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**Submission in Response to:
Bioprospecting: Harnessing Benefits for New Zealand
A policy framework discussion**

**To the Bioprospecting Review
Ministry of Economic Development**

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I am an intellectual property lawyer with a particular interest in indigenous rights. I have consulted to various government bodies in New Zealand and Australia including the Ministry of Economic Development, the Department of Industry, Tourism and Resources (Australia) and to a number of other organisations including the Media and Advertising Copyright Board. I am the author of *'International Protection of Performers' Rights'*, a monograph on performers' rights. I am the author of chapters in other books on copyright, including *'Copyright and Design'*, and I am the author of numerous articles on copyright and trade marks including *'Protecting Indigenous Signs and Trade Marks – the New Zealand Experiment'*

Introduction

I support the formation of a comprehensive policy framework for bioprospecting activities on the basis that it is important that organisations engaged in bioprospecting have a clear, simple and inexpensive process that facilitates access to biological materials and information about those materials while enabling their activities to be monitored efficiently. In the main, I support the options proposed in the discussion paper. However, I would like to make it clear that I believe that further work is required in the areas of enforcement and benefit sharing and that any policy in that area must recognise that discoveries that benefit mankind, made from material sourced from New Zealand, should be available for the people of all nations. On a more specific point, I suggest that it is very difficult, if not impossible, to separate bioprospecting issues and to analyse them in isolation from the later steps that follow on from bioprospecting.

The format of my submission is that it answers the questions posed in the *Bioprospecting: Harnessing Benefits for New Zealand – a policy framework discussion* ('the discussion paper').

1. On New Zealand's biological resources:

1.1 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.

I assume that the question is directed to the current situation, i.e. a situation in which New Zealand does not have a comprehensive policy framework. If the extent of bioprospecting activities cannot be accurately determined, there is an information gap that makes it difficult to formulate appropriate policy. For example, if information shows that there is little or no bioprospecting and there is no indication that there will be significant activity in the immediate or short term future, then these are factors that must be taken into account in determining whether a policy framework is required. The need to be able to justify a policy framework is sufficient reason, on its own, to try and ensure that an accurate database of information about bioprospecting activities is created.

Another reason suggested in the discussion paper, and one which I agree with, is that the lack of knowledge about current activities is one of the reasons why: 'It is difficult to quantify the extent to which New Zealand may be missing out on any potential benefits arising from bioprospecting'.

As a final point, I suggest that the implementation of a comprehensive framework is not the end of the matter. On its own, this will not obviate the need for information. It is important that an efficient and reliable information flow is maintained to enable the monitoring of activities in accordance with the framework and any agreements reached between bioprospectors and other parties.

1.2 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? If so, please describe them.

I have no experience as a traditional knowledge holder, bioprospector and/or access provider, however, intuitively, I suggest that the concerns of private landowners will not necessarily be the same as those of government departments. Equally, the interests of Māori will differ from non-Māori. Any policy framework needs, therefore, to be robust and flexible enough to accommodate a variety of interests.

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

2.1 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?

It is important that the organisations engaged in bioprospecting activities have a clear, simple and inexpensive framework. Currently, there is no central processing point that grants applications for licences, for example, and then monitors the activities of the licensees. The process of authorising and monitoring bioprospecting is also complicated by the fragmentation of control amongst a number of government departments and other bodies that have a hand in providing access to biological resources. There is no obligation on organisations that engage in bioprospecting to share information about their activities and, for reasons of commercial sensitivity, they are most unlikely to do so on a voluntary basis. Nor are landowners and/or the owners or those responsible for the administration of other resource areas obliged to disclose information about the activities that occur on or in their resources. Another gap in the monitoring and enforcement framework is that there may be no regulations that prevent the removal of biological material from the country.

There is anecdotal evidence that the absence of a national framework is an obstacle to bioprospecting in New Zealand in that organisations, including therapeutic drug companies, are discouraged from undertaking prospecting in New Zealand by the lack of certainty about the process of bioprospecting and by the number of departments that oversee bioprospecting activities. A well constructed framework with a single portal may therefore function as an incentive to investment by those firms.

Apart from the benefit to bioprospectors, the existing access frameworks would also benefit from being subsumed within a co-ordinated and comprehensive framework. This would enable efficient monitoring of bioprospecting activities and assist in ensuring that objectives, such as ensuring that the physical environment is not damaged by those activities, are more easily achieved. There may also be opportunities to make cost savings by reducing the duplication that currently amongst organisations that provide access to resources.

The discussion paper suggests that a co-ordinated approach would:

- Enable a broader view of bioprospecting activities
- Provide a central contact point
- Assist in streamlining bioprospecting processes
- Ensure that frameworks are in place that seek to optimise benefit return
- Provide for systematic gathering and storing of information.

I have indicated my support for some of these benefits above. Ultimately, the framework should be seen as a means of facilitating the search for bioactives and achieving an equitable benefit sharing regime.

3. On a comprehensive bioprospecting framework for New Zealand:

3.1 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.

New Zealand already regulates access for bioprospecting activities in a variety of ways and by a variety of authorities. Subject to the need to obtain further information that would justify a comprehensive policy framework, I have indicated above that I believe that a co-ordinated and comprehensive framework will be an important and necessary development for the regulation of bioprospecting in New Zealand and the long term capture of benefits. If closer regulation of bioprospecting access and activities is to be undertaken, it is important that it is based on a comprehensive policy framework. Regulations should not be developed on an ad hoc basis. On the contrary, they should be developed in a structured manner that ensures that they comply with government policy and initiatives in related areas.

The interests of Māori, which are critical to this whole discussion, will also be served by the development of a policy framework. There is, however, a caveat – any framework would need to give effect to the Treaty of Waitangi and be compatible with the final settlement of the Wai 262 claim.

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

The proposed vision

I have reproduced the proposed vision below and I have highlighted the major questions that occur to me in respect of the current drafting. I appreciate that a vision statement cannot accommodate the demands of all interested parties, however, the proposed statement lacks clarity and is uncertain in its approach.

*that access to New Zealand's biological resources for bioprospecting is facilitated in a way that ensures the benefits derived [1. **benefits for whom and derived by whom**] are captured and shared [2. **with whom or amongst whom**], that social, cultural and environmental values [3. **whose values**] are respected [4. **why aren't they to be protected**], and Māori traditional knowledge of biological resources is recognized [5. **how is it to be recognised**] and, where appropriate, protected [6. **who decides when it is appropriate**] [7. **what is the form of protection**].*

1. The statement does not make it clear who owns or controls the benefits of bioprospecting and how or by whom those benefits are derived. The current discussion paper is primarily concerned with bioprospecting and not with the science and the commercialisation that follows on from bioprospecting. However, I believe that it is impossible to completely separate these elements. The vision statement itself implicitly acknowledges the interconnection of these elements as it begins with a benefit sharing statement
2. A problem with benefit sharing that needs to be addressed, and is not addressed in the proposed vision statement, is: Who is to share in the benefits that accrue downstream from the bioprospecting activities? Are the benefits to be distributed to owners of the primary resource, to Māori or to the state on behalf of the citizens?
3. To require respect for social, cultural and environmental values implies that those values are recognised and accepted by the majority of the state's citizens. Another problem is that 'values' is a difficult word with a variety of meanings.
4. The vision statement calls for the values to be 'respected', however, this does nothing to ensure that the values are actually adhered to. Further on, the statement requires that Māori traditional knowledge is protected. The social, cultural and environmental values should likewise be protected, if and when they are identified.
5. It is not clear what is intended by the requirement that Māori traditional knowledge be recognised. Presumably, this means that bioprospectors and/or firms that commercialise the discoveries made with the assistance of Māori traditional knowledge acknowledge the derivation of the discovery. The obvious question are: What form will this acknowledgement take? And, what value does this acknowledgement have? If 'recognised' is intended to mean that bioprospectors should respect or reward the use of Māori traditional knowledge, then this needs to be made clear.
6. Protection for Māori traditional knowledge is to be provided 'where appropriate'. I suggest that Māori traditional knowledge should be protected without regard for a criterion of appropriateness.
7. The means by which indigenous traditional knowledge is to be protected is an issue that many countries are wrestling with. It is a critical policy question that hasn't yet been determined in New Zealand.

Given the problems that I have identified above, I question the value for such a statement. Certainly, in its current form, I suggest that it is fatally flawed.

The proposed policy principles

A general criticism of the proposed policy principles as they stand is that they do not read as principles within a policy framework but rather as part of a regulatory framework. In other words, the so-called policy principles read as mandatory rules or regulations. I suggest that the principles should be redrafted as follows:

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

- takes account of issues of ecological sustainability;
- gives effect to the Treaty of Waitangi and Treaty settlements;
- emphasises acknowledgement and respect for Māori traditional knowledge, and acknowledges the need to seek permission from holders of the traditional knowledge for its use in bioprospecting;
- analyses issues of benefit sharing and proposes equitable solutions;
- provides for an environment in which 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 commercial or 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
- proposes a solution within which the implementation of the government's desired policy option, and its associated institutional and administrative arrangements, can occur in a cost-effective manner.

International dimensions

In terms of the proposals to achieve the vision on an international level, I suggest that the following principle be added:

- does not disadvantage New Zealand in its relations with other countries.

i. Potential policy benefits and costs

General comment:

I believe that, in the main, the discussion paper adequately addresses the costs and benefits of a comprehensive policy framework. However, I suggest that greater consideration needs to be given to issues of enforcement. If a policy framework is implemented, then the regulatory elements that it proposes must be capable of being enforced; and enforcement is, of course, a significant cost element in any framework. For example, the framework should identify the range of sanctions available if bioprospectors do not comply with the requirements of the policy; it should also be clear

what resources are to be made available to track breaches of the policy and/or regulation. However, enforcement should not be construed solely in terms of regulation of prospecting activities in New Zealand. Enforcement is a complex and far-reaching issue. It includes, for example, a consideration of the means by which agreements which have been negotiated as part of the process of granting access to biological material are to be enforced with parties that are domiciled outside New Zealand.

Countries with similar frameworks will have similar issues of benefit sharing and costs. (And it should be noted that there will be a relatively high number of countries with similar frameworks because of their obligations under the Convention for Biological Diversity and their adherence to the Bonn Guidelines.) A point on which a number of countries will differ from New Zealand is in the level of protection which is given to indigenous interests and indigenous knowledge. Leaving the latter point aside, it seems sensible that New Zealand should structure its costs so that they are similar to countries like Australia and Canada so as to avoid diverting prospective bioprospectors purely on the basis of perceived costs of prospecting.

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

Although the discussion paper discusses potential benefits or costs, wisely, it does not attempt to put a dollar figure on either benefits or costs. It is my belief that the level of dollar benefits derived from bioprospecting and consequent commercial development which will accrue to stakeholders in New Zealand will be relatively low. Likewise, the costs to bioprospectors, in terms of simple bioprospecting, will be relatively low in relation to the overall costs involved in scientific research and long term commercialisation of discoveries. The discussion paper correctly refers to a number of possible costs as including finding out about bioprospecting access; finding and contacting the appropriate access provider. However, these are costs that can be addressed by the formulation of a comprehensive bioprospecting framework that is promoted to the appropriate people. In short, my submission is that the benefits and costs of a bioprospecting framework should not be measured in dollar terms.

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

It follows from my comments in answer to question 3.3 above that I believe that New Zealand should be looking to obtain non-monetary benefits. I note that the discussion paper suggests as one such non-monetary benefit 'joint ownership of intellectual property rights'. I would be surprised if a major pharmaceutical drugs company, for example, would be prepared to agree to joint ownership of intellectual property rights as a condition of access for bioprospecting purposes. I believe that joint ownership is an option that would require greater investment than is justified by the mere provision of

access to a biological resources even if it is combined with access to Māori traditional knowledge. I suggest that a better approach would be to negotiate a specific licence regime for any discovery made from materials sourced from New Zealand's biosphere.

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

It may be impossible to undertake a cost/benefit analysis. For example, how do you validly measure 'institutional capacity building'.

ii. Policy scope

3.6 What are your thoughts on the current definition of bioprospecting?

The current definition of bioprospecting is deficient on at least four counts and it is not consistent with elements covered in the discussion paper: (i) It ignores the question of access to biological resources, although access is an essential element of bioprospecting. Access is acknowledged elsewhere in the discussion paper – it is one of the factors included in Figure 1 and access is also part of the vision statement. (ii) The definition also ignores the process of approaching Māori with a view to obtaining access to and permission to use Māori traditional knowledge. The need to protect Māori traditional knowledge is also acknowledged in the vision statement. (iii) The definition is restricted to activities which are undertaken for 'the purpose of developing a commercial product'. I explain why I think this is too restrictive in response to question 3.4 on the "in scope" and "out of scope" boundaries of bioprospecting below. Suffice to say at this point that the definition is deficient if it excludes non-commercial research. (iv) The sentence regarding 'bioprospecting policy' is unnecessary, however, it could be retained if it is separated from the primary definition and effectively becomes an explanation of the primary definition.

I understand that the term bioprospecting is open to interpretation; however, the definition used in New Zealand should be appropriate to New Zealand circumstances. Therefore, I suggest that the definition be redrafted as follows:

Bioprospecting includes (i) obtaining access to biological material; (ii) where appropriate, negotiating the use of Māori traditional knowledge; and, (iii) collecting biological material and the analysis of its material properties, or its molecular, biochemical or genetic content for the purposes of commercial or non-commercial research and development.

Bioprospecting policy excludes the later steps in the chain of product development.

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

Rather than review all the resources which are currently 'in scope' and 'out of scope', it is simpler and clearer to adopt a holistic approach.

The revised definition of bioprospecting refers to 'biological material'. Therefore, it is arguable that all biological material should be in scope. In respect of 'human genetic material', the discussion paper points out that it is excluded under the Bonn Guidelines. This is not a good enough reason to exclude it as out of scope. The Bonn Guidelines are not mandatory and do not fetter New Zealand's rights over its natural resources whatever they might be.

The discussion paper includes commercial activities which arise from non-commercial research activities as in scope. Apart from making it clear that these activities are included in scope, there is no need for this entry. All commercial activities should be in scope; and, I have suggested above, that all non-commercial activities should also be in scope.

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

Non-commercial research activities are currently out of scope. It is my strong submission that the distinction between commercial and non-commercial research cannot be maintained. The discussion paper gives a number of compelling reasons for including non-commercial research activities in scope. I agree with those reasons. The discussion paper sets out a number of 'potential disadvantages' of including non-commercial research in scope. The costs to the government of increased numbers of applications should be covered by the fees charged. In any event, it is very unlikely that the numbers of applications will increase dramatically as a result of promulgating a framework; the level of non-commercial research activities depends on other factors. The costs to researchers are also small. The dollar cost of the applications would be included as an overhead in funding applications. Researchers at tertiary institutions and crown research institutes ('CRI's') are accustomed to making similar applications for approval, such as ethics applications, to university committees and health boards.

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

Only activities which fall within the revised definition of bioprospecting above should be included in the scope of the policy.

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

Non-commercial researchers should be required to meet the same levels of compliance expected of commercial researchers. Researchers in CRI's and tertiary institutions would, as a matter of course, include any dollar costs in the overheads which they are required to specify in applications to funding bodies such as FRST.

3.9 Which kinds of biological resources should be accessed for bioprospecting?

There should be no restriction on bioprospecting based on the nature of the biological resource.

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

For the reasons which I set out above, I submit that a central access portal should be created. Logically, this should be the responsibility of central government and be administered by central government.

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

Yes, ex situ collections should be included in a comprehensive bioprospecting policy, subject to ensuring that the policy and framework remain simple and clear.

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

Indigenous and endemic biological material should be included. Biological material which has been introduced should also be included provided that it was not deliberately introduced. Plants, such as gorse, which was deliberately introduced by the European settlers would not be included; while species such as Pacific oysters, which were accidentally introduced as recently as the 1970's, would be included.

iii. Administrative frameworks

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

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

I think that a national focal point (or central portal, as I have named it above) is a necessary element in bioprospecting framework. In my view, this body would be housed in an appropriate department, probably within the Ministry of Economic

Development. The Bonn Guidelines appear to envisage a national focal point as being the point for information access for bioprospectors. The Guidelines also propose a competent national authority that would be responsible for granting access and advising on matters such as 'the negotiating process; requirements for obtaining prior informed consent'. I do not believe that a dual system is required or desirable in New Zealand. A single body could be charged with being responsible for the bioprospecting process. An important consideration is that it would need to have competence in dealing with Māori issues, a consultative committee could be the model.

4. On mātauranga Māori:

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

No submission. This question requires specific input from Māori stakeholders and depends on the outcome of the Wai 262 claim.

4.2 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)?

I support the suggestions made in the discussion paper, subject to the informed opinion of Māori. However, only a code of best practice seems practicable at this time.

5. On international bioprospecting frameworks:

5.1 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?

The Bonn Guidelines should be treated in accordance with their name – that is, as a guide to be considered in the development of a bioprospecting framework. It is desirable to have a reference point or a benchmark against which it is possible to measure domestic proposals. However, in my opinion, the Bonn Guidelines descend to a level of detail that is undesirable in a policy document. For example, in Article 11, the Guidelines propose 12 objectives; in Article 16, the roles and responsibilities of competent national authorities are set out in 25 separate clauses. Clearly, the value of the Guidelines lies in their being used as a resource. Policy makers should refer to the Guidelines for those components and examples that are useful to New Zealand. It is important, however, that the Guidelines should not be regarded as a set of rules that must be adopted in total.

5.2 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?

At this stage in the development of a policy framework, I suggest that attention should be focused on the basic factors addressed in questions 1 and 2. The international bioprospecting frameworks comprise a set of resources. However, they are resources that should be used carefully and sparingly. It is always useful to have a variety of inputs, but those inputs must be relevant. The most relevant of the existing frameworks will be those that are established in countries that are similarly biodiverse to New Zealand and have a strongly politicised, indigenous population that is determined to protect its heritage.

6. On any other issues:

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

Issues of international controls may be outside the scope of this discussion paper. However, I submit that the national bioprospecting policy framework depends the international framework implemented by the members of international treaties and conventions, such as the Convention on Biological Diversity. At treaty negotiations, three basic imperatives should guide New Zealand's participation:

- (i) The interests of the country as a whole.
- (ii) The specific interests of Māori.
- (iii) International protection against unauthorised bioprospecting coupled with international controls to ensure agreements reached in one country (the country of source) are enforceable in a second country (the country of exploitation), eg as to an agreement to provide a benefit if a successful product is developed.