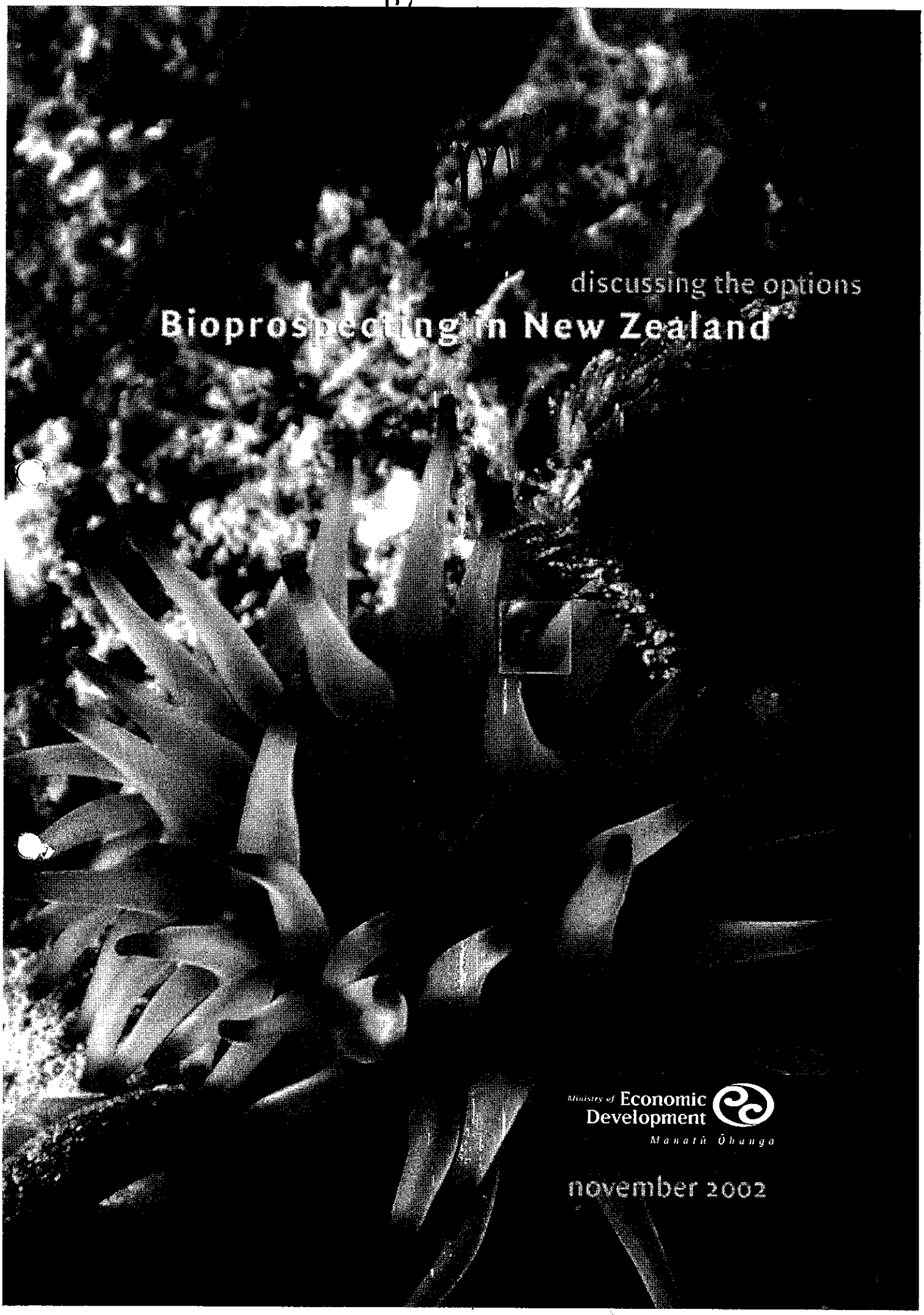
"M"



discussing the options

Bioprospecting in New Zealand

Ministry of Economic Development
Manatū Ōhanga

november 2002

Published by

Resources and Networks Branch, Ministry of Economic Development, 33 Bowen Street, PO Box 1473, Wellington, New Zealand.

Ph: +64 4 472 0030, Fax: +64 4 499 0969, Email: bioprospecting@med.govt.nz

November 2002, ISBN 0-478 26318X

SUMMARY

Bioprospecting is the examination of biological resources (e.g. plants, animals, micro-organisms) for features that may be of value for commercial development. These features may include chemical compounds, genes and their products or, in some cases, the physical properties of the material in question. The main distinguishing feature from other biotechnology research is the concept of 'prospecting' – the search for biological material for as-yet undiscovered applications.

Bioprospecting can create a wide range of benefits for the source nation. In New Zealand, there is some bioprospecting occurring. There needs to be consideration of how to best realise the potential benefits for us from bioprospecting. The analysis of potential benefits is strongly influenced by the fact that much research takes place in collaboration with overseas agencies. This raises questions about how the benefits can be shared in a way that maximises returns to New Zealand, while recognising the cost and risks borne by research collaborators.

The regulatory framework for bioprospecting in New Zealand is ad hoc, fragmented and reliant on legislation designed for other purposes. It is not well suited to maximising potential benefits or managing potential risks from bioprospecting activities.

Three major problems have been identified:

- the lack of an overarching framework for bioprospecting;
- uncertainty of the policy environment and lack of information; and
- ad hoc controls over access by foreign interests.

The current policy context and government goals have been examined to identify possible principles and objectives to guide further consideration of bioprospecting policy. The proposed principles and objectives are:

- New Zealand has a right to gain benefit from the use of its own biological resources;
- bioprospecting can contribute to the growth of an innovative economy, and to increasing the skills of New Zealanders;
- there is a requirement for an integrated policy and legislative framework for managing bioprospecting, including arrangements for sharing benefits;
- policy should facilitate responsible access to biological resources, with prior informed consent of the owners/managers of the resource, on mutually agreed terms;
- there should be a fair and equitable sharing of benefits arising from bioprospecting activities;
- bioprospecting policy should recognise the principles of the Treaty of Waitangi;
- the value of Maori knowledge about biological resources should be recognised and protected; and
- the environment should be protected from any possible adverse effects of bioprospecting.

These principles and objectives have been used to determine a proposed overarching policy objective for bioprospecting activities:

To ensure New Zealand takes advantage of economic development opportunities and other benefits from the bioprospecting of our biological resources, while safeguarding associated environmental, social and cultural values, by:

- establishing clear rules about access to biological resources on Crown-owned/managed areas;
- ensuring bioprospecting policy recognises the principles of the Treaty of Waitangi;
- establishing mechanisms to facilitate the capture of benefits from bioprospecting activities;
- gathering information on bioprospecting activities to ensure New Zealand can track the use of its biological resources; and
- ensuring clear and consistent rules to manage the environmental effects of bioprospecting activities in Crown-managed areas.

To help meet this objective, three policy options are presented here for discussion:

- a proposed government policy statement on bioprospecting;

  The government currently does not have a stated bioprospecting policy. Formulating a government policy statement would give government agencies guidance in the discharge of their statutory functions

- mechanisms for enhanced co-ordination and information sharing;

  Better co-ordination and information sharing in relation to bioprospecting activities could be achieved through giving oversight responsibility on bioprospecting to an existing or new government authority.

- a framework for benefit-sharing arrangements.

  A framework could be developed to help researchers structure their activities, funding arrangements and intellectual property management in a manner that will help maximise possible benefits to New Zealand, and provide for better involvement of relevant stakeholders, and Maori.

BIOPROSPECTING DEFINED

1.1 Bioprospecting is the examination of biological resources (e.g. plants, animals, micro-organisms) for features that may be of value for commercial development. These features may include chemical compounds, genes and their products, or in some cases, the physical properties of the material in question. The main distinguishing feature from other biotechnology research is the concept of 'prospecting' - the search for biological material for as-yet undiscovered applications.

1.2 Bioprospecting is usually a 'targeted search' for a certain use. The number of screening techniques available to modern science, along with the huge complexity of living organisms, means the researcher often starts with an end in mind, and prospects biological material he or she considers more likely to provide a specific use.

1.3 In the context of this paper, 'bioprospecting' is also taken to include the downstream testing and development activities following discovery of a useful substance. This is because the greatest benefit from the initial discovery is obtained at these stages.

1.4 Bioprospecting is not genetic modification. For this reason, this paper does not consider genetic modification issues. Genetic modification is one possible technique used in downstream development that could be applied to a bioprospecting 'discovery'. However, genetic modification research can occur in a number of different ways. Bioprospecting is only one example of how such research may be initiated. Genetic modification issues are being dealt with in response to the report of the Royal Commission on Genetic Modification. This is discussed further in Chapter 4.

1.5 This discussion paper does not consider any issues associated with the collection and use of human tissues or genetic material, such as DNA banking or human genetic research. Some of these issues will be considered by a review of the Human Tissues Act, being led by the Ministry of Health.

1.6 A typical pharmaceutical bioprospecting research project could involve the following steps:

- **Discovery:** collecting material, screening for useful properties or 'bio-activities', isolating and purifying new and active chemicals, describing new chemical structures;
- **Protection of intellectual property:** largely the patenting of new structures and/or specific types of bioactivity (e.g. antibiotic, insecticidal or anti-tumour properties);
- **Product development:** modifying chemical structures to improve their efficacy, conducting clinical and/or field trials to demonstrate and compare the effectiveness and safety of the product with others currently on the market;
- **Manufacturing:** developing techniques for larger scale industrial production of the chemicals (e.g. by total laboratory synthesis or by purification from cultivated biological material); and
- **Marketing** the final product.

1.7 This definition of bioprospecting is deliberately broad, so as to capture the range of activity currently taking place in New Zealand. Examples of bioprospecting are given throughout this paper to indicate the scope of relevant activities, from high-tech pharmaceutical projects to small enterprises capturing the benefits of traditional knowledge.

CROWN-MANAGED ENVIRONMENTS AND PRIVATE LAND

1.8 Bioprospecting takes place both on private land, and in environments owned or managed by the Crown. (For the sake of simplicity, the latter environments are referred to as 'Crown land' although many bioprospecting activities take place in the marine environment.) The discussion in this paper is equally applicable to both Crown and private land, although the different legislative frameworks relating to each create significant differences in how policies may be implemented.

BENEFITS OF BIOPROSPECTING

1.9 Bioprospecting activities can create a wide range of potential benefits, as discussed below, when implemented within the proper framework. This paper discusses the possible downsides of an inadequate bioprospecting framework in Chapter 3.

ADDING VALUE THROUGH THE CHAIN OF DEVELOPMENT

1.10 One means of securing benefit is to add as much value as possible throughout the chain of testing and development. Rather than focusing on an end point of commercialisation, New Zealand institutions can look to involve themselves in earlier steps, such as preliminary screening. This creates direct financial benefits, for example, through the sale of valuable knowledge. It also creates flow-on effects in employment and capacity-building in local biotechnology industries.

1.11 For example, if a New Zealand institution discovers a potentially useful bioactive compound in collaboration with an overseas agency, the two organisations could arrange for initial screening work to be done in New Zealand, rather than immediately sending samples offshore. This creates work in New Zealand, and adds value to the product. Eventually it may be the case that all further work will have to be done overseas, but New Zealand will have contributed as far as possible, and maximised benefits from the discovery of the compound.

BENEFIT TO LOCAL COMMUNITIES

1.12 Value-adding through the chain of development can also include benefit-sharing regimes with the local community. For example, bioprospecting activities undertaken in Costa Rica involved the training and employment of local people to collect biological samples. In the New Zealand context, there are opportunities for benefit-sharing arrangements with local communities in general and Maori in particular, should there be a connection between indigenous knowledge and the biological material in question.

DOWNSTREAM PRODUCTION RELATED TO SCIENTIFIC DISCOVERIES

1.13 Bioprospecting also has the potential to lead to industries around the production of valuable substances. This could involve the production of the raw biological material. For example, a joint initiative between NIWA, the University of Canterbury and an offshore biotechnology company looked at the feasibility of an aquaculture project to grow sea sponges containing a substance of potential use as an anti-cancer drug. New industries could also involve production of a finished product, for example natural skincare products.

Royalties from eventual commercial development

1.14 It is possible to secure royalty streams for New Zealand researchers through the retention of intellectual property in a downstream commercial product. Such benefits, however, rely on eventual commercialisation. A small proportion of bioactive substances make it to the stage of commercial production. In addition, the complexity of inputs into commercialisation means intellectual property around a substance discovered in New Zealand may be a proportionately small part of the end product.

Increased capacity of New Zealand's scientific sector

1.15 Involvement in bioprospecting projects enhances the skills and knowledge of New Zealand researchers. This also improves the downstream opportunities for New Zealand to add value through the development chain of a substance.

1.16 Research can therefore contribute to the economic development of New Zealand in ways other than the direct discovery of bioactives with commercial potential. The education and training of new researchers with valuable skills is an input into the New Zealand economy in its own right.

Increased scientific knowledge of biology and ecology

1.17 Bioprospecting increases the understanding of our natural systems, regardless of whether the substance in question eventually leads to financial returns. This knowledge has intrinsic value in its own right. It may also contribute to conservation and environmental management practices.

Bioprospecting activities in New Zealand

1.18 The main bioprospecting agencies in New Zealand are Crown Research Institutes (CRIs), universities and private biotechnology companies. There are several foreign biotechnology companies and universities undertaking bioprospecting in New Zealand, although usually in collaboration with local agencies.

1.19 Interest in bioprospecting New Zealand's resources is partly driven by the nature of the country's biodiversity. As a group of isolated islands, our indigenous biodiversity has developed in a particular way. New Zealand also has a large Exclusive Economic Zone, providing a rich source of marine biodiversity. For example, the large number of hydrothermic vents in New Zealand's Exclusive Economic Zone offers an opportunity to study micro-organisms that have developed in extreme environments.

1.20 In the context of bioprospecting, possible scientific discoveries from New Zealand's biodiversity are not necessarily unique. While there are some species endemic to New Zealand, the bioactive properties identified by bioprospecting could possibly be found in other species, in other parts of the world. In some cases, it is also possible to synthesise substances in a laboratory, without prior knowledge of their existence in nature.

FUNDING BIOPROSPECTING ACTIVITIES IN NEW ZEALAND

1.21 New Zealand does not have the capacity to fund all proposed bioprospecting research. Many researchers collaborate with overseas biotechnology companies and universities. Collaboration enables research that otherwise would not take place. These joint ventures, however, also raise issues of how risks and benefits can be shared fairly between New Zealand and the collaborator. Overseas collaboration can allow benefits to flow offshore, through intellectual property and physical access to biological material.

1.22 Bioprospecting research can be an expensive activity. Collecting samples and screening for bioactive substances requires a high level of expertise and investment. Downstream activities - such as the development, testing and approval of pharmaceutical drugs - can require multi-million dollar investments.

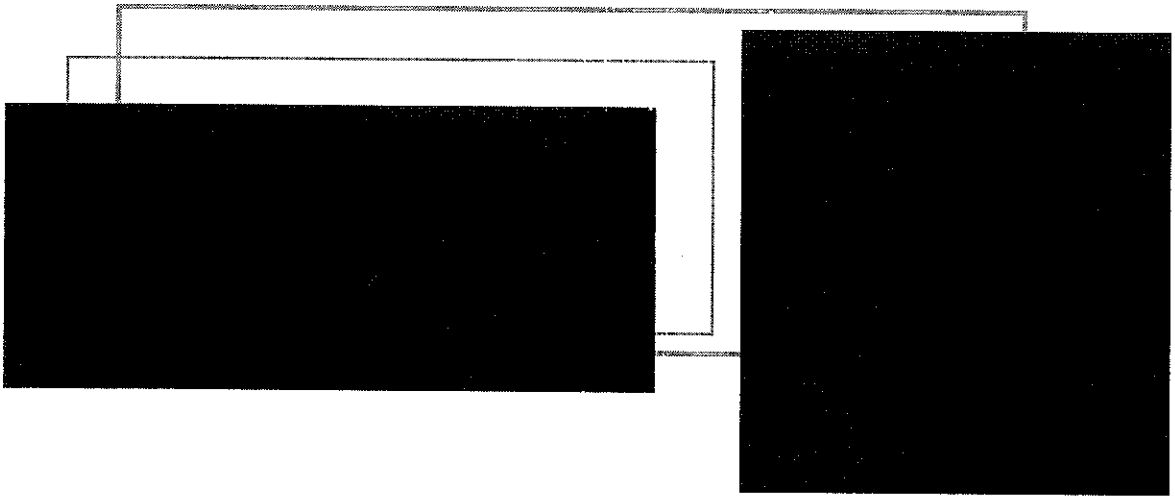
1.23 There is an element of risk involved with investment. Bioprospecting is a field where discoveries can be very valuable, but hard won. It may take a large amount of money to search for and develop a substance that never becomes a commercial product.

FRST AND OTHER PUBLIC FUNDING

1.24 Some researchers receive public funding through the Foundation for Research, Science and Technology. The Foundation is the major distributor of public research funds in New Zealand. Public research funds are also available through the Health Research Council, the Marsden Fund and direct funding to public bodies such as universities. The majority of the Foundation's research providers are Crown Research Institutes and universities.

1.25 The Foundation's purchasing policies and related contractual obligations with research providers impose a number of conditions relevant to bioprospecting. Research providers:

- are required to make the primary results of their research available to New Zealanders. However, they may choose not to distribute these results widely if to do so would be contrary to the benefit of New Zealand;
- have the right to apply for intellectual property rights over their research, and they are required to endeavour to ensure the exploitation of intellectual property is for the benefit of New Zealand; and
- are required to report to the Foundation on transactions they conclude with overseas parties, including income streams from intellectual property sale, licensing, or assignment.



1.26 In addition, major science providers will soon be required to submit a confidential annual report on Foundation-supported intellectual property, detailing:

- registered intellectual property developed during the previous year, and what is being done with it;
- changes from previous reports in what has been done with existing registered intellectual property;
- the sale or licensing of intellectual property outside New Zealand, and why (this is required now);
- plans to develop, or assign to its inventors, codified intellectual property still not used after three years; and
- income generated from intellectual property, by item.