Intellectual Property, Bioprospecting and Traditional Knowledge: Who Benefits?

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Introduction

This paper explores the benefit side of the "access and benefit-sharing" discussion by focusing on the intellectual property implications of bioprospecting. While a range of benefits may accrue from bioprospecting activities, the focus of this paper is on intellectual property rights only.

A basic outline of New Zealand's intellectual property rights framework is provided, as background, with a particular emphasis on the Patents Act 1953 and the boundaries of patentability.

The paper also considers a number of issues that have arisen at the international level concerning intellectual property, genetic resources and the traditional knowledge of indigenous and local communities. These include, for example, the grant of patents to third parties for inventions based on traditional knowledge. A number of potential responses are canvassed including the work of the World Intellectual Property Organisation ("WIPO") on the development of model intellectual property clauses for inclusion in access and benefit-sharing agreements involving bioprospecting companies and traditional knowledge-holding communities, and suggested changes to patent laws.

The Bioprospecting Review and Intellectual Property Law Reform Distinguished - Access and Benefits

While this paper considers a number of intellectual property issues associated with bioprospecting, it is important to note that the review of New Zealand's policy framework for the regulation of bioprospecting activities is a separate exercise and distinct from the reform of New Zealand's intellectual property rights statutes. Submission processes have, for example, recently closed in the reviews of the Patents Act 1953 and the Plant Variety Rights Act 1987.

The information provided here is to put the bioprospecting review in context and to provide an example of one of the benefits that may result from bioprospecting activity.

There are, however, a number of changes to patent law being considered internationally, designed to ensure the disclosure of biological resources and associated traditional knowledge in patent applications and thereby realise the access and benefit-sharing objectives of the Convention on Biological Diversity (CBD). As New Zealand does not have a formal access and benefit-sharing regime the current reviews of the Patents Act and the Plant Variety Rights Acts have not considered this issue. The outcome of the current bioprospecting review will be instructive in this regard.

What is Intellectual Property?

Intellectual property is a generic term that refers to a range of property rights accorded to "creations of the mind", including inventions, industrial designs, literary and artistic works, symbols, names, images, and related rights such as performances and recordings[1].

Intellectual property rights provide creators and innovators with exclusive rights, usually for a limited time, to control what others do with their works. The justification for the grant of limited monopoly rights is to provide incentives for creation and investment in innovation. If the opportunity to generate a return on creativity and investment was not present it is likely that much creative or innovative activity would not take place, thereby depriving society of many useful goods or services. At the same time it is important that the public has access to these “creations of the mind”, for example, to encourage cumulative innovation.

There are a number of intellectual property rights afforded by New Zealand law:

- The Copyright Act 1994 protects original “works” including literary, dramatic, artistic or musical works, and sound recordings, films, broadcasts, cable programmes and typographical arrangements.
- The Trade Marks Act 2002 (soon to replace the 1953 Act) provides protection for a sign or symbol used to distinguish the goods and services of one trader from those of another.
- The Designs Act 1953 provides registered design protection for the external appearance of a manufactured article.

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[1] “Intellectual property” is defined in the Convention Establishing the World Intellectual Property Organisation (WIPO), 1967 as including rights 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;
- Trade marks, service marks, and commercial names and designations;
- Protection against unfair competition; and
- All other rights resulting from intellectual activity in the industrial, scientific, literary or artistic fields.

- The Layout Designs Act 1994 protects the layout of semi-conductors and integrated circuits.

- Geographical indications are protected under the Fair Trading Act 1986 and the common law tort of "passing off". The Geographical Indications Act 1994 has not yet been brought into force.

- The Plant Variety Rights Act 1987 provides *sui generis* protection for new plant varieties.

- The Patents Act 1953 protects inventions that are "methods of new manufacture".

Patents and plant variety rights are obviously the most relevant to the discussion of bioprospecting.

Patent Protection

A patent is an exclusive right granted for an invention. Three criteria are generally recognised internationally to be the minimum requirements for the grant of a patent. Under these criteria an invention must be new, involve an inventive step (not be obvious) and be useful (capable of industrial application)[2].

To be protected by a patent in New Zealand, the Patents Act 1953 provides that an invention must be "new" and a "manner of new manufacture"[3]. Lack of usefulness and inventive step are currently grounds for revoking a patent.

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 patent application. No notice is taken of information published outside New Zealand but not publicly available within New Zealand.

The term "manner of new manufacture" has been interpreted by the courts to exclude such things as "products of nature", mathematical operations, bare

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[2] Members of the World Trade Organisation (WTO) are required under TRIPS (Agreement on Trade-Related Aspects of Intellectual Property Rights) to allow patents to "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".

Under Article 27(3)(b) members may exclude from patentability: "plants and animals other than micro-organisms, and essentially biological processes for the production of plants and animals other than non-biological and microbiological processes". Plant varieties must be protected either by patents or by a sui generis system or a combination of the two.

[3] Section 2 of the Patents Act 1953 sets out the definition of invention. As part of the Review of the Patents Act the Government is currently considering changes to the definition of invention to bring it into line with international practice and to maximise the benefits of the patent system for New Zealand.

principles, mathematical algorithms, schemes or plans and methods of medical treatment of humans.

In addition to these judge-made exclusions to patentability section 10 of the Patents Act states that claims for a new substance shall not be construed as extending to that substance when found in nature. The Intellectual Property Office of New Zealand (IPONZ), therefore, does not allow claims for micro-organisms which occur in nature when they are found in their natural state.

Section 17 of the Patents Act provides that the Commissioner of Patents may refuse applications where the use of an invention would be contrary to morality. As a matter of policy, IPONZ does not grant patents for human beings on the basis that human beings do not fall within the definition of invention. The grant of such patents may also be contrary to morality.

The scope of inventions that can be patented is, therefore, quite broad. An invention is patentable provided that it comes within the scope of the definition of "invention" in the Act, and is not expressly excluded from patentability. Some practical examples of inventions that may be patentable include:

- A new product;
- A new process of manufacturing;
- An improvement to an existing product or process;
- A new method or process relating to the testing or control of an existing manufacturing process;
- New chemical compounds or compositions;
- Biotechnological matter [plants, animals, genes and gene fragments];
- Electrical devices and circuits;
- A second pharmaceutical use for a known chemical compound or composition; and
- Computer technology and software.

The grant of a patent for an invention provides the owner with a right to exclude others from making, using or selling the patented invention during the term of the patent. In return for the grant of a patent, the owner must make public a complete description of the invention.

In New Zealand, a patent will last for twenty years from the date IPONZ receives a complete application, provided that renewal fees are paid on time. After that time, the knowledge becomes part of the "public domain" for all to use. During the period of protection the owner may licence others to use the invention.

A patent granted by IPONZ will only protect the invention within New Zealand. To receive overseas protection applications must be filed with intellectual property offices in countries of interest. An international application may be filed under the Patent Co-Operation Treaty which will provide preliminary advice as to the likely patentability of the claimed invention.

It is important to note that rules about the patentability of inventions are distinct from the development and use of such inventions. The fact that a patent has been granted doesn't 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.

As part of the Review of the Patents Act the Government is currently considering whether any changes should be made to boundaries of patentability[4]. Policy advice, based on a submissions process undertaken last year, is currently being formulated.

Plant Variety Rights

New Zealand is a member of the International Convention for the Protection of New Varieties of Plants (UPOV)[5]. Protection for new plant varieties[6] is provided through the provisions of the Plant Variety Rights Act 1987.

Plant varieties are essentially “cultivars” or cultivated varieties. Cultivated plants may arise from hybridisation, selection from existing cultivated stock or selection from variants within a wild population, maintained as a recognisable entity solely by continued propagation[7]. A cultivar is commonly defined as a variety produced by horticultural or agricultural techniques and not normally found in natural populations[8].

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[4] Issues being considered include the definition of invention, the patentability of computer software, business methods and methods of medical treatment of humans, and ethical and cultural concerns regarding the granting of patents over living organisms and inventions involving genetic modification and traditional knowledge.

[5] New Zealand is a signatory to the 1978 revision of the UPOV Convention, but as part of the Review of the Plant Variety Rights Act, is considering whether to become a party to the 1991 revision.

[6] Section 2 of the Plant Variety Rights Act 1987 defines a plant as including a fungus but not an alga or bacterium. A "variety" is defined 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.

[7] International Code of Nomenclature for Cultivated Plants (1995).

[8] Penguin Dictionary of Botany (1992).

A plant variety right will be granted if the variety is "new, distinct, homogenous, and stable"[9]. A variety is "new" if there has been no sale of that variety with the consent of any relevant owner of the variety. A variety is "distinct" if it is distinguishable from any other known variety by one or more characteristics, for example, colour of flowers, time of flowering, dimensions of leaves. A variety is "stable" if it remains true to its description after repeated reproduction or propagation.

The grant of a plant variety right gives the owner the exclusive right to produce for sale, and sell, reproductive material of the variety concerned. It does not prevent the propagation, growing or use of the protected variety for non-commercial purposes. Any person may use reproductive material from the protected variety for human consumption or other non-reproductive purposes[10].

A plant variety right lasts for 23 years from the date of grant of the right in the case of woody plants or their rootstocks, and for 20 years for all other varieties.

It is also possible for plants to be granted patents under the Patents Act. Where a plant is protected by a patent, the rights of the patent owner are greater than those conferred by the grant of a plant variety right. For example, the owner of a plant variety right cannot prevent other breeders exploiting another variety bred from the protected variety. The grant of a patent, however, would prevent the exploitation of varieties derived from a patented plant.

The Plant Variety Rights Act 1987 is currently being reviewed to consider issues such as the protection of derived varieties, the export of reproductive material, farm saved seed and whether the 1991 revision of the UPOV Convention should be ratified.

[9] Section 10(2)(d) Plant Variety Rights Act 1987.

[10] Plant Variety Rights Act 1987, s18 (exceptions).

Intellectual Property and Bioprospecting

The acquisition of intellectual property rights is one phase of a typical bioprospecting research project. The first stage, the discovery or collection of biological resources or material, does not itself constitute or create intellectual property. A discovery does not equate to an invention.

To be eligible for a patent the biological material must first be screened for useful properties. New and active chemicals must be isolated or purified and new chemical structures described.

Patents will not be granted in New Zealand for micro-organisms that occur in nature when found in their natural state. If, however, these naturally occurring micro-organisms have been isolated (removed from their natural state and modified in some way), it is possible to make patent claims in relation to them. New structures or types of bioactivity may, therefore, be patented including, for example, antibiotic, insecticidal or anti-tumour properties of the biological materials collected.

A plant variety right may be available for the discovery of a new variant of a native species, found in nature, which has been cultivated and which has distinct, uniform and stable characteristics that are retained when propagated.

Following the acquisition of intellectual property rights product, development, manufacturing and marketing of a final product may occur. It is important to note that very few patented substances are developed into commercially successful products.

Intellectual property rights may be bought and sold just like any other form of property. . A research team, having collected biological material and isolated patentable properties may, for example, not have the resources or expertise to progress the research project to the later stages. They may assign their rights to any patents obtained to a pharmaceutical company for a fixed sum or a share of any royalties later obtained. Researchers might also sell material collected before obtaining intellectual property rights.

Intellectual Property Clauses in Benefit-Sharing Contracts

The role of intellectual property rights in the sharing of benefits arising from the use of biological resources (and associated traditional knowledge) is often construed in the form of intellectual property clauses in access and benefit-sharing contracts. Contractual agreements are certainly the most common legal tool, currently used, for regulating access to genetic resources and benefit-sharing. In practice, such contracts often determine, at the point of access, how down-stream intellectual property rights will be dealt with, and in particular how intellectual property rights can be used as a means of equitably sharing benefits.

Contractual agreements may take a variety of forms, and are generally referred to as Material Transfer Agreements ("MTAs"). Intellectual property-related clauses form an important part of MTAs and reflect a range of policy objectives including conservation, food security and the interests of the various stakeholders. MTAs often include the following intellectual property provisions:

- That utilisation of material be for research purposes only;
- That the recipient of biological resources not file patent applications;
- That any intellectual property rights obtained be shared by the parties (for example, the owner of the land where the material is found, the owners of any associated traditional knowledge, the bioprospecting company and any other parties that may have a role in research and development);
- Where a product is successfully developed commercially, an agreement that royalties will be shared between the parties according to an agreed formula;
- Provisions concerning the ownership of intellectual property rights in relation to derivative material;
- Grant-back licences to a biological resource provider for an invention the recipient of the material may patent;
- An obligation to defer publication of any discoveries of resulting inventions.

Contractual agreements may also arrange for a number of other, non-intellectual property-based benefits to be shared with indigenous peoples and local communities in recognition of their contributions. These include, for example, up-front monetary payments, research funding, salaries or infrastructure to resource or land owners, participation in research activities, support for conservation projects, capacity building, assistance with language

revival, recovery and recording of traditional knowledge, receipt of technologies developed, and others[11].

The WIPO Intergovernmental Committee on Intellectual Property and Genetic Resources, Traditional Knowledge and Folklore ("the IGC") has developed, as a pilot project, an on-line database of contractual practices and clauses relating to intellectual property, access to genetic resources and benefit-sharing[12]. The object of the database is to provide a practical resource to assist those involved in negotiations about the access to and the use of genetic resources, through the provision of a range of options for dealing with intellectual property issues in access and benefit-sharing contracts.

The IGC has signalled its intention to use the database for the development of guide contractual practices, guidelines and model intellectual property clauses. The object of this exercise is to provide a practical contribution to the other international processes considering access and benefit-sharing issues, including, for example, the CBD and the Food and Agriculture Organisation ("FAO").

[11] *Access to Biological Resources in Commonwealth Areas, Commonwealth Public Inquiry* (Australia), July 2000, p19.

[12] www.wipo.int/globalissues/databases/contracts/

International Dimensions -Intellectual Property, Genetic Resources and Traditional Knowledge

There has been a considerable amount of discussion by intergovernmental organisations, in recent years, about the relationship between intellectual property and genetic resources. The debate has spread to also concern the traditional knowledge of indigenous peoples and local communities associated with those resources. It has become a mainstream issue in a number of international fora including the World Intellectual Property Organisation (WIPO), the Convention on Biological Diversity (CBD), the World Trade Organisation (WTO) and a host of others[13].

The intellectual property related issues arising in these fora are diverse and only some of them are considered in this paper. While not wishing to overly simplify matters, the issues can be broadly divided into two areas:

- Access to biological resources and benefit-sharing; and
- The protection of traditional knowledge, innovations and creativity, whether or not associated with biological resources.

The issues raised in the first category relate to the potential impact of the grant of intellectual property rights on access to genetic resources. Some countries consider that intellectual property should guarantee the protection of a country's biological and genetic heritage. It has been proposed that changes be made to patent laws to ensure that access to genetic resources continues and that fair and equitable benefit-sharing occurs, as required by the CBD. Suggested changes include the compulsory exclusion of plants and animals from patentability and a requirement that evidence of the source of genetic materials and prior informed consent be provided with patent applications.

The issues raised about intellectual property, genetic resources and associated traditional knowledge focus, in particular, on what is considered to be the inappropriate or exploitative use of traditional knowledge by third parties through the grant of intellectual property rights for inventions based on that knowledge. Traditional knowledge holders, and some governments, are concerned about “biopiracy” and the patenting of inventions based on traditional knowledge or resources without consent, compensation or acknowledgement of the intellectual contributions of indigenous peoples and local communities concerned.

Only some of the issues surrounding intellectual property and traditional knowledge relate to biological resources. While it is not the purpose of this paper to consider a definition of traditional knowledge, it is sufficient to note

[13] See also discussion in UNESCO, UNCTAD, WSSD, UNCHR, ILO, WHO, APEC-IPEG, UNEP, FAO, and CW.

that traditional knowledge subject matter is often divided, for the purposes of discussion, into traditional knowledge associated with the environment and with traditional cultural expressions (folklore). This paper does not consider the issues relating to traditional cultural expressions.

The remainder of this paper summarises the debate on these issues by WIPO, and to a lesser extent the WTO and the CBD. The primary focus is on the discussions of WIPO, as the expert body on intellectual property matters, in particular the IGC. This is not to suggest that WIPO has expertise on actual traditional knowledge. Solutions to the issues raised by traditional knowledge holders about the misappropriation or protection of traditional knowledge may well lie outside of the conventional intellectual property rights framework. The adaptation of existing intellectual property mechanisms, or the development of new ones, is, however, expected to address some of the concerns that have been raised.

WIPO Intergovernmental Committee on Intellectual Property and Genetic Resources, Traditional Knowledge and Folklore

The IGC first met in April 2000. It was mandated to discuss intellectual property issues that arise in the context of:

- Access to genetic resources and benefit-sharing;
- The protection of traditional knowledge, whether or not associated with genetic resources; and
- The protection of "expressions of folklore".

Genetic Resources

The IGC's discussions on the interface between intellectual property protection and genetic resources has focused, to a large extent, on contractual agreements for access to genetic resources and benefit-sharing (considered above) and the use of existing intellectual property frameworks, particularly patent law, for the legal protection of biotechnological inventions.

It has been suggested by some Member States that the origin of genetic resources, and any associated traditional knowledge, be disclosed in patent applications. It has also been suggested that applicants provide documentary evidence of prior informed consent (of land owners or traditional knowledge holders) and compliance with the access and benefit-sharing regimes of the countries in which the biological material was obtained.

The IGC has undertaken a draft study, at the invitation of the Conference of the Parties of the CBD, on disclosure requirements in patent applications related to genetic resources and traditional knowledge. The study is expected to be completed in time for the Fifth Session of the IGC in July this year.

Traditional Knowledge

In the traditional knowledge area the IGC has focused its attention on two aspects:

- The availability of intellectual property protection for traditional knowledge holders; and
- The acquisition by parties other than traditional knowledge holders of intellectual property rights over traditional knowledge-based creations and innovations.

Much of the IGC's work in this area has focused on defensive measures designed to prevent the inappropriate grant of patent rights to third parties. The IGC has, for example, considered ways to improve the availability of

public domain traditional knowledge to patent examiners to prevent the inappropriate grant of patents for inventions based on traditional knowledge where there is in fact no novelty or inventiveness. The IGC has discussed ways that traditional knowledge documentation can be integrated into searchable prior art that patent examiners have reference to when making findings about novelty and inventive step. This work has concentrated on the compilation of inventories of traditional knowledge-related periodicals and databases.

While a number of countries have stressed the utility of documenting traditional knowledge in databases so that it is available as prior art, others (New Zealand included) have expressed concerns about the risks of documentation initiatives. The IGC is, therefore, developing an Intellectual Property Documentation Toolkit to assist traditional knowledge holders to address the intellectual property implications of the recording of traditional knowledge and any subsequent disclosure and dissemination of that knowledge.

The IGC has also studied a range of positive legal measures for protecting traditional knowledge through existing intellectual property mechanisms and through systems specifically designed for that purpose. The Committee has shared national experiences in this area and discussed the possible characteristics of new mechanisms for the protection of traditional knowledge. A composite study is being prepared for the Fifth Session, which will include approaches to the definition of traditional knowledge, existing models of protection and the elements of potential new mechanisms.

The IGC is also undertaking a number of projects relating to traditional cultural expressions (folklore) that are outside the scope of this paper.

The Convention on Biological Diversity

A full account of the objectives and work of the CBD is not included in this paper as other seminar presenters will address these issues. Intellectual property rights are, however, a subject of discussion in the CBD particularly in relation to access to genetic resources, benefit-sharing (Articles 15 and 16), and the knowledge, innovations and practices of indigenous and local communities (Article 8(j)).

The *Ad Hoc* Open-ended Intercessional Working Group on Article 8(j) is, for example, assessing the effectiveness of existing intellectual property rights instruments and the issue of *sui generis* systems for the protection of traditional knowledge. The working group is also developing strategies for the protection of traditional knowledge and innovations and practices based on a combination of approaches, including the use of intellectual property mechanisms.

World Trade Organisation

The Council for TRIPS[14] has been directed, by the WTO Ministerial Conference (held in Doha in November 2001), to consider the following issues in the context of its review of Article 27(3)(b) of the TRIPS Agreement and the review of the implementation of TRIPS under Article 71.1:

- The review of Article 27(3)(b), which allows Members to exclude plants and animals (other than micro-organisms) from patentability. Many developing countries consider that this exclusion should be mandatory so as to prevent the inappropriate granting of patents over traditional knowledge and genetic resources.

- The relationship between the TRIPS Agreement and the CBD. A number of countries consider that there is an inherent conflict between the two agreements as one allows for private rights to be established over inventions based on genetic resources through patents and the other provides that countries have sovereign rights over their genetic resources. Proponents of this view argue that Article 27(3)(b) be amended to make the grant of patents contingent on the provision of a declaration of the origin of genetic resources, proof of prior informed consent where the genetic resources are the subject of traditional knowledge and evidence of fair and equitable benefit-sharing, thereby ensuring compliance with CBD provisions.

Other countries consider that no conflict exists as the agreements have different objectives and deal with different subject matter, and that patents can be granted for genetic material while complying with the CBD - its just a matter of how the agreements are implemented.

- The protection of traditional knowledge and “folklore”. Concerns have been raised in the TRIPS Council about the grant of patents or other intellectual property rights covering traditional knowledge to persons other than those indigenous peoples or local communities who have created and control that knowledge. A related concern is that traditional knowledge is being used without the knowledge or consent of the legitimate owners without proper sharing of any benefits that might accrue from such use.

Substantive discussion on these issues has not progressed particularly far in the TRIPS Council. At this point much of the discussion has been centred on which forum or fora should progress this work. It has been suggested that priority should be given to the work already being undertaken in WIPO so as to avoid duplication of effort.

[14] Agreement on Trade Related Aspects of Intellectual Property Rights.

Concluding Comments

Intellectual property rights are one potential benefit of a successful bioprospecting project. Patents may be obtained for biological substances that have been isolated, purified, described and found to contain useful properties. Successful product development, manufacturing and marketing may or may not follow.

At the time of arranging access for the collection of samples, an access and benefit-sharing contract may stipulate how any benefits, including those that may result from obtaining intellectual property rights, will be shared by the parties concerned (including land owners, researchers, investors, government agencies and traditional knowledge holders). Bioprospecting frameworks developed in some countries make the conclusion of access and benefit-sharing contracts compulsory. This is a potential option for New Zealand.

Some States have also suggested changes to international patent law to require compulsory disclosure of genetic resources and associated traditional knowledge in patent applications. The aim is to ensure that patents are not granted for inventions based on resources not acquired in accordance with access and benefit-sharing regulations established pursuant to the CBD.