this take? If it were decided that plants should be protected by patents only this would mean repeal of the Plant Variety Rights Act 1987. The future course of the Plant Variety Rights Act 1987 is discussed in a Discussion Paper released simultaneously with this paper.

Are Patents an Appropriate form of Protection for Plants?

162. The rights provided by a patent are greater than those that may be allowed by the grant of a plant variety right. For example, if a plant or plant variety is the subject of a patent, then, as noted earlier, farmers would not be able to save or store seed to sow a subsequent crop. While this may be of benefit to patent owners, it may disadvantage farmers who would have to pay to use saved seed, when in the past they have not had to do so. If it was considered desirable that farmers continue to be able to freely use their saved seed, it would be necessary for the Patents Act to specifically exclude plants from patent protection.

163. The granting of patents for genetically modified plants has lead to fears that growers whose crops are accidentally contaminated by these plants may be sued for patent

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[26] The 1991 UPOV Convention states that: "A variety shall be deemed to be essentially derived from another variety ('the initial variety') when: it is predominantly derived from the initial variety, or from a variety that is itself predominantly derived from the initial variety, while retaining the expression of the essential characteristics that result from the genotype or combination of genotypes of the initial variety, if it is clearly distinguishable from the initial variety, and except for the differences which result from the act of derivation, it conforms to the initial variety in the expression of the essential characteristics that result from the genotype or combination of genotypes of the initial variety."

infringement. A recent judgement of the Canadian Federal Court[27] has, however, indicated that mere accidental contamination of a crop with a patented plants would not infringe the patent.

164. One possible disadvantage of this approach is that there may be some plants which, although excluded from patent protection, would also not be eligible for a plant variety right. For example, it has been suggested that physiological or biochemical differences in a cultivar, such as pine trees with different fibre characteristics than other pine trees, or changed oil content in an oil seed such as sunflowers might not be protectable by plant variety rights.[28]

Questions

Biotechnology and Patents

12. Should New Zealand's patent legislation exclude plants or animals from patentability? If so, why?

13. Should some biotechnological inventions be excluded from patentability. If so, which ones? Why? What benefits or costs could there be to New Zealand in providing such exclusions?

14. Should New Zealand's patent legislation contain an explicit requirement that an invention be "useful" before it can be granted a patent?

Plants and Patents

15. Is it appropriate that plant breeders should be able to gain both patent protection and plant variety rights protection for the same genus or species? If so, why?

16. If only one form of protection for plant varieties is provided, what should this be? Why?

17. If plant breeders can obtain only one form of protection for their new plant varieties, should plant breeders be able to decide which form of protection should be applied to a particular variety, or should this be specified in legislation?

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[27] *Monsanto Canada Inc. and Monsanto Company v Percy Schmeiser and Schmeiser Enterprises Ltd*.

[28] Daniel Hampton and Dr Astrid Baker, "Protecting Plant Breeders' Investment: Patents and New Plant Cultivars in New Zealand" *New Zealand Intellectual Property Journal*, August 2000, page 269.

6. New Issues in Patentability 2: Business Methods and Software

A. Business Method Patents

What is a Business Method?

165. There is no universally agreed definition of a "business method". One definition that gives a good idea of the sort of things covered by the term "business method" is that provided by the draft United States Business Methods Improvement Act 2000[29] (HR 5364):

> (1) a method of
>
> (a) administering, managing, or otherwise operating an enterprise or organisation, including a technique used in doing or conducting business; or
>
> (b) processing financial data;
>
> (2) any technique used in athletics, instruction, or personal skills; and
>
> (3) any computer-assisted implementation of a method described in paragraph (1) or a technique described in paragraph (2).

Why Are Business Methods an Issue?

166. Business methods, along with computer software have, in the past, not been considered suitable subject matter for patent protection by many countries. In recent years, however, some countries, particularly the United States, have begun to allow such patents. Developments in computer technology, particularly the Internet, have made business method patents a potentially large source of income for the owners of such patents.

167. The grant of these patents has not been without controversy. This has largely centred around the suggestion that Patent Offices do not have the appropriate expertise to adequately examine all applications in this fields. It has been alleged that this has resulted in patents being granted for business methods and software that are not novel or inventive. It has also been suggested that allowing patents for business methods may in fact stifle innovation in these fields rather than encourage it, and that business methods should not be patentable at all.

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[29] The Business Methods Improvement Act 2000 has been referred to the Judiciary Committee of the United States Congress, and has not been passed into law. This legislation is an attempt to make business method patents harder to obtain, and easier to challenge, in the United States. The text of this Act can be found at: http://www.house.gov/berman/HR5364.pdf

Business Method Patents in New Zealand

168. The definition of a patentable invention in the New Zealand Patents Act 1953[30] does not specifically exclude the granting of patents for business methods. IPONZ will grant patents for such methods if they are considered to fall within the definition of invention, that is, if they constitute a "manner of new manufacture".

169. The question of whether a particular method falls within the definition of a patentable invention is ultimately determined by the Courts. The High Court of Australia in *National Research and Development Corporation v Commissioner of Patents*[31] stated that for a process to be considered a "manner of new manufacture" it must result in a product that is an "artificially created state of affairs" that has utility in the field of economic endeavour.

170. The Australian patents legislation in force at the time of the "National Research" decision, (the Patents Act 1952) contained the same definition of invention as the New Zealand Patents Act 1953. The New Zealand courts, and hence IPONZ, have followed this decision.

171. Any method (and not just a business method) that meets the requirement set out above will be granted a patent provided it meets the other requirements of the Patents Act 1953.

172. Methods that are no more than mere schemes or plans would not be considered manners of new manufacture,[32] as they do not give rise to an "artificially created state of affairs", and are unlikely to be granted a patent. Such methods may, however, be patentable if they are linked to some mode of carrying out the method, for example, by implementing the method using a computer. As a result, many business method patents include the use of a computer or computer software.

Patenting of Business Methods in Other Countries

European Union

173. According to Article 52(1) of the EPC, European patents shall be granted for "any inventions which are susceptible of industrial application, which are new and which involve an inventive step." Subparagraph 2 of Article 52 sets out exceptions to this rule:

- discoveries, scientific theories and mathematical methods;
- aesthetic creations;

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[30] "Invention" means any manner of new manufacture the subject of letters patent and grant of privilege within section 6 of the Statute of Monopolies and any new method or process of testing applicable to the improvement or control of manufacture. (S2, Patents Act 1953).

[31] [1959] CLR 252

[32] See, for example, *D.A.& K's Application*, 43 RPC 154; *Hiller's Application* [1969] RPC 267; *I.B.M.'s Application*, [1980] FSR 564.

- schemes, rules and the methods for performing mental acts, playing games or doing business, and programs for computers;
- presentations of information.

Methods of doing business, among others, are specifically excluded from patentability. The EPC, however, does not specifically define a “method for doing business”.

174. In a recent decision[33] of the Board of Appeal of the European Patent Office, it was observed:

> Having technical character is an implicit requirement of the EPC to be met by an invention within the meaning of Article 52(1)EPC.

and

> Methods only involving economic concepts and practices of doing business are not inventions within the meaning of Article 52(1)EPC. A feature of a method which concerns the use of technical means for a purely non-technical purpose and/or for processing purely non-technical information does not necessarily confer a technical character to such a method.

United States

175. The definition of a patentable invention in the United States Patent Act[34] does not specifically exclude business methods. It was long considered that business methods were inherently unpatentable. In 1998, this practice was overturned by the United States Court of Appeals for the Federal Circuit (CAFC) in a decision (the “State Street” decision)[35] which held that the subject matter of a United States patent is not inherently unpatentable merely because it relates to a method of doing business.

176. Guidelines[36] to United States patent examiners dealing with business method applications state:

> The claimed invention as a whole must accomplish a practical application. That is, it must produce a "useful, concrete and tangible result." State Street, 149 F.3d at 1373, 47 USPQ2d at 1601-02. The purpose of this requirement is to limit patent protection to inventions that possess a certain level of "real world" value, as opposed to subject matter that represents nothing more than an idea or concept, or is simply a starting point for future investigation or research (Brenner v. Manson, 383 U.S. 519, 528-36, 148 USPQ 689, 693-96); In re Ziegler, 992, F.2d 1197, 1200- 03, 26 USPQ2d 1600, 1603-06 (Fed. Cir. 1993)). Accordingly, a

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[33] Case No T 0931/95 – 3.5.1 see http://www.european-patent-office.org/dg3/pdf/t950931eu1.pdf

[34] United States Code 35 §101: “Whoever invents or discovers any new or useful process, machine, manufacture, or composition of matter, or any new or useful improvement thereof, may obtain a patent therefor, subject to the conditions and requirements of this title.”

[35] *State Street Trust and Bank Company vs Signature Financial Group, Inc.*, 149 D.3d 1368, (Fed. Cir. 1998)

[36] *United States Patent and Trademark Office Manual of Patent Examining Practice*, §. 2106, (II)(A)(1)

> complete disclosure should contain some indication of the practical application for the claimed invention, i.e., why the applicant believes the claimed invention is useful.

and

> A process that consists solely of the manipulation of an abstract idea is not concrete or tangible.

Australia

177. S18(1) of the Australian Patents Act 1990 states that an invention is a patentable invention if the invention (so far as claimed in any claim) is:

> a manner of manufacture within the meaning of Section 6 of the Statute of Monopolies; and, when compared with the prior art base as it existed before the priority date of that claim, is novel, and involves an inventive step, and is useful.

178. Whether business methods can be patented will depend on whether the method meets the requirements set down in s18(1), in particular the requirement that the invention be a "manner of manufacture." In its publication *Patents for Schemes or Plans*[37], IPAustralia (the trading name of the Australian Patent Office) states:

> Essentially a patent may be granted for a scheme or plan where there is a means for putting the scheme or plan into effect.

Examples of such patentable schemes are:

> A method of analysing business performance by operating a computer system to set specified parameters and thresholds in accordance with preselected criteria and to compare business performance against the parameters and thresholds.

and

> A method of raising funds by seeking sponsors to donate products, and programming a computerised random number generator to operate in a specified way to conduct a raffle of those products.

179. *Patents for Schemes or Plans* goes on to state:

> …a scheme (including a business scheme) or plan is, in itself, not suitable for a patent because it does not specifically give rise to an artificially created end result of economic utility."
> Examples of unpatentable schemes are given as:
> "A method of raising funds by seeking sponsors to donate products, and conducting a raffle of those products."
> and
> "A method of analysing the performance of an investment by creating a benchmark, and comparing the investment to the benchmark.

[37] http://www.ipaustralia.gov.au/library/PDFS/patents/schemes.pdf

This suggests that unpatentable schemes can be turned into patentable subject matter by implementing them in some way, for example on a computer.

B. Computer Software

What Is Computer Software?

180. Computer software or computer programs can be defined as "a series of instructions written in a computer language which enables the computer hardware to perform a particular function". In many countries, including New Zealand, computer software was, in the past, generally regarded as not being suitable subject matter for a patent.

Why Is Computer Software an Issue?

181. The issues surrounding the patenting of computer software are similar to those surrounding the patenting of business methods. That is, that Patent Offices do not have the expertise or resources to adequately examine all patent applications for inventions involving software, resulting in patents being granted for software that is neither new or inventive. It has also been suggested that the patenting of computer software would act to stifle innovation, and that computer software should not be patentable at all.

182. It should be noted that computer software already enjoys copyright protection under the Copyright Act 1994. This gives protection against direct copying of the software, but does not protect the principles or ideas underlying the software.

Computer Software Patents in New Zealand

183. Up until 1993, computer software was held to be unpatentable in New Zealand. On 30 June 1993, the Commissioner of Patents released a decision on Patent Application No 193718, in the name of Clarks Limited.[38] This application concerned a method of producing a pattern for a shoe by providing a computer with information defining the three dimensional shape of the last. The Commissioner eventually allowed a patent to be granted, notwithstanding some reservations on whether such subject matter should be eligible for patent protection under New Zealand law.

184. The decision on Clark's Application was followed in 1995 by a further decision of the Commissioner in patent applications 221797, 233797 and 233798 in the name of Hughes Aircraft Company. The Hughes Aircraft applications concerned methods for calculating a conflict alert status for an aircraft using a computer. In allowing these applications, the Commissioner followed the decision of the Federal Court of Australia in *International Business Machines Corporation v the Commissioner of Patents*,[39] and adopted the guidelines for patentability of computer software-related inventions as used at the time by the Australian Patent Office following this Court decision. These guidelines are now used

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[38] Decisions of the Commissioner of Patents can be found on the Intellectual Property Office of New Zealand website, www.iponz.govt.nz.

[39] (1992) IPR 417.

by IPONZ. This means that computer software is now patentable in New Zealand, provided that it meets the requirements in the guidelines.

185. The guidelines for determining the patentability of computer software related inventions now used by IPONZ are as follows:

- A method-type claim must define a method, which either directly, or by implication embodies [a] commercially useful effect.
- A claim to a mathematical algorithm *per se* is not patentable, because it does not produce a commercially useful effect. A commercially useful effect can only arise when the mathematical algorithm is implemented in some manner to produce a result.
- A claim to a mathematical algorithm **when used** in a computer is patentable so long as a commercially useful effect is produced.

The term "commercially useful effect" in this context is an "artificially created state of affairs that has utility in the field of economic endeavour" as set out in the *National Research and Development Corporation v Commissioner of Patents*.[40]

Patentability of Computer Software in Other Countries

Australia

186. As in New Zealand, computer software had long been held to be unpatentable in Australia. This policy was changed after the decision in *IBM v Commissioner of Patents* referred to above in the discussion on the patentability of software in New Zealand. Since then, the Australian Patent Office has adopted amended guidelines, based on another Australian Federal Court decision, *CCOM v Jeijing*.[41] This case was an appeal from an earlier decision revoking a patent. The patent in question was for an apparatus for storing and retrieving Chinese characters in a word processor.

187. The test now used by IPAustralia for determining the patentability of software patents is whether there is:[42]

> a mode or manner of achieving an end result which is an artificially created state of affairs of utility in the field of economic endeavour

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[40] Wood, "Patents in Computer Software – Commercially Useful is Not Enough", (1998) 9 *Australian Intellectual Property Journal* 134.

[41] (1993) 27 IPR 577

[42] *Australian Patent Office Manual of Practice and Procedure*, Volume 2, Para. 8.2.7.2.

United States

188. Following a series of judicial decisions,[43] computer software is now considered to be patentable in the United States provided it meets certain conditions. For example, USPTO's "Examination Guidelines for Computer-Related Inventions"[44] includes the following statement:

> A process that merely manipulates an abstract idea or performs a purely mathematical algorithm is non-statutory despite the fact that it might inherently have some usefulness. For such subject matter to be statutory, the claimed process must be limited to a practical application of the abstract idea or mathematical algorithm in the technological arts. For example, a computer process that simply calculates a mathematical algorithm that models noise is non-statutory. However, a claimed process for digitally filtering noise employing the mathematical algorithm is statutory.

European Community

189. Article 52(2) of the European Patent Convention sets out those things that are excluded from patentability. These include:

- discoveries, scientific theories and mathematical methods;
- aesthetic creations;
- schemes, rules and the methods for performing mental acts, playing games or doing business, and programs for computers; presentations of information.
- This specifically excludes computer programs.

The Board of Appeal of the European Patent Office has, however, held that the exclusion from patentability of computer programs as such in Article 52(2) does not prevent the patenting of computer-related inventions. "Case Law of the Boards of Appeal", Part 1, Chapter A, Section 1.1[45] states:

> Decision **T 208/84** (OJ 1987, 14) set out the principles governing the patentability of computer-related inventions. Even if the idea underlying an invention may be considered to reside in a mathematical method, a claim directed to a technical process in which the method is used does not seek protection for the mathematical method **as such**. A claim directed to a technical process carried out under the control of a program (whether by means of hardware or software) cannot be regarded as relating to a computer program **as such**. A claim which can be considered as being directed to a computer set up to operate in accordance with a specified program (whether by means of hardware or software) for controlling or carrying out a technical process cannot be regarded as relating to a computer program **as such**.

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[43] For example, *Re Freeman* 197 USPQ 464 (1978); *Diamond v Diehr* 209 USPQ 1 (1981).

[44] http://www.uspto.gov/web/offices/com/hearings/software/analysis/files/guides.doc

[45] See http://www.european-patent-office.org/case_law/english/I_A_1-1.htm

This means that computer software is now patentable in the European Community, provided the software is directed to carrying out a “technical process”.

How Should New Zealand Treat Patent Applications for Business Methods and Computer Software?

190. As mentioned above, under New Zealand law, there is no absolute bar to the patenting of business methods. Such methods can be patented, provided that they result in an “artificially created state of affairs that has utility in the field of economic endeavour”. As there is no specific definition of “business method”, it is not possible to state how many “business method” patents have been granted in New Zealand.

191. Similarly, computer software can also be patented in New Zealand, again as long as it is connected with an “artificially created state of affairs that has utility in the field of economic endeavour”.

192. The first question that arises is whether New Zealand should be granting patents for computer software or business methods at all. At present, New Zealand’s international obligations do not require New Zealand to grant such patents, so it is possible for New Zealand to consider the issue from a local point of view, that is, what provides the most benefit (or least cost) to New Zealand.

What Are the Arguments for and against Granting Patents for Business Methods and Computer Software?

193. The main arguments advanced in favour of granting patents for business methods and software are:

- the granting of patents is necessary to stimulate innovation; and
- that inventors of new computer software and business methods are entitled to protection for their intellectual property, just as other inventors are, and that there is no logical reason to exclude these things from patentability.

194. The theoretical justification for the granting of patents, as set out in Section 1 of this document, is that the exclusive right conferred by the patent stimulates innovation by giving innovators an opportunity to profit from their investment in research and development. In return society gains something that it might not otherwise have had – the disclosure of an invention that is new and innovative. This gain to society is considered to provide a benefit to society that exceeds the costs of granting an exclusive right.

195. If innovation is occurring without the stimulation of patents, there may be no benefit to society by granting patents, as there may be no increase in innovation. On the other hand, society will still have to bear the costs imposed by the existence of the patents. In this case the granting of patents would not be justified, as the costs would exceed the benefits.

196. On 1 November 2000, the United Kingdom Patent Office released a consultation document[46] *Should Patents Be Granted for Computer Software or Ways of Doing Business*. After considering the responses, the United Kingdom government concluded:

> There is no sign, at least to date, of a want of innovation in computer-implemented business methods, and nor was there in the US before business methods became patentable in 1998. Intense innovation has characterised this field. The Government's conclusion is that those who favour some form of patentability for business methods have not provided the necessary evidence that it would be likely to increase innovation. Unless and until that evidence is available, ways of doing business should remain unpatentable.

(The United Kingdom is a party to the European Patent Convention, and the United Kingdom Patents Act 1977 incorporates the Convention's exclusion from patentability of methods for doing business and computer programs.)

197. With regard to computer software, the United Kingdom government concluded:

> The Government's conclusion is thus to reaffirm the principle that patents are for technological innovations. Software should not be patentable where there is no technological innovation, and technological innovations should not cease to be patentable merely because the innovation lies in software. However, the Government agrees with those respondents who said that at present the law is not clear enough, and that this is damaging. Clarification is needed. This raises complex and technical questions, but the central difficulty can be expressed simply: how to define the boundary determining when software is, and is not, part of a technological innovation, so that what is patentable will be clear in specific cases in future. The Government intends to take this matter up with its partners in the European Union and the European Patent Convention as a matter of urgency.

This raises the question as to whether New Zealand should clarify its patent legislation to require patents to be for "technological innovations".

198. The other main argument advanced for granting patents for business methods and computer software is that there is no logical reason for denying them patent protection. Developers of other inventions can receive patent protection; why should developers of software and business methods not be able to receive similar protection?

199. An argument against the granting of patents for business methods and in particular, computer software, is that it actually discourages rather than encourages innovation. If new advances in these fields are patented, the argument goes, they will be unavailable for others to use during the life of the patent. It is suggested that new computer software builds incrementally on existing software. If programmers are unable to use the ideas in this existing software because it is protected by patents, innovation will be stifled, especially given the short commercial "life" of most software.

200. It is also argued that the software industry has flourished in the past without the incentive of patent protection. Much of the software developed in recent times is not the subject of patent protection. It has even been argued that it was the lack of patent

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[46] http://www.patent.gov.uk/about/consultations/annexa.htm

protection, and consequent free access by developers to the innovations of others before them, that is responsible for the growth and prosperity of the software industry.

201. The arguments raised against the patenting of business methods and software could be raised against the patenting of any newly developed technology. Most inventions, whether patented or not, are improvements on already existing inventions. In the past, software and business methods were generally not patentable. As a result, people developing new software or business methods were accustomed to building on the ideas of others. If software and business methods are patentable, this activity may become more difficult. This may have negative implications for local developers, as most New Zealand patents, and therefore most business method and software patents, are granted to foreign owners.

202. The granting of patents to business methods and computer software has attracted considerable criticism overseas, particularly in the United States. The criticism has largely centred around the alleged inability of patent offices to adequately examine such applications rather than whether it is appropriate to grant patents at all for business methods and software. It is claimed that this has led to the granting of patents for business methods and software which are neither new nor inventive. While such patents would be held to be invalid by the Courts in revocation proceedings, the process of challenging the validity of a patent can be expensive. As a result, not all of these invalid patents may be subject to challenge.

203. The criticism of patent offices has been:

- that patent examiners lack the knowledge and appropriate resources to adequately examine applications for business method and software patents; and
- that much of the "prior art"[47] involving business methods and software may be difficult for patent examiners to locate.

These issues are likely to be relevant in New Zealand as well.

204. One other problem that may arise in New Zealand is that IPONZ currently does not examine patent applications for inventive step or "obviousness". As a result, some business methods and computer software that are obvious variants of known methods or software may be granted a patent. While obviousness is a ground for revoking a patent, the revocation process can be costly and time-consuming, and, as noted previously, not all invalid patents may be challenged.

205. It does seem then, that any problems associated with business method and software patents in New Zealand are likely to be due to difficulties in examining such patent applications, rather than with the principle of patenting business methods or software. Changes proposed to the Patents Act in Stage 1 and Stage 2 of the current Review however, may go some way towards mitigating these problems.

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[47] "Prior art" is material published prior to the filing date of a patent application that is relevant in determining whether an invention is novel and inventive.

206. Included among the changes is a proposal to introduce examination for inventive step. This will reduce the likelihood of invalid patents being granted. If invalid patents are granted, other changes that have been proposed will make it easier to challenge the validity of a patent. To this end, a re-examination procedure has been proposed as well as a simplified revocation procedure. The re-examination procedure will allow anyone to submit to IPONZ any material which may suggest that a patent or patent application is not new or lacks an inventive step.

207. Another factor that may need to be considered is the effect of any change to the definition of invention in the Patents Act. If the current definition is replaced, the criteria now applied by IPONZ in assessing the patentability of inventions involving business methods and software may no longer apply. This may mean for example, that inventions involving methods that do not produce an "artificially created state of affairs that has utility in the field of economic endeavour" would become patentable. This could include such things as mere schemes or plans, and mathematical algorithms. Would this be desirable?

International Obligations

208. The TRIPS agreement specifies, in Article 27.1 that "patents shall be available for any inventions, whether products or processes, in all fields of technology, provided that they are new, involve an inventive step and are capable of industrial application." The TRIPS agreement was negotiated at a time when most countries did not allow patents for business methods and computer software as they were thought to be inherently unpatentable. As a consequence, it is not clear whether the TRIPS agreement includes or excludes business methods and software. It can be noted though, that the European Patent Convention has retained its exclusions of business methods and computer programs despite the provisions of TRIPS.

209. Any restrictions on the patenting of business methods and computer software may not be inconsistent with TRIPS. Such restrictions however, may attract criticism from other countries with more liberal patenting regimes. Such restrictions would also mean that New Zealand would be out of step with Australia.

Questions

18. Business methods and computer software are currently patentable in New Zealand. Should they continue to be patentable? Why?

19. If business methods and/or computer software should continue to be patentable in New Zealand, are the criteria for granting a patent adequate? If not, what should they be?

20. Should there be an explicit requirement for business methods and computer software to possess "technical character" in order to be patentable.

21. What resources might IPONZ require to ensure that it is able to adequately examine patent applications involving business methods and computer software?

22. If business methods were to be excluded from patent protection, should some other form of protection be given to them? If so, what should this be?

23. Should schemes or plans, mathematical algorithms and other abstract concepts remain unpatentable? If not, why not?

24. If mathematical algorithms, schemes and plans, and other abstract concepts were to remain unpatentable, should they be the subject of specific exclusions in the Patents Act?

7. Patents for Methods of Medical Treatment of Humans

What Is a Method of Medical Treatment of Humans?

210. The term "method of medical treatment of humans" covers methods of treating human illness. These may include such things as surgical procedures, such as a method of doing heart surgery, or drug treatment regimes, such as treating a medical condition by taking a particular drug or combination of drugs. It does not include such things as pharmaceuticals or surgical apparatus that may be used in a method of treatment.

Why Are Methods of Medical Treatment an Issue?

211. Currently, methods of medical treatment of humans are not patentable in New Zealand. Most other countries do not allow such methods to be patented either. The New Zealand Court of Appeal has held that any change in this policy should be made by Parliament, not the Courts, given the commercial, economic, ethical and social implications involved. Despite this, there have been several challenges to the current policy of refusing patent protection to methods of medical treatment. As the Courts have made it clear that the issue is one that must be dealt with by Parliament, the current review of the Patents Act 1953 provides a good opportunity to discuss the issue. Whatever the outcome, the result will be greater certainty for all concerned.

What Is the Situation in New Zealand?

212. The definition of invention in s2 of the Patents Act 1953[48] does not specifically exclude methods of medical treatment of humans from patentability. The definition of invention in the Patents Act 1953 is the same as that in the United Kingdom Patents Act 1949 (now repealed). Decisions[49] of the United Kingdom courts, interpreting this definition, established that a method of medical treatment of human beings to prevent or cure disease is not a "manner of manufacture". On the basis of these decisions, patents for methods of medical treatment of humans have been refused by IPONZ. These decisions were followed by the New Zealand Court of Appeal[50] which held that a method of treatment of human illness or disease did not qualify for the granting of a patent. In this decision all three judges agreed not only that such a method should not be granted a patent, but also that any change in this policy was a matter for the legislature, not the courts, to decide.

213. More recently, the New Zealand Court of Appeal has held[51] that methods of medical treatment can no longer be treated as not being an invention. The Court also held that if

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[48] "'Invention' means any manner of new manufacture the subject of letters patent and grant of privilege within section 6 of the Statute of Monopolies."

[49] For example, *Schering A.G.'s Application* [1971] RPC 337; *Upjohn Co. (Robert's) Application*, [1977] RPC 185.

[50] *Wellcome Foundation v. Commissioner of Patents* 1983 NZLR 385

[51] *Pharmaceutical Management Agency Ltd vs The Commissioner of Patents and Others* (CA 56/99)

methods of medical treatment were to be excluded from patentability, it must be on moral or policy grounds, but did not go so far as to say that patents must be granted for such methods. The earlier decision, that a change in policy relating to the patenting of methods of medical treatment of humans was a matter for the legislature, was not challenged. IPONZ has continued to refuse patent claims to methods of medical treatment.

214. Although methods of medical treatment of humans are not patentable in New Zealand, not all methods involving medical treatment are excluded. Previous United Kingdom court decisions have attempted to draw a line between what is and is not an unpatentable method of medical treatment. The line is somewhat arbitrary, but essentially, methods of medical treatment of humans are excluded only where the treatment is for an illness, or to relieve pain and suffering. Methods of treatment of humans that have been held to be patentable include the following (the list is not exhaustive):

- The human is not ill, i.e. is not actually suffering from a disease, for example cosmetic surgery;
- The human is suffering from a condition which is part of a continuum from one extreme to another, in which variation from an arbitrary norm is regarded as being an illness, e.g. baldness, infertility, obesity;
- Elective treatments for conditions which are not in themselves illness, e.g. contraceptive methods or reducing the desire to smoke;
- Diagnostic testing which does not require surgery, or treatment of conditions which do not actually require treatment of the human, e.g. killing bacteria on the skin;
- Treatment of minor conditions where the active ingredient is incorporated into an over-the-counter product.

Second Medical Use

215. The ban on the patentability of methods of medical treatment has caused problems where a known substance already used to treat a particular medical condition is found to be useful in treating some other medical condition, this second use having been previously unrecognised. An example of this would be the discovery that aspirin was useful in reducing the risk of heart attacks. Because the substance is not new, it cannot be patented (it may have already been patented). If methods of medical treatment cannot be patented, then the second use cannot be patented either, as the only novelty is in the use to which the substance is put. This leaves the discoverer of the second medical use with no patent protection, even though the costs of investigating the second medical use may be high. Without patent protection, there may be little incentive to investigate the properties of existing pharmaceuticals to determine if they have other, previously unknown, medical uses.

216. In the European Community, where methods of medical treatment are also unpatentable, the "Swiss type" claim was devised to enable second medical uses to obtain some patent protection. "Swiss type" claims are patent claims[52] of the form:

> the use of [known compounds] for the production of pharmaceutical compositions for the treatment of [a particular medical condition]

The term "Swiss-type" comes from a 1984 decision of the Swiss Intellectual Property Office to allow claims in this form. IPONZ now allows "Swiss-type" claims. This practice was upheld in the Court of Appeal Decision in *Pharmaceutical Management Agency v The Commissioner of Patents and Others* (CA56/99).

Medical Treatment Patents in Other Countries

Australia

217. The Australian Patents Act 1990 does not specifically exclude methods of medical treatment of humans from patentability. The definition of invention in the 1990 Act[53] (and in the now repealed 1952 Act) contains wording similar to that in the New Zealand Patents Act 1953. Despite this, in 1994, the Australian Federal Court ruled[54] that methods of medical treatment were patentable in Australia. The Court reasoned that since the Australian Parliament had not specifically excluded medical treatment when it passed the 1990 Act, Parliament did not intend that such methods should remain unpatentable.

European Community

218. Article 52(1) of the EPC states that "European patents shall be granted for any inventions which are susceptible of industrial application, which are new and which involve an inventive step." Paragraph 4 of Article 52 states that:

> Methods for treatment of the human or animal body by surgery or therapy and diagnostic methods practised on the human or animal body shall not be regarded as inventions which are susceptible of industrial application within the meaning of paragraph 1. This provision shall not apply to products, in particular substances or compositions, for use in any of these methods.

219. Methods of medical treatment are therefore not eligible for the grant of European patents. All states that are parties to the EPC[55] have implemented the EPC as part of their national patent legislation.

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[52] Patent claims are a series of statements, usually found at the end of a patent specification, which provide the legal definition of the exclusive right claimed by the patent owner.

[53] S18(1)(a) requires a patentable invention to be "a manner of manufacture within the meaning of section 6 of the Statute of Monopolies."

[54] *Anaesthetic Supplies Pty Ltd v Rescare Ltd* [1994] IPR 383 at 421.

[55] Austria, Belgium, Switzerland, Cyprus, Germany, Denmark, Spain, Finland, France, Turkey, Greece, Ireland, Italy, Liechtenstein, Luxembourg, Monaco, Netherlands, Portugal, Sweden, United Kingdom.

United States

220. The United States Patents Act does not exclude methods of medical treatment of humans from patentability. Such methods may be granted a patent in the United States. From July 1996 newly issued medical process patents[56] are, however, no longer enforceable against medical professionals who infringe while performing a medical or surgical procedure[57]. This exemption from infringement proceedings only applies to surgical or medical procedures, and not methods of treatment using pharmaceutical compositions.

International Agreements

221. Article 27.3 of the TRIPS Agreement allows member countries to exclude from patentability "diagnostic, therapeutic and surgical methods for the treatment of humans or animals." Most countries exclude methods of medical treatment of humans from patentability.

What Should New Zealand's Policy on Patents for Medical Treatment Methods Be?

222. In considering what policy New Zealand should adopt, there appear to be just three basic options:

- Maintain the status quo;
- Allow methods of medical treatment to be patented;
- Allow methods of medical treatment to be patented, but provide that medical practitioners who use a patented method without the patent owner's permission would be exempt from infringement proceedings.

223. In deciding what policy New Zealand should adopt with regard to methods of medical treatment, it will be necessary to weigh up the costs and benefits to New Zealand of each of the options identified above. In the discussion that follows, the possible costs and benefits of each option are set out, although no attempt is made to quantify them.

Option i): Continue to Refuse to Grant Patents for Methods of Medical Treatment of Humans

224. If New Zealand continues to refuse to grant patents for methods of medical treatment, the main benefit is likely to be that the medical profession will continue to have free access to new medical procedures. The potential costs of license fees and patent litigation will be

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[56] A "medical process" is one that involves the performance of a medical or surgical procedure on a body, but does not include the use of a pharmaceutical in a medical treatment.

[57] United States Patents Act, Section 287, paragraph (c).

avoided. The ethical problems that might arise where doctors had a financial interest in particular procedures would also be avoided.

225. It is not clear that there would be any disadvantage to New Zealand in continuing to refuse to grant patents for methods of medical treatment of humans. There appears to be no empirical evidence to suggest that this acts as a disincentive to medical research in New Zealand (or anywhere else). One possible problem might be that owners of medical treatment patents overseas may try to prevent the use of their methods in New Zealand if they cannot be patented here. It is, however, difficult to see how this could be achieved without keeping details of the method secret. This would not be possible though, if the method had already been patented in another country. In any case, there is no evidence that New Zealanders' access to new methods of medical treatment has been restricted by the current ban on the patenting of such methods.

226. A possible disadvantage of maintaining the current position on patents for methods of medical treatment is that it would place New Zealand's patent regime out of step with that of Australia, which allows such patents. Does this cause any problems for businesses in the two countries? Most patents granted in Australia and New Zealand are granted to owners who are not resident in either country. Few, if any, local businesses may be affected by the differences in patent law on this issue.

Option ii): Allow Patents to Be Granted for Methods of Medical Treatment of Humans

227. Those in favour of the grant of patents for methods of medical treatment argue that the reasons for granting patents in the first place – to encourage innovation and to provide an opportunity to benefit from effort and investment in research and development – apply equally to medical treatment as to anything else. If patents are not granted for methods of medical treatment, it is argued, inventors or businesses may be unwilling to invest in research and development.

228. As noted earlier, there appears to be no empirical data to support this argument. In any case, financial rewards may not be the only incentives to innovation in the field of medical treatment, particularly where the innovator is a doctor or other medical practitioner. Rewards such as prestige, peer recognition, and respect by society may be other drivers of innovation. Some doctors may be motivated to develop new medical treatments by the need to improve the health or quality of life of their patients rather than by any desire for personal advancement.

229. The development of new methods of medical treatment, particularly surgical methods, may be much cheaper than the cost of, say, developing a new drug. This may reduce the need for an exclusive right to provide an opportunity for the inventor of the new method to recover the development costs.

230. Another argument in favour of granting patents to methods of medical treatment is one of consistency: that is, why should methods for the treatment of disease be singled out for exclusion from patent protection? What logical justification is there for saying that methods that produce that produce a cosmetic or functional result are patentable, while those that produce a curative result are not? Why should substances and devices used in medical treatment be patentable, while methods for their use are not? Against this, it could be argued that the matter is one of public policy. That is, the question of whether

methods of medical treatment of humans should be patentable or not should be decided by considering what is in the best interests of society as a whole.

231. Most developed countries have placed some restrictions on the patenting of methods of medical treatment of humans. The lack of patents to methods of medical treatment does not seem to have slowed the advances in medical technology that have taken place in the last 30 years.

232. The one area where the granting of patents may have a positive effect is in the field of second medical use. Investigating a second or subsequent medical use of a known compound is likely to involve considerable investment. In such a case, the availability of patent protection may be necessary to provide an incentive for research. The allowance of "Swiss-type" claims (see above) is a way of providing this incentive without the potential disadvantages of allowing claims to methods of medical treatment.

233. One of the main disadvantages of granting patents for methods of medical treatment would the likely increases in the costs of healthcare. Doctors and other health providers may face increased costs for patent licenses, and may also have to take into account the cost of patent infringement litigation. These extra costs would add to the costs of the health system. Most New Zealand patents are granted to overseas owners, and this is also likely to be the case for medical treatment patents. As a result, most of the revenue generated by these patents will flow offshore.

234. Another possible disadvantage is that access to medical procedures such as surgical methods may be restricted if such procedures are patented. Doctors, health providers and patients may be unwilling or unable to pay the license fees demanded by patent owners. Patent owners may also restrict the number of licenses that they are willing to grant. If licenses are restricted, then some patients may find that they have a reduced choice of doctor or surgeon. In some cases, patients may be denied access to a particular method because they are unable to find a doctor who is licensed to perform it.

235. The granting of patents to methods of medical treatment may raise ethical problems. Doctors who have a financial interest in a patented method of treatment may use that method, or refer patients to doctors who use that method in preference to others, even though that method may not be the most appropriate for that particular patient. On the other hand, doctors who are unable, or unwilling, to obtain a license to use a patented method may use some other method, even though this may not be as appropriate for the patient as the patented method.

236. Allowing patents to methods of medical treatment may stifle the sharing of information between physicians, which may actually slow down the rate of innovation. Doctors and medical researchers may be unwilling to share information, because this may jeopardise their chances of getting a patent. Although it is a requirement of the patents system that there be full disclosure of the invention, this information cannot readily be used until the patent has expired.

Option iii): Allow Patents for Methods of Medical Treatment, but Exempt Medical Practitioners from Infringement

237. The only country that has adopted this approach is the United States. As noted earlier, the United States Patents Act exempts medical practitioners from infringement proceedings if they infringe while performing an medical or surgical procedure. The

provision of this exemption was in response to an attempt by an ophthalmic surgeon who had taken out a patent to a particular method of cataract surgery to sue another surgeon for patent infringement.[58]

238. The possibility of exempting medical practitioners from infringement proceedings has also been suggested in a recent decision of the New Zealand Court of Appeal[59], where it was stated in paragraph 65:

> Bearing in mind the rationale for the method of treatment exception permitted under TRIPS, Art 27:3, - that there should be no interference with the medical practitioner's diagnosis and treatment of patients – perhaps the logical approach would be to permit claims to extend to the method of treatment using the compound or composition, but to require from the patentee a disclaimer of any right to sue the practitioner.

239. Under this option, patents for methods of medical treatment of humans could not be enforced against medical practitioners. If the patented method was a surgical method, or some other therapy not directly involving the use of drugs, then this could effectively render the patent worthless if the method was one that only medical practitioners were able to carry out.

240. Where the patented method primarily involves the use of pharmaceuticals, rather than a surgical method, then the fact that the method could not be enforced against medical practitioners may not affect the rights of the patent owner very much. Such methods would usually be commercially exploited by the sale of packages containing the drug or drugs involved in the method, together with instructions for their use. Medical practitioners may be unwilling to take the time to buy the pharmaceuticals separately for use in the method.

241. Under this option medical practitioners would not incur the extra costs of license fees or patent litigation. If methods of treatment that primarily involve the use of drugs become patentable, however, then there could be an increase in the cost of such treatments. Other health workers, such as nurses, rescue or first aid workers, or practitioners of alternative medicine could still be liable for infringement if they used patented methods of medical treatment without the permission of the patent owner.

What Does the Medical Profession Think?

242. The views of the medical profession in New Zealand do not appear to have been canvassed on this issue. The American Medical Association (AMA) had this to say on the subject on the subject:[60]

> …medical process patents potentially threaten the integrity of the medical profession.

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[58] *Pallin v. Singer* (36 U.S.P.Q.2d 1050 (1995))

[59] *Pharmaceutical Management Agency Limited vs. The Commissioner of Patents and Others*, CA56/99.

[60] "Patents on Methods of Medical Treatment: Where Should the Balance Lie*?", New Zealand Intellectual Property Journal*, Nov. 1996

The AMA expressed the view that the grant of patents for methods of medical treatment could reduce the professionalism of physicians who may put economic goals above those of patient health.

243. The World Medical Association Association Statement on Medical Process Patents[61] included the statement:

> the patenting of medical procedures poses serious risks to the effective practice of medicine by potentially limiting the availability of new procedures to patients.

In light of this, it would be important to take account of the views of the New Zealand medical profession before making any change to New Zealand's current policy regarding patents for methods of medical treatment of humans.

If the Status Quo Is Retained, How Might It Be Implemented?

244. If it is decided that methods of medical treatment should remain unpatentable in New Zealand, it may be desirable to amend the Patents Act so that these are clearly excluded from patentability. This would result in certainty for patent applicants and the Courts and could significantly reduce future litigation on the subject. To ensure this, any exclusion relating to medical treatment would have to clearly spell out what was meant by "method of medical treatment of humans". What sort of treatment methods would be excluded? Such an exclusion would have to comply with Article 27.3(a) of the TRIPS agreement. Perhaps some or all wording in this article could be adopted to provide for this.

245. Another option would be to leave the current definition of invention in S2 of the Patents Act 1953 unchanged and rely on past Court decisions to maintain the ban. That is, under this option there would be no specific exclusion for methods of medical treatment. There is a risk with this approach. A Court could decide that because Parliament did not provide for a specific exclusion when it had the opportunity to do so, Parliament did not have any particular desire to maintain the ban on patenting of methods of medical treatment of humans. The result would be that IPONZ would be required to grant patents for such methods. As discussed previously, this is essentially what happened in Australia.

Methods of Medical Treatment of Animals

246. The TRIPS agreement allows parties to exclude methods of medical treatment of animals from patent protection. Such methods are currently patentable in New Zealand. The EPC contains an exclusion for these methods. Is there a case for New Zealand to exclude methods of medical treatment of animals from patentability?

Questions

25. Should methods of medical treatment of humans remain unpatentable in New Zealand? If not, why not?

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[61] Adopted by the 51st World Medical Assembly Tel Aviv, Israel, October 1999, http://www.wma.net/e/policy/17-777_e.html.

26. If methods of medical treatment were to become patentable in New Zealand, what benefits would there be for New Zealand? What would be the costs?

27. If methods of medical treatment were to become patentable in New Zealand, should such patents be enforceable against medical practitioners?

28. If methods of medical treatment of humans were to remain unpatentable, should they be the subject of a specific exclusion the Patents Act? If not, why not?

29. If the Patents Act were to contain a specific exclusion for methods of medical treatment of humans, what treatments should be excluded? Should there be a definition of "medical treatment of humans" in the Patents Act, or should the interpretation of this term be left to the courts?

30. The TRIPS agreement also allows for methods of medical treatment of animals to be excluded from patentability. These methods are currently patentable in New Zealand. Should such methods be excluded from patentability? If so, why?

8. Stringency Test for Patentability

Introduction

247. The New Zealand Patents Act 1953 is very similar to the United Kingdom Patents Act 1949 and the Australian Patents Act 1952. The United Kingdom Courts have ruled[62] that the role of the Patent Office in administering the Patents Act 1949 is not to finally decide whether an invention is patentable, but only to refuse to allow an application to proceed which on no reasonable view could be said to be eligible for a patent. It was ruled that it was up to the High Court to determine actual patentability.

248. The High Court of Australia held that, under the Patents Act 1952, the grant of a patent should only be refused if it was practically certain that if a patent was granted it would be held to be invalid.[63] If there is any dispute, the applicant must be given the benefit of the doubt. The justification for this policy is that the Patent Office would not, at the examination stage, have the benefit of the arguments of counsel and oral evidence.

249. The New Zealand courts have followed these United Kingdom and Australian decisions. As a consequence, IPONZ has also followed these rulings, and is required to give the applicant the benefit of the doubt when deciding whether or not to grant a patent.

Why Is This an Issue?

250. If IPONZ can only refuse to grant a patent when it is "practically certain" that any patent granted would be held by a Court to be invalid, it is possible that patents which might be likely (but not almost certain) to be held invalid will be granted.

251. Invalid patents cannot be enforced: that is, they would held to be invalid in infringement or revocation proceedings. However, the outcome of litigation, particularly patent litigation that can involve complex technical matters, is always uncertain. Any party challenging the validity of a patent would have to meet the ongoing costs of litigation, and if the challenge were unsuccessful the challenger might have to meet the patent owner's costs as well. If an unsuccessful challenger was also found to be infringing the patent, the challenger might be liable for damages. Under these circumstances, many patents that are likely to be held to be invalid might never be challenged.

252. The grant of a patent provides the patent owner with an exclusive right to exploit the patented invention. That is, the patent owner has a form of monopoly until the patent expires. If a patent is granted that the courts would find to be invalid, the monopoly rights enjoyed by the patent owner are greater than the owner is entitled to. These greater rights have the potential to restrict competition and raise prices to consumers, and may restrict the activities of local businesses who lack the resources to challenge the validity of the patent. The fact that most New Zealand patents are granted to foreign owners means that

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[62] *Swift & Co's Application* [1962] RPC 37 at 46.

[63] *Microcell Ltd and Others' Application* [1977] FSR 163 at 172.

most of the financial benefits of these patents will flow out of New Zealand. The persistence of these invalid patents might impose a significant economic cost on New Zealand.

Situation in Other Countries

253. The Australian courts have continued to apply the precedents discussed earlier under Australian Patents Act 1990. Consequently, IPAustralia is required to give applicants the benefit of the doubt when deciding whether or not to grant a patent.

254. In a recent review of the Australian Patents Act 1990, the Australian Intellectual Property and Competition Review Committee (IPCR)[64] recommended changing the Patents Act 1990 to require a "balance of probabilities" approach to be used during examination, rather than conferring the "benefit of the doubt" to the applicant as at present. This recommendation has been adopted by the Australian Government, and a bill to appropriately amend the Patents Act 1990 was introduced to the Federal Parliament.[65] This bill was subsequently passed on 27 September 2001 as the Patents Amendment Act 2001.

255. This is essentially the same approach now used in the United Kingdom under the Patents Act 1977. Under this Act, the onus is upon applicants to show that their applications meet the legislative requirements when faced with a reasonable challenge. Effectively, objections are made or maintained according to whether, on the balance of probabilities, they are appropriate.[66]

Should the Stringency Tests for Granting a New Zealand Patent Be Changed?

256. While the recommendation to change the stringency test in Australia was made in the light of what was considered to be an overly liberal application of the "benefit of the doubt" criterion by IPAustralia, it may be worth considering this change in New Zealand. This would increase the likelihood that granted patents are valid, and would harmonise New Zealand law with that of Australia. This would also bring New Zealand practice into line with practice in other countries.

257. The review of the Australian Act, referred to above commented:

> While there may be some increase in costs due to more protracted arguments between applicants and examiners, these are likely to be small and to be reduced as each side becomes more familiar with the new stringency of testing. The benefits in terms of improved certainty and validity are likely to be considerable.

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[64] The section of the report dealing with the patent system can be found at: http://www.ipcr.gov.au/ipcr/finalreport1dec/patentdesigns3.htm

[65] Patents Amendment Bill 2001. Details can be found at IPAustralia's website, www.ipaustralia.gov.au.

[66] Advisory Council on Industrial Property (Australia) *Review of Enforcement of Intellectual Property Rights* 1999, p. 15

258. Should consideration be given to changing the stringency test for deciding whether or not to grant a patent from the present “benefit of the doubt” to a “balance of probabilities” test? If such a test were to be adopted, then there would be increased certainty for both patent owners and third parties, as there would be a greater certainty that granted patents would be held to be valid by the Courts. Given that such a test is being adopted in Australia, it may be desirable to adopt it in New Zealand, so as to provide greater certainty for businesses operating in both countries.

Questions

31. Is the stringency test for granting a patent in New Zealand too liberal? If so, why? If not, why not?

32. If the test is too liberal, what test should be adopted?

33. If a more restrictive test were to be adopted, would there be any advantages or disadvantages other than those identified above?