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10.

Intellectual property

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Intellectual property

Key issues:

- The scope of intellectual property rights
- Balancing community interests and individual rights
- Intellectual property rights and life forms
- Protection of traditional knowledge
- Changes required to present system.

Introduction

1. The Commission’s Warrant asked that we investigate and hear views on the intellectual property issues involved, now and in the future, in relation to the use in New Zealand of genetic modification, genetically modified organisms, and products.

2. In the course of its consultation, the Commission heard a variety of views about intellectual property rights (IPRs). Some suggested IPRs were “inherently evil”. According to a number of value systems, it was unethical or immoral to allow an individual (corporate or otherwise) to own or control the “stuff of life”.¹ Also, IPRs were seen as increasing costs and denying access to new and improved products and processes. But other submitters pointed out that, consistently, innovation and economic benefits were higher in countries having well-developed systems for recognising and rewarding inventions through intellectual property rights.² These submitters emphasised the nature of the social contract that IPRs represent, between individuals rewarded for their innovation or foresight, and society as a whole, which accrues benefits from the development of new products and processes and the enhancement of the sum of human knowledge.

3. Many submitters argued that the protection provided by an intellectual property (IP) system is a basic necessity for the development of genetic modification technology. A strong IP system means that New Zealand inventors can protect their ideas and investment and receive the benefits from their commercial

applications.³ Indeed, the New Zealand Institute of Patent Attorneys (NZIPA) [IP71] submitted that New Zealand must expand and update its patent and plant breeders' rights legislation to provide adequate protection and comply with international obligations.⁴ The Commission is indebted to the NZIPA and its principal witness Doug Calhoun for their comprehensive presentation. We have drawn on the evidence of Mr Calhoun, a past president of the NZIPA, for material included in this chapter.

4. The Commission notes there is a worldwide movement for development and harmonisation of IPR regimes, as there seems to be acceptance that the social and economic benefits of such systems are of universal application.⁵

Nature of intellectual property rights

5. This section discusses the various IPRs, how they are created and their application to biotechnology and genetically modified organisms and products. This is to address the confusion in general perceptions about the scope of IPRs. We need to explain what intellectual property rights do and, as importantly, what they do not.

What are intellectual property rights?

6. Intellectual property rights are rights in creations of the mind, such as inventions, industrial designs, literary and artistic works, symbols, and names and images. "Intellectual property" is defined in Article 2(viii) of the 1967 Convention Establishing the World Intellectual Property Organization (WIPO) to include rights relating to:

- literary, artistic and scientific works
- performances of performing artists, sound recordings, and broadcasts
- inventions in all fields of human endeavour
- scientific discoveries
- industrial designs
- trademarks, service marks, and commercial names and designations
- protection against unfair competition
- all other rights resulting from intellectual activity in the industrial, scientific, literary or artistic fields.

New Zealand is a member of WIPO.

7. IPRs can be divided into two main categories:

- The protection of **industrial property** covers patents, utility models, industrial designs, trademarks, service marks, trade names, geographical

indications (indications of source or appellations of origin), and the repression of unfair competition.

- **Copyright** includes literary and artistic works, such as novels, poems and plays, films, musical works, and drawings, paintings, photographs and sculptures, computer software, databases, and architectural designs. **Related rights** include the rights of performing artists in their performances, producers of sound recordings in their sound recordings, and those of broadcasters in their radio and television broadcasts.
8. Additionally, **plant varieties** can be protected in many countries under IP-related systems of plant breeders' rights.
9. Under the WIPO Convention,⁶ “intellectual property” is not confined to the examples given above. The definition in the Convention concludes with the phrase “all other rights resulting from intellectual activity in the industrial, scientific, literary or artistic fields”. It is clear that “intellectual property” is a broad concept and can include productions and things outside the existing categories of intellectual property, provided they result from “intellectual activity in the industrial, scientific, literary or artistic fields.” Other means of protecting intellectual property are available, such as trade secrets and private agreements for access to “know how”.

Patents

10. Patents are a form of social contract, where inventors receive an exclusive right for a specific period (20 years) to exploit their invention commercially in return for public disclosure of information about it. During the term of the patent, only the patentee may make, use or sell the invention.

11. A patent is granted for an invention, being a product or process offering a new technology, device or material. To be protected by a patent, an invention must:

- be novel, that is, the invention must have some new characteristic which is not known in the body of existing knowledge
- show an inventive step or be non-obvious
- be useful or a manner of new manufacture, and
- be sufficiently and fairly described.

12. Under the Patents Act 1953, all inventions may be patented as long as they meet the above criteria, with the exception of any the use of which would be contrary to morality.⁷ Other relevant features of patents include:

- patenting is an expensive process
- enforceability is geographically limited

- universality is expensive
- only reasonable exploitation is allowed
- statistically only a small number of patent applications are successful.

Plant variety rights

13. The intellectual property rights known as plant breeders' rights or plant variety rights (PVRs) are supplementary to the patent system. New Zealand is a signatory to the 1991 international convention known as the Union for the Protection of New Varieties of Plants (UPOV)⁸ but has yet to update the Plant Variety Rights Act 1987 to comply with this version of the convention. In order to gain protection, a plant variety must be:

- new
- distinct
- uniform, and
- stable.

14. A “distinct” plant variety is sufficiently different from existing plant varieties such that there is no confusion in identifying members of the new variety as separate from members of the old variety. A plant variety is “uniform” when the plants that make it up are sufficiently similar. A variety is “stable” if it remains unchanged through successive generations of reproduction or propagation. The “stability” of genetically modified plants is discussed in chapter 4 (Environmental and health issues).

15. PVRs are subject to two exceptions, differentiating them from the exclusivity provided by a patent. Other breeders may use a variety to develop new varieties and farmers may save seed for their own sole use in crop production, but not for sale.

16. However, because of the breeders' exemption, a person who patented a genetically modified variety of an existing variety would have exclusive rights. They would not require the permission of the New Zealand breeder of the variety they had genetically modified. Genetic modifiers could potentially free ride on years of research in breeding the unmodified varieties. For example, we were told of research overseas to develop a genetically modified Royal Gala apple. Commercial production of this variety has the potential to damage our market if consumers stop buying all Royal Gala apples because they cannot tell the difference between genetically modified and non-genetically modified apples.

17. This gap in protection was recognised internationally by provision of the concept of “essential derivation” in the 1991 version of the UPOV Convention. An essentially derived variety is one that is distinct from the initial variety in one

characteristic but otherwise has all of the characteristics of the initial variety. The essentially derived variety can be protected. However, it cannot be exploited without permission of the owner of the PVR for the initial variety. We agree with the NZIPA submission that, to protect New Zealand's classically bred varieties, the New Zealand Plant Varieties Act ought to be amended to introduce the concept of essential derivation.

Recommendation 10.1

that the New Zealand Plant Variety Rights Act 1987 be amended to introduce the concept of essential derivation.

What IPRs are not

18. An inventor can register an IPR only over a new, non-obvious, inventive and useful idea. Anything that is in nature is part of the public domain. Traditionally a basic test of patentability has been whether the product or process has arisen from “a product of human ingenuity”.

19. A further point is that “invention” is not the same thing as “discovery”. For example the identification of a cell line or other genetic material is a discovery. To be granted a patent or other intellectual property over that discovery requires the application of that discovery to create a new product or process.

20. This means there is a distinction between a life form or its DNA and an industrial, agricultural or technological use of that life form or DNA. This leads to the distinction between the ownership of genes, as they exist in nature and a patent or other IPR over a gene or gene sequence. It has long been a feature of the patent system that naturally occurring products or “laws of nature” cannot be patented because they are not new or inventive and patentees could not describe how to make them.

21. Furthermore the grant of a patent does not confer immunity from challenge. If any part of a patent is shown to be invalid, the whole patent is invalid. Patents are also contestable. If a patent application is too wide, it can be challenged for “covetous claiming”.

22. On the other hand, the issue of a patent does give force to the patented product or process. This means people may choose to pay for licences to use potentially invalid patents rather than challenge the patent itself. This is often a commercial decision based on the cost and benefits of challenge against negotiating a licence and using the possibility of challenge as a bargaining tool.

23. Further, the grant of a patent is not an automatic right to use the invention. Any use by a patent holder is controlled under other applicable legislation, such

as the Hazardous Substances and New Organisms Act 1996 (HSNO), the Agricultural Compounds and Veterinary Medicines Act 1997 (ACVM), the Medicines Act 1981 and so on.

24. A patent granted under the Patents Act is effective only in New Zealand and Tokelau. New Zealand patents are also effective in Niue and the Cook Islands under the domestic laws of each country.¹⁰ Patents granted in other countries cannot be enforced in New Zealand. While there is no such thing as a worldwide patent, an international patent application may be filed under the Patent Cooperation Treaty¹¹ to protect an invention between the time of filing an application at home and the filing of applications in other countries where IP protection is sought. (Also see the box “The use of insulin in diabetes” in chapter 9: Medicine.)

25. The exercise of a patent is also limited to commercial activities.¹² Generally, information disclosed in a patent can be the basis of further experimentation or research without the authorisation of the patentee. This is subject to some limitations: if the patent is for a research application or tool then research is also the commercial use and must be licensed, and if the research user of information disclosed in a patent later wishes to market their invention which uses the first invention, they would need a licence from and pay royalties to the patent-holder.

International obligations applicable to intellectual property rights

26. New Zealand is a member of the World Trade Organization (WTO) and a party to the WTO Agreement on Trade-Related Aspects of Intellectual Property Rights (TRIPS). The TRIPS Agreement, which came into effect on 1 January 1995, is a comprehensive multilateral agreement on intellectual property rights.

27. The areas of intellectual property that it covers are: copyright and related rights (ie, the rights of performers, producers of sound recordings and broadcasting organisations); trademarks, including service marks; geographical indications, including appellations of origin; industrial designs; patents, including the protection of new varieties of plants; the layout-designs of integrated circuits; and undisclosed information, including trade secrets and test data.

28. The Agreement sets out the minimum standards of protection to be provided by each Member:

- The substantive obligations of the main conventions of the WIPO (the Paris and Berne Conventions) must be complied with. Secondly, the TRIPS Agreement adds a substantial number of additional obligations on matters where the pre-existing conventions were silent or seen as inadequate.

- Certain general principles are applicable to all IPR enforcement procedures. In addition, provisions specify procedures and remedies that must be available so that right holders can enforce their rights.
- Disputes between WTO members about the TRIPS obligations [are] to be subject to the WTO's dispute settlement procedures.¹³

29. In addition the Agreement provides for certain basic principles that prohibit discrimination. These require equality of treatment between nationals of member countries, and between a member's nationals and nationals of other members (articles 4 and 13). "Nationals" include companies as well as persons. Additionally, there are some general rules to ensure that procedural difficulties in acquiring or maintaining IPRs do not nullify the benefits that should flow from the Agreement.

30. Article 27(3) of TRIPS provides that members may exclude from patentability:

- (a) diagnostic, therapeutic and surgical methods for the treatment of humans or animals;
- (b) plants and animals other than microorganisms, and essentially biological processes for the production of plants or animals other than non-biological and microbiological processes.

The provisions of that subparagraph are to be reviewed four years after the date of entry into force of the Agreement. That review was initiated last year.

31. WIPO is an international organisation promoting the use and protection of intellectual property. It is one of the 16 specialised agencies of the United Nations system of organisations, administering 21 international treaties dealing with different aspects of intellectual property protection. WIPO counts 175 nations as member states, of which New Zealand is one.

32. UPOV is an intergovernmental organisation, based on the International Convention for the Protection of New Varieties of Plants, as revised since its signature in Paris on 2 December 1961. The objective of the Convention is the protection of new varieties of plants by an intellectual property right. The main activities of UPOV are concerned with promoting international harmonisation and cooperation, mainly between its member states, and with assisting countries, in the introduction of plant variety protection legislation. New Zealand has been a member of UPOV since 1981.

Community and individual rights

33. This section looks at the balancing of community interests against the economic and property rights of individuals, and the impact of international obligations. This section also considers questions of access and costs in relation to IPRs over genetic modification techniques and products.

Objectives of IP systems

34. The primary purpose of IP systems is to promote and protect human intellectual creativity and innovation. IP law and policy does so by striking a balance between the rights and interests of innovators and creators to benefit from their work, on the one hand, and of the public at large to have access to new ideas and technology on the other.

35. The argument in favour of IP systems is that, by granting exclusive rights in an invention, they encourage further innovation, reward creative effort, and protect the (often substantial) investment necessary to make and commercialise the invention. Public dissemination is an important IP objective. The patent system encourages people to disclose inventions, rather than retain them as trade secrets, increasing publicly available knowledge and promoting further innovation by other inventors. These submitters believe the progress and well-being of humanity rests on its capacity for new creations in areas of technology and culture.

36. Likewise, such submitters argue that the promotion and protection of IP can also spur economic growth, create new jobs and industries, and improve the quality and enjoyment of life. However, the IP system also responds to the needs of the public at large. Generally IPRs are of limited duration, after which they fall into the public domain (only trademarks and geographical indications can subsist indefinitely).

The demerits of IP systems

37. Dr Ulrich Loening, a molecular biologist who founded the Centre for Human Ecology, Scotland, gave written evidence on behalf of the Koanga Gardens Trust [IP72]. He referred to the economic and social implications raised by the introduction of gene biotechnology into regular agricultural usage, pointing out that without patenting and corporate ownership the present generation of genetically engineered crop plants would not exist. His view was that this results in the central control of products, reducing social and biological diversities with “monolithic consequences” for agriculture.¹⁴ Dr Vandana Shiva (Director of the Research Foundation for Science, Technology and Ecology, India) who wrote a witness brief for the Pacific Institute of Resource Management [IP84] made similar statements about the monopoly control on seeds through IPRs and the growing concentration of ownership control over agricultural inputs, which will increase food insecurity for millions of poor farmers.¹⁵ Dr Shiva also maintained that the monopolisation of life forms through IPRs makes for

“absolute rights and absolute irresponsibility” which she described as a recipe for disaster.¹⁶

38. Friends of the Earth New Zealand [IP78] made similar submissions about access to and use of seeds of genetically modified plants subject to patents.¹⁷

39. Professor Jonathan King, chair in molecular biology at the Massachusetts Institute of Technology, USA, was a witness by videolink on behalf of Greenpeace New Zealand [IP82]. On the issue of access to information, and who should control and benefit from it, he argued that the biotechnology revolution was the product of a broad-based biomedical research and training enterprise based in colleges, universities and medical schools.¹⁸ Essential to these efforts were the free communication and exchange of materials and ideas, and the organisation of research in the public interest. Major scientific advances, such as the determination of the amino acid sequences that made up protein chains, were openly communicated and entered the public domain.

40. Professor King’s opinion was that, because oral reports, abstracts, grant proposals and published papers all constitute prior art, individuals or groups planning to file for a patent have to avoid public disclosure of the work before the filing of the claim.¹⁹ Patent attorneys regularly advise researchers to restrict presentations to colleagues, so as not to jeopardise planned patent submissions. Professor King said that the resulting undermining and reversal of the scientific culture of open communication and exchange was one of the most destructive impacts of gene patents.²⁰ Whatever validity these arguments may have, the Commission considers they are not specific to gene patents.

41. NZIPA presented a different point of view. In the patent social contract the patentee’s consideration includes a full disclosure of the patented invention and the best way of practising that invention.²¹ Patent Cooperation Treaty international applications are published before a patent is granted in any country giving the public at large a description of what is intended to be protected. The discovery that led to the invention may be used in further academic research. For instance, although the sequences to the breast cancer genes BRCA have been patented, a recent Medline search shows several hundred papers have been published discussing these genes.

42. NZIPA submitted that another issue arising with patents generally, and no less so with those for genetic modification, was the relationship between the pioneer patent and improvement inventions.²² A simplistic example is a patent for a mousetrap (the pioneer patent) and a subsequent patent for a better mousetrap (the improvement patent). The exploitation of any patented invention must comply with all other laws, and that includes avoiding infringement of other

patents. It is likely that exploitation of the better mousetrap invention will, in the absence of permission from the pioneer, be an infringement of the pioneer patent. On the other hand the owner of the pioneer mousetrap patent may not exploit the better mousetrap invention without the permission of the owner of the improvement patent. Both owners have a negotiating chip and the commercial outcome of bargaining between them depends upon the relative commercial values of their respective inventions.

43. Further, NZIPA pointed out that the recognised pioneer US patents for genetic modification (US 4468464 and 4740470, biologically functional molecular chimeras) were licensed on a non-exclusive basis to anyone who applied.²³ The royalty rules were based on the level of commercialisation for which the licence was granted.

44. It was almost inevitable, in NZIPA's submission, that different owners will hold patents for different genes and different modification techniques.²⁴ Just as the mousetrap and better mousetrap patent owners need to strike a bargain, likewise the owners of patents for the different aspects of genetic modification to be used together in commercialisation must reach some accommodation. This is discussed further in chapter 8 in the boxed section on Golden Rice at page 180.

45. To a degree, the New Zealand Patents Act also guards against a patentee not making an invention available in New Zealand. Section 46 provides for an application to the High Court for issue of a compulsory licence to a third party if a market for the invention covered by a New Zealand patent is not being supplied on reasonable terms. This helps ensure that the patentee is not draconian about issuing licences or locking up the invention.

46. The New Zealand Dairy Board [IP67] told the Commission that:

... in many areas of genetic modification, the intellectual property is already closed off. Accessing this intellectual property for the purposes of research and development involves payment of royalties. For example, in the case of isogenic or transgenic cloning, currently the Roslin Institute in Edinburgh owns most of the intellectual property involved in the production of cloned or transgenic animals. It licenses this intellectual property to other organisations, such as Geron and PPL. Even the intellectual property represented by the tools used for phenotypic research or to produce genetic markers for use in breeding programmes is licensed.²⁵

47. The Board said it is therefore essential for the New Zealand dairy industry to obtain intellectual property so that it can have a base of IPRs to bargain with when seeking access to the intellectual property owned by others.²⁶

48. NZIPA provided the following estimate of genetic modification patent applications filed and/or granted in New Zealand to 24 October 2000:²⁷

Class description	Class number	Number of patents and applications
Cells modified by introduction of foreign genetic material, eg virus transformed cells	C12N5/10	538
Mutation or genetic engineering; DNA or RNA concerning genetic engineering vectors, eg plasmids, or their isolation, preparation or purification; use of hosts therefor	C12N15/00	580
Genes encoding animal proteins	C12N15/12	405
Genes encoding plant proteins	C12N15/29	137
Medicinal preparation containing genetic material which is inserted into cells of the living body to treat genetic diseases; gene therapy	A61K48/00	228

49. To put this in context, NZIPA advised that over the period July 1999 to June 2000 the Intellectual Property Office of New Zealand (IPONZ) recorded a total of 4187 patent applications (including International Patent Cooperation Treaty filings within New Zealand).²⁸ NZIPA commented that, while genetic modification patents represent a relatively small proportion of total patents filed, in the last decade there has been a significant increase in the number of biotechnology patent applications internationally.²⁹

50. In NZIPA’s submission, if biotechnology is to be an important part of New Zealand’s economic future, maintenance and improvement of intellectual property protection for genetic modification and genetically modified organisms is essential.³⁰ If patents for the product of research on genetic modification and genetically modified organisms could not be obtained in New Zealand, a number of negative economic outcomes would follow, including:

- increased cost for New Zealand to access international intellectual property, with less bargaining power from reciprocal information exchange
- the cost and difficulty in maintaining information as a trade secret

- exploitation of unprotected New Zealand information and products by others
- loss of revenue from licensing and royalties
- loss of revenue consequent on loss of competitive advantage.³¹

Moral and ethical issues

51. Submitters drew attention to the problem of accommodating moral and ethical considerations in the grant of IPRs. Section 17 of the Patents Act provides that:

- (1) If it appears to the Commissioner in the case of any applicant for a patent ...
- (b) That the use of the invention in respect of which the application is made would be contrary to law or morality ... he may refuse the application.

52. Article 27(2) of the TRIPS Agreement (see paragraphs 86 to 89) allows Members to 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.³²

53. The relevance of the moral concerns is also recognised in Article 7 of TRIPS:

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

54. Moral concerns and public policy issues, therefore, are not excluded from the ambit of intellectual property law. However, we were not made aware of any instance where a New Zealand patent application had been refused on the basis of section 17.

55. NZIPA submitted that issues of “morality” or ethical considerations, particularly those arising in connection with the patenting or granting of IP rights over genetic material or genetic modification processes, should not be dealt with under the IP framework or legislation.³³

56. The Commission recognises that biotechnology and genetic modification have ethical components not generally present in other IP applications. This is part of our reasoning for the establishment of Toi te Taiao : the Bioethics Council. In the case of an application for a patent that raises issues of public morality or ethics, IPONZ should have the ability or option to seek the views of the Council,

which will have the membership and expertise to consider issues sitting over and above the usual considerations for the grant of IPRs or PVRs.

Patenting living organisms

57. This section addresses the question “should we allow intellectual property rights over life forms?” There is public concern about the ownership of property rights in genetic material, and issues associated with such rights.

58. Current criteria of patent systems date from the eighteenth century, long before development of the technology that allowed the genetic modification of living organisms. Initially patents were mainly concerned with chemical compounds and industrial processes and devices. The commercial possibilities of the novel products and processes that could be developed through genetic engineering quickly led to applications for protection under intellectual property regimes.

59. Professor King argued on behalf of Greenpeace that an aspect of the rapid commercialisation of biotechnology troubling people was the transformation of biological entities into private property through the use of IPRs.³⁴ They were the products of hundreds of millions of years of evolution and this transformation represented a radical change in the relations between human societies and biological species and resources. Professor King went on to say that the mutation of the common biological heritage into corporate property through patent monopolies was proceeding without social oversight or democratic input.³⁵

60. Te Runanga o Ngai Tahu [IP41] said that it is as if:

every living species has suddenly become a reservoir of potentially useful genes or the possible hosts for the cultivation of interesting genes or substances that can later be extracted.³⁶

61. While the “product of nature” doctrine protected biological entities from patentability, genetic modification of microorganisms and other products has challenged this. In 1980 the United States Supreme Court allowed a patent on a new genetically engineered bacterium³⁷ and eight years later the Harvard “oncomouse” was patented.³⁸ In Europe, the patentability of living organisms did not proceed as quickly as in the United States. An EU Directive on the Protection of Biological Inventions allows patents on plants and animals if the invention is applicable to more than one variety, so genetic modification of plants with the Bt gene is patentable.

62. The debate on patenting living organisms also covers the identifying and characterising of particular biological molecules or genes.

63. From the time of development of the first agrarian society, humans have held and traded property in life forms. New Zealand's predominantly agricultural economy is founded on the principle that plants and animals can be owned, bred and sold. Despite this, a common public concern about gene modification relates to the legitimacy of "owning life". Various groups objected to the concept of private ownership of genetic material or activities associated with it.³⁹ NZIPA submitted that these concerns were based on a misunderstanding of the patent system and the extent of the property rights granted.⁴⁰

64. Natural products and naturally occurring DNA sequences cannot be patented in their natural source or environment because they are not new or inventive. This means that genes, whether human or not, must have been isolated, purified or recombined to a degree that does not exist in nature before patent protection can be obtained. To ensure a valid patent the applicant for a patent must also establish the function of a gene sequence. Furthermore, a gene sequence is not "life". It is the chemical code for a sequence of DNA. Genes used in genetic modification are synthesised constructs based on this code. However, once genes are inserted into an organism such as a plant or animal, this new life form may also be patented and the patentee has the right to defend the invention from unauthorised commercial exploitation by others.

Ethical, social and cultural objections to patenting genetic material

65. A strong theme in a number of submissions to the Commission was that the obtaining of patents on genetically modified cells and organisms represented a sharp departure from the traditions of human societies. Farmers have always owned the crops they grew, but they had no legal rights to restrict others from growing those crops. Professor King submitted:

The Monsanto patent on transgenic cotton extends to all the progeny of such plants and allows Monsanto to prevent farmers from saving the seed of crops they have grown and planting them the next season. The cloning of Dolly was not announced until the Roslin Institute had filed patents not just for cloned sheep, but for all animals produced anywhere in the world by a similar process. The patent claims being filed within the US on the genes of humans, sheep or corn are being enforced on a worldwide scale. They expropriate the common heritage of New Zealanders and humans everywhere. Such private expropriation of fundamental biological resources reflects a qualitative change in access to basic biological knowledge and to the relations between human society and the natural world.⁴¹

66. SAFE (Save Animals From Exploitation) [IP85] submitted that the patenting of sentient beings was morally wrong and that the notion of intellectual property

should not extend to the legal ownership of a genetically modified species of a sentient being. It argued that “it is a significant and dangerous jump to move from ownership of individual animals to ownership of an entire species of animal that has been genetically engineered”.⁴²

67. By way of comment on the SAFE submission, the Commission has already noted that an essential feature of patentability is the product has arisen as “a product of human ingenuity”. On this ground, patenting has been unavailable in respect of the establishment of new lines of progeny by conventional breeding, whereas when similar results are now produced by genetic modification, patents may be available to protect the process.

68. Greenpeace also called for a halt to the granting of any patents on life, its parts, products and processes.⁴³

“Patenting of humans”

69. The morality question also arises when considering whether patents should be granted for humans and human related matter. The morality section (section 17) of the Patents Act is the basis for IPONZ policy to refuse patents for humans. Also, sections 2 and 10(7) prevent the patenting of a substance found in nature. Further, as already noted, the novelty requirement means that the invention to be patented cannot constitute something already known or disclosed to the public, which therefore excludes body parts and organs.

70. Taken together, these patent criteria ought to mean that a patent cannot be obtained over a human, a human body part, or a human gene in its natural host, a human. At best a patent could be granted for a synthetic DNA molecule carrying the same information as found in the human body, or a method for producing a novel human organ or body part suitable for transplantation. It should be noted that the discovery of a method of producing a liver “in vitro”, for example, would only give the patentee a right to exclude others from producing livers using this method. It gives no ownership rights to any person’s liver. Consequently any public perception that “people are being patented” is a misconception of patent law.

71. Under existing New Zealand legislation and practice it is unlikely that a patent covering human beings would be granted. However, to put the issue beyond doubt it would be desirable to cover the point specifically by statute.

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 section 18 of the Patents Act 1990 (Commonwealth).

Protection of traditional knowledge

72. This section discusses particular concerns raised by Maori submitters about the IPR system.

73. A fundamental issue was the incompatibility of the Western IPR system with the principles of the IPR systems of indigenous people. This has two aspects: at the national level, Maori submissions pointed out how the IPR system within New Zealand is in conflict with Maori values such as kaitiakitanga, tapu, mana o te iwi, and communal ownership. At the international level, states that are signatories to international agreements, such as TRIPS, are restricted in how far they can change their IPR systems unilaterally to meet the concerns of indigenous peoples.

74. A second major issue was that of sovereignty over genetic resources, in particular native flora and fauna. This is the subject of claims to the Waitangi Tribunal, the WAI 262 and WAI 740 claims.

Intellectual property rights and traditional knowledge

75. Native flora and fauna, and traditional knowledge of their properties and uses, can be used as a resource for furthering Western scientific knowledge, or for commercial exploitation, for example through processes which may use genetic modification techniques.⁴⁴ This in turn gives rise to issues of ownership, veto, access, and benefit sharing with indigenous peoples who have developed the knowledge, and have guardianship responsibilities for the plants and animals. There are values held in common amongst indigenous peoples worldwide which are relevant to such issues. The WAI 262 claimants, Ngati Wai, Ngati Kuri, Te Rarawa [IP89] submission,⁴⁵ for instance, referred to a draft code of ethics prepared by the International Society of Ethnobiologists which records such principles as traditional guardianship, confidentiality, and the communal nature of “rights” to natural resources.⁴⁶

Te Ao Maori and IPRs

76. Submissions to the Commission set out how IPRs and the traditional values of Maori society are at odds.

77. Te Runanga o Ngai Tahu said:

There is inadequate legal protection of biodiversity-related knowledge. The conventional intellectual property rights systems that are based on the concepts of individual ownership and private property rights are designed essentially to act as an incentive for inventions and to facilitate technology transfer and access. Current processes are inadequate to protect indigenous knowledge essentially because it is based on the protection of individual rights while the ownership of traditional knowledge is by and large collective in nature.⁴⁷

78. Sister Makareta RMJ (Atihaunui-a-Paparangi) at the Wanganui hui reminded people that the celebrated composer Ngoingoi Pewhairangi of Ngati Porou refused to copyright her songs:

as the gift belonged to her hapu and not only to her. And so, to copyright her songs in her name as an individual would be to deny her whakapapa.⁴⁸

79. The WAI 262 submission summarised the problems in this way:

The IPR system is concerned with private economic rights whilst those of indigenous people are collectively based and consider obligations to and respect for natural resources as important as the right to use those resources.⁴⁹

80. To look at the issues in more detail, it seems that the basic criteria for obtaining, say a patent, are opposed to the relevant principles in te ao Maori. For example, a patent is:

- *Not available in respect of material or a process that is known and not novel.* Traditional knowledge has been developed over time: by definition, it is not the new creation of an individual or group. Traditional knowledge does not meet the first criterion for patentability.
- *Limited in time.* Traditional knowledge is ancestral and held in trust for future generations. A time frame of 20 years protection is inconsistent with these obligations. When the patent expires, the knowledge is open for all to exploit, even if this transgresses tapu and degrades taonga and mana. Ngai Tahu Taua, Cath Brown, explained at our Christchurch hui that the Maori weavers group, Te Roopu Raranga-Whatu o Aotearoa, had applied to patent an extract from coprosma used to dye flax baskets yellow in order to head off a French company which was investigating its use as a hair dye. On the question of time limits she stated:

It has worked so far but then you lose your patents – they wear out after so many years and then what do we do?⁵⁰

- *Public.* For a patent to be granted, it must be fully and sufficiently described and that description published. This is in conflict with the Maori way of storing knowledge orally, with a few trusted people, protected by ritual and karakia. Publication undermines the integrity of traditional knowledge.

81. Issues of seeking to reconcile indigenous and Western IPR systems are becoming more pressing as rapid advances are made in biotechnology. The need for action, domestically or internationally or both, was raised by a wide range of submitters.⁵¹ We refer to the international aspect below.

82. Within New Zealand we consider there is room for both immediate and longer term change. Review of the current statutes governing IPR, for example the Patents Act 1953, has been under consideration for some time. In 1994 the then Ministry of Commerce established Maori focus groups to review such matters as trade marks and patenting of life forms. A discussion paper issued by the Maori Trade Marks Focus Group proposed:

- no registration if culturally inappropriate
- culturally aggrieved persons could oppose applications or apply to have trade marks removed from the register
- establishment of a Maori consultative committee to IPONZ
- applicants required to prove they had permission to use Maori symbols, words, sounds.⁵²

83. Some of these proposals do not need legislative change, for instance establishing a consultation process.⁵³ It seems that IPONZ does not yet have any formal system of consultation with Maori about applications it receives, although we understand that applicants must show that they have consent from relevant Maori sources, for instance an iwi authority, in appropriate cases. Given the concerns raised by submitters in relation to genetic modification, and patents and plant varieties in particular, we consider that an established system of consultation is overdue. We have discussed the general importance of consultation elsewhere in this Report. It is sufficient here to note that a systematic approach of consulting Maori who are mandated by, and accountable to, the Maori community is required in the area of applications to IPONZ as well. In relation to patents, any recourse to Toi te Taiao : the Bioethics Council as suggested in paragraph 56 would be an additional source of assistance if required.

84. More generally, both the Maori Congress [IP103] and the WAI 262 claimants proposed that protection for Maori intellectual heritage rights be developed, and developed primarily by Maori. Both parties suggested the elements for a protective framework must:

- recognise the tino rangatiratanga of hapu and iwi in relation to their own cultural heritage rights and taonga

- be flexible so that differences and shared interests between tribes can be reflected and accommodated
- contain protocols for dealing with internal issues between individuals and the collective based on appropriate tikanga of the group and for dealing with persons outside the collective wishing to gain access to knowledge and taonga
- include sanctions and penalties for infringement, procedures for prior informed consent, compensation/financial protocols where relevant, and enforcement procedures
- provide for special legislation developed to give effect to mechanisms and protocols.

Recommendation 10.3

that a Maori Consultative Committee be established by the Intellectual Property Office of New Zealand to develop procedures for assessing applications, and to facilitate consultation with the Maori community where appropriate.

International obligations

85. In the international context, there is discussion about the need to amend conventions and agreements on intellectual property to allow reservations on grounds of protecting cultural heritage. This includes safeguards against proposals that are culturally offensive to indigenous peoples. However, progress is slow.

86. One aspect is the issue of amendments to the TRIPS Agreement, Article 27, and similar provisions in associated conventions requiring reciprocal registration of trademarks, patents and industrial designs. As noted earlier Article 27(2) of TRIPS allows signatory countries to exclude inventions from patentability where this is necessary to protect “public order or morality”. The latter terms are not defined, but a central issue for Maori is that it is not clear that they allow signatory countries to exclude applications on the basis of cultural offence. An example might be an application to patent a process to extract and modify genes from tuatara for a product to promote longevity.

87. In 1993 New Zealand ratified the Convention on Biological Diversity (CBD) which provides for signatories to:

... respect, preserve and maintain knowledge, innovations and practices of indigenous and local communities embodying traditional lifestyles relevant for the conservation and sustainable use of biological diversity ...

88. But there are tensions between the CBD and TRIPS. The CBD, for example, states that access to genetic resources should be subject to “prior informed consent”, meaning that authorisation of the donor or community holding the resource or material should be sought and obtained in order to access the resource and/or the knowledge. TRIPS on the contrary, assumes free access and does not mention the concept of consent or consultation in accessing source material.

89. Moreover, TRIPS does not provide for collective rights. The Preamble states that “intellectual property rights are private rights”. This in itself appears incompatible with the communal approach common to many indigenous people. Again, TRIPS does not have any provision recognising the principle of benefit-sharing or acknowledging relationships or rights between donors of material and patent holders. The absence of provisions for acknowledgment or protection of sources of IPRs in TRIPS, and the incorporation of such a principle in the CBD, demonstrates a fundamental difference between the two agreements.⁵⁴

90. The need for reforms in this area, at home and internationally, clearly extends beyond the field of genetic modification. However, the specific categories of patents and PVRs are directly relevant to genetic modification. For this reason, and in response to the call we heard for reforms, we have considered the issues in some detail. Domestic law reform cannot proceed completely independently of international change. With the Mataatua Declaration of 1993 (see box page 292) members of the New Zealand community showed world leadership in the area of promoting international indigenous rights to intellectual property. We believe this initiative should be maintained to pursue progress in this area.

Recommendation 10.4

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

Recommendation 10.5

that New Zealand pursue the amendment of the World Trade Organization Agreement on Trade-Related Aspects of Intellectual Property Rights and associated conventions to include a reference to the avoidance of cultural offence as a specific ground for exclusion or reservation.

Sovereignty over genetic resources: flora and fauna

91. The question submitters raised was who owns native flora and fauna? This led to issues about profits derived from exploiting native plants and animals, and whether and how Maori should share in such profits. Some took the view that any profits made should stay in New Zealand, rather than flow overseas to multinational corporations. The Federation of Maori Authorities (FoMA) [IP69] for instance, said there was concern in the Maori community about what was being sold in this country, and that the thought of purchase by foreign companies of assets here, of things belonging to Maori as a people, was abhorrent.⁵⁵

92. Most Maori submitters⁵⁶ saw patents, copyrights and plant variety rights as an extension of private ownership, with private economic benefits, that shut out Maori.

93. There was some confusion over what was patentable and what was not. Mr Calhoun (NZIPA) said:

A naturally occurring substance is not an invention. However, the discovery of a product of nature, and the industrial application of that discovery is an invention. Thus, water from the hot pool in Rotorua was not an invention, but the microorganism was when isolated in an artificial environment where it produced proteins.⁵⁷

94. When asked about the example we had been quoted of a patent on a variety of pohutukawa, Mr Calhoun said:

That seems to be one of those rural or urban myths. There was a story about a French company owning the plant variety right on the pohutukawa, and the Commissioner of Plant Varieties ... keeps a register and he says he has no Plant Variety Right which has that. I guess anybody who does state that as an example, ask them for the number of the PVR.⁵⁸

95. There was concern that Maori could be shut out by patents from using traditional materials such as plant-derived dyes. A case in point is that of the Maori weavers group referred to earlier and their application to patent a plant extract specifically to prevent its use by an overseas company.

96. There was also concern that Maori would see little in the way of benefit sharing of profits from the use of native flora and fauna under the current intellectual property regime. As Pare Bennett (Atihaunui-a-Paparangi, Muaupoko) at the hui at Wanganui said:

Ko te take kaore te hunga whai rawa i te tohatoha atu nga rawa ki te katoa no reira kaore matau te ropu i te whakapono i te korero kua whakaputa mai ma te katoa tenei hangarau hou. Ko te take, ko te whai moni, whai putea me te mana.⁵⁹

(The wealthy are not sharing the wealth with everyone, so we (the group) do not believe the statement that this new technology will benefit everyone. Their sole concern is the pursuit of money, wealth and power.)

97. She expanded this:

E ai ki a matau, kei nga hapu o Aotearoa nei te mana motuhake i runga i raro, i roto i waho, i nga ira tipu taketake, i nga ira kararehe taketake, o nga ira tangata whenua hoki.⁶⁰

(In our view, the hapu of Aotearoa have the mandate and last say over the control of the genes of indigenous plants, animals and indigenous people.)

Ownership and the Treaty of Waitangi

98. Article 2 of the Treaty of Waitangi guarantees Maori:

te tino rangatiratanga o ratou wenua o ratou kainga me o ratou taonga katoa.

(the full exclusive and undisturbed possession of their Lands and Estates Forests Fisheries and other properties which they may collectively or individually possess so long as it is their wish and desire to retain the same in their possession)

99. To what degree the Treaty of Waitangi gives Maori ownership and control over the exploitation of native flora and fauna is disputed, and is currently being heard in the Waitangi Tribunal as the WAI 262 claim.

100. In our formal process we received a submission from three hapu in Tai Tokerau who are joint claimants in WAI 262 along with Ngati Kahungunu, Ngati Porou and Ngati Koata. At two of our hui, Hastings and Blenheim, we heard from iwi members involved in other parts of the claim. We also heard from Fred Allen (Te Atiawa) at the Wellington hui, who has a parallel claim, WAI 740, being heard at the same time. There was concern from submitters about the need to resolve the claims and the issues as quickly as possible. As Tuwhakairiora Williams presenting for Maori Congress said:

The findings of the [Waitangi] Tribunal in relation to WAI 262 are absolutely critical to this whole debate, this whole issue of genetic modification.⁶¹

101. The Commission agrees. We were told that the WAI 262 claim was lodged with the Waitangi Tribunal in 1991, but traditional knowledge hearings commenced only in September 1997.

102. Mr Williams went on to say:

It's been difficult for the Tribunal to make further progress on WAI 262 due to a lack of resources that are required to ensure that this claim can be heard in a timely manner.⁶²

103. Whether or not lack of resources has been a factor in delaying progress with this claim, the fact that it is still unresolved means that even alternatives to the ownership model asked for by hapu in the WAI 262 claim cannot be considered. FoMA submitted that native flora and fauna should be owned in trust for all New Zealanders. Greenpeace and Maori Congress pointed out that other countries were investigating ways that economic benefits derived from their native flora

and fauna could be retained. The submission listed Costa Rica, Tonga and the countries bordering the Andes.

104. Currently, as a signatory of TRIPS, New Zealand is not permitted to make any distinction between exploitation by local and international applicants. Under Article 27(2), however, it may exclude patentability where prevention of commercial exploitation is necessary “to protect human, animal or plant life or health”, or to avoid “serious prejudice” to the environment. As far as New Zealand is concerned, it is not clear that any finding by the Waitangi Tribunal that Maori own or control access to particular material or information can, on its own, prevent others from using that material and information to generate their own novel inventions or

Mataatua declaration

In 1993, the nine tribes of Mataatua in Aotearoa New Zealand convened the First International Conference on the Cultural and Intellectual Property Rights of Indigenous Peoples.

Over 150 delegates from 14 nations attended, including indigenous representatives from Ainu (Japan), Australia, Cook Islands, Fiji, India, Panama, Peru, Philippines, Surinam, United States and Aotearoa.

The Conference met to discuss issues including the value of indigenous knowledge, biodiversity, biotechnology, customary environmental management.

Over the course of six days, delegates considered principles of the cultural and intellectual property rights of indigenous peoples.

On the final day, delegates agreed on the terms of a declaration, known as the Mataatua Declaration on Cultural and Intellectual Property Rights of Indigenous Peoples, June 1993.

In summary, the Preamble to the Declaration provides that the indigenous peoples of the world:

Declare they have the right to self determination and to be recognised as the exclusive owners of their cultural and intellectual property

Acknowledge a commonality of experience

Affirm that their knowledge is of benefit to all humanity

Recognise that they are capable of managing their traditional knowledge but offer it to all humanity provided their fundamental rights to define and control this knowledge are protected by the international community

Insist that the first beneficiaries of indigenous knowledge must be the indigenous descendants of such knowledge

Declare that all forms of discrimination and exploitation of indigenous peoples, their knowledge and cultural and intellectual property rights must cease.

processes. Nevertheless, resolution of the claim is likely to be a major element of any moves to reform the IPR system in this country.

Recommendation 10.6

that all parties concerned work to resolve the WAI 262 and WAI 740 claims currently before the Waitangi Tribunal as soon as possible.

Bioprospecting

105. Currently, there is no legislation specifically regulating bioprospecting in New Zealand, except to the extent that the Crown or private individuals could prevent or restrict entry on to Crown land or private property for the protection of particular plants or animals and their habitats. Some countries have developed systems to license and control such activity to protect their cultural heritage or to benefit the local peoples and communities, eg Costa Rica, Iceland and the Andean Community system. This is an area that ought to be considered in conjunction with the investigation and setting up of a framework to address the concerns raised by Maori before this Commission, and more generally by indigenous peoples around the world.

106. Furthermore, while ownership issues remain unsettled, it is difficult to prevent overseas companies seeking patents based on native flora and fauna which may not return any economic benefits to New Zealand. This is called biopiracy or bioprospecting, depending on whether one approves of it or not. Biopiracy was raised with the Commission by Maanu Paul, Chair of the New Zealand Maori Council [IP105], in regard to an indigenous purple forest berry, which has interesting hormone substances that may have medical uses.

Changes to current system

Confidentiality of data provided in applications to ERMA

107. Submitters raised concern regarding the confidentiality of data provided for the purposes of approvals to experiment with, or market, new compounds and organisms under HSNO and the Agricultural Compounds and Veterinary Medicines Act (ACVM).⁶³ NZIPA submitted that when such information is released it has a major adverse impact on the future patentability of products, especially in cases where approval is required at an early stage.⁶⁴ They were concerned that when HSNO came fully into force, and other pending legislative changes were in effect, current provisions protecting “confidential supporting

information” would disappear.⁶⁵ Consequently, any confidential information supplied to ERMA concerning genetically modified organisms would potentially be available to the public, including an applicant’s competitors.

108. The Commission recognises the importance of this matter to applicants before ERMA. The requirement to protect confidential information in the approval of pharmaceutical or agricultural chemical products that contain new chemical entities is recognised by Article 39(3) of the TRIPS Agreement. In 1994 such provisions were incorporated into the Medicines Act, the Pesticides Act 1979 and the Animal Remedies Act 1967. They provided that “confidential supporting information” should remain confidential to the regulating authority and should not be used by regulating authorities in assessing any subsequent application for the same chemical or biological entity.

109. The Pesticides and Animal Remedies Acts will both be repealed when the provisions of HSNO come into force for hazardous substances. The protection they currently give to confidential supporting information will disappear with them.

110. Section 55 of HSNO imports the provisions of sections 23A to 23C of the Medicines Act and sections 35A to 35C of the Animal Remedies Act. The protection for undisclosed information provided under these Acts will only apply where the information held by ERMA is in connection with an application for approval of a hazardous substance, and it is also the subject of an innovative medicine application or an innovative animal remedy application, respectively.

111. When ACVM comes into force, section 55 of HSNO will be amended to import the provisions of Part VI of ACVM. The protection for undisclosed information provided under ACVM will apply where the information held by ERMA is in connection with an application for approval of a hazardous substance, but only when it is also the subject of an innovative agricultural compound application.

112. Genetically modified organisms do not fall within the statutory definition of a hazardous substance. Even if they are also the subject of an innovative medicine or animal remedy/agricultural compound application, the provisions for protection of undisclosed information imported under section 55 will not apply.

113. The end result of these legislative changes is that confidential supporting information relating to genetically modified organisms submitted to ERMA is not given the protection under HSNO it formerly had under the Medicines Act, the Pesticides Act and the Animal Remedies Act. This protection should be restored so that New Zealand complies with its obligations under Article 39(3) of TRIPS.

Application of Official Information Act

114. HSNO section 57 provides for information, including trade secrets, submitted in support of an application to ERMA for approval to be withheld under section 9(2)(b) of the Official Information Act 1982 (OIA). Following public notification, if ERMA receives a request for information from a third party and ERMA is of the opinion that the requested information may be withheld under section 9(2)(b), or the supplier of the information has marked it as commercially sensitive, the applicant will be notified of the OIA request. The applicant is allowed 10 working days from receipt of the notice to respond. In the absence of a response, ERMA may release that information without further reference to the applicant.

115. Submitters and their advisors were concerned that a trade secret, perhaps worth millions of dollars, could be released and its value lost because of such a provision, with its potential for miscommunication and timing delays. The Commission considers this concern is valid.

116. It was submitted that section 57 should be repealed, and likewise section 12 of the ACVM Act, which is modelled on section 57.

Recommendation 10.7

that the Hazardous Substances and New Organisms Act 1996 and the Agricultural Compounds and Veterinary Medicines Act 1997 be amended to give appropriate protection to all commercially sensitive or confidential supporting information provided with applications for approval.

Conclusion

117. The economic benefits of intellectual property systems are generally considered to be positive. Removing biotechnology developments from coverage by patent or property rights systems would not necessarily have the effect that opponents to such applications want. New inventions or ideas would probably be kept as trade secrets or “know how”, and, in the absence of the disclosure required by patents and PVRs, be held even more tightly. Not allowing New Zealand inventors and investors to protect their work under an IPR would leave them in an invidious position against the rest of the world. It would also place New Zealand in breach of its obligations under major trade agreements.

118. The Commission sees a need to address some tensions or gaps, notably in the exemption for patenting of human beings and their biological processes, and the development of an appropriate framework for the protection of traditional knowledge and taonga of Maori. However, we are not persuaded that the IPR system is antithetical to the appropriate development and regulation of genetic modification.