

# Bioprospecting: Harnessing Benefits for New Zealand

A policy framework discussion





## Ministry of Economic Development

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ISBN 978-0-478-31052-8 (Print version)  
ISBN 978-0-478-31054-2 (HTML)  
ISBN 978-0-478-31053-5 (PDF)

Front cover images (from top left to bottom right): Sponge Mycale hentscheli, Mike Page, NIWA; Harakeke, D R Towns, Crown Copyright, Department of Conservation (DOC); Scenic Reserve, 1985, Crown Copyright, DOC; Harakeke – Flax flowers, K Smith, 1982, Crown Copyright, DOC; Sponge Mycale hentscheli, Mike Page, NIWA; Pōhutukawa, Terry C Greene, 1987, Crown Copyright, DOC; Kawakawa, Dick Veitch, Crown Copyright, DOC; Diver and seeding line, Mike Page, NIWA; Pink Mānuka, Ian Flux, 1992, Crown Copyright, DOC; Chatham Island Nīkau, Ian Flux, 1999, Crown Copyright, DOC; Pink Mānuka, P Anderson, Crown Copyright, DOC.

# Foreword

New Zealand has a long history of building its prosperity through making the most of its abundant natural resources. Our relationship with our unique flora and fauna is central to our identity as New Zealanders.

For many years, our biotechnology scientists have been world leaders across a number of specialisations. Their ability to identify and develop high value products and services is helping transform our economy and build economic prosperity.

Bioprospecting is the term for the gathering of biological material from flora and fauna for potential commercial gain. It offers great opportunity for our economy but we need good and clear policies if we are to better realise its potential.

Many readers of this document will be aware that there is a relationship between the Waitangi Tribunal claim WAI 262 (known as the “flora and fauna claim”) and bioprospecting policy. The Government is mindful of this relationship and is of the view that proceeding with early consultation on the development of a bioprospecting policy should help inform Government’s consideration of the Tribunal’s recommendations on WAI 262 when they are made.

The purpose of this discussion document is to gather information about bioprospecting in New Zealand and facilitate a discussion on how a policy framework might be structured. Such a framework should also allow for the relationship between bioprospecting activities and traditional knowledge to be recognised.

I am keen to receive feedback on the ideas set out in this document from all with an interest in bioprospecting so that policy development is better informed and we can find a common way forward.



A handwritten signature in green ink that reads "David Parker".

Hon David Parker  
**Minister of Energy**

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# 1. Introduction

New Zealand currently has no comprehensive policy framework for bioprospecting activities. Present legislative frameworks provide, in part, for bioprospecting activity. However, gaps in the overall management of these activities may be leading to biological material being taken from New Zealand without our knowledge. Moreover, a more co-ordinated and comprehensive policy approach may be more likely to generate and optimise the capture of benefits. For instance, the fact that we have different frameworks for bioprospecting, with little co-ordination between them, may be limiting international interest in bioprospecting in New Zealand. In addition, a lack of clear guidelines around the use of traditional knowledge creates uncertainty over knowledge ownership and the rights to use that knowledge.

There is also a relationship between the Waitangi Tribunal claim WAI 262 (known as the “flora and fauna claim”) and bioprospecting policy. The Government is mindful of the relationship and is of the view that proceeding with early consultation on the development of a bioprospecting framework sits comfortably with the Tribunal’s consideration of WAI 262 and will help inform Government consideration of the Tribunal’s recommendations.

In addition, through the Convention on Biological Diversity, discussions are currently taking place on an international framework for access to biological resources and benefit sharing that has the potential to influence domestic bioprospecting policy settings. Consequently, it is necessary to gain a greater understanding of New Zealand’s interests in order to positively contribute to these international developments.

In 2002, initial policy discussions took place with the release of a public discussion document *Bioprospecting in New Zealand: Discussing the Options*. This initial discussion was spurred by a number of concerns including those about the conservation of New Zealand’s biodiversity,<sup>1</sup> the taking of biological material from New Zealand without our knowledge, and New Zealand not fully realising the potential benefits of bioprospecting activities. Further examination of these issues suggested that the current situation in New Zealand was not well suited to optimise possible benefit capture as well as minimise the potential risks that may stem from these pursuits.

The purpose of this discussion document and associated consultation is to:

- gather further information about bioprospecting in New Zealand;
- facilitate an informed discussion about the development of bioprospecting policy;
- help determine how a bioprospecting framework might be structured; and
- allow policy development to better address the issue of traditional knowledge, in particular mātauranga Māori, relating to natural resources within a bioprospecting framework.

An important aim of this consultation process is to find out more about *what* benefits could be generated by bioprospecting activities as well as focus on *how* these benefits could be better captured for New Zealand. At this stage of the policy process, the focus is not on how these potential benefits should be distributed.

It is also not the aim of this document to address issues around the ownership of biological resources. Consequently, the term “access provider” is generally used in this document instead of “owner”. However, it is noted that “access providers” and “owners” are not necessarily the same person or organisation.

This discussion document and consultation will provide better information to guide Government decisions about an appropriate bioprospecting framework for New Zealand.

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<sup>1</sup> See section 3.3 in this document entitled “Related government policies”.

## 2. Bioprospecting: what is it?

### 2.1 What does bioprospecting mean and what does it involve?

The term bioprospecting can have a range of meanings.<sup>2</sup> Some explanations can have a relatively narrow perception of bioprospecting, while others can be very broad. As the name implies, bioprospecting is a form of “prospecting” but, unlike prospectors looking for gold, a bioprospector is looking for something of value in biological material. In more formal terms and taking a broad view, bioprospecting is the search for and gathering of biological material that will then be examined for features of potential value. The “examination” or research phase of a bioprospecting activity is sometimes called *biodiscovery*.

Our working definition of bioprospecting, which is further elaborated on in the last section of this discussion document, is:

*Bioprospecting is the collection of biological material and the analysis of its material properties, or its molecular, biochemical or genetic content, for the purpose of developing a commercial product. Bioprospecting policy excludes the later steps in the chain of product development.*

Typically, only small biological samples are needed for bioprospecting activities. Bioprospecting does not usually include the subsequent activity of bioprospectors or researchers obtaining larger quantities of biological material for their research. An example of this would be the harvesting of a certain species to obtain greater quantities of a natural product that has biological activity.<sup>3</sup>

Biological material for bioprospecting activities can come from two main sources: directly from its natural environment, or from a collection. If biological material is collected from its natural environment, it could be taken from a number of ecosystems, namely terrestrial, freshwater or marine.<sup>4</sup> If the biological material has already been taken from its natural environment and placed in a collection, for example, a zoo, an aquarium or a culture collection, this can be an alternative source of interesting material for bioprospecting activities.<sup>5</sup>

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<sup>2</sup> • M. Polski, ‘The institutional economics of biodiversity, biological materials and bioprospecting’, *Ecological Economics*, 2005, 53, 543–557: bioprospecting means the “search for useful biological materials in micro-organisms, plants, fungi, animals and humans”;  
• Biotechnology New Zealand: “bioprospecting is the examination of biological resources (for example, plants, animals, micro-organisms) for features that may be of value for commercial development.” See [www.nzbio.org.nz/files/default.asp](http://www.nzbio.org.nz/files/default.asp); and  
• Ministry of Research, Science and Technology, New Zealand: “the search for plant and animal species from which medicinal drugs and other commercially valuable compounds can be obtained”. See [www.morst.govt.nz/current-work/environment/bioprospecting](http://www.morst.govt.nz/current-work/environment/bioprospecting).

<sup>3</sup> A natural product that has biological activity can also be called a “bioactive” or “bioactive compound”.

<sup>4</sup> The technical term for finding biological material in its natural environment is that the biological material was found *in situ*.

<sup>5</sup> The technical term for finding biological material outside of its natural environment, for example, if it is found in a zoo, aquarium or culture collection, is that the biological material was found *ex situ*.

Bioprospecting activities have provided humanity with many very valuable products and commercial applications, for example, the discovery of natural products that can be used as medicines. These natural products can also be a crucial starting point for making related products that have improved medicinal properties. Approximately 57 per cent of the top 150 prescription drugs sold in the United States are derived from natural resources.<sup>6</sup> Other examples of important products and applications that have arisen from bioprospecting activities include cosmetics, industrial lubricants, adhesives and micro-organisms to make industrial processes cleaner and more efficient. At present, there is particular international interest in:

- developing new methods to process lignin, cellulose, other carbohydrates and/or oils to produce biofuels;
- discovering novel and more active medicines;
- using biotechnology to create starting materials for industrial processes; and
- nutritional supplements and other “natural health and wellness” products.

### Paclitaxel – a medicinal compound from the Pacific yew tree

Paclitaxel (Taxol<sup>®</sup>) is a naturally occurring compound found in the Pacific yew tree (*Taxus brevifolia*). Paclitaxel is biologically active, and it is used as a medicine to treat, amongst other ailments, ovarian, breast and lung cancer. This medicine was first brought to market in 1993, and quickly became a top-selling pharmaceutical. In 2000, sales peaked at nearly US \$1.0 billion.

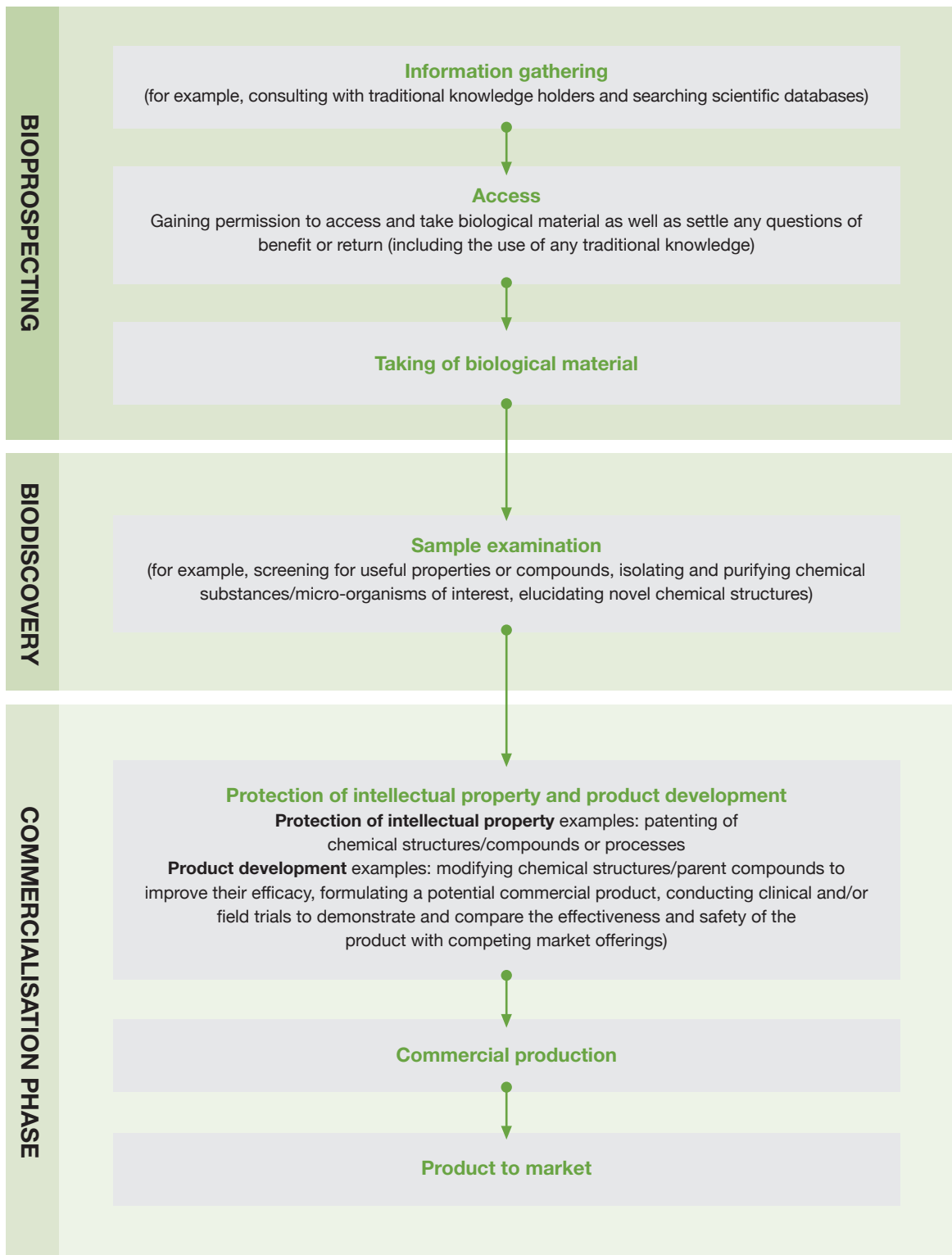
The journey of discovery to reach this point was long and it involved a number of different research groups. In 1958, the National Cancer Institute (NCI) commissioned botanists in the Department of Agriculture to collect samples of over 30,000 plants that would be then tested for anti-cancer activity. It wasn't until 1963 that a researcher discovered that the bark from the Pacific yew tree had anti-cancer properties. Later, in 1967, researchers isolated the bioactive compound paclitaxel as responsible for the valuable medicinal properties. In the years that followed, an enormous amount of research and development went into discovering more about paclitaxel, for example, what it looked like chemically, why it was biologically active and how it could be produced in large quantities without harvesting the slow-growing Pacific yew trees.

Sources: K. C. Nicolau, W. M. Dai, R. K. Guy, *Angewandte Chemie International Edition*, 1994, 33, 15–44 and references cited therein; M. McCarthy, *The Lancet*, 2002, 359(9323), 2092.

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<sup>6</sup> The contribution of natural products to sales in the world's top pharmaceutical companies ranges from 10 per cent to more than 50 per cent. S. K. Kam, 'Biopiracy in Paradise?: Fulfilling the Legal Duty to Regulate Bioprospecting in Hawaii', *University of Hawaii Law Review*, 2006, 28(2) 387.

Figure 1: A possible research project involving bioprospecting



## Bioprospecting: Harnessing Benefits for New Zealand

A research project involving bioprospecting may include many steps, as shown in Figure 1. The natural product paclitaxel is a real-life example of such a research project. Research projects of this kind can have the following features:

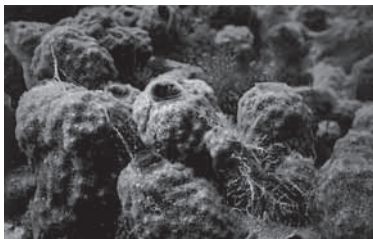
- The boundaries between the various steps and activities can be quite blurred and can also occur in a different order to that shown in Figure 1.
- They can be very interdisciplinary and require a wide range of skills and expertise from many different people.
- The original sample of biological material can pass through the hands of many different researchers and research organisations as the various project steps are carried out.
- They can be quite time-consuming. For example, in the crop protection sector, 2–14 years of research and development are needed, whereas in the pharmaceutical sector, over 15 years may be necessary.

Bioprospecting projects can be expensive. Collecting samples and screening for biologically active natural products (bioactives) or other interesting properties requires a high level of training and significant investment. The statistical chance of finding a valuable commercial application is relatively low (Appendix 1). However, if such a discovery is made, benefits can be considerable. An example of a promising discovery made in New Zealand is given below.

### Peloruside A – a promising new bioactive compound

Peloruside A is a novel potential anti-cancer compound that was jointly discovered at Victoria University of Wellington and the National Institute of Water and Atmospheric Research (NIWA). The development of Peloruside A is being conducted in collaboration with American-based organisations UT Southwestern Medical Center and Reata Pharmaceuticals Inc. This bioactive compound was first found in a marine sponge originating from Pelorus Sound (South Island). Peloruside A is one of the few compounds being assessed as a second generation cancer therapy agent. It has superior properties to the existing treatment drug, paclitaxel (see page 5 for a discussion of paclitaxel).

Source: [www.vic-link.co.nz/media/potential-anti-cancer.htm](http://www.vic-link.co.nz/media/potential-anti-cancer.htm)



The sponge *Mycale hentscheli*,  
Mike Page, NIWA.

## 2.2 Why is New Zealand of potential interest to bioprospectors?

New Zealand has unique and diverse flora and fauna that have evolved as the result of a long period of geographical isolation, evolution without carnivorous terrestrial mammals, and across the wide range of latitudes covered by our country. In addition, New Zealand has a large marine area<sup>7</sup> and a number of geothermal areas and aquatic hydrothermal vents that may contain particularly novel life forms.

Factors that make a country's biological resources attractive to bioprospectors include the:

- degree of biological diversity;
- degree of endemism, that is, the extent to which species are only found within that country; and
- level of taxonomic knowledge about the species present.

In general terms, New Zealand's indigenous biological resources (Appendix 2) have a:

- moderately low degree of biological diversity with the exception of more highly diverse marine invertebrates;
- high degree of endemism, that is, many species in New Zealand can only be found here; and
- varied (but generally low) level of taxonomic knowledge about the species present.

The chance of finding novel bioactives may be highest in New Zealand's marine invertebrates and terrestrial plants. Commercial bioactives are already being developed from these groups. A number of novel compounds have also been isolated from marine macroalgae, and the chances of finding more appear good. However, a lack of taxonomic knowledge hampers bioprospecting in macroalgae and in some other groups (such as micro-organisms).

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<sup>7</sup> New Zealand has jurisdiction over an Exclusive Economic Zone (EEZ) that extends 200 nautical miles from the coast. We have the fourth largest EEZ in the world. We also have jurisdiction over the seabed in our continental shelf area, which, in many places, extends even further. The outer limits of our continental shelf have been lodged with the United Nations Commission on the Limits of the Continental Shelf for their recommendations.

### Novel products derived from a micro-organism

Products derived from a micro-organism originally found by New Zealand scientists in a volcanic vent are being launched into the billion dollar global DNA extraction market. One of these products can be used to extract human DNA from crime scene samples and thereby help tackle the major international crime sample DNA testing backlog. US law enforcement and criminal forensic laboratories in 50 American states suggest that there are untested samples from more than 500,000 crime cases – 250,000 of them being unsolved rapes and homicides since 1982.

Where could these new products have a competitive edge over current market offerings? New Zealand's ZyGEM Corporation market these products as being able to extract DNA from smaller samples at three times the speed, and at a considerably lower cost. In addition, DNA samples can be processed in a single unopened tube. This permits automated procedures to be used while avoiding the potential danger of samples infecting staff, as well as chances of the sample becoming contaminated.

Source: [www.zygem.com/news.php](http://www.zygem.com/news.php)

## 2.3 Bioprospecting in New Zealand: the current situation

The main New Zealand-based bioprospecting agencies operating in this country are government Crown Research Institutes, universities and private biotechnology companies. Through these domestic agencies, a proportion of benefits are already captured in New Zealand.

A number of foreign biotechnology companies have also shown an interest in bioprospecting in New Zealand, often in collaboration with local agencies.

It is difficult to quantify the extent to which New Zealand may be missing out on any potential benefits arising from bioprospecting, with reasons including that:

- the New Zealand bioprospecting sector is relatively diverse and small;
- there is a lack of co-ordinated information gathering about this activity;
- it is possible that biological material is being taken from New Zealand without our knowledge; and
- the inherent nature of prospecting makes it difficult to gauge the magnitude of undiscovered benefits that might be found in New Zealand's biological resources.

## 2.4 Does bioprospecting pose a risk to New Zealand's environment, heritage and culture?

It is important that bioprospecting activities are ecologically sustainable given that bioprospectors will use elements of New Zealand's biological diversity (biodiversity).<sup>8</sup> In addition, it is also important that these activities do not endanger New Zealand's historical and cultural sites, for example, archaeological or wāhi tapu areas.

For bioprospecting activities to be ecologically sustainable, bioprospectors need to:

- use the components of biodiversity in a way and at a rate that does not lead to the long-term decline of biodiversity;
- not impair the ability of the target population to reproduce, repopulate an area or colonise;
- minimise or avoid disturbances to areas of habitat important to threatened species; and
- leave the ecosystem in a state where the function of its natural variability is unaffected.

In general, any activity in the environment can potentially cause harm. Concerning bioprospecting activities, factors that could influence the level of environmental impact include how a sample site is accessed, how a sample is taken, how often a sample is taken and the size of the sample relative to the abundance of the biological resource.

The development of bioprospecting policy would recognise the need to avoid, remedy or mitigate any potential environmental or ecological impacts resulting from these activities. In addition, the potential impacts of bioprospecting activities on archaeological or wāhi tapu sites would require an assessment of effects, and application to the New Zealand Historic Places Trust (Pouhere Taonga).

If bioprospecting is undertaken sensitively, the damage from taking samples directly from the natural environment (*in situ*) should be low because:

- only very small samples are usually required; and
- the source site does not normally need frequent access. If repeated access was necessary, further permissions may need to be sought from the access provider.

Sensitivity, guidance and monitoring of activities are especially necessary in relation to threatened species as well as to rare and threatened ecosystems.

The potential risks associated with bioprospecting for biological material are managed by a number of legislative frameworks, for example, the Resource Management Act 1991 (RMA) and the Historic Places Act 1993, depending on the access provider to these resources (see section 4).

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<sup>8</sup> Biodiversity includes the variability among living organisms from all sources, including terrestrial, marine and other aquatic ecosystems, and the ecological complexes of which they are part. The components of biodiversity include genetic, species and ecosystem diversity.

## 3. Why develop a comprehensive bioprospecting policy?

New Zealand currently has no comprehensive policy framework for bioprospecting activities. Creating such a framework could enhance co-ordination between providers of biological resources as well as optimise benefit capture for our country. In thinking about policy development, consideration must be given to a number of issues. These include the Māori dimension, related government policies, and the interaction with existing and developing international legal and policy frameworks. Other considerations are the potential benefits and costs of a comprehensive bioprospecting framework.

### 3.1 Where are we now and where could we go?

Current legal and policy frameworks that govern access to New Zealand's biological resources have some differences between them. A few central government departments have developed processes for allowing access to the biological resources that they manage. However, not all of these existing government processes have a benefit-capture focus. These current systems are detailed in section 4.

In addition, access to biological material on privately-owned land is currently negotiated between the private land owner and the bioprospector. Without any comparison to other potential bioprospecting agreements, private land owners may not be realising reasonable levels of benefit capture.

If New Zealand co-ordinated the management of bioprospecting activities at a centralised level, this co-ordination could promote consistency, certainty and transparency in the negotiation of benefit sharing between bioprospectors and all respective access providers to biological resources.

A co-ordinated approach would:

- enable a broader view of bioprospecting activities;
- provide a central contact point for international as well as domestic bioprospectors, where information could be gained about how to access biological resources and the appropriate access providers;
- where required, co-ordinate and help with the streamlining of bioprospecting processes;
- ensure that frameworks are in place that seek to optimise possible benefit return to New Zealand. For example, managing a co-ordinated system for foreign activities could ensure that benefits are not unduly flowing offshore and thereby leading to insufficient returns to New Zealand. Facilitating interaction between foreign and domestic organisations could promote the adding of value<sup>9</sup> in New Zealand after the initial bioprospecting activity; and

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<sup>9</sup> The term "adding of value" refers to activities that are conducted after the biological sample is collected, for example the screening of biological samples and other scientific activities.

- enable the systematic gathering and storing of information about what bioprospecting activities are occurring in New Zealand, as well as the associated costs and benefits of these pursuits. This information could be valuable for a number of reasons, including maintaining an overview of the scope and nature of bioprospecting activities in New Zealand, monitoring the general success of bioprospecting policy, and improving the alignment of the bioprospecting framework to policy objectives.

## 3.2 The Māori dimension

### 3.2.1 Waitangi Tribunal Claim WAI 262

#### About the claim

WAI 262 was lodged with the Waitangi Tribunal on behalf of six iwi (Ngāti Kuri, Ngāti Wai, Te Rarawa, Ngāti Porou, Ngāti Kahungunu and Ngāti Koata) in 1991. The claim asserts tino rangatiratanga and kaitiakitanga rights over mātauranga Māori and indigenous species of flora and fauna.<sup>10</sup> The claim also asserts that the Crown is in breach of Article II of the Treaty of Waitangi through the enactment of legislation inconsistent with those rights, including that the Crown has failed to design systems that adequately recognise Māori rights to indigenous flora and fauna and to mātauranga Māori about that flora and fauna.

On 6 July 2006, the Tribunal released its final Statement of Issues. The scheduled hearings and closing submissions were completed very recently, in June 2007. The Tribunal's subsequent report is not expected to be available for at least a year.

There are important links between bioprospecting policy and the WAI 262 claim. It is important that the government develops its understanding of bioprospecting issues, in particular its understanding of the relationship between bioprospecting and mātauranga Māori. Moreover, consultation and policy work on bioprospecting will not limit WAI 262 proceedings and should enhance the Crown's ability to respond to the Tribunal's findings and recommendations.

#### Policy development and the WAI 262 claim

Since the WAI 262 claim was lodged in 1991, some related policies and initiatives have been developed, including:

- the Matauranga Kura Taiao fund has been established to support hapū and iwi attempts to retain and promote mātauranga Māori and its use in biodiversity management;<sup>11</sup>
- the Trade Marks Act 2002 established a Māori Advisory Committee to advise the Commissioner of Trade Marks on whether a proposed use or registration of a trade mark derived from a Māori text or image is, or is likely to be, offensive to Māori; and
- the development of a draft Patents Bill. Once enacted, this legislation will set up a Māori Consultative Committee to advise the Commissioner of Patents in relation to patent applications for inventions that involve traditional knowledge, or indigenous plants and animals. (This may lead to such applications being refused if the invention is found to be non-novel or obvious in light of existing traditional knowledge, or if commercial exploitation of the invention would be contrary to Māori values.)

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<sup>10</sup> The term "kaitiaki" is defined by the Waitangi Tribunal for the purpose of its statement of issues (SOI, page 5) as follows: "Kaitiaki in respect of tāonga works, biological and genetic resources in indigenous and/or tāonga species, the environment, te reo Māori, tikanga Māori and mātauranga Māori, means the individual(s), whānau, hapū or iwi (as the case may be) whose relationship of kaitiakitanga and tino rangatiratanga with those tāonga gives rise to an obligation and a corresponding right to: protect, preserve, control, regulate, use, develop, and/or transmit those tāonga and the relationship of kaitiakitanga with them; and kaitiakitanga is intended to have a corresponding meaning. For the purpose of the WAI 262 statement of issues the term "tino rangatiratanga" includes the right of kaitiaki to make and enforce laws and customs in relation to their tāonga."

<sup>11</sup> The Matauranga Kura Taiao fund is a contestable fund that is administered by the Department of Conservation under the New Zealand Biodiversity Strategy.

### 3.2.2 The use of traditional knowledge and mātauranga Māori

Traditional knowledge relating to biological resources may be as valuable to bioprospectors as the resource itself. For this reason, a comprehensive bioprospecting policy in New Zealand would have to apply not only to these biological resources, but also to the associated traditional knowledge. Because the knowledge held by Māori (mātauranga Māori) makes up a major portion of New Zealand's traditional knowledge, this section will focus closely on this particular aspect.

#### Traditional knowledge and mātauranga Māori

“Traditional knowledge” and “mātauranga Māori” are terms frequently used in this discussion document. Traditional knowledge is a phrase in common domestic and international usage, encompassing knowledge arising from all local communities, including that held by indigenous communities. Usually, a link could be expected to exist between the location of specific biological material and local communities' knowledge about and relationship to that material. This phrase is also the language used in the Convention on Biological Diversity.

By comparison, mātauranga Māori is the term often used in New Zealand to refer to Māori knowledge originating from Māori communities. Mātauranga Māori is the generally preferred term used in the WAI 262 claim. As part of the consultation process, understanding of these concepts in relation to bioprospecting will be better developed.

Currently, New Zealand has no recognised guidelines or regulations on bioprospectors' use of traditional knowledge or mātauranga Māori. This seems particularly undesirable from the point of view of Māori who either may not wish their knowledge to be used in ways inconsistent with their customary laws and practices, or have their knowledge exploited without any benefits flowing back to them. It is also undesirable from the point of view of bioprospectors who want certainty that their use of mātauranga Māori is legal and ethical.

New Zealand has signed and ratified the 1992 Convention on Biological Diversity (section 3.4.1). Article 8(j) of this convention relates to the use of traditional knowledge. It calls on parties 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 and promote their wider application with the approval and involvement of the holders of such knowledge, innovations and practices and encourage the equitable sharing of the benefits arising from the utilisation of such knowledge, innovations and practices.

In New Zealand, some bioprospectors may wish to draw on mātauranga Māori to inform their research into uses of biological resources. For example, Māori knowledge of the use of indigenous flora and fauna for medicinal purposes may be of interest to pharmaceutical companies. This information can, for example, reduce companies' search costs, thereby making the overall bioprospecting process comparatively less costly.

## Mātauranga Māori: indigenous plants as a source of medicines

Māori have used indigenous plants as a source of medicines for centuries, for example:

- Harakeke or New Zealand flax: this plant had many uses. Aside from its fibre being widely used for clothing, matting and baskets, gum exuded from the base of flax leaves or cut leaves could be applied to burns, wounds and abscesses;
- Koromiko: an infusion of Koromiko leaves was a powerful astringent for dysentery, and bruised leaves were applied as poultices for ulcers and venereal disease;
- Ngaio: an infusion of Ngaio leaves was rubbed on the skin to prevent mosquito and sandfly attacks. Ngaio bark could be used to heal ulcers and eruptions of the skin;
- Nīkau: parts of this plant were used in childbirth due to its laxative properties and to relax the (pelvic) ligaments of the body;
- Northern Rata: the bark from this tree was used against ringworm, venereal disease, sores, wounds and abscesses; and
- Pōhutukawa: an infusion of the inner bark was valued as a remedy for diarrhoea, and to dispel inflammation and promote healing in wounds.

Sources: There is a broad range of websites and publications that have information about New Zealand flora and fauna, a selection of which is – M. Riley, *Māori Healing and Herbal, New Zealand Ethnobotanical Sourcebook*, Viking Sevenses N.Z. Ltd, 1994; <http://peopleplants.landcareresearch.co.nz/webforms/default.aspx>; [www.aotearoa.co.nz/native/native.html](http://www.aotearoa.co.nz/native/native.html); [www.nzpcn.org.nz](http://www.nzpcn.org.nz); [www.kaitiakitanga.net](http://www.kaitiakitanga.net); and [www.nzplants.ac.nz/](http://www.nzplants.ac.nz/)



Harakeke,  
K Smith, 1982.

Nīkau,  
Ian Flux, 1999.

Crown Copyright, Department of Conservation.

## Overseas practices

A number of national bioprospecting frameworks include provisions related to the use of traditional knowledge. For example, Australian regulations require that a permit is obtained before taking indigenous specimens from Federal areas for bioprospecting. One of the conditions for obtaining a permit is that there must be a benefit-sharing agreement between the bioprospector and the traditional knowledge holders that includes “protection for, recognition of and valuing of any indigenous people’s knowledge to be used...”<sup>12</sup>

In Colombia, Ecuador and Peru, patent applicants must present evidence of access agreements to biological resources and to any traditional knowledge that was used. This provides some degree of protection, but does not stop products being patented in other countries. (See section 3.4.1 ‘Certificates of Origin’ for further discussion on this topic.)

<sup>12</sup> Environment Protection and Biodiversity Conservation Amendment Regulations (2005) (No. 2) under the Environment Protection and Biodiversity Conservation Act (1999).

In most countries that have developed bioprospecting frameworks, consent is required to use traditional knowledge that is not in the public domain,<sup>13</sup> but is not required for the use of traditional knowledge that has already entered the public domain. However, in Peru, although consent is not required to use traditional knowledge in the public domain, the user is required to provide some benefit in return.<sup>14</sup>

In some countries, registers and databases of traditional knowledge have been developed to protect traditional knowledge by reducing the likelihood of intellectual property rights being granted where, in view of prior traditional knowledge, there is no uniqueness or novelty.

### A patent revoked by the European Patent Office

In 1995, a patent based on the antifungal properties of an Indian medicinal plant, Neem (*Azadirachta indica*), was granted by the European Patent Office (EPO) to international concerns. A number of parties opposed this move on the grounds that the biological activity of this plant had been known in India for over 2,000 years. Neem is used by Indian communities in a range of products, for example, as an oil against fungus growth, in soaps, contraceptives, cosmetics and insect repellents. On this basis, the patent was eventually revoked in 2005.

Source: [www.epo.org/about-us/press/releases/archive/2000/10052000.html](http://www.epo.org/about-us/press/releases/archive/2000/10052000.html);  
D. Dickson, K. S. Jayaraman, *Nature*, 1995, 377, 95.

### New Zealand context

As noted above, New Zealand has no recognised guidelines or regulations on bioprospectors' use of mātauranga Māori. Under the status quo, and assuming a best practice approach, a bioprospector should attempt to identify and negotiate with the most appropriate knowledge holders. In cases where an individual or localised community holds the knowledge of interest, this might be a relatively straightforward process, but where there are multiple knowledge holders, it becomes more difficult to determine whose permission is needed for use of relevant knowledge, and who should receive any subsequent benefits. (For a discussion of potential benefits from bioprospecting, see section 3.5 below.)

Within groups that hold mātauranga Māori, there may be certain customary practices and procedures that must be respected and followed for consent to be given to use that knowledge. There are no formal processes in place to ensure that these practices and procedures are followed.

Where mātauranga Māori is already in the public domain, it may be difficult to find an organisation or organisations representing all the original holders of the knowledge being used.

An added consideration is that, without the establishment of clear guidelines, a bioprospector facing such complexities could decide to proceed with using mātauranga Māori without identifying or negotiating use with the most appropriate holders of the relevant knowledge. Aside from the lack of consent or control, this would also make it less likely that benefits would be captured for the holders of that knowledge.

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<sup>13</sup> In the context of this discussion, the "public domain" means publicly available. It does not mean knowledge protected through intellectual property rights.

<sup>14</sup> This is outlined in the Peruvian law "Introducing a protection regime for the collective knowledge of indigenous peoples derived from biological resources" (2002). Article 13 says: "...In cases where the collective knowledge has passed into the public domain within the previous 20 years, a percentage of the value, before tax, of the gross sales resulting from the marketing of the goods developed on the basis of that knowledge shall be set aside for the Fund for the Development of Indigenous Peoples provided for in Articles 37 et seq." See [www.grain.org/brl/?docid=81&lawid=2041](http://www.grain.org/brl/?docid=81&lawid=2041)

### Mātauranga Māori: indigenous plants as a potential source of food flavours

Crop & Food Research Ltd (a Crown Research Institute or CRI) has partnered with the largest Māori business network, the Federation of Māori Authorities (FoMA), to help identify the traditional use of native plants in foods and flavourings with the view to developing distinctive New Zealand food products.

This new research project has the potential to transform the current small-scale, wild source gathering of flavour materials into a commercial food ingredient industry capable of targeting niche, high-value export markets. Once flavours have been identified, scientists intend to extract them from the native plants and determine their suitability as food-flavouring ingredients. This work will be conducted in collaboration with companies exporting meat, dairy and seafood convenience food products.

Source: [www.crop.cri.nz/home/news/releases/1173305992948.jsp](http://www.crop.cri.nz/home/news/releases/1173305992948.jsp)



Kawakawa, Dick Veitch.

Crown Copyright, Department of Conservation.

## 3.3 Related government policies

In detailing the development of a bioprospecting policy, a number of related policy areas and processes would need to be considered to ensure compatibility of policy development.

### New Zealand Biodiversity Strategy

The New Zealand Biodiversity Strategy (the NZBS) was launched in 2000 in response to New Zealand's obligations under the Convention on Biological Diversity. Although the NZBS concentrates on the conservation of biodiversity, it includes the aim of "the development of an integrated policy and legislative framework for managing bioprospecting in New Zealand". Indeed, the NZBS states that current piecemeal approaches to managing bioprospecting are no longer adequate, and that there is a need for a consistent national framework. Initial workstreams on bioprospecting flowed out of the NZBS, and were initially managed by the Department of Conservation. In 2001, this work was passed on to the Ministry of Economic Development.

### New Zealand Biotechnology Strategy

The Biotechnology Strategy was launched in 2003. The Strategy was developed "to ensure New Zealand kept abreast of developments in biotechnology, and that these were used to national advantage while preserving essential social, cultural and environmental values". Bioprospecting is one of the many activities that come under the biotechnology umbrella. One of the actions the Biotechnology Strategy recommended in 2003 was to complete a review of regulations for bioprospecting, with the aim of establishing an overarching framework. The framework was to include a policy for benefit sharing, including recognising Māori interests in biological resources.

## 3.4 International considerations

A number of international initiatives have provided additional impetus for the development of a bioprospecting policy in New Zealand. In particular, an international regime is being developed under the auspices of the Convention on Biological Diversity (CBD). This regime has the potential to influence national bioprospecting policy settings. In order to manage risks around discussions on an international regime, a better understanding of New Zealand's interests and policy options is required. This section provides some basic information about the CBD, and presents some of the other international agreements that are relevant to bioprospecting in New Zealand.

### 3.4.1 The Convention on Biological Diversity (CBD)

Prior to the CBD, there was no international regime that directly regulated access to genetic resources and the sharing of benefits derived from the utilisation of those resources. As a consequence, resources were taken from a number of environments for the purpose of developing new products and little consideration was given to the countries or communities that had provided that biological material. A number of major discoveries deriving from biological resources, sometimes involving the use of traditional indigenous knowledge, did not result in benefits being returned to the respective source country. An example of such a situation is given in the information box below.

#### Discovery of the anti-rejection drug Cyclosporin A – an example from Norway

A researcher spent a couple of weeks' holiday with his wife in Norway's Hardangervidda National Park. While there, he also collected a number of soil samples. One of the samples contained the soil fungus *Tolypocladium inflatum* that also happened to produce a compound called Cyclosporin A. This compound has a range of biological activities, the most important of which being its immunosuppressant properties. In fact, Cyclosporin A began a new generation of medicines that could be used to aid such procedures as organ transplants. In 1997, the annual sales revenue from Cyclosporin-based products totalled US\$1.2 billion. In the absence of benefit sharing policies, Norway has not been able to capture a share of these financial benefits.

Source: H. Svarstad, H. C. Bugge, S. S. Dhillon, *Biodiversity and Conservation*, 2000, 9, 1521–1541.

New Zealand has signed and ratified the 1992 CBD. The main objectives of the CBD are:

- the conservation of biological diversity;
- its sustainable use; and
- the sharing of benefits derived from allowing access to “genetic resources”.<sup>15</sup>

Concerning the third objective above, Article 15(2) of the Convention states that parties should:

...endeavour to create conditions to facilitate access to genetic resources for environmentally sound uses by other contracting parties. Access should be through the prior informed consent of the sovereign state and on mutually agreed terms.

<sup>15</sup> The text of the CBD uses the term “genetic resources” rather than the approximately equivalent terms “biological material” or “biological resources” used in this document. The text also uses the term “Access and Benefit Sharing” or “ABS” to refer to the principle that benefits can be expected in return for authorising access to biological materials. Although the term “ABS” is theoretically wider than “bioprospecting” (because it could also apply to non-research activities such as the collection of firewood for fuel), discussion at international fora rarely, if ever, focuses on these wider activities, and the word is often used in a way that is equivalent to “bioprospecting” as used in this discussion document.

Article 8j of the CBD is directly relevant to traditional knowledge and practices (see section 3.2.2).

Parties to the CBD have agreed to develop an international regime on access to biological material, and sharing benefits in return for allowing access. It is intended that work on this international regime will be completed before June 2010.

### The Bonn Guidelines

In 2002, the *Bonn Guidelines on Access to Genetic Resources and Fair and Equitable Sharing of the Benefits arising out of their Utilization* were adopted by the parties to the CBD.<sup>16</sup> These guidelines are voluntary and are intended to provide guidance for countries developing national frameworks to regulate bioprospecting activities. In essence, the Bonn Guidelines:

- have conservation and sustainable use of biodiversity as core objectives;
- emphasise the obligation for users of biological material to seek consent from the providers before taking any samples;
- clarify the roles and responsibilities of users and providers;
- suggest elements for inclusion in agreements to access biological material and for “material transfer agreements”;<sup>17</sup>
- provide an indicative list of both monetary and non-monetary benefits that could be included in access agreements; and
- suggest that human genetic resources are excluded from national frameworks.

The Bonn Guidelines also cover accountability, means for verification and dispute settlement. They recommend that each country have two core elements in a national bioprospecting framework, namely a “National Focal Point” and one or more “Competent National Authority(ies)”.

### Certificates of Origin

Parties to the CBD are exploring whether there is value in an international certification system to verify the origin of particular biological material. If such a system was to be introduced, it might promote compliance with national bioprospecting policies, including that of New Zealand. Certificates of Origin are likely to be most useful in this respect if they not only verify where material is sourced from, but also that it has been taken in accordance with permit/access systems for both biological material and any traditional knowledge used.

At the World Intellectual Property Organization’s (WIPO) meetings, there has been discussion about the desirability of instituting a system of voluntary or mandatory declarations of the origin of biological material used to contribute to a patent application. The idea of linking this with an international certification system has also been mooted.

## 3.4.2 Other international considerations

There are a number of other international legal and policy frameworks that could potentially influence the policy settings of a bioprospecting framework in New Zealand. These conventions and agreements are briefly outlined.

### World Intellectual Property Organization (WIPO)

WIPO is an international organisation dedicated to protecting the rights of creators and owners of intellectual property. WIPO has established an Intergovernmental Committee on Intellectual Property and Genetic Resources, Traditional Knowledge and Folklore. The work of the committee includes considering ways to promote effective benefit sharing from the use of biological resources, including effective benefit sharing with indigenous people.

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<sup>16</sup> See [www.cbd.int/programmes/socio-eco/benefit/bonn.asp](http://www.cbd.int/programmes/socio-eco/benefit/bonn.asp)

<sup>17</sup> “Material transfer agreements” are agreements about the transfer of biological specimens, after collection, to third parties.

### Trade Related Aspects of Intellectual Property (TRIPS)

The World Trade Organization Agreement on Trade Related Aspects of Intellectual Property Rights (TRIPS) sets the international framework for conventional intellectual property rights. Article 27(1) of TRIPS states that: “patents shall be available for any inventions, whether products or processes, in all fields of technology, provided that they are new, involve an inventive step and are capable of industrial application”.

### International Union for the Protection of New Varieties of Plants (UPOV Convention)

The 1991 UPOV Convention states that a plant breeder can be granted rights of protection if the plant variety developed is distinct, uniform, stable and new. This grant of “Plant Variety Rights” is, in some respects, comparable to that given to an inventor by a patent grant.<sup>18</sup> In line with this, New Zealand legislation grants plant breeders’ rights to those who breed new varieties, or discover and develop them. Plant breeders’ rights granted in New Zealand apply only in this country.

### International Treaty on Plant Genetic Resources for Food and Agriculture (ITPGRFA)

New Zealand has not yet determined whether it will ratify this treaty. Should it do so, it will oblige New Zealand to make certain plant genetic resources held in its public sector gene banks<sup>19</sup> available on terms agreed under the ITPGRFA. The ITPGRFA applies to a list of species that are regarded as significant food crops.

## 3.5 Potential benefits of a comprehensive framework

New Zealand’s natural resources provide a wide range of benefits. These potential benefits can be both non-monetary and monetary in nature.<sup>20</sup> The sorts of benefits that could be captured with a bioprospecting policy would depend on what exactly was negotiated in terms of access to the desired biological material. These benefits can be captured immediately, for example in the form of access fees, or they can be captured at some stage in the future depending on the outcome of the bioprospecting project, for example, in the form of royalties.<sup>21</sup> Overseas experience indicates that it is not easy to stipulate what a reasonable level of benefit is, because each application has its own characteristics and needs to be considered individually.

### 3.5.1 Potential non-monetary benefits

A range of potential non-monetary benefits could be negotiated in return for access to a particular biological resource including:

- institutional capacity-building through, for example, participation in product development and access to external facilities such as databases and equipment;
- increased connectivity and sharing of research and development results between research entities;
- joint ownership of relevant intellectual property rights;
- contributions to the local economy such as employment; and
- increased scientific and public knowledge of the natural environment, for example, taxonomic information.

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<sup>18</sup> It should be noted that there are also significant differences between these two forms of intellectual property rights. The term “patent” should not be used when referring to a variety protected by the Plant Variety Rights Act.

<sup>19</sup> In other words, gene banks (*ex situ* collections) held by Crown Research Institutes.

<sup>20</sup> Within the *Bonn Guidelines on Access to Genetic Resources and Fair and Equitable Sharing of the Benefits Arising out of their Utilization*, Appendix II Monetary and Non-monetary Benefits provides a detailed list of possible benefits. See [www.biodiv.org/programmes/socio-eco/benefit/bonn.asp](http://www.biodiv.org/programmes/socio-eco/benefit/bonn.asp)

<sup>21</sup> For example, in agreements related to State-managed resources, permission to access and take biological material could also be conditional on screening work being undertaken in New Zealand, and/or taxonomic information being made publicly available.

### **Raising the capacity of New Zealand's scientific sector**

In the New Zealand context, an important benefit that could be secured through a bioprospecting policy would be to help New Zealand institutions be involved in the flow-on benefits that might arise from initial bioprospecting activities, thereby adding as much value as possible to the chain of development in New Zealand rather than off-shore. This could create a number of spin-off benefits for the science sector in New Zealand including:

- enhancing the skills and knowledge of New Zealand researchers through investment in training and equipment, thereby aiding New Zealand's drive to have a knowledge-based economy;
- generating employment in the scientific sector; and
- promoting the exchange of information between New Zealand and international research institutions, thereby creating valuable networks.

### **Benefit to local communities**

In addition, local and rural communities could benefit from value-adding through the later chain of development, for example, by being trained and employed to collect biological material. Investment into local research institutions could also increase employment in more specialised areas.

### **An example of partnerships providing opportunities for locals**

New Zealand's mānuka honey is known for its antibacterial properties, on account of the so-called "unique mānuka factor" (UMF®). Mānuka honey can be taken for digestive health and used as a topical application to help heal wounds.

Especially high levels of the UMF® are thought to be found in mānuka honey from the east coast of the North Island. This discovery initiated a partnership in 2003 between the New Zealand company Comvita and the local iwi, Ngāti Porou. Reports suggest that positive outcomes have arisen from this collaboration, as well as from a collaboration between Horouta Manuka and CRI Crop & Food Research Ltd (funded by the Foundation for Research, Science and Technology or FRST). Examples include the training and employment of locals to collect honey and maintain beehives as well as the use of previously "unproductive" land to generate an income for local iwi land owners.

Source: [http://comvita.com/mediareleases\\_20.html](http://comvita.com/mediareleases_20.html); [www.crop.cri.nz/home/news/archives/2004/1094765396733.jsp](http://www.crop.cri.nz/home/news/archives/2004/1094765396733.jsp)



Pink Mānuka, Ian Flux, 1992.

Crown Copyright, Department of Conservation.

### **Increased scientific knowledge of New Zealand's flora and fauna**

Bioprospecting activities can also provide valuable information that assists with conservation and environmental management. Bioprospectors often need to record information on taxonomy, species distribution and the variation of species' density over time.

### **3.5.2 Potential monetary benefits**

A range of potential monetary benefits could be negotiated in return for access to a particular biological resource including:

- up-front payments/access fees/fee per sample collected;
- milestone payments (commonly payable at certain stages of research or product development);
- payment of royalties and licence fees in case of the commercialisation of intellectual property;
- special fees to be paid to trust funds supporting conservation and sustainable use of biodiversity;
- research funding; and
- joint ventures and joint ownership of relevant intellectual property rights.

#### **Royalties and licence fees from intellectual property rights**

Royalty streams and licensing fees for New Zealand researchers, traditional knowledge holders and other stakeholders can be secured and retained through legal mechanisms, such as intellectual property rights. However, the capture of such monetary benefits is dependent on the product reaching a commercialisation stage, and being brought to market. In addition, because this commercialisation path is usually long and complex, monetary benefits may be only a small percentage of the returns from the final product.

## **3.6 Potential costs of a comprehensive framework**

The previous discussion focused on the benefits that could arise from co-ordinating and managing bioprospecting activities. However, it is also important to bear in mind the possible costs associated with implementing such a framework, as well as how practically enforceable a framework could be.

### **3.6.1 Possible costs to stakeholders**

When considering cost, it is important to consider how a comprehensive bioprospecting framework could affect different stakeholders.

#### **Bioprospectors**

There are some differences between domestic and international bioprospectors and how they are likely to use any potential framework which, in turn, influence the potential costs to these stakeholders. For example, for international bioprospectors, costs could also increase if New Zealand determined that certain phases of research had to be conducted here.

In very general terms, costs to bioprospectors can include the costs of:

- finding out about the bioprospecting process in New Zealand;
- finding and contacting the appropriate access provider;
- negotiating the terms of access and benefit sharing;
- gaining access to the desired resource;
- complying with any government monitoring and enforcement policies; and
- establishing certainty that samples were legally collected.<sup>22</sup>

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<sup>22</sup> Companies considering making large investments generally apply stringent diligence to ensure they have the legal right to the biological material (and any associated traditional knowledge). This is to protect their investment. For this reason, some biotechnology organisations require State endorsement of their legal right to use certain material to develop a product. Agreement from local communities or non-State organisations alone is sometimes seen as having an unacceptable element of risk.

Domestic bioprospectors are likely to incorporate any potential bioprospecting framework into their compliance procedures. This could mean that research organisations would seek to streamline procedures and build relationships with access providers in ways that make any framework easier to manage, and sufficiently reduce costs to make collection worthwhile. Domestic bioprospectors might often carry out bioprospecting as part of their organisation's research or data collection roles. Domestic bioprospectors are likely to compare the costs and benefits of a comprehensive framework, but will probably also be concerned with costs that could affect their ability to access biological resources for non-bioprospecting work.

International bioprospectors are more likely to want to interact with a framework through a focal point, before proceeding with any bioprospecting activity. Compared with domestic bioprospectors, they are likely to require considerably more relationship mediation with access providers, as well as information about legislation and regulations. International bioprospectors will probably usually be more interested in the bioactivity of collected material, rather than general information about the material, and so therefore might offer to provide the material to domestic organisations for more general research and collections. International bioprospectors are likely to compare costs with frameworks of other countries, and expect benefits from collaboration or good compliance.

### Access providers

Compared with maintaining the status quo, a key consideration for access providers will be any additional costs for them, alongside possible benefits.

The design of a framework can affect costs in a number of ways, including:

- implementation and running costs; and
- monitoring and enforcement costs.

A number of factors need to be taken into account in determining what monitoring and enforcement measures may be appropriate, including:

- because of the vast areas of land and sea of potential interest to bioprospectors, it would be difficult to physically catch bioprospectors illegally taking samples. In addition, it would be very difficult to use border control measures to prevent small biological samples being sent overseas;
- if a product derived from illegally-taken biological material is patented in another country, under existing international arrangements, the source country cannot claim redress; and
- it may be difficult to determine whether samples collected or purporting to be collected for non-commercial research are subsequently used for commercial purposes, especially overseas.

The more a comprehensive bioprospecting framework is aligned with and utilises existing resources and systems, the more costs can be kept to a minimum.

### Consumers

Depending upon the design of a comprehensive bioprospecting framework, the costs borne by bioprospectors could, in the long term, be passed on to consumers who use the products and services generated from bioprospecting activities.

## 4. Existing frameworks to access biological resources in New Zealand

This section discusses the existing legal frameworks governing the ownership of biological resources and the frameworks that govern access to these biological resources.

### 4.1 Legal frameworks

Under New Zealand law, the legal ownership of biological material is fragmented, and in some cases, ownership is not defined. Under the Wildlife Act 1953, all animals living in a wild state in New Zealand are deemed to be owned by the Crown (although there are exceptions to this). The Wildlife Act includes indigenous land mammals (bats), most birds, some reptiles, amphibians and some invertebrates. Common law vests ownership of specimens of plants, micro-organisms and fauna with the relevant landowner (except where statute, such as the Wildlife Act, provides otherwise).

Ownership of particular biological material, because of ownership of a particular block of land on which a population of an interesting species is located, does not provide legal rights over similar specimens or populations possessed by other owners. Nor does it give rights over the information derived from studying this material. Moreover, it is not possible to obtain an intellectual property right over a naturally occurring organism (though under certain conditions it is possible to obtain an intellectual property right to information derived from studying this material).

Ownership issues for New Zealand's marine fisheries resources are managed under the Fisheries Act 1996. New Zealand's fisheries regime does not assert ownership over fisheries resources while they are in their natural environment. However, once fish are commercially caught, in accordance with the law, the fish and the benefits that can be obtained from that fish belong to the catcher. The right to develop new products, including putting caught fish through a biodiscovery process, and the right to sell the fish for this purpose, are contained within this law.

#### 4.1.1 Foreshore and Seabed Act 2004

The foreshore and seabed is an area containing a range of biological resources of potential interest to bioprospectors. Any bioprospecting framework must be designed so that it is consistent with the Foreshore and Seabed Act 2004.

Under section 28(1) of the Foreshore and Seabed Act 2004, the Minister of Conservation exercises, in relation to the public foreshore and seabed, all the functions, duties and powers of the Crown with respect to the public foreshore and seabed.

What does the Foreshore and Seabed Act 2004 do? This Act:

- guarantees general rights of public access and recreation in, on, over and across the public foreshore and seabed and general rights of navigation within the foreshore and seabed;
- provides mechanisms to enable groups who may have held rights at common law in the public foreshore and seabed to participate in the administration of a foreshore and seabed reserve or to enter into formal discussions on redress; and
- provides for the recognition and protection of on-going customary rights to undertake or engage in activities, uses or practices in areas of the public foreshore and seabed.

## 4.2 Central government access providers

A large proportion of New Zealand's biological resources, including some *ex situ* collections, are currently managed through the various access systems developed by government agencies or government-funded organisations. However, there is little co-ordination across these systems.

In principle, there is a distinction between allowing access to the place where biological specimens can be taken and allowing samples to be collected. However, approvals often cover both aspects together. So, for example, a landowner may sign a single agreement that allows a bioprospector to have physical access to their property and also to take certain biological samples.

The Department of Conservation, the Ministry of Fisheries and other organisations such as Land Information New Zealand are responsible for administering access to Crown-managed and/or owned biological material in their jurisdictions. The Department of Conservation has developed systems that explicitly allow for bioprospecting applications. Other agencies may allow for bioprospecting but, at present, do not have specific systems for dealing with this activity. Crown Research Institutes have discretion over allowing other parties to access biological material they hold in *ex situ* collections.

### 4.2.1 Department of Conservation

Access to biological material managed by the Department of Conservation is determined by its concessions and authorisations systems. These systems cover a broad range of activities and, generally, rents, fees or royalties can be required under them.

The concessions and authorisations systems provide a transparent process for all applications for commercial uses such as for telecommunications structures, filming activities, tour guiding and commercial research (such as bioprospecting). Access is subject to General Policies (issued in 2005 under the Conservation Act and the National Parks Act). One of the General Policies is a requirement that "any property rights, including intellectual property rights, should be safeguarded for the benefit of the Crown on behalf of the people of New Zealand". An appropriate safeguard could be an agreement with conditions for bioprospecting, such as those around benefit sharing and minimising or avoiding environmental impacts.

### 4.2.2 Ministry of Fisheries

Access to fisheries resources (fish, aquatic life and seaweed) in New Zealand fisheries waters (including the EEZ, territorial sea, internal waters and other fresh and estuarine waters) is administered by the Ministry of Fisheries with a few exceptions. The Fisheries Act 1996 does not cover juveniles of whitebait species, sports fish, ornamental fish, unwanted aquatic life, micro-organisms or fungi. The last two are likely to be of particular significance for bioprospecting. Organisms covered by the Wildlife Act and the Marine Mammals Protection Act 1978 are managed by the Department of Conservation.

The following description applies primarily to New Zealand nationals as there are limitations on access for non-New Zealanders, for example, a requirement for foreign vessels to hold a licence from the Ministry, and restrictions on owning quota or holding fishing permits. In general, this means that the simplest way to access fisheries resources is in partnership with New Zealand organisations and individuals, which may provide opportunities for significant benefit sharing.

#### Access rights – Quota Management System

Under the Quota Management System (QMS), quota owners collectively hold rights to all of the available commercial catch in a fish stock and to the commercial value that can be gained from owning those fish once caught, including the sale of the organisms to bioprospectors. They can pass these rights on by leasing their yearly fishing rights (Annual Catch Entitlement or ACE). Any bioprospecting framework would need to respect the rights already allocated under the QMS.

### Access permits – fishing permits

Commercial access to fisheries resources is managed under fishing permits. Access to a fishing permit is open to any New Zealand individual, who must then comply with fisheries management rules and obtain quota or ACE if they are taking quota species. The fisheries access regime currently makes no distinction between bioprospecting and other commercial uses.

Bioprospecting can, therefore, take place under a fishing permit. Any bioprospecting framework would need to take into consideration the access rights already allocated under fishing permits.

### Special permits

The Ministry of Fisheries also operates a special permit regime. Special permits provide for fishing activities where no other suitable mechanism exists. However, the granting of a special permit should not undermine the integrity of fisheries management frameworks. Some bioprospecting is likely to already be occurring under the investigative research category of special permits, mostly as part of wider research projects.

## 4.2.3 Ministry of Foreign Affairs and Trade

The Continental Shelf Act 1964, which is administered through the Ministry of Foreign Affairs and Trade, covers some aspects of activity on the floor of the continental shelf. This includes the gathering of sponges and other sedentary species (organisms that, at the harvestable stage, either are immobile on or under the seabed or are unable to move except in constant physical contact with the seabed or subsoil). However, it does not cover the collection of living organisms that are not attached in some manner to the continental shelf. In practice, access to fisheries resources within the EEZ is managed under the Fisheries Act 1996, and therefore the provisions of the Continental Shelf Act 1964 are relevant only to sedentary species in areas of the continental shelf beyond 200 nautical miles.

Under the United Nations Convention on the Law of the Sea (UNCLOS), before a foreign vessel enters New Zealand waters for the purpose of marine scientific research, it must get New Zealand's consent. This is done through the Ministry of Foreign Affairs and Trade. While this requirement provides a means of regulating access, the system is not explicitly designed to optimise benefits for New Zealand.

### Foreign research vessels in New Zealand waters

New Zealand's large Exclusive Economic Zone (EEZ) makes it an attractive candidate for marine research. Foreign research vessels frequently apply for access to the EEZ, through the Ministry of Foreign Affairs and Trade.

The *FSV Marion Dufresne* and the *Deep Water New Zealand Expedition* are two recent examples of prominent research vessels in New Zealand waters. Although these vessels are primarily on oceanographic missions, many declare an interest in collecting biological samples. In normal circumstances, New Zealand is required by UNCLOS to consent to these types of projects if the research is being carried out for peaceful purposes and in order to increase scientific knowledge of the marine environment for the benefit of all humankind. In any case, as this work is usually done in close collaboration with New Zealand scientists, granting consent can be in New Zealand's interests. Collaboration also enables biological samples to be collected and stored by local researchers, adding to *ex situ* collections and information about biological resources in New Zealand's territory.

#### 4.2.4 Land Information New Zealand

Land Information New Zealand administers substantial areas of land (including riverbeds) throughout New Zealand under various Acts, including the Land Act 1948, the Crown Pastoral Land Act 1998 and the Crown Forests Assets Act 1990. At present, Land Information New Zealand has no specific system for processing bioprospecting applications over land that it administers.

### 4.3 Local government access providers

Local government is both a regulator and an administrator of natural and physical resources. As a regulator, local government administers the Resource Management Act 1991 (RMA). The RMA promotes the sustainable use of natural and physical resources (which are defined to include all forms of plants and animals). Local government implements the RMA through regional policy statements, and regional and district plans. The RMA covers most potential environmental effects of any bioprospecting activity through controls in regional and district plans. Under the Historic Places Act 1993 (HPA) and section 6 of the RMA, local government together with the Historic Places Trust, manages and protects areas of historical and cultural significance, for example, archaeological and wāhi tapu sites.<sup>23</sup>

Local government controls the use of land (including activities such as excavation and disturbance of land for purpose of access, disturbance of habitats of plants or animals), the use of water, discharge of contaminants and the use of the coastal marine area (including disturbance of the foreshore and seabed). In sensitive areas, where significant vegetation or habitats could be affected, there may be restrictions on the removal of plants and animals, and there may also be controls on access tracks or disturbance of the area. Resource consents may be required for larger-scale activities associated with bioprospecting, and an assessment of the environmental effects (including cultural effects such as the association of Māori with tāonga and the exercise of kaitiakitanga) of the activities to be undertaken would be required as part of the consent process.

As an administrator of land, local government owns and/or manages areas, on their own behalf and on behalf of the Crown. For example, local government is responsible for large areas of reserves. Under the Reserves Act 1977, certain categories of reserves (such as local purposes reserves and historic reserves) are managed by local government, while ownership stays with the Crown.

### 4.4 Private access providers

In addition to any environmental controls under the RMA, where land is in private ownership, a bioprospector needs permission to access the land for the purpose of taking samples. In other words, it is up to each private access provider to permit access to the biological resources found on their land.

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<sup>23</sup> Under the Historic Places Act 1993, it is illegal to destroy, damage or modify such sites without an archeological authority from the Historic Places Trust. An example of where damage can arise is the taking of even very small samples from an area where there is evidence of human activity in the form, for example, of bird tissue, shell samples, remnant food or artefacts. Bioprospectors should be aware of any presence of archaeological or wāhi tapu sites by checking sources such as the National Registry of the Historic Places Trust and local government schedules. See [www.historic.org.nz/heritage/heritage\\_index.html/](http://www.historic.org.nz/heritage/heritage_index.html/)

# 5. International bioprospecting frameworks

Before examining a possible framework for managing bioprospecting in New Zealand, it is useful to examine bioprospecting frameworks designed by other countries.<sup>24</sup> Many frameworks in these countries have been developed in response to their biological diversity as well as to the emergence of the Convention of Biological Diversity.<sup>25</sup>

## 5.1 The Andean communities: Bolivia, Colombia, Ecuador, Peru and Venezuela

Bolivia, Colombia, Ecuador, Peru and Venezuela<sup>26</sup> are all “megadiverse countries”,<sup>27</sup> making their biological resources of considerable interest to bioprospectors. Over ten years ago, these countries developed a common system to access biological resources in their respective jurisdictions. One of the aims of this common system was to ensure that national access regulations were consistent and in alignment with minimum standards that had been identified by these countries.

National Focal Points and Competent National Authorities have been established in a few of the member countries. An important aspect of the common framework developed by these countries is that it requires bioprospectors to obtain prior informed consent of, and share benefits with, both the Competent National Authority and indigenous, Afro-American and local communities.

In general, the scope of the bioprospecting policies developed by these countries encompass not only all indigenous biological resources, but also those found in these countries due to their natural migration. Furthermore, there is no distinction between commercial and non-commercial research activities in these policy frameworks. Their policy aims to promote the participation of nationals in research activities, general capacity-building measures and the sharing of information about research findings. In the case of public disclosure of research, the country of origin must be mentioned.

Since the implementation of a bioprospecting policy framework, a number of bioprospecting applications have been granted. The framework has been particularly popular in Venezuela, with more than 30 applications approved.

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<sup>24</sup> K. Garforth, I. Noriega, J. Cabrera Medaglia, G. R. Nemoga, *Overview of the National and Regional Implementation of Access to Genetic Resources and Benefit Sharing Measures*, Feb. 2005, preliminary draft, available on email request from [bioprospecting@med.govt.nz](mailto:bioprospecting@med.govt.nz)

<sup>25</sup> How traditional knowledge issues are addressed within these international bioprospecting frameworks will not be discussed here. They have already been touched on in section 3.2.2.

<sup>26</sup> See [www.law.unimelb.edu.au/ipria/research/trad\\_know.html](http://www.law.unimelb.edu.au/ipria/research/trad_know.html)

<sup>27</sup> The “megadiverse” countries are a group of nations in which less than the 10 per cent of the global land surface has more than 70 per cent of the land’s biodiversity.

## 5.2 Australia

Australia is a megadiverse country with over 80 per cent of Australian species being endemic to the country.<sup>28</sup> Australia's biological diversity makes it an attractive target for bioprospectors. Australia also has a growing biotechnology sector and a strong scientific and research base. These issues helped spur the State, Territory and Commonwealth governments to develop specific policies to address the regulation of bioprospecting activities. The overarching policy aims are to capture the potentially large commercial value of these unique biological resources, as well as deliver a range of non-monetary, social and environmental benefits.

After establishing a nationwide direction for bioprospecting, an important consideration has been to allow the individual States, Territories and the Commonwealth governments to develop their individual policy frameworks according to their respective jurisdictions. This development is still in progress in some Australian jurisdictions.<sup>29</sup>

Taking the Australian Commonwealth and Northern Territories governments as an example, both jurisdictions have a Competent National Authority fulfilling a range of roles and responsibilities. The Commonwealth government has the added task of being the National Focal Point for Australia. In terms of the scope of the bioprospecting policy frameworks developed by these jurisdictions, all indigenous biological material is included, and there is no differentiation between commercial and non-commercial research activities. However, on an operational level, the Australian Commonwealth and Northern Territories governments differ on the level of compliance costs expected from bioprospectors engaged in non-commercial research.

### New opportunities arise from having a bioprospecting policy

A large association of Japanese companies recently visited the Northern Territory (NT) to discuss the new Biological Resources Act 2006. This association had previously refused to do business with Australian jurisdictions lacking a clear framework governing access to and use of biological resources for the purpose of bioprospecting. As a direct result of this visit and the NT's legislation and policy, a large Japanese company<sup>30</sup> is currently negotiating a non-disclosure agreement with the NT government, prior to entering into discussions for a benefit sharing agreement for access to biological resources.

Source: Department of Business, Economic and Regional Development, Northern Territory Government, Australia.

Quantifying how beneficial these frameworks have been since their introduction is a difficult task because they have not been in place for long. In general, frameworks have been successful and a range of benefits, especially those of a non-monetary nature, have been delivered. The core aspects of the Australian Commonwealth and Northern Territories frameworks are outlined in greater detail in Appendix 3.

<sup>28</sup> See [www.amonline.net.au/biodiversity/what/australia.htm](http://www.amonline.net.au/biodiversity/what/australia.htm) and [www.deh.gov.au/biodiversity/about-biodiversity.html](http://www.deh.gov.au/biodiversity/about-biodiversity.html). About 85 per cent of flowering plants, 84 per cent of mammals, more than 45 per cent of birds and 89 per cent of inshore freshwater fish are unique to Australia.

<sup>29</sup> For example, in Tasmania, a bioprospecting policy is still being formulated.

<sup>30</sup> For reasons of confidentiality, this company cannot be named.

## 5.3 Canada

The Canadian government is in the process of deciding how it wants to move forward in the area of bioprospecting and the associated aspect of benefit sharing for access to biological resources. In addition to its provinces, Canada has three territories: the Yukon, the Northwest Territories and Nunavut. All three have similar systems to license research and thereby serve as a form of bioprospecting regulation.

The licensing of research in Canada's Northwest Territories and Nunavut is governed by a single piece of legislation called the Scientists Act. This Act requires anyone who wishes to conduct scientific research or collect samples for scientific research purposes to obtain a licence. Consequently, this Act does not distinguish commercial from non-commercial activities.

The Northwest Territories and Nunavut research licensing systems are used frequently, and many licences have been granted in the various areas of research covered by this Act.

## 5.4 The Nordic countries: Norway, Denmark, Finland, Iceland and Sweden

The Nordic countries share a common approach – the Strategy for Conservation of Genetic Resources in the Nordic Region (2001–2004). At the beginning of 2002, a follow-up document to this strategy's provisions was released concerning rights and access to genetic material.<sup>31</sup> It stated that Nordic countries do not require the sharing of benefits when (wild) biological material is collected for bioprospecting. This is because the costs of developing and administering a bioprospecting framework were considered likely to outweigh the benefits that would be received. It also considered that unregulated access to resources would promote its biotechnology sector. However, the possibility of regulating bioprospecting in the future was not excluded in this document.

Although not a megadiverse country, Norway has biological material of interest for bioprospectors (see information box in 3.4.1). Despite sharing the general approach of the Nordic countries' strategy as outlined above, bioprospecting legislation is still in the process of being reviewed in Norway. Recently, a draft Bill on the Protection of the Natural Environment, Landscape and Biological Diversity was presented. This included some provisions on access to genetic material and called for respect for traditional use by indigenous people and local communities.

## 5.5 South Africa

South Africa is a biologically megadiverse country, and for this reason, it is an attractive target for bioprospectors. In the early 1990s, South Africa developed bioprospecting and biodiversity policy frameworks in response to a number of factors, for example, the imminent ratification of the Convention of Biological Diversity. One of the aims of these developments was to “ensure that benefits derived from the use and development of South Africa's genetic resources serve national interests”.

A National Focal Point and/or Competent National Authority have not been officially designated in South Africa. By default, the issuing authority for bioprospecting permits under the National Environmental Management: Biodiversity Act 2004 is the minister responsible for national environmental management.

The scope of the bioprospecting policy implemented by South Africa is of note because, although it includes all indigenous biological resources,<sup>32</sup> there is (unlike in the Andean, Australian and Canadian policies) a distinction between commercial and non-commercial research activities. In other words, bioprospecting is defined as “research on indigenous

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<sup>31</sup> See *Access and Rights to Genetic Resources – A Nordic Approach*, from [www.norden.org](http://www.norden.org)

<sup>32</sup> The exclusions to this definition include indigenous biological resources listed in the International Treaty on Plant Genetic Resources for Food and Agriculture (ITPGRFA, see section 3.4.1), most exotic species and human genetic material.

biological resources for commercial or industrial exploitation”. Thus, purely academic research is excluded from the scope of the legislation. In addition, no distinction is made between public and private land, nor between *in situ* and *ex situ* resources. However, an access and benefit sharing agreement with private landowners must be in place before a permit is issued to a bioprospector venturing on their property.

Numerous applications have been approved under the South African bioprospecting framework. Many have been between national research institutions and international research universities and companies.

### 5.6 Lessons that can be learned from these frameworks

Independent studies of bioprospecting frameworks already established in other countries (Colombia, Costa Rica, Brazil and the Philippines, all of which are megadiverse countries) reveal a number of valuable insights.<sup>33</sup> For example:

- the benefits from a bioprospecting framework are, for the most part, non-monetary in nature. Monetary benefits take longer to accrue because of variables such as the time lag between collecting biological samples and the development of marketable products;
- a major condition for an effective bioprospecting framework is the question of adequate institutional capabilities, especially in technical and legal areas;
- a bioprospecting framework can be complicated by unclear or inefficient property rights;
- it is essential, although difficult, to ensure the fair and equitable sharing of benefits and to keep track of biological resources as they pass between users during a research project;
- the over-regulation of bioprospecting can counteract the facilitation of this activity;
- bioprospecting policies should be reviewed on a regular basis; and
- a two-track bioprospecting process is best to deal with commercial and non-commercial bioprospecting activities. Non-commercial activities should have a more straightforward process as compared with commercial ventures, in order to avoid discouraging valuable research activities such as studies into biodiversity conservation.

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<sup>33</sup> L. M. Davalos, R. R. Sears, G. Raygorodetsky, B. L. Simmons, H. Cross, T. Grant, T. Barnes, L. Putzel, A. L. Porzecanski, 'Regulating access to genetic resources under the Convention on Biological Diversity: an analysis of selected case studies', *Biodiversity and Conservation*, 2003, 12, 1511–1524; C. Richerzhagen, K. Holm-Mueller, 'The effectiveness of access and benefit sharing in Costa Rica: Implications for national and international regimes', *Ecological Economics*, 2005, 53, 445–460.

## 6. Building a comprehensive bioprospecting framework for New Zealand

The previous sections have outlined why the government is looking at the development of a comprehensive bioprospecting policy in New Zealand, what needs to be considered, and what can be learned from examining frameworks that already exist internationally. This section introduces a framework for considering how bioprospecting policy might best meet New Zealand's needs.

### 6.1 Vision and principles to guide New Zealand's bioprospecting policy

The following vision and principles are proposed to guide the development of bioprospecting policy in New Zealand.

The proposed vision for a bioprospecting policy in New Zealand is:

*that access to New Zealand's biological resources for bioprospecting is facilitated in a way that ensures the benefits derived are captured and shared, that social, cultural and environmental values are respected, and Māori traditional knowledge of biological resources is recognised and, where appropriate, protected.*

To achieve this vision on a domestic level, New Zealand needs to ensure that a bioprospecting policy framework:

- is ecologically sustainable;
- takes appropriate account of the Treaty of Waitangi and Treaty settlements;
- ensures acknowledgement and respect of Māori traditional knowledge, and the need to seek permission from holders of the traditional knowledge for its use in bioprospecting;
- ensures the equitable sharing of benefits;
- ensures that applications to bioprospect are treated fairly, with all applications judged against transparent criteria and according to law;
- encourages the timely processing of applications related to bioprospecting, with applicants' transaction costs kept to an optimum level;
- does not unduly inhibit non-commercial scientific and academic research;
- is integrated with New Zealand's Biotechnology Strategy, and encourages national and international investment in biotechnology research and development in New Zealand; and
- ensures the implementation of the government's desired policy option, and its associated institutional and administrative arrangements, occur in a cost-effective manner.

To achieve this vision on an international level, New Zealand needs to ensure that a bioprospecting policy framework:

- gives effect to New Zealand’s obligations under the Convention on Biological Diversity (CBD) to endeavour to create conditions that facilitate access to biological resources in return for a fair and equitable share of benefits from their use;
- is consistent with the *Bonn Guidelines on Access to Genetic Resources and Fair and Equitable Sharing of the Benefits Arising out of their Utilisation*, which are voluntary and were developed under the auspices of the CBD;
- is consistent with New Zealand’s interests and responsibilities arising from other international agreements and New Zealand’s strategic interests; and
- only includes terms and conditions that New Zealand would support in other countries’ frameworks.

## 6.2 Bioprospecting policy scope: what’s in and what’s out?

The design of a comprehensive bioprospecting framework in New Zealand will depend heavily on what activities and resources will be managed under the policy.

This section explores the current working definition of “bioprospecting” and discusses whether the current scope is adequate.

### 6.2.1 The current definition of “bioprospecting”

Our working definition of bioprospecting for this discussion paper is:

*Bioprospecting is the collection of biological material and the analysis of its material properties, or its molecular, biochemical or genetic content, for the purpose of developing a commercial product. Bioprospecting policy excludes the later steps in the chain of product development.*

What is currently in scope and currently out of scope of a comprehensive bioprospecting framework is shown in Figure 2.

**Figure 2: What’s in and what’s out currently**

	Commercial bioprospecting activities	Non-commercial biological research activities
Central government access providers to indigenous biological resources	in scope	currently out of scope
Local government access providers	currently out of scope	
Private access providers		
<i>Ex situ</i> collections		
Non-indigenous biological resources		

### What is “in scope”?

The following are currently in scope:

- naturally occurring (wild-type) biological resources;
- commercial bioprospecting activities;
- the exploratory stages of commercial biodiscovery activities;
- commercial activities that arise originally from non-commercial research activities. If biological material is originally collected for non-commercial purposes and this material then becomes the subject of commercial research and development, these activities would become in scope of a comprehensive bioprospecting policy; and
- establishing mechanisms to facilitate and better capture the potential benefits arising from activities that occur after the collection of biological samples.

### What is “out of scope”?

The following are currently not included and are therefore “out of scope”:

- genetically modified organisms and other man-made varieties;
- non-commercial biological research activities. The benefits of non-commercial research, for example, taxonomy and ecological research, are generally not appropriated by the researcher or any particular individual or organisation;
- the taking and collecting of biological samples for purposes other than research and analysis. Examples of such “out of scope” activities include seed collection for sale to the nursery trade, or collection of biological material for food or as firewood. In these cases, the material is valued for its immediate physical properties rather than the information that can be derived from analysing its properties and constituents;
- those processes that are already regulated by such Acts as the Hazardous Substances and New Organisms Act 1996, the Patents Act 1953 and the Plant Varieties Act 1987; and
- the collection and use of biological material of human origin. This is firmly excluded from the CBD’s Bonn Guidelines.<sup>34</sup>

## 6.2.2 Should non-commercial activities be included?

Of the activities currently not captured by the current working definition of “bioprospecting”, the desirability of including non-commercial activities is one that warrants some discussion because:

- it is often hard to draw the line between commercial and non-commercial activities. This apparently “simple” question has been the cause of legal dispute;
- non-commercial activities on biological samples can become, quite unexpectedly, commercial activities. This change in “status” can occur over a long timeframe as well as between completely unconnected research groups. An example of this would be one research group publishing their findings about an interesting biological activity in a plant. A few years later, another research group may use this information to develop a commercial product; and
- non-commercial research that involves the use of mātauranga Māori should be managed in the interests of knowledge holders.

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<sup>34</sup> These guidelines state that “all genetic resources and associated traditional knowledge, innovations and practices covered by the Convention on Biological Diversity and benefits arising from the commercial and other utilisation of such resources should be covered by the Convention on Biological Diversity, **with the exclusion of human genetic material**”.

### **Potential advantages of inclusion**

Comprehensive information about all activities involving the collection and analysis of biological material can be gathered and monitored on a nationwide basis, with the advantages that:

- it would be possible to track samples either held here and/or taken overseas in case the research results were later commercialised;
- if a biological sample collected for non-commercial activities is then used for commercial activities, documentation would be available to confirm this chain of events; and
- potential cases of biopiracy could be detected.

The transformation of domestic non-commercial activities into commercial activities could be facilitated and supported.

### **Potential disadvantages of inclusion**

Depending on the design of the framework, there could be an associated increase in the costs to various stakeholders, for example:

- to the government. This could occur through, for example, raised running and monitoring costs caused by a larger number of applications; and
- to non-commercial biological researchers. This could occur as a result of introducing aspects, such as additional procedures and processes, before and during a research project. This could be perceived as delaying project progress and raising compliance costs.

Some activities could be unintentionally considered bioprospecting, for example, biological samples collected from the natural environment that are used for teaching purposes in a laboratory. Specific exclusions to a broader definition of bioprospecting would have to be carefully considered in order not to influence such activities.

In summary, there may be potential benefit in including non-commercial research “in scope” as long as compliance costs are minimal.

## **6.2.3 Which biological resources should be accessed for bioprospecting?**

This section explores which resources should be accessed for bioprospecting activities. As outlined in section 4.2, government access systems that cover bioprospecting activities are already presumed to be included.

### **Local government access providers to biological material**

Local government manages access to significant areas of New Zealand as well as the biological resources associated with it. Although the potential environmental impacts of accessing biological resources are currently managed for the most part through the Resource Management Act 1991 (RMA), not all bioprospecting activities may be subject to these processes. In addition, there are no procedures in place to facilitate the capture of potential benefits arising from bioprospecting activities.

### **Private access providers to biological material**

Private access providers are generally private owners who can control access to biological resources found, for example, on privately-owned land or in *ex situ* collections.

Some stakeholders may view the current situation, whereby a private access provider to biological material can negotiate an access agreement and receive benefits in return, as inappropriate because the private access provider, for example, may not be in the position to negotiate a reasonable level of benefit (that related to the true value of the resource to bioprospectors).

Including private access providers within the scope of a comprehensive bioprospecting policy would provide a mechanism to protect against the inappropriate use of traditional knowledge or mātauranga Māori associated with the sampled biological material.

On the other hand, placing additional processes on the use of biological material provided by private access providers may be viewed as an infringement of existing property rights, and would have associated administrative, compliance and monitoring costs.

### Biological resources in *ex situ* collections

*Ex situ* collections are collections of biological material located outside their natural environment. They include zoos, aquariums, botanical gardens, nurseries, herbaria and repositories of extracts and frozen biological material, for example, micro-organisms. These collections hold a large variety of indigenous biological material. Collections of material held for research purposes generally have a database to support them. These databases may record information about the appearance, location and habitat of the material collected.

### *Ex situ* collections in New Zealand

*Ex situ* collections are significant sources of biological material for bioprospectors. Many of New Zealand's research organisations maintain collections and databases of native flora and fauna, some of which are internationally significant. Collections include the Allan Research Herbarium, the Cawthron Micro-algae Collection and the International Collection of Micro-organisms from Plants. These collections are made available to bona fide researchers, but charges are levied where appropriate. New Zealand has an interest in having collections of species, as they often form the basis of research for environmental and economic outcomes that benefit New Zealand. These benefits usually come from research activities other than bioprospecting. These organisations are tasked with maintaining collections through funding arrangements with the Foundation for Research, Science and Technology.

The CBD's Bonn Guidelines state that consent to use biological material in *ex situ* collections "should be obtained from the competent national authority(ies) and/or the body governing the *ex situ* collection concerned as appropriate".<sup>35</sup>

### Non-indigenous biological material

In New Zealand, there may never be much interest in bioprospecting based on non-indigenous resources because of the relatively narrow genetic base of introduced biological material. If a national framework covered indigenous biological material only, there would need to be some guidance on how it would apply in cases where it was difficult to determine whether or not a species is indigenous.

The access articles of the CBD<sup>36</sup> apply to resources that occur *in situ*. The Convention defines "*in situ* conditions" as "conditions where genetic [biological] resources exist within ecosystems and natural habitats, and, in the case of domesticated or cultivated species, in the surroundings where they have developed their distinctive properties". This definition could include both indigenous and non-indigenous species.

Some countries, such as Colombia, Ecuador, Chile, Costa Rica, the Philippines and Thailand, have included both indigenous and non-indigenous biological resources. Others, for example South Africa, Australia and Mexico, cover only indigenous biological resources.

<sup>35</sup> See [www.cbd.int/programmes/socio-eco/benefit/bonn.asp](http://www.cbd.int/programmes/socio-eco/benefit/bonn.asp)

<sup>36</sup> In particular, Article 15(2), which is quoted at 3.4.1.

## 6.3 Designing a comprehensive bioprospecting framework: what do we have to consider?

Although there are important domestic drivers for a comprehensive bioprospecting policy framework, it is useful to first take a look at the international guidelines used to design bioprospecting frameworks.

### 6.3.1 International considerations

In considering the design of a comprehensive bioprospecting framework, it is worth looking at the international context. The CBD's Bonn Guidelines are particularly relevant because they are intended to aid the development of national bioprospecting frameworks (section 3.4.1). The suggested "National Focal Point" and "Competent National Authority" building blocks have been implemented in some countries that have developed bioprospecting frameworks according to the CBD's guidelines. Federal and State/Territorial regimes developed in Australia see these aspects as core to effective management of bioprospecting activity.

Another interesting set of international guidelines has been developed by the Biotechnology Industry Organization. However, these guidelines concern a voluntary code of conduct for bioprospectors.

#### Biotechnology Industry Organization guidelines

The Biotechnology Industry Organization is an international organisation that has developed educational guidelines for members engaged in bioprospecting. A significant purpose of these guidelines is to represent "best practices" that can be followed by companies that engage in these activities. These practices are consistent with emerging international norms, notably the CBD. They cover topics such as how a bioprospector should go about obtaining prior consent to take biological material, the sharing of benefits and research results, measures to protect the rights of indigenous communities, and environmental protection.

Sources: [www.bio.org/ip/international/200507memo.asp](http://www.bio.org/ip/international/200507memo.asp); [www.bio.org/ip/international/200507guide.asp](http://www.bio.org/ip/international/200507guide.asp)

### 6.3.2 The Māori dimension

Section 3 discussed a number of issues that are important on a national level, some of which are of particular importance to Māori. In designing a comprehensive bioprospecting framework, it is important to bear these issues in mind, in particular those related to the interface between bioprospecting and traditional knowledge.

#### Traditional knowledge considerations

The protection and use of traditional knowledge, in particular mātauranga Māori, is an issue much broader than bioprospecting policy. Traditional knowledge extends beyond the use of biological resources and includes elements such as house building, fishing methods and ethics. With respect to bioprospecting, unless there is greater clarity on how to access and use mātauranga Māori, then commercial interest in New Zealand for bioprospecting may be limited due to the perceived risk relating to intellectual property issues. The following approaches are suggested as options to stimulate thought on this important matter, though each belongs to broader on-going discussions. Some possible approaches could be to:

- establish a voluntary register of traditional knowledge;
- ensure the existence of legally registered and fully mandated governance entities; and
- establish a code of "best practice" for the use of traditional knowledge by bioprospectors.

### A voluntary register?

A voluntary register (part of which could be confidential) could help to protect mātauranga Māori. If an interested party, for example, a bioprospector, wished to know whether mātauranga Māori exists in relation to a particular subject, they could apply to the appropriate body. This body could check against the mātauranga Māori register for information about the appropriate knowledge holders. Then, if the interested party wished to use this information, they would negotiate terms with the registered knowledge holders.

If mātauranga Māori of relevance to the interested party's enquiry was not registered, the interested party could go ahead to develop their product, on the assumption that their potential intellectual property could not reasonably be challenged because of pre-existing knowledge.

### Ensuring legally registered and fully mandated governance entities?

There is currently a complex mix of governance bodies representing Māori for settlement or land holding (or other) purposes. While some of these entities may already have the mandate and resources to encourage activities through the ability to offer secure contracts and any associated use of mātauranga Māori, others may not have sufficient resources, or their mandate to negotiate contracts may not be sufficiently strong to facilitate activities in their rohe (area). Some strengthening of governance entities might be desirable to achieve maximum benefits from bioprospecting for Māori.

### Code of “best practice” for bioprospectors?

Similar to the concept developed by the Biotechnology Industry Organization, an approach to provide clarity and guidance around bioprospectors' use of mātauranga Māori could be to develop a code of “best practice”. This code would need to balance measures to prevent the misappropriation and misuse of mātauranga Māori with the benefits Māori and others might stand to gain from a system that:

- does not give rise to numerous legal disputes (between Māori groups, or between Māori and bioprospectors); and
- does not make compliance so difficult that almost no bioprospectors use mātauranga Māori, and therefore no benefits are made available in return for its use.

Such a code would not apply if a bioprospector did not use mātauranga Māori. However, in line with international practice, a bioprospector could not seek intellectual property protection for a product or use that was not novel (that is, it already existed in the form of prior knowledge).<sup>37</sup>

A further option could be to consider the establishment of an advisory council to assist a Competent National Authority with facilitating the negotiation of benefit sharing upon usage of mātauranga Māori (and traditional knowledge more broadly, if appropriate). It might also be appropriate for such an advisory body to develop guidelines for the use of mātauranga Māori, and assist with identifying the most appropriate knowledge holders to negotiate terms with.

A framework for mātauranga Māori would provide greater certainty for mātauranga Māori holders and bioprospectors – firstly, that knowledge holder interests are respected and acknowledged; secondly, that the bioprospector's need for certainty is addressed so that investment into any one product or activity can proceed. The potential benefit to Māori, and to New Zealanders generally, could therefore be greatly enhanced.

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<sup>37</sup> A useful current information source is Te Puni Kōkiri's Te Kāhui Māngai website [www.tekahuimangai.govt.nz](http://www.tekahuimangai.govt.nz). It includes maps indicating general rohe, and lists iwi and hapū organisations and contacts for regions.

## 6.4 The building blocks of a comprehensive bioprospecting framework: what do we have to work with?

There are a number of building blocks that can be considered in designing a comprehensive bioprospecting policy framework. In fitting these building blocks together, it is important to think about our domestic considerations, what we know about international guidelines and what has been learned from them.

### A National Focal Point

The Bonn Guidelines recommend a National Focal Point to act as a link between New Zealand and the CBD and to be an initial point of contact with bioprospectors. On an operational level, a National Focal Point could be, for example, a website or 0800 number.

### A Competent National Authority

The Bonn Guidelines recommend a Competent National Authority as a centrally co-ordinating and policy implementing body that also acts as a second point of contact with bioprospectors to provide in-depth information and individual assistance. Under these guidelines, there is a range of roles and responsibilities that this body could fulfil. In the New Zealand context, a Competent National Authority could, for example, have one or more of the following functions:

- direct the bioprospector to the appropriate access provider;
- gather and store information about all bioprospecting activities in New Zealand – establish a database and facilitate the formation of linkages between bioprospectors, research facilities and access providers;
- monitor a code of best practice as suggested above and inform bioprospectors about the use of mātauranga Māori;
- on request, assist bioprospectors and access providers in the negotiation of access and benefit sharing agreements;
- act as a final permit issuing authority for all access providers. For example, the issuing of permits could be conditional on the negotiated use of mātauranga Māori being suitable and conducted with the appropriate holders of that knowledge and/or the general adequacy and legitimacy of benefit sharing between bioprospectors and the respective resource providers; and
- conduct the entire bioprospecting process from beginning to end, including negotiating access/benefit sharing agreements with bioprospectors and issuing permits upon approval.

### Central government access providers

Other building blocks to consider are the existing central government access systems. A large proportion of New Zealand's biological resources are already managed through various access systems by government agencies or government-funded organisations (section 4.2).

## Bioprospecting: Harnessing Benefits for New Zealand

Making use of these existing systems and adapting them to align with a comprehensive bioprospecting policy framework should be an efficient use of public resources. For instance:

- Department of Conservation: this department already has systems in place to deal with bioprospecting applications. However, this access system would need to align, in particular, with comprehensive policy developed for benefit capture;
- Ministry of Fisheries: bioprospecting is already taking place under both the special permit and fishing permit systems. However, further work will be needed in developing a bioprospecting policy to identify whether any changes are necessary, for example, in relation to providing for some aspects of benefit sharing;
- Ministry of Foreign Affairs and Trade: this Ministry is responsible for approving requests for foreign-flagged vessels to undertake marine scientific research in New Zealand's territorial waters and exclusive economic zone as well as on its continental shelf. The distinction between marine scientific research and bioprospecting is often blurred, however, and the relationship between these two activities has not yet been clearly defined. If bioprospecting activities were considered to be marine scientific research for the purposes of the United Nations Convention on the Law of the Sea, such activities would be subject to the international legal regime for marine scientific research established under that Convention; and
- Land Information New Zealand: to date, there are no specific systems in place to deal with bioprospecting activities. However, a framework may be able to be developed to accommodate this activity if it complies with relevant statutes<sup>38</sup> and can take into account the difficulties surrounding the roles of third parties such as lessees, licensees and potential beneficial owners of Land Information New Zealand administered land.

### Local government access providers

Another building block for consideration is the inclusion of the resources accessed through local government. Not all bioprospecting activities may currently be subject to RMA processes. This aspect of local government planning, as well as the associated capture of potential benefits, will need further consideration.

### Private access providers

If private resources were to be included (section 6.2.3) under a comprehensive bioprospecting framework, they would thereby become another building block in the bioprospecting framework. It could be desirable for private access providers to be represented in some form, for example, by the Competent National Authority (if established). This organisation could oversee bioprospecting activities and offer a number of services to private access providers, for example, to:

- assist with the negotiation of benefit sharing arrangements upon access to biological material by offering model contracts and advice;
- monitor compliance and enforcement of those agreements;
- provide certainty that the bioprospector has complied with all requirements developed, for example, a code of best practice on the use of mātauranga Māori; and
- issue permits on the private owner's behalf.

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<sup>38</sup> Statutes here include the Land Act 1948, the Crown Pastoral Land Act 1998 and the Crown Forest Assets Act 1990.

# Have your say

The government welcomes feedback on the issues raised in this document. In forming your views on these important issues, we are particularly interested in the following questions. (This form can be downloaded and/or filled in online at [www.med.govt.nz/bioprospecting](http://www.med.govt.nz/bioprospecting)).

## 1) On New Zealand's biological resources:

Do you think we need to have good information about bioprospecting activities in New Zealand, including the type and nature of such activities? Please give reasons for your answer.

As a traditional knowledge holder, bioprospector and/or access provider, what are your experiences of bioprospecting in New Zealand? Can you provide any information that would be useful to develop a bioprospecting framework in New Zealand, for example, provide information about bioprospecting costs, benefits, outcomes and current benefit sharing agreements? Please describe, if so.

## 2) On New Zealand's current frameworks to access biological resources:

Do you think the existing access frameworks would benefit from operating within a more co-ordinated and comprehensive bioprospecting framework? If so, why? If not, why not?

## 3) On a comprehensive bioprospecting framework for New Zealand:

Do you think that New Zealand should have a comprehensive policy framework to manage bioprospecting activity in this country? Please give reasons for your answer.

What are your views on the proposed vision and policy principles to guide New Zealand's bioprospecting policy?

### i) Potential policy benefits and costs

Do you see any other potential benefits or costs arising from a bioprospecting framework apart from those discussed in this document?

Which benefits do you think would be the most beneficial for New Zealand to capture?

Do you think that there are potential benefits that are not worth capturing because of the costs involved in doing so?

### ii) Policy scope

What are your thoughts on the current definition of bioprospecting?

What are your views on how the "in scope" and "out of scope" boundaries of bioprospecting have been defined?

Do you think that non-commercial research activities should be within the scope of a bioprospecting policy? If so, why? If not, why not?

If yes, can you think of any specific activities that should nonetheless be excluded from the scope of a bioprospecting policy?

If yes, what levels of compliance should be expected from non-commercial researchers?

Which kinds of biological resources should be accessed for bioprospecting?

In your view, which of the three tiers of access (central government, local government and private) should be included in a bioprospecting framework?

Do you think that *ex situ* collections should be included in a bioprospecting policy?

Do you think that non-indigenous biological material should be included in a bioprospecting policy?

### iii) Administrative frameworks

Do you think that New Zealand should have a National Focal Point? If yes, what form could it take?

Do you think that New Zealand should have a Competent National Authority? If yes, what roles and responsibilities could it have?

## 4) On mātauranga Māori:

How do you think use of mātauranga Māori for bioprospecting can be most appropriately managed and protected?

What do you think of the suggestions made in this document as options to protect mātauranga Māori (a voluntary register, ensuring legally and fully mandated governance entities, a code of best practice for bioprospectors, or an advisory council to a Competent National Authority)?

## 5) On international bioprospecting frameworks:

What aspects of the Bonn Guidelines of the Convention on Biological Diversity (CBD) do you believe should be considered in developing a domestic bioprospecting framework?

Are there aspects of international bioprospecting frameworks as outlined in section 5 (or any others you know about) that could be useful to consider during the development of a bioprospecting framework in New Zealand?

## 6) On any other issues:

Do you have any further suggestions or comments on the issues raised in this document?

# Meetings

It is intended that a series of seminars will be held in Auckland, Wellington and Christchurch to facilitate discussion of the issues raised in this document. In addition, a series of hui will be held with Māori in regional centres to facilitate input from Māori and to discuss the interface between bioprospecting and mātauranga Māori.

**For a schedule of venues and dates** see the Ministry of Economic Development's website at [www.med.govt.nz/bioprospecting](http://www.med.govt.nz/bioprospecting).

# Submissions

We would like to know what you think about the issues raised in this discussion document. When responding, please state whether you are responding as an individual or representing the views of an organisation. If responding on behalf of an organisation, please make it clear who the organisation represents and, where applicable, how the views of members were assembled.

Submissions are due by **5pm, Friday 12 October 2007**. A response can be sent electronically by email (preferred), by filling in the response form on the Ministry of Economic Development's website at [www.med.govt.nz/bioprospecting](http://www.med.govt.nz/bioprospecting), or by post to:

**Postal address:**

Bioprospecting Review  
Ministry of Economic Development  
PO Box 1473  
WELLINGTON

**Email address:**

[bioprospecting@med.govt.nz](mailto:bioprospecting@med.govt.nz)

## Confidentiality and data protection

Respondents should note that written submissions or comments provided to the Ministry of Economic Development on this discussion document will be subject to the Official Information Act (OIA) 1982. The OIA requires information to be made available unless there is good reason, pursuant to the Act, to withhold the information, and that good reason outweighs the public interest in making the information available.

If you want information that you provide to be treated as confidential, please clearly identify the material and explain to us why you believe the information should be withheld under the provisions of the OIA.

# Glossary of terms

**Bioactive/bioactive compound:** a biologically active compound derived from biological material that has the potential to confer benefits to people, plants or animals.

**Biodiscovery:** the analysis of a biological material's properties, or its molecular, biochemical or genetic content, for the purpose of developing a commercial product.

**Biological material/biological resources:** includes organisms, parts of organisms, genetic resources, populations and any other biotic component of an ecosystem with actual or potential use or value for humanity.

**Bioprospecting:** the collection of biological material and the analysis of its material properties, or its molecular, biochemical or genetic content, for the purpose of developing a commercial product. Bioprospecting policy excludes the later steps in the chain of product development.

**Biotechnology:** any technological application that uses biological systems, living organisms, or derivatives of living organisms, to make or modify products or processes for commercial use.

**Crown Research Institute(s):** New Zealand government-owned science research businesses, for example, AgResearch Ltd, Industrial Research Ltd and Landcare Research New Zealand Ltd.

**Endemic:** a term describing species that are native to a particular geographic area or continent. For example, the kiwi is endemic to New Zealand.

**Endemism:** the percentage of the fauna or flora that is endemic.

**Ex situ:** biological material located outside an organism's natural environment, such as in a zoo, aquarium, botanical gardens nursery, herbaria, or storage place. *Ex situ* collections include collections of biological material held in storage as an extract or in a frozen state.

**Genetic resources:** any material of plant, animal, microbial or other origin that contains functional units of heredity and has actual or potential value for humanity.

**Indigenous:** native organisms, not introduced by humans.

**In situ:** located inside an organism's natural environment.

**Mātauranga Māori/traditional knowledge:** mātauranga Māori is a term often used in New Zealand in preference to the term traditional knowledge, because mātauranga Māori refers to Māori knowledge originating from Māori communities (usually, a link could be expected to exist between the location of specific biological material and local communities' knowledge about and relationship to that material). Mātauranga Māori is the generally preferred term used in the WAI 262 claim. Part of this consultation process is directed at developing our understanding of these concepts in relation to bioprospecting.

**Mātauranga Māori/traditional knowledge in the public domain:** mātauranga Māori/traditional knowledge that is publicly available, for example, on the internet or in published material.

**Material transfer agreements:** agreements about the transfer of biological specimens, after collection, to third parties.

**Mutually agreed terms:** in accordance with Article 15, paragraph 7 of the Convention on Biological Diversity (CBD), there are some basic requirements for the development of “mutually agreed terms”. For example:

- legal certainty and clarity;
- minimisation of transaction costs;
- inclusion of provisions on user and provider obligations;
- development of different contractual arrangements for different resources and for different uses, and development of model agreements;
- different uses may include, *inter alia*, taxonomy, collection, research, commercialisation;
- mutually agreed terms should be negotiated efficiently and within a reasonable period of time; and
- mutually agreed terms should be set out in a written agreement.

**Prior informed consent:** in accordance with Article 15, paragraph 5 of the CBD, access to genetic resources is subject to “prior informed consent” given by the contracting party providing the resources, unless determined otherwise. The basic principles of prior informed consent are:

- legal certainty and clarity;
- access to genetic resources should be facilitated at minimum cost;
- restrictions on access to genetic resources should be transparent, based on legal grounds, and not run counter to the objectives of the CBD;
- the consent of the relevant Competent National Authority(ies) in the provider country should be obtained; and
- the consent of the relevant stakeholders, such as subject to domestic law, should also be obtained.

**Taxonomic:** the practice of classifying, for example, living organisms.

**Traditional knowledge/mātauranga Māori:** traditional knowledge is a phrase in common domestic and international usage, encompassing knowledge arising from all local communities, including that held by indigenous communities. This phrase is the language used in the CBD. In this document, we have generally used “mātauranga Māori” instead of “traditional knowledge”, when discussing Māori traditional knowledge.

# Appendices

## Appendix 1: The chances of finding a “valuable commercial application” with biological material

The statistical chance of finding a valuable commercial application from bioprospecting activities is relatively low. Quantifying “relatively low” varies depending on how “a valuable commercial application” is defined. A number of figures can be found in the scientific literature:

- On average, finding a single potentially commercially valuable medicinal species requires bioprospectors to examine at least 10,000 plants.  
See J. L. Trotti, ‘Compensation Versus Colonization: A Common Heritage Approach to the Use of Indigenous Medicine in Developing Western Pharmaceuticals’, *Food Drug L.J.* 2001, 56, 367, 367.
- The probabilities of developing a successful product lie between 1 in 5,000 to 1 in 10,000 according to C. Richerzhagen, K. Holm-Mueller, ‘The effectiveness of access and benefit sharing in Costa Rica: Implications for national and international regimes’, *Ecological Economics*, 2005, 53, 445–460.
- Another report states that “the odds of finding a new drug from botanical samples are still very low (from 1:80,000 to 1:250,000 plant samples)”.  
See J. M. Feinsilver and I. H. Chapela, ‘Will Biodiversity Prospecting for Pharmaceuticals Strike “Green Gold”?’’, *Diversity*, 1996, 12(2), 20–21.

## Appendix 2: A summary of New Zealand’s biodiversity, endemism and level of taxonomic knowledge for different taxonomic groups

Entry	Taxonomic group	NZ diversity	NZ endemism	Taxonomic knowledge level
1	Micro-organisms	unknown	unknown	very low
2	Microalgae	moderate	low	low
3	Macroalgae	moderately high	high	relatively low
4	Terrestrial plants	moderately low	very high	good
5	Terrestrial invertebrates	moderate	high	low-moderate
6	Fungi	moderate	moderate	low
7	Marine invertebrates	high	moderate-high	moderate
8	Vertebrates	low	moderate-high	good

Source: NIWA Client Report: AKL2005-42, June 2005, *New Zealand’s Biological Resources*.

## Appendix 3: Australian bioprospecting frameworks

### Bioprospecting in Australia

The biological resources in Australia have long been of potential interest to bioprospectors. An example of this is the Natural Product Discovery (NPD) centre at Griffith University (Queensland), which was established in 1993 with the beginning of a partnership between this university and Swedish pharmaceutical firm AstraZeneca. This collaboration is one of the largest public-private partnerships in Australia. AstraZeneca has invested A\$100 million into the NPD programme. The centre collects, screens and isolates material found in plants, micro-organisms and marine animals with the aim of discovering biologically active compounds that may lead to the development of new pharmaceuticals. To date, 41,000 samples have been examined. There have been a number of benefits from this partnership including strengthening of Griffith University's research capabilities, increasing scientific links with Sweden, and the gathering of valuable information about environmental biodiversity. For example, more than 3,000 sponges have been collected during research conducted by NPD, and over 50 per cent of these were new to science.

Source: [www3.griffith.edu.au/03/ertiki/tiki-read\\_article.php?articleId=761](http://www3.griffith.edu.au/03/ertiki/tiki-read_article.php?articleId=761);  
[www.investaustralia.gov.au/media/CS\\_BIO\\_Astrazeneca.pdf](http://www.investaustralia.gov.au/media/CS_BIO_Astrazeneca.pdf)

As the information box above illustrates, bioprospectors find Australia an interesting source of biological resources. In view of this and other considerations, State, Territory and Commonwealth governments have been spurred on to develop the following policies:<sup>39</sup>

- The National Strategy for the Conservation of Australia's Biological Diversity, developed to provide a general framework for protecting Australia's biodiversity. Objective 2.8 states: Ensure that the social and economic benefits of the use of genetic material and products derived from Australia's biological diversity accrue to Australia.
- The National Biotechnology Strategy, launched in 2000.
- The Nationally Consistent Approach for Access to and the Utilisation of Australia's Native Genetic and Biochemical Resources, endorsed by all State/Territorial governments in 2002. This framework sets general principles that must be applied when developing or reviewing access and benefit sharing systems established within Australian jurisdictions.<sup>40</sup>

### Australian Commonwealth areas

Commonwealth areas in Australia consist of areas of land, sea and airspace owned or managed by the Australian government. They include national parks such as Kakadu and Uluru-Kata-Tjuta, all declared marine protected areas, and the band of marine area between the outer edge of the Australian Fishing Zone and three nautical miles from the coast.

<sup>39</sup> See [www.deh.gov.au/biodiversity/index.html](http://www.deh.gov.au/biodiversity/index.html)

<sup>40</sup> These principles include certainty, transparency and accountability for facilitating biodiscovery; sustainable use of biological resources; and equitable sharing of benefits.

One of the aims of the bioprospecting policy implemented by the Australian Commonwealth government is to encourage research and bio-based industry development by, for example, facilitating access to resources, and offering legal certainty and user flexibility. Operationally, this framework can be divided up into two broad categories, namely commercial and non-commercial activities.<sup>41</sup>

### Framework for commercial activities

A simplified and idealised pictorial representation of the bioprospecting framework for Commonwealth areas is given in Figure 3. Bioprospecting activity in Commonwealth areas is regulated by the Environment Protection and Biodiversity Conservation Act 1999.<sup>42</sup>

**Figure 3: Commonwealth area bioprospecting framework**

(Steps 2 and 3 may be interchanged)



<sup>41</sup> Regardless of the commercial or non-commercial nature of an activity, bioprospectors are required to keep sample records that include:

- a unique identifier for each sample, marked either on a label attached to the sample, or the container holding the sample;
- the date the sample was taken;
- the place from which the sample was taken;
- an appropriate indication of the quantity or size of the sample;
- the scientific name of, or given to, the sample;
- the location of the sample when first entered in the record; and
- the details about any subsequent transfer of the sample, including the names and addresses of others having possession of the sample, or part of the sample.

<sup>42</sup> See [www.deh.gov.au/biodiversity/publications/access/regs/index.html](http://www.deh.gov.au/biodiversity/publications/access/regs/index.html)

**Step 1:** Contact the Competent National Authority: A first point of contact for potential bioprospectors who need information about the bioprospecting process in Australia is provided by the Australian Commonwealth government, Department for the Environment and Heritage. This department has the dual role of being the first point of contact for Australia, as well as being the Competent National Authority (i.e. responsible for bioprospecting activities) in Commonwealth areas.

**Steps 2 and 3:** It is important to note these steps are interchangeable:

- Step 2: The applicant must negotiate a benefit sharing agreement/contract with the access provider of the biological resource.<sup>43</sup>
- Step 3: The applicant requests an access permit from the Minister for the Department of Environment and Heritage to undertake bioprospecting<sup>44</sup> activities in Commonwealth areas.

**Step 4:** Before permits are issued by the Minister for the Department of Environment and Heritage, they must be satisfied that two basic conditions are met – namely that there is no environmental harm involved and that a benefit sharing agreement is in place. The order in which these two conditions are met is not important. In more detail, considerations include:

- that an environmental assessment (if required) has been undertaken;
- that the proposed access is ecologically sustainable and consistent with the conservation of Australia's biodiversity;
- that submissions from interested parties (if required) have been taken into account;
- that there is an adequate benefit sharing agreement between the parties addressing the following issues:
  - informed consent of any indigenous owners of biological resources (when applicable);
  - mutually agreed terms;
  - protection for and valuing of “indigenous knowledge”; and
  - if practicable, provision for some benefits to be used for biodiversity conservation in the area from which the resources are to be sourced.

To ensure transparency, all permit approvals are published on the internet.<sup>45</sup>

There is a permit application fee of A\$50 for commercial research. Applications for permits can be completed online. To avoid delay in decision making and granting permits, specific timeframes are included in the regulations.

### Framework for non-commercial activities

Permit requirements for obtaining access for non-commercial scientific research are more flexible and less detailed. The applicant is simply required to obtain written permission from the access provider and provide a statutory declaration that includes agreeing to certain obligations.<sup>46</sup> There is no fee for access to biological material for non-commercial research.

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<sup>43</sup> This benefit sharing agreement/contract does not come into effect unless a permit is issued. It can be negotiated and agreed upon, but it has no validity without the agreement of the Minister for the Department of Environment and Heritage.

<sup>44</sup> In Australia, the term “biodiscovery” is often used in a way that is more or less synonymous with what many countries refer to as bioprospecting.

<sup>45</sup> See [www.deh.gov.au/grid/public/perrep.jsp](http://www.deh.gov.au/grid/public/perrep.jsp)

<sup>46</sup> These include accepting the obligation to negotiate a full benefit sharing agreement should the purpose of research and development change, and to obtain permission from the access provider before passing the sample on to anyone else.

### Made easy – a biodiversity survey

This Commonwealth system made a non-commercial biodiversity survey conducted by the South Australian Museum in a remote Commonwealth area a relatively straightforward exercise. The access provider was the Department of Defence (Commonwealth). With the help of the Department of Environment and Heritage, permission for access was obtained. The museum signed the statutory declaration stating that the research was for non-commercial purposes and that, if the non-commercial nature of their work should change, they were obliged to negotiate a full benefit sharing agreement with the Department of Defence. The final outcome of the project was that taxonomic specimens were collected and good information on the distribution of biodiversity in this area was obtained.

Source: Genetic Resources Management Policy, Department of the Environment and Heritage, Commonwealth government, Australia.

### Australia's Northern Territory

The Northern Territory of Australia consists of areas of land, sea and airspace owned or managed by the Northern Territory government. This accounts for about one sixth of Australia's total land mass and 13,500 km of coastline as well as the associated marine area extending out from the coast to the limit of the Australian Fishing Zone.

One of the purposes of the bioprospecting framework<sup>47</sup> implemented by the Northern Territory government is to ensure that bioprospecting is managed to foster the growth and development of the Territory and that it is carried out in a sustainable manner.

#### Bioprospecting framework

Under Northern Territory policy, all bioprospecting activities come under its jurisdiction. In other words, commercial and non-commercial activities are, in principle, not differentiated, and a benefit sharing agreement is still required for either pursuit. One of the advantages of not distinguishing between the two pursuits is that samples can be easily traced, and this improves the recognition of biopiracy.<sup>48</sup> In addition, in the event of non-commercial bioprospecting becoming commercial in nature, the benefit capture process is simplified.

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<sup>47</sup> In this policy framework, bioprospecting and biodiscovery are separate activities. Bioprospecting is defined as "the taking of samples of biological resources, existing *in situ* or maintained in an *ex situ* collection of such resources, for research in relation to any genetic resources, or biochemical compounds, comprising or contained in the biological resources". Biodiscovery is defined as "research on samples of biological resources, or extracts from those samples, to discover and exploit genetic or biochemical resources of actual or potential value for humanity". Because of the broadness of the bioprospecting definition, certain activities could be unintentionally classified as bioprospecting, for example, the taking of aquatic life within the meaning of the Northern Territories Fisheries Act. To overcome this situation, the Northern Territories government has specifically excluded such activities.

<sup>48</sup> The term "biopirate" is used for those who acquire biological samples for biodiscovery and commercialisation purposes without, for example, fair compensation to the access provider.

### Made easy – biopiracy detection

The Northern Territory's permit and benefit sharing framework provides a system of traceability and allows possible instances of biopiracy to be readily identified. The utility and importance of the arrangements were demonstrated when an officer of the Northern Territory government came across an article on the internet referring to plant samples taken from the Territory and the results of research on those samples. According to the article, the plant had shown efficacy against malaria, anthrax and golden staph amongst others, and two patents had been registered. The researcher was from an overseas institution.

Investigation of the government's records showed that the researcher did not have a permit, nor did the researcher's organisation. Contact was made with the researcher, and legal discussions are continuing. Under the Northern Territory's legislation, these samples can be retrospectively covered by a benefit sharing agreement.

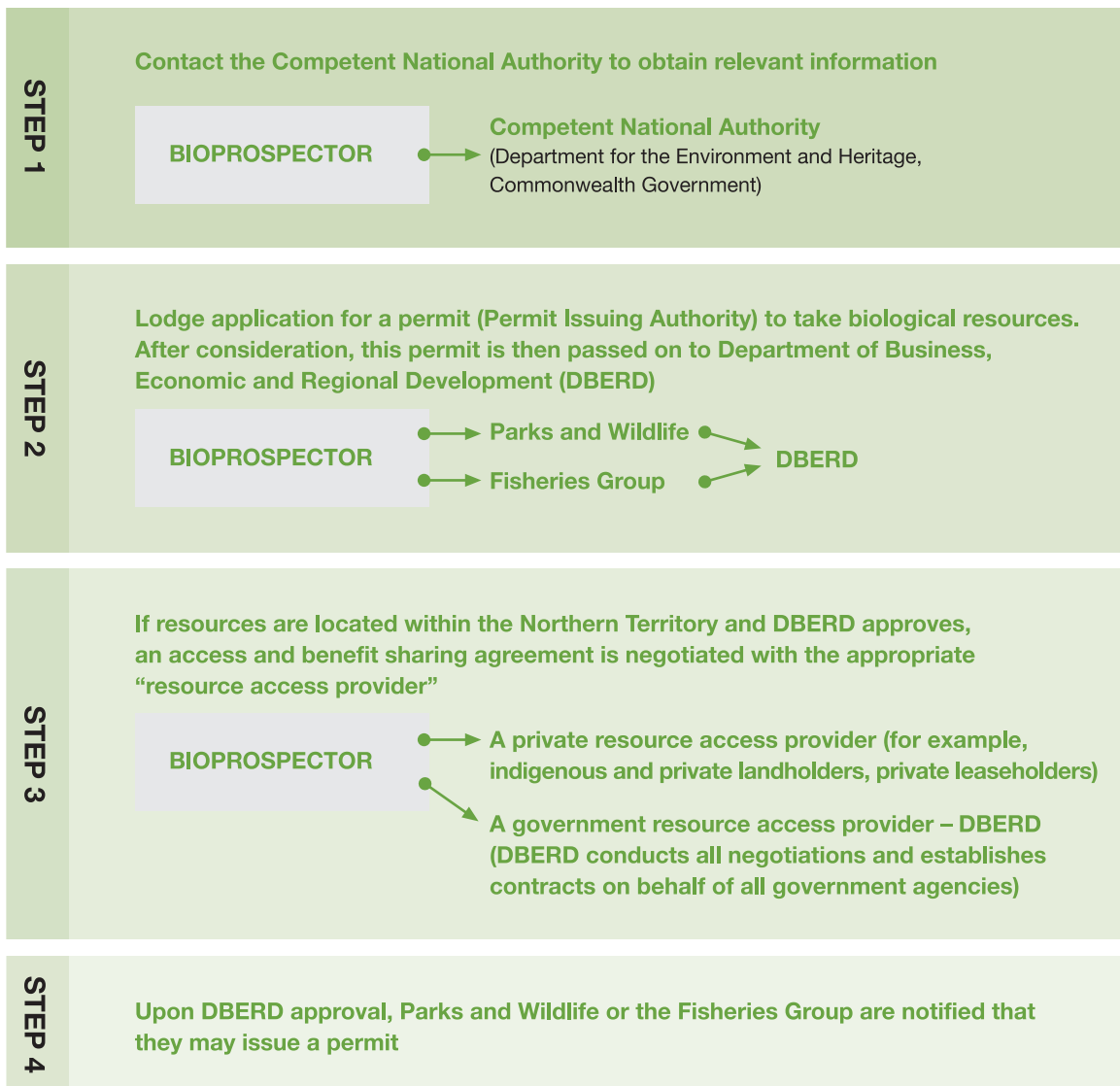
Source: Department of Business, Economic and Regional Development, Northern Territory government, Australia.

A simplified and idealised pictorial representation of the bioprospecting framework for the Northern Territory is given in Figure 4. Bioprospecting activity is regulated by the Biological Resources Act 2006, the Biological Resources Regulations 2006, the Policy for Access to and Use of Biological Resources in the Northern Territory, as well as the Strategy for Conservation through Sustainable Use of Wildlife in the Northern Territory.<sup>49</sup>

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<sup>49</sup> See [www.nt.gov.au/business/assistance.cfm?assistanceid=58](http://www.nt.gov.au/business/assistance.cfm?assistanceid=58) and [www.nt.gov.au/nreta/wildlife/pdf/strategy\\_for\\_conservation\\_through\\_sustainable\\_utilisation\\_of\\_wildlife.pdf](http://www.nt.gov.au/nreta/wildlife/pdf/strategy_for_conservation_through_sustainable_utilisation_of_wildlife.pdf)

Figure 4: Northern Territory bioprospecting framework



**Step 1:** Contact the Competent National Authority. As with the Commonwealth example, the first point of contact for potential bioprospectors who need information about the bioprospecting process in Australia is provided by the Department for the Environment and Heritage, Australian Commonwealth government. This Authority would then direct the bioprospector to the relevant organisation in the Northern Territory.

**Step 2:** The bioprospector makes a permit application to the Permit Issuing Authorities, namely the Parks and Wildlife and the Fisheries Group departments. After evaluation, this permit is then passed on to the Department of Business, Economic and Regional Development (DBERD) for further assessment. It is important to note that, if a benefit sharing agreement already exists, it may accompany the permit application.

**Step 3:** DBERD evaluates the permit application with a number of considerations in mind, including if:

- the activity under consideration is bioprospecting;
- the proposed collection site is under Northern Territory jurisdiction;
- sufficient information has been provided with the permit application;

- the proposed activity will be conducted without significant damage to the environment, namely in accordance with existing Northern Territory law;
- there are economic and social impacts from the application;
- the business, financial and professional credibility of the bioprospector is adequate;
- the interests of indigenous people in the use and ownership of traditional knowledge, innovations and practices on indigenous land have been considered; and
- benefit sharing agreements are:
  - in evidence. If no agreement exists, permit issue is conditional on the formation and suitability of the contract. If an agreement does already exist, DBERD evaluates if it is adequate;
  - between a bioprospector and a private resource provider. The nature, distribution and application of benefits flowing from such an agreement are determined by the parties involved. However, private resource access providers have to certify to the Northern Territory government that the agreement in place is in alignment with legal requirements; and
  - between private owned/leased land as well as indigenous landholders. If this is the case, these parties may request guidance and advice from DBERD when entering into a benefit sharing agreement with the bioprospector.

**Step 4:** Once DBERD is satisfied that all conditions have been met, they notify the Permit Issuing Authorities that they may issue a permit to the bioprospector.

Collection permits are valid for a maximum of 12 months. If the bioprospector wishes to renew, a renewal fee may apply, the level of which is determined on a case by case basis.<sup>50</sup> The bioprospector may also be required to sign a Deed of Variation to include the new permit number under the existing agreement.<sup>51</sup>

When benefits are in excess of a nominal monetary value per year, a percentage thereof is transferred to an appropriate fund or organisation that supports biodiversity conservation projects in the Northern Territory.

For successful applicants, the fulfilment of benefit sharing terms and conditions is determined by DBERD through periodic performance reports submitted by the applicant.

Annual reports are submitted to the Minister for Business and Economic Development on any significant developments.

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<sup>50</sup> The price of a renewal fee is fixed at the nominal amount reflecting the existence of the benefit sharing agreement between the parties involved and subsequent benefits flowing to the broader Northern Territory community.

<sup>51</sup> A Deed of Variation is essentially an amendment to a contract. In this case, the original agreement is still in place, and the new permit number is simply brought under the original agreement by the Deed of Variation. This removes the requirement of negotiating a whole new agreement.

### Resource access provider helps researchers patent their bioactive compound

An Australian university<sup>52</sup> (the bioprospector) contacted the Northern Territory government (the resource access provider) regarding undertaking bioprospecting in the Northern Territory. A benefit sharing agreement was entered into and a permit issued. The bioprospector found a new anti-inflammatory compound and, as agreed under the reporting requirements of the benefit sharing agreement, notified the resource access provider. The bioprospector and the resource access provider agreed it would be appropriate to register a provisional patent in order to further explore commercialisation opportunities. Costs for the provisional patent were shared equally between both parties.

Source: DBERD, Northern Territory government, Australia.

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<sup>52</sup> For reasons of confidentiality, this university cannot be named.





