

# Patents, Property Rights and Benefit Sharing

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## Outline

- Introduction to New Zealand's intellectual property rights ("IPRs") framework
- Acquisition of intellectual property rights as part of a bioprospecting project
  - what is patentable?
- Access and benefit sharing systems
- International issues re patentability of genetic resources
- IPRs and the Antarctic Treaty

## What is Intellectual Property?

- Not simply knowledge or discovery
- 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

- Minimum standards in international agreements (e.g. WTO TRIPS)
- Rights provided in legislation:
  - Patents Act 1953 (under review)
  - Plant Variety Rights Act 1987 (under limited review)

## Intellectual property framework (2)

- Other legislation
  - Trade Marks Act 2002 (soon to come into force)
  - Designs Act 1953
  - Copyright Act 1994
  - Layout Designs Act 1994 (semi-conductors and integrated circuits)
  - Geographical Indications Act 1994

## Patents

What is and isn't patentable?  
Exclusive rights of patent owners

## Patent Protection

- An exclusive right granted for an invention
- Not all inventions are patentable
- Requirements for the grant of a patent (int.):
  - new (novelty)
  - not obvious (inventive step)
  - useful (capable of industrial application)

## Patent Protection in NZ

- Invention - “new” plus “manner of new manufacture” (and exclusions not apply)
  - Lack of usefulness and inventive step are grounds for revocation
- New - if description of the invention has not been published in NZ before filing date
  - inventions should not be published, displayed, communicated or worked in public before patent application is filed (destroy novelty)
  - some exceptions (eg gazetted field days)

## What can't be patented?

- Products of nature/new substances when found in nature
- 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 (int.)

- 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*)

## Examples of 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

## Examples most relevant to bioprospecting

- 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 up to 20 years
  - may be licensed or sold
  - does not prohibit non-commercial research
- In return for full public disclosure of invention (when filed) and contribution to public domain at expiry of patent term
- Protection only in countries where filed

## Plant Variety Rights

- Plant Variety Rights Act 1987
- Cultivated varieties (incl. hybridisation)
- 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 in NZ

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## Intellectual Property and Bioprospecting

Obtaining IP as part of a bioprospecting project

Access and benefit sharing

Convention on Biological Diversity

Contractual approaches

## Where does IP fit?

- 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)

## Access and benefit sharing

- Convention on Biological Diversity (“CBD”)
  - conservation of biological diversity
  - sustainable use of natural resources
  - fair and equitable sharing of benefits derived from use of genetic resources

## CBD, bioprospecting and IP

- Article 15 (access and benefit sharing)
  - authority to determine access to genetic resources rests with national governments
  - States should endeavour to create conditions to facilitate access by other contracting parties, for environmentally sound uses
  - access subject to “prior informed consent” of resource provider and on “mutually agreed terms”

## Benefit sharing

- Art. 15 also requires that parties adopt measures that aim to achieve fair and equitable sharing of benefits arising from commercial (and other) utilisation of genetic resources and the results of research and development, with the State providing the resource
- Art. 8(j) - benefit sharing with indigenous and local communities
- Art 16 - access to and transfer of technology

## 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, traditional knowledge holders, governments, researchers, investors etc...

## Contracts (2)

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

### Intellectual Property and Genetic Resources Impacts of patenting on access and benefit sharing (“ABS”)

## Intellectual Property and Genetic Material

- 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 (as part of patent process)
  - calls to ban the patenting of all life-forms
  - grant of patents without novelty or inventive step (patents granted too easily without full examination)

## Intergovernmental Organisations considering these issues

- World Intellectual Property Organisation (WIPO) Intergovernmental Committee
- Convention on Biological Diversity (ABS, Bonn Guidelines and Article 8(j))
- World Trade Organisation (WTO) TRIPS Council
- UNCTAD, WSSD, 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

## World Trade Organisation

- Relationship between WTO and CBD
  - a conflict?
  - TRIPs enables patents to be granted without evidence of prior informed consent or source of genetic materials
  - suggestion that Article 27(3)(b) of TRIPs be amended to meet CBD ABS requirements
  - no agreement on this issue in TRIPs Council

## Antarctic Treaty

### Implications of patenting for scientific research and conservation

## IP and Article III

- Article III: *Scientific observations and results from Antarctica shall be exchanged and made freely available*
- Patenting requires confidentiality until specification is published by IP office
- Issue: does patenting of inventions, resulting from bioprospecting in Antarctica, constrain scientific research and exchange (in conflict with Article III)?

## Patents granted

- WO 01/44275 (int. publication number)
  - processes and organisms for the production of anti-freeze proteins
  - protein isolated from bacterium collected from Antarctic lake sediment
  - prevents water crystals from growing too large, effecting a smoother textured ice cream
- Others in USA and UK (and NZ)

## Some observations

- Patenting requires full disclosure of the patent specification, made publicly available by IP offices
- Initial confidentiality may cause some delays in disclosure
- No time limit or method for exchange of information is specified in the Treaty
  - practices vary and delays usually occur
- Suggest no inherent conflict

## (2)

- Another issue - benefit sharing:
  - is regulation required to ensure that benefits from commercialisation of bioprospecting research are shared?
  - Should further conditions be placed on access (in addition to environmental effects)?
  - e.g. subject to a benefit sharing agreement or regulations
    - utilisation of samples (research/commercial)?
    - patenting permissible?
    - Use of royalties for antarctic purposes?

## Summary

- 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 for Antarctica might require ABS agreements or compliance with benefit sharing regulations
- Patenting may delay sharing of Antarctic research but does not appear to be inconsistent with Art. III



## Appendix - NZ Bioprospecting Review

- MED review of policy framework for regulation of bioprospecting activities
- Currently fragmented and reliant on legislation designed for other purposes
- Submissions received on discussion paper released November 2002
  - comments re rules about access, mechanisms to track use and capture benefits, prior informed consent and traditional knowledge
- Policy advice July 2003

