

Intellectual Property, Bioprospecting and Traditional Knowledge: who benefits?

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Introduction

- Intellectual Property as a potential benefit
- How rights are obtained and for what
- Wider policy issues in an international context (intellectual property debates):
 - private rights and access and benefit sharing
 - protection of traditional knowledge associated with genetic resources
- Intellectual property as context for the bioprospecting review - separate reform exercises

Outline

- Introduction to New Zealand's intellectual property rights framework
 - Patents Act 1953
 - Plant Variety Rights Act 1987
- Acquisition of intellectual property rights as part of a bioprospecting project
 - what is patentable?
 - benefit sharing and IP clauses in access contracts

Outline (2)

- International dimensions (WIPO and others)
 - intellectual property and genetic resources - access and benefit-sharing - sovereignty and private rights
 - intellectual property and the protection of traditional knowledge associated with genetic resources
 - concerns about patenting of life-forms and inventions based on traditional knowledge
 - suggested approaches

What is Intellectual Property?

- A range of property rights accorded to “creations of the mind” - resulting from intellectual activity in the industrial, scientific, literary or artistic fields

(Convention Establishing the World Intellectual Property Organisation)

New Zealand's Intellectual Property Framework

- Patents Act 1953 (under review)
- Plant Variety Rights Act 1987 (under limited review)
- Trade Marks Act 2002 (soon to come into force)
- Designs Act 1953
- Copyright Act 1994
- Layout Designs Act 1994 (semi-conductors and integrated circuits)

Intellectual property framework (2)

- Geographical Indications Act 1994
- Minimum standards in international agreements (e.g. WTO TRIPS)

Patent Protection

- Exclusive rights granted to control the production/marketing of inventions
- Requirements for the grant of a patent (int.):
 - new (novelty)
 - not obvious (inventive step)
 - useful (capable of industrial application)
- NZ - “new” plus “manner of new manufacture”. Lack of usefulness and inventive step are grounds for revocation

What can't be patented?

- Products of nature/new substances when found in nature (s10)
- Where use contrary to morality
- Human beings do not come within the definition of invention
- Bare principles, schemes, plans, methods of medical treatment of human beings etc
- Boundaries of patentability currently under review

Exclusions (2)

- Article 27(3)(b) TRIPS - members may exclude plants and animals (other than micro-organisms) and biological processes for their production (but not non-biological processes or microbiological processes)
- Must have some form of protection for plant varieties (patents and/or *sui generis*)

What can be patented?

- New products and manufacturing processes
- Improvements to existing products and processes
- New methods or processes relating to the testing or control of existing manufacturing processes
- Electrical devices and circuits
- Computer technology and software

What can be patented (2)

- New chemical compounds or compositions
- Biotechnological matter
- A second pharmaceutical use for a known chemical compound or composition

Rights of Patent Owners

- Exclude others from making, using or selling the patented invention for 20 years
- In return for full public disclosure of invention and contribution to public domain at expiry of patent term
- Protection only in New Zealand unless applications made to other national patent offices (note PCT)

Plant Variety Rights

- Plant Variety Rights Act 1987
- Protection for varieties that are “new, distinct, homogenous, and stable”
- Can include new varieties found in nature cultivated with above characteristics
- Exclusive rights to produce for sale and to sell reproductive material of the variety
- Patents also available for plants (if meet criteria)

IP rights and bioprospecting

- IP a potential benefit in a bioprospecting research project (low hit rate)
- Stage one - discovery and collection of biological materials/substances
 - **no intellectual property, no invention, no patents for micro-organisms which occur in nature found in their natural state**

IP rights and bioprospecting (2)

- Stage two - screen for useful properties, isolate, purify and describe new chemical structures (e.g. antibiotic, insecticidal or anti-tumour properties of biological materials collected)
- Stage three - apply for patent re biological material which has useful properties
- Product development, manufacturing and marketing of final product may follow (assuming investment and uptake)

Sharing the Benefits - IP clauses in access contracts

- Contractual agreements a common tool to regulate access
- Can determine how benefits will be shared including how down-stream IP rights will be dealt with
- To recognise contributions of land-owners, indigenous peoples and other holders of traditional knowledge

Contracts (2)

- e.g. material transfer agreements (MTAs)
- IP clauses can reflect a range of policy objectives (conservation, food security, stakeholder interests)
- May be at the discretion of the parties or a requirement of national bioprospecting/ABS frameworks

Common IP-related Clauses

- Utilisation of material for research purposes only (no commercialisation)
- Obligation not to file for patent
- IP rights to be shared by the parties
- Royalty sharing where successful commercialisation occurs
- IP rights in derivative material
- Grant-back licences
- Defer publication of discoveries

Non-IP Benefits (e.g.)

- Up-front monetary payments
- Research funding
- Salaries or infrastructure funding
- Participation in research activities
- Support for conservation projects
- Capacity building
- Assistance with preservation/recording of traditional knowledge

International context - IP, genetic resources and traditional knowledge

- Concerns about the grant of IPRs over genetic material, the impact on access and the lack of benefit sharing
 - protection of biological and genetic heritage
 - potential inconsistency with ABS requirements of CBD
 - declaration of origin of source country, prior informed consent
 - calls to ban the patenting of all life-forms
 - grant of patents without novelty or inventive step

International Context (2)

- Concerns about the exploitation of biodiversity related traditional knowledge and the grant of IPRs to third parties for biotech inventions based on traditional knowledge
 - lack of novelty and inventive step
 - prior informed consent
 - no recognition of contribution or benefit sharing

Intergovernmental Organisations and IP

- World Intellectual Property Organisation (WIPO) Intergovernmental Committee
- Convention on Biological Diversity (ABS, Bonn Guidelines and Article 8(j))
- World Trade Organisation (WTO) TRIPS Council
- UNESCO, UNCTAD, WSSD, UNCHR, ILO, WHO, UNEP, FAO, APEC, CW and others

WIPO

- Intergovernmental Committee on Intellectual Property and Genetic Resources, Traditional Knowledge and Folklore
 - access to genetic resources and benefit sharing
 - the protection of traditional knowledge, whether or not associated with genetic resources
 - the protection of expressions of “folklore”

WIPO (2)

- Genetic resources:
 - contractual agreements for access to genetic resources and benefit sharing
 - on-line database of actual IP-related clauses and practices
 - development of guide contractual practices, guidelines and model IP clauses
 - draft study re technical disclosure requirements in patent law (origin, prior informed consent)

WIPO (3)

- Traditional knowledge (bio-diversity related):
 - examination of availability of IP protection for TK-holders (existing and *sui generis*);
 - defensive measures to prevent grant of IPRs to third parties over TK-based creations and innovations e.g.. TK as prior art, inventories of periodicals and databases, documentation toolkit

Conclusion

- Bioprospectors may be able to acquire IPRs for inventions based on biological substances
- As a condition of an access contract, agreements may be reached about sharing the benefits resulting from obtaining a patent or any eventual commercialisation
- A bioprospecting framework may require ABS contracts of this kind
- There have been calls internationally to link ABS regulations to patent laws (e.g. origin of source, prior informed consent)