MINISTRY OF BUSINESS, INNOVATION & EMPLOYMENT
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Discussion paper

Disclosure of origin of genetic resources and traditional knowledge in the patents regime

September 2018

newzealand.govt.nz

How to have your say

Submissions process

The Ministry of Business, Innovation and Employment (MBIE) seeks submissions on the issues raised in this document by **5pm on Friday, 21 December 2018**.

Your submission may respond to any or all of these issues. We also encourage your input on any other relevant issues. Where possible, please include evidence to support your views, such as references to independent research, facts and figures, or relevant examples.

Please use the submission template provided at here: ***http://www.mbie.govt.nz/info-services/business/intellectual-property/patents/disclosure-of-origin-requirements-in-the-patents-regime/consultation***. This will help us to collate submissions and ensure that your views are fully considered. Please also include your name, or the name of your organisation, and contact details.

Digital submissions must be provided in a machine-readable Word or PDF format. Please do not provide scanned digital copies of your submissions.

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  Business Law
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  Ministry of Business, Innovation & Employment
  PO Box 1473
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The information provided in submissions will be used to inform MBIE's policy development process and will inform advice to Ministers on patent disclosure of origin requirements.

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Contents

Glossary and Acronyms

Descriptions of key terms here are not intended to be definitions.

ABS	Access and benefit-sharing
CBD	Convention on Biological Diversity
CPTPP	Comprehensive and Progressive Agreement for Trans-Pacific Partnership
FTAs	Free trade agreements
genetic resources	Genetic material of actual or potential value. 'Genetic material' refers to any material of plant, animal, microbial or other origin containing functional units of heredity (CBD definition) (e.g. mānuka plant)
IGC	Intergovernmental Committee on Intellectual Property and Genetic Resources, Traditional Knowledge and Folklore
in situ	In its natural habitat
IPONZ	Intellectual Property Office of New Zealand
PMAC	Patents Māori Advisory Committee
MAT	Mutually agreed terms
mātauranga Māori	The Waitangi Tribunal referred to mātauranga Māori as "the unique Māori way of viewing the world, incorporating both Māori culture and Māori traditional knowledge" (Wai 262 report)
MBIE	Ministry of Business, Innovation and Employment
Nagoya Protocol	Nagoya Protocol on Access to Genetic Resources and the Fair and Equitable Sharing of Benefits Arising from their Utilization to the Convention on Biological Diversity
PCT	Patent Co-operation Treaty
PIC	Prior informed consent
prior art	In relation to an invention so far as claimed in a claim, this is all matter (whether a product, a process, information about a product or process, or anything else) that has at any time before the priority date of that claim been made available to the public (whether in New Zealand or elsewhere) by written or oral description, by use, or in any other way (Section 8, *Patents Act 2013*)

PVR Act	*Plant Variety Rights Act 1987*
PVR Issues Paper	*Review of the Plant Variety Rights Act 1987: Issues Paper*
traditional knowledge	According to WIPO, "traditional knowledge" in the narrow sense refers to knowledge as such, in particular the knowledge resulting from intellectual activity in a traditional context, and includes know-how, practices, skills, and innovations. Traditional knowledge can be found in a wide variety of contexts, including: agricultural knowledge; scientific knowledge; technical knowledge; ecological knowledge; medicinal knowledge, including related medicines and remedies; and biodiversity-related knowledge We discuss this in more detail on page 3
TRIPS	World Trade Organization Agreement on Trade Related Aspects of Intellectual Property Rights
Wai 262 report	Waitangi Tribunal report entitled *Ko Aotearoa Tēnei: A Report into Claims Concerning New Zealand Law and Policy Affecting Māori Culture and Identity*
WIPO	World Intellectual Property Organization
WTO	World Trade Organization

Executive summary

1. ‘Disclosure of origin’ describes a type of information disclosure requirement on applicants for intellectual property rights. In the patents context, these requirements generally require applicants to disclose the origin of any genetic resources and/or traditional knowledge used in their inventions. Internationally, disclosure of origin requirements are generally implemented to support the rights and interests of states, and indigenous peoples and local communities in relation to genetic resources and/or traditional knowledge.

2. The Ministry of Business, Innovation and Employment is considering whether New Zealand should adopt a disclosure of origin requirement in its patents regime, and how it should approach international discussions on disclosure of origin requirements. There are two main drivers for this work:

    a. The Waitangi Tribunal recommended that the Government implement a disclosure of origin requirement in the patents regime in its report on the Wai 262 inquiry, *Ko Aotearoa Tēnei: A Report into Claims Concerning New Zealand Law and Policy Affecting Māori Culture and Identity.* The Waitangi Tribunal recommended this change to facilitate consideration of Māori rights and interests in indigenous plant and animal species and mātauranga Māori (in this context, Māori traditional knowledge).

    b. Disclosure of origin requirements are also discussed in a variety of international forums – in particular, the World Intellectual Property Organization and the World Trade Organization. Many states that have domestic disclosure of origin requirements advocate for an international disclosure of origin requirement – for example, through a new international instrument, or by introducing a new requirement in existing agreements, such as the Agreement on the Trade-Related Aspects of Intellectual Property Rights.

3. We are seeking views and evidence to inform our approach to patent disclosure of origin requirements, domestically and internationally.[1]

4. We consider that there are two problems that could be addressed by the introduction of a disclosure of origin requirement in New Zealand’s patents regime, as follows:

    a. New Zealand’s patents regime has measures to prevent the grant of patents over inventions for which commercial exploitation could be offensive to Māori. Relevant applications should be referred to the Patents Māori Advisory Committee. However, there is a currently a risk that patent applications for inventions that involve indigenous plant and animal species or mātauranga Māori may be missed during the patent examination process, and therefore not be referred to the Patents Māori Advisory Committee for consideration. A disclosure of origin requirement would help to ensure relevant applications are put before the Committee.

[1] We are also considering our approach to disclosure of origin requirements in New Zealand’s plant variety rights regime. This is covered in the Issues Paper for the *Plant Variety Rights Act* review, and is discussed further below.

b. It is difficult for interested groups, including Māori, the public and government, to find information on uses of New Zealand genetic resources and/or mātauranga Māori. This is an issue for all providers of genetic resources and traditional knowledge. A disclosure of origin requirement would allow New Zealand's patents register to be used by interested groups to potentially identify some uses and users of genetic resources and/or traditional knowledge that they have an interest in.

5. In this paper, we consider three different options for implementing a disclosure of origin requirement. These options range from disclosure of the country of origin of genetic resources and/or traditional knowledge if known, through to compulsory disclosure of evidence of compliance with access and benefit-sharing laws of the country of origin of genetic resources and/or traditional knowledge. We undertake a preliminary options analysis by assessing the options against four objectives and considering the findings of an economic evaluation we commissioned for these options. We seek your views on this analysis.

6. Our preferred option at this stage is to implement a requirement that patent applicants disclose the origin of genetic resources and traditional knowledge used in their inventions. If this information is not known, applicants would be required to disclose the direct source of the genetic resource and/or traditional knowledge. This option best balances the objectives of information availability and high-quality decision-making in the patents regime with the need to minimise compliance costs for patent applicants and Intellectual Property Office of New Zealand. We also seek your views on the design features of any potential disclosure of origin requirement, including the subject matter of disclosure and sanctions and remedies.

7. If the Government decides to implement a disclosure of origin requirement in the patents regime, New Zealand will then need to consider whether, how and in what contexts we might support the introduction of an international disclosure requirement. New Zealand would likely also benefit from greater information availability and better quality decision-making in other countries' patents regimes. New Zealand could gain economic benefits from the introduction of disclosure of origin requirements in other economies with pharmaceutical, cosmetic and biotechnology industries where New Zealand's genetic resources may be used. The introduction of a disclosure requirement in such jurisdictions could incentivise researchers to consult and share benefits with states, and indigenous peoples and local communities, including iwi and hapū. We seek your views on how New Zealand should approach international discussions relating to disclosure of origin requirements.

Introduction

1. The Ministry of Business, Innovation and Employment (**MBIE**) is considering whether New Zealand should adopt a disclosure of origin requirement in its patents regime.[2] While disclosure requirements differ internationally, in general, they require patent applicants to disclose the origin of genetic resources and/or traditional knowledge used in their inventions.

2. Genetic resources are the genetic material of plants, animals or micro-organisms that have, or may have, value to us. There has been, and continues to be, a great deal of research into the beneficial properties of genetic resources from plants, animals and micro-organisms. In the context of the biotechnology industries, research may lead to the development of new products and practices (like new medicines, or improved agricultural crops) that are commercially lucrative.

3. Traditional knowledge includes the know-how, practices, skills, and innovations of indigenous peoples and local communities, resulting from intellectual activity in a traditional context. It occurs in a variety of contexts, and may be agricultural, scientific, technical, ecological, medicinal, biodiversity-related and more. Traditional knowledge may be associated with genetic resources and, in some cases, molecules, properties and/or active ingredients of genetic resources have been identified with the support of traditional knowledge.

4. Disclosure of origin requirements provide a mechanism for states and indigenous peoples and local communities to monitor the use of their genetic resources and traditional knowledge in research and development that results in new inventions.[3] This is particularly important where indigenous peoples and local communities have not permitted access to the genetic resources or traditional knowledge, or the benefits from the commercialisation of those inventions could be shared with them. Disclosure of origin requirements may also facilitate better quality patent examination, by providing intellectual property offices with information that is relevant to patentability. However, this process may be costly for patent applicants and researchers.

5. New Zealand is involved in discussions about disclosure of origin requirements in the World Intellectual Property Organization, the World Trade Organization (**WTO**) and other international contexts, including some free trade agreement negotiations. Implementing a disclosure of origin requirement was also recommended by the Waitangi Tribunal (the **Tribunal**) in its report on the Wai 262 Inquiry, *Ko Aotearoa Tēnei* (the **Wai 262 report**).

6. To inform New Zealand's approach to disclosure of origin both domestically and internationally, we are consulting on whether New Zealand should introduce a disclosure of

[2] We use 'disclosure requirement' and 'disclosure of origin' interchangeably in this document to mean 'disclosure of origin requirement'.

[3] Genetic resources themselves (for example, naturally occurring DNA sequences) cannot be directly protected as intellectual property: they occur in nature, and are not creations of the mind. However, research into genetic resources may result in new developments that can be commercialised, such as new pharmaceuticals or improved agricultural crops. These new inventions may be eligible for patent protection.

origin requirement in its patents regime. In this paper, we seek feedback on our preliminary assessment of the need for a disclosure of origin in New Zealand, possible options, and the design features of a potential new requirement.

What is the scope of this paper?

7. We are exploring whether patents applicants should be required to disclose the origin of any genetic resources or traditional knowledge used in developing their inventions. We do not consider, in this paper, the disclosure of origin in other intellectual property regimes.

8. Separately, MBIE is also considering the issue of disclosure of origin requirements in the context of the plant variety rights regime through the review of the *Plant Variety Rights Act 1987* (**PVR Act**). We have released the *Review of the Plant Variety Rights Act 1987: Issues Paper* (**PVR Issues Paper**) concurrently with this discussion document. In the PVR Issues Paper, we seek the public's views on what information should be accessible on the Plant Variety Rights register, and how accessible information about the origin of genetic material is for plant breeders. The PVR Act review is at an early stage in the policy development process. We are focusing on getting a better understanding of any problems with the way the PVR regime currently operates.

9. Disclosure of origin requirements are related to biological prospecting, or 'bioprospecting'. Bioprospecting is the gathering of biological material from flora and fauna for the development of new products. How New Zealand regulates this activity is outside of the scope of this paper. We discuss the relationship between disclosure requirements and bioprospecting policy further in paragraph 106.

What does this paper cover?

10. This paper has four sections.

11. Before moving to our analysis, we provide context and background information. In **section 1**, we give an overview of the patents regime and how information disclosure works currently under New Zealand's regime. We then explore what disclosure of origin requirements are, the reasons that states have implemented them, and how they have been discussed both domestically and internationally.

12. Our analysis begins in **section 2**. Here, we explain our view of the problem definition, and the objectives that we might seek to achieve to address the problems we identify. Then, in **section 3**, we outline and analyse three possible options for a new disclosure of origin requirement. We assess the options against the objectives, and consider the findings of an economic evaluation that MBIE commissioned to quantify the costs and benefits of a disclosure of origin requirement. Following this analysis, we discuss our preferred option.

13. In **section 4**, we outline and seek feedback on some of the key design features of a potential disclosure requirement.

What happens next?

14. Submissions close at **5pm, 21 December 2018**. Instructions on how to make a submission are on page i.

15. All relevant matters raised in submissions will be taken into account in MBIE's advice to the Minister of Commerce and Consumer Affairs. Depending on which option the Government decides on, MBIE may undertake further public consultation on the design of that option.

16. If the Government decides to proceed with legislative change, the public would have another opportunity to comment on any changes as part of the select committee consideration of those changes.

1 Context and purpose

17. This section provides background on the patents regime in New Zealand and in particular, how standard information disclosure works in the regime. We then discuss what disclosure of origin requirements are, and why other jurisdictions have chosen to implement them. We also cover the Tribunal's discussion of disclosure of origin in its Wai 262 report, and the current state of international debate on disclosure of origin requirements.

The patents regime and information disclosure

The patent bargain

18. The purpose of patent law is to promote innovation. It does this by granting inventors the right to prevent others from commercially exploiting their new inventions for a limited time through the grant of a patent. In exchange for this monopoly right, inventors must disclose their inventions so that others may repeat the invention, and society may benefit. The right to exclude competitors from the market is intended to incentivise research and development that would not otherwise occur, and the disclosure of technical information that inventors might otherwise keep secret. This is known as the patent bargain.

19. In New Zealand, the patents regime is regulated under the *Patents Act 2013*. Under the *Patents Act*, the grant of a patent for an invention provides the patent owner with the right to prevent others exploiting their patented invention for at least twenty years from the date the patent application was filed.

Standard information disclosure under the patents regime

20. To gain patent protection in New Zealand, an application must be filed with the Intellectual Property Office of New Zealand (**IPONZ**). Applicants must provide certain information in their applications, including their details, the details of the inventor/s, and an address for service. Applicants must also provide a patent specification. A complete patent specification must contain:

    a. a patent abstract – a concise summary of the invention;

    b. a full and complete written description of the relevant invention that is clear enough and complete enough for the invention to be performed by a person "skilled in the art", as well as the best method of performing the invention that is known to the applicant; and

    c. the patent claims, which define the protective boundaries of the invention (the "scope of the monopoly").[4]

[4] Section 39, *Patents Act 2013*.

21. Applicants may choose to file a provisional specification before filing a complete specification. Provisional specifications must still describe the invention, but require less detail than complete specifications. This allows applicants to 'buy' more time for research and development if their invention is at an early stage of development. A complete specification must be filed between 12-15 months after an application with a provisional specification is made, or the application will be considered abandoned.

22. The patent specification is published online by IPONZ. This usually takes place 6 months after the date that the patent application was filed. Publication does not guarantee that a patent will be granted.

23. The complete specification and claims are examined by IPONZ to determine whether they meet the requirements for granting a patent. If they do not, the applicant is given an opportunity to amend the specification and claims. Once the examiner is satisfied that all the requirements are met, the patent application is accepted. Once accepted, third parties can oppose the grant of a patent if they think the patent should not be granted. Once granted it is possible for third parties to apply to have the patent revoked if they think that it should not have been granted.

Disclosure and patentability

24. The information provided in a patent specification is used to help patent examiners at IPONZ to assess whether an invention is patentable.

25. To be patentable, an invention must be a manner of manufacture, it must be novel and it must involve an inventive step. The invention must also be useful. Lastly, it must not be subject to an exclusion. There are specific exclusions from patentability – for example, "human beings and biological processes for their generation". There is also a general rule that inventions are not patentable if the commercial exploitation of the invention is contrary to public order or morality.

26. Under the *Patents Act*, applications may be referred to the Patents Māori Advisory Committee (**PMAC**) established in 2014 to provide advice, where relevant. The PMAC provides advice to the Commissioner of Patents when requested on whether:[5]

    a. an invention claimed in a patent application is derived from Māori traditional knowledge or from indigenous plants or animals; and

    b. if so, whether the commercial exploitation of that invention is likely to be contrary to Māori values.

27. The Commissioner will take this advice into account in considering whether an invention is contrary to public order or morality.

28. Patent applicants have the option of disclosing whether their invention is derived from Māori traditional knowledge or indigenous plants or animals in their applications. This disclosure can act as a flag to patent examiners that the application should be considered by the PMAC.

[5] Sections 15(3) and 226, *Patents Act 2013*.

Disclosure of origin requirements

What are disclosure of origin requirements?

29. "Disclosure of origin" is an umbrella term that describes a kind of disclosure requirement in patents regimes that has been adopted in approximately 30 countries. These requirements vary from country to country but, essentially, they require patent applicants to disclose the origin of genetic resources or traditional knowledge used in their inventions. Disclosure of origin requirements are additional to standard patent disclosure requirements. Such disclosure is not normally required because the information gathered may not be strictly relevant to whether an invention is patentable. In New Zealand, patent applicants can provide this information voluntarily.

Different countries have implemented disclosure of origin requirements for different reasons

30. Calls for the introduction of disclosure of origin requirements first arose in the mid-1990s, amid discussions about the relationship between the protection of biological diversity (biodiversity) – in particular, genetic resources and associated traditional knowledge – and the intellectual property system.

31. These discussions followed the adoption of the Convention on Biological Diversity (**CBD**) in 1992. The CBD affirms the sovereign rights of states over their genetic resources. It establishes an obligation among contracting parties to endeavour to create conditions to facilitate access to genetic resources on mutually agreed terms (**MAT**) and subject to prior informed consent (**PIC**). In addition, users of genetic resources should share the benefits of research and development with countries who have provided genetic resources. Benefit-sharing must be fair and equitable, and also on MAT. These are known as access and benefit-sharing (**ABS**) rules.

32. In implementing the CBD, some countries recognised limits in their ability to monitor the use of genetic resources and verify compliance with ABS contracts. The intellectual property system (in particular, the patents and plant variety rights regimes) was identified as a potential tool for providing greater transparency about the use of genetic resources. Where benefits were to be had, users of genetic resources could be expected to seek intellectual property protection. Intellectual property regimes could act, then, as a notification system for ABS compliance. Some states began implementing disclosure of origin requirements for the purpose of encouraging users' compliance with their rights as recognised in the CBD.

33. An example of this is the disclosure of origin requirement implemented on a regional, 'club' basis in the Andean Community. Patent applicants using genetic resources from the Andean region in their inventions are required to show compliance with ABS laws in the country that provided the genetic resources. If they cannot do so, they will be denied patent protection.[6]

[6] ***http://www.wipo.int/wipolex/en/details.jsp?id=9446*** Second complementary provision in Decision 391 of the Andean Community: "Member Countries **shall not acknowledge rights**, including intellectual property rights, over genetic resources, by-products or synthesized products and associated intangible components, that

34. In 2010, a supplementary agreement to the CBD – the **Nagoya Protocol**[7] – was adopted to assist in creating greater legal certainty and transparency for providers and users of genetic resources, and traditional knowledge associated with genetic resources. The Nagoya Protocol is intended to establish more predictable conditions for access to genetic resources and help to ensure benefit-sharing when genetic resources leave the country providing genetic resources. Some of the obligations of parties to the Nagoya Protocol include:

    a. taking measures providing that genetic resources utilised within their jurisdiction have been accessed in accordance with PIC, and that MAT have been established, as required by another contracting party; and

    b. monitoring the use of genetic resources after they leave a country by designating effective checkpoints at every stage of the value-chain: research, development, innovation, pre-commercialisation, or commercialisation.

35. While disclosure of origin requirements are not mentioned under the Nagoya Protocol, some states consider them to be a useful tool for meeting their obligations. For example, a simple disclosure of origin requirement in one country may bring unknown uses of genetic resources or traditional knowledge from another country to light, and aid the latter country (or indigenous people or local community) to enforce its rights against the relevant user.

36. Supporters of disclosure of origin requirements have also argued that they can enhance efficiency and legal certainty in the patents regime itself. This is particularly relevant where inventions are based on traditional knowledge. One of the benefits of a disclosure requirement is that it requires, or may give rise to, the provision of information that may be relevant to the patentability of an invention.

37. For an invention to be patentable, it must be novel over what is already known from the **prior art base**. The prior art base encompasses all matter (whether a product, a process, information about a product or process, or anything else) that has been made available to the public, whether by written or oral disclosure, prior to the priority date of a patent application.[8]

38. Disclosure of origin by patent applicants may provide information that patent examiners can further investigate to establish whether an invention is novel and inventive, and prevent the grant of patents for inventions that are not. Once the application has been published, disclosure may also act as a notification to indigenous peoples and local communities whose traditional knowledge is used in the relevant invention – or other third parties who are familiar with the traditional knowledge – and who may consider that that traditional knowledge disqualifies that invention from patentability as it is not novel. Indigenous peoples and local communities, and other third parties, may use pre-grant opposition procedures to provide patent offices with prior art information. This can enhance the efficacy of the patents regime and increase certainty about the status of patents containing genetic resources and traditional knowledge.

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were obtained or developed through an access activity that did not comply with the provisions of this Decision. Furthermore, the Member Country affected may request nullification and bring such actions as are appropriate in countries that have conferred rights or granted protection."

[7] Nagoya Protocol on Access to Genetic Resources and the Fair and Equitable Sharing of Benefits Arising from their Utilization to the Convention on Biological Diversity.

[8] The priority date is generally the date of filing of the first application.

A disclosure of origin requirement has been recommended by the Waitangi Tribunal

39. The Tribunal recommended that a disclosure of origin requirement be implemented in the patents regime in its report on the Wai 262 inquiry, *Ko Aotearoa Tēnei*. The Wai 262 inquiry was the Tribunal's first whole-of-government inquiry, spanning almost 20 years – reflecting the significant breadth and complexity of the claims. It has been said[9] that the inquiry was about the place of Māori culture, identity, traditional knowledge and values in New Zealand's laws, government policies and practices, and contemporary New Zealand life. Part of the inquiry examined the interface between te ao Māori (the Māori world) and New Zealand's intellectual property regimes.

40. In Chapter 2 of the Wai 262 report, the Tribunal considered the rights and interests of Māori in the genetic and biological resources of taonga species and mātauranga Māori, in the context of bioprospecting, genetic modification and intellectual property policy (patents and plant variety rights). It considered that, while the Treaty of Waitangi does not guarantee ownership in taonga species (or mātauranga Māori), it does guarantee tino rangatiratanga. This requires Crown recognition and protection of the kaitiaki (guardian) relationships that Māori have with taonga species and mātauranga Māori.

41. The Tribunal described the ethic of kaitiakitanga (guardianship) as follows:[10]

> *Kaitiakitanga is the obligation, arising from the kin relationship, to nurture or care for a person or thing. It has a spiritual aspect, encompassing not only an obligation to care for and nurture not only physical well-being but also mauri[11].*

42. The Tribunal recommended that a mandatory disclosure of origin requirement be implemented in the patents regime to facilitate protection of the kaitiaki interest. It recommended that patent applicants be required to disclose, where applicable:[12]

    a. *the source and country of origin of any genetic or biological resource that contributed in any material way to the invention*

    b. *mātauranga Māori that was used in the course of research, including traditional knowledge that is not integral to the invention that led to the relevant patent application.*

43. The Tribunal was concerned that a disclosure of origin requirement should not have a chilling effect on genuine innovation. It recommended that the consequences of failure to disclose this information be a matter of discretion for the Commissioner of Patents, together with the chair of the PMAC.[13]

44. We discuss the Tribunal's analysis further in the problem definition section below.

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[9] ***https://waitangitribunal.govt.nz/news/ko-aotearoa-tenei-report-on-the-wai-262-claim-released/***

[10] Waitangi Tribunal *Ko Aotearoa Tēnei: A Report into Claims Concerning New Zealand Law and Policy Affecting Māori Culture and Identity: Te Taumata Tuatahi* (Wai 262, 2011) vol 1 at 17.

[11] *Ibid*, the Waitangi Tribunal defined mauri as a "living essence or spirit".

[12] Waitangi Tribunal *Ko Aotearoa Tēnei: A Report into Claims Concerning New Zealand Law and Policy Affecting Māori Culture and Identity: Te Taumata Tuarua* (Wai 262, 2011) vol 1 at 204.

[13] Ibid, 205.

Disclosure of origin requirements are also discussed at the international level

45. Proposals to introduce an international disclosure of origin requirement are being discussed in several international forums. States that are proponents for these proposals argue that there is a need for an internationally-harmonised mandatory disclosure of origin requirement as the ability of states to regulate and monitor access and use of genetic resources and traditional knowledge is limited. They note the cross-border nature of research and development activities; the difficulty of monitoring compliance with ABS contracts once genetic resources and traditional knowledge leave their jurisdictions; and low-quality patent examination in some countries as reasons for implementing an international disclosure of origin requirement.

46. Opponents argue that the costs of an international disclosure requirements would outweigh any purported benefits. In particular, they argue that an international disclosure requirement would complicate the international patents system and create legal uncertainty for patent applicants.

47. The main international body for discussions on whether disclosure of origin should be mandatory is the World Intellectual Property Organization (**WIPO**) Intergovernmental Committee on Intellectual Property and Genetic Resources, Traditional Knowledge and Folklore (**IGC**).

48. The IGC was established in 2000 to consider how the intellectual property system can better protect the intellectual property of indigenous peoples. Since 2009, the IGC's mandate has been to undertake text-based negotiations "with the objective of reaching agreement on one or more international legal instruments relating to intellectual property to ensure the balanced and effective protection of genetic resources, traditional knowledge and traditional cultural expressions".[14] Disclosure of origin is one of the key proposals for discussion in the negotiations on the text relating to genetic resources. It has not yet been decided whether the resulting instrument/s will be binding treaties, or non-binding instruments.

49. Disclosure of origin is also discussed as a standing agenda item of the WTO Agreement on Trade Related Aspects of Intellectual Property Rights (**TRIPS**) Council. The TRIPS Council is the body responsible for administering the TRIPS Agreement.

50. This consultation process will help to inform New Zealand's approach to these and other negotiations.

[14] See ***http://www.wipo.int/export/sites/www/tk/en/igc/pdf/igc_mandate_2018-2019.pdf*** for the IGC's current mandate.

2 Problem definition

51. In this section, we explore and define the problems that could be addressed by the introduction of a disclosure of origin requirement in New Zealand.

52. The two key issues are:

    a. the potential that patent applications may not be recognised as being relevant to Māori and requiring consideration by the PMAC.

    b. the lack of information available about the use of genetic resources and traditional knowledge – especially New Zealand genetic resources and mātauranga Māori – in research.

There is a potential for patent applications relevant to Māori to be missed

53. As we have outlined above, patent applications may be referred to the PMAC for its consideration where IPONZ considers that a claimed invention may be derived from indigenous plants or animals, or mātauranga Māori. If the PMAC finds the commercial exploitation of an invention to be likely to be contrary to Māori values, it can advise the Commissioner of Patents accordingly. The Commissioner may decide to refuse the patent.

54. PMAC consideration of a patent application facilitates recognition and protection of the relationship that kaitiaki have with mātauranga Māori and taonga species when they are used in inventions. No applications have been referred to the PMAC as yet.[15] Initiating this process relies on patent applicants to disclose the use of mātauranga Māori or indigenous flora and fauna in their claimed inventions or, otherwise, on IPONZ to recognise the relevance of the application to the PMAC. As disclosure of these matters is currently optional, the responsibility falls to IPONZ's patent examiners.

55. The difficulty with this is that, as the Tribunal has recognised, "patent examiners are often trained in Western science but not in tikanga Māori, and so may not recognise the existence of the Māori interest in a particular patent application".[16] This may result in patent applications that are of interest to Māori not being referred to the PMAC. It may also mean that patent examiners are less likely to identify relevant prior art (as mātauranga Māori is often not documented in scientific databases), and do not become aware of information that may be relevant to patentability.

[15] This does not mean, however, that no applications relating to indigenous plants and animals or mātauranga Māori have been made since the establishment of the PMAC. Applicants must request examination before the substantive aspects of their application are considered. They have five years after filing a complete specification to request examination (or five years from their international filing date, if they are applying through the Patent Co-operation Treaty process).

[16] Waitangi Tribunal *Ko Aotearoa Tēnei: A Report into Claims Concerning New Zealand Law and Policy Affecting Māori Culture and Identity: Te Taumata Tuarua* (Wai 262, 2011) vol 1 at 204.

56. This may lead to the grant of patents that do not actually meet the criteria for patentability, and may have a negative effect on the relationship of kaitiaki with taonga species or mātauranga Māori, which is entitled to protection under the Treaty. As the Tribunal has also noted, if a patent is erroneously granted, it is more difficult and expensive for kaitiaki or other third parties to object to a patent post-grant than would have been to engage with IPONZ once the application had been published pre-grant.

There is not enough information available about how genetic resources and traditional knowledge are used in research

57. Where genetic resources and/or mātauranga Māori contribute to inventive activity, there may be an impact on the kaitiaki relationship. There are few formal mechanisms for kaitiaki to monitor or control the use of mātauranga Māori or taonga species. The Tribunal noted the role that the patents regime could play in facilitating this, perhaps even leading to ABS arrangements between patent applicants and kaitiaki. While New Zealand does not yet have a formal bioprospecting regime, the patents regime could act as a notification system for kaitiaki who may wish to know about uses of genetic resources that they have an interest in.

58. Others may also benefit from more availability of information about the use of New Zealand's genetic resources or mātauranga Māori in inventions. This information could also be used by:

    a. the New Zealand public, who may consider commercial exploitation of New Zealand genetic resources to be inappropriate or offensive; and

    b. government agencies, to inform policy work outside of the patents regime (conservation or bioprospecting, for example).

59. As we have mentioned above, many states and indigenous peoples and local communities have difficulty monitoring the use of the genetic resources and traditional knowledge – particularly outside of their jurisdictions. New Zealand's patents regime could bring to light to information about the use of genetic resources and traditional knowledge from other jurisdictions (and, where relevant, indigenous peoples and local communities). This may have been recognised by the Tribunal, which recommended that the disclosure of origin requirement apply to any "genetic or biological resource" – not just indigenous flora and fauna. There is an opportunity for New Zealand's patents regime to be a source of information not only about the use of New Zealand genetic resources and mātauranga Māori in inventions, but also genetic resources and traditional knowledge more generally. This may be of particular assistance to smaller states and indigenous peoples and local communities that may provide genetic resources and traditional knowledge, such as New Zealand's Pacific neighbours, if patent applicants would be more likely to seek protection in New Zealand.

Question

1	Do you have any comments on the problem definition?

3 Options analysis

60. We consider that the introduction of a disclosure of origin requirement could assist the problems outlined above by increasing available information on the use of genetic resources and traditional knowledge through New Zealand's patents regime, and supporting quality patent examination.

61. In this section, we outline three options for a possible disclosure of origin requirement. We then undertake a preliminary options analysis (that includes drawing on independent economic analysis of the three options) and conclude our analysis by discussing our preferred option. Your submissions will help to inform our final analysis.

Objectives

62. Taking into consideration the broader objectives of the *Patents Act* and the problems identified in the previous section, we have identified the following objectives:

- **Objective A:** Aid better quality decision-making in the patents regime.
- **Objective B:** Obtain quality information about the use of genetic resources and traditional knowledge (especially New Zealand genetic resources and mātauranga Māori).
- **Objective C:** Minimise compliance and administrative costs.
- **Objective D:** Aligns with New Zealand's international obligations and interests.

63. We assign a higher weighting to objectives A and B, as they directly respond to the problem definition. It is important, however, that the right balance is struck so that these objectives are met in a way that is not overly burdensome for New Zealand patent applicants or costly for IPONZ, and aligns with New Zealand's international obligations. This is recognised through the inclusion of objectives C and D.

64. We assess the options we have identified against these objectives below.

Question

2	Do you agree with the objectives that we have identified? Do you agree with the weighting we have given the objectives?

Status quo and options

65. Below, we outline the status quo and three options ranging from basic to strong mandatory disclosure of origin.

Status quo: Voluntary disclosure

66. In New Zealand, patent applicants have the option of disclosing whether their invention is derived from Māori traditional knowledge or indigenous plants or animals in the online patent application process. Applicants have the option of ticking a box to disclose this. No patent applicants have indicated the use of indigenous flora or fauna or mātauranga Māori in their inventions since the tick-box was made available through the application process in 2014.[17]

67. Patent applicants may also disclose the origin of any genetic resources or traditional knowledge in their patent specifications. This is not compulsory.

Option 1: Disclosure of country of origin, if known (basic mandatory disclosure)

68. Under Option 1, patent applicants would be asked to disclose the country of origin of any genetic resources and/or traditional knowledge used in their inventions. If the country of origin is not known or not applicable, applicants may make a declaration to that effect.

69. For genetic resources, the country of origin would be defined in alignment with the CBD definition of "country of origin of genetic resources" as meaning "the country which possesses those genetic resources in **in situ** conditions".[18] The country of origin may not be applicable in certain circumstances – for example, to marine genetic resources that are sourced outside of national jurisdiction.

70. For traditional knowledge, the country of origin may be the same as the country of origin of genetic resources. It may also be different – for example, if the genetic resources occur naturally in multiple countries and have been sourced from a different country to the traditional knowledge. Applicants would also have the option of declaring that the country of origin of the traditional knowledge is not known.

71. Option 1 is a formal requirement. Compliance with the requirement, through the provision of information or a declaration, would be required for an application to progress. However, the information disclosed would not be examined by IPONZ for accuracy.

Option 2: Disclosure of source (medium mandatory disclosure)

72. Option 2 requires further specificity in the content of information required for disclosure of origin as compared to Option 1.

[17] However, IPONZ have identified some pending applications to refer to the PMAC on their own initiative once the applicants request examination.
[18] Convention on Biological Diversity, article 2.

73. For genetic resources, applicants are still required to disclose the country of origin. If this is not known, or not applicable, they must make a declaration to that effect *and* disclose known information relating to the source of the genetic resources. For example, the applicant might disclose the gene bank that they directly acquired the genetic resources from.

74. For traditional knowledge, applicants are required to disclose the specific indigenous people or local community who supplied the traditional knowledge. If an indigenous people or local community did not supply the traditional knowledge, or the indigenous people or local community is not known to the patent applicant, the applicant must make a declaration to that effect and disclose known information relating to the source of the traditional knowledge. For example, the applicant might disclose a publication containing traditional knowledge. Like Option 1, Option 2 is a formal requirement.

Option 3: Disclosure of ABS compliance (strong mandatory disclosure)

75. Under Option 3, patent applicants are required to disclose:

    a. the country of origin of genetic resources, if applicable;

    b. the indigenous people or local community who supplied the traditional knowledge, if applicable; and

    c. evidence of compliance with the ABS legislation of the country of origin of genetic resources and/or traditional knowledge, if applicable.

76. Unlike Options 1 and 2, Option 3 is a substantive requirement. Under this option, IPONZ would be responsible for assessing whether compliance with other countries' ABS conditions has been achieved. Failure to provide evidence of compliance with relevant ABS legislation would be grounds for refusal to grant a patent, or revocation of the patent if it has been granted. This would be the case even if making the correct disclosure would have made no difference to the decision to grant the patent.

Preliminary options analysis

77. In our options analysis, we first assess how the options align with the objectives, as compared to each other and the status quo. To help us with this analysis, we draw on the findings of an economic evaluation of the options completed by Castalia Advisory Group, commissioned by MBIE. We conclude by discussing our preferred option.

Assessment of options against the objectives

Objective A: Better quality decision-making in the patents regime

78. Better quality decision-making, in the New Zealand context, includes:

    a. ensuring that relevant patent applications are referred to the PMAC; and

    b. helping to prevent the erroneous grant of patents.

79. All of the options would perform well against the status quo where patent applicants know the country of origin. However, we have heard anecdotally that it is not unusual for researchers to be unaware of the country of origin of the genetic resources used in their research when they have not accessed them in situ. We are interested in submitters' views on this.

80. Under Options 1 and 2, if patent applicants do not know the country of origin, they may declare their lack of knowledge. These declarations would not provide much assistance to IPONZ. The additional requirement under Option 2 to disclose the source of any genetic resources and traditional knowledge, however, could provide useful information relevant to patentability. For example, IPONZ may choose to refer an application to the PMAC where the applicant is unsure of the origin, but the source has been identified as New Zealand and the relevant species is indigenous to New Zealand.

81. Option 3 requires patent applicants to provide the largest quantity of additional information in order to be granted a patent: the country of origin and/or the indigenous people or local community who supplied the traditional knowledge, and evidence of compliance with the ABS regime of the relevant country of origin.

82. Applicants would have to disclose the country of origin of any genetic resources or traditional knowledge used in their inventions to be granted an enforceable patent (i.e. they could not declare lack of knowledge). For inventions that use New Zealand genetic resources or mātauranga Māori, this would potentially decrease the likelihood of relevant applications avoiding going through PMAC consideration. For inventions that use overseas genetic resources and traditional knowledge, Option 3 could result in IPONZ receiving more information relevant to patentability as compared to Options 1 and 2. For example, in some countries, compliance with bioprospecting regulation may require a competent authority's endorsement for the proposed use of a genetic resource, or traditional knowledge. This may support findings of novelty or inventive step.

Objective B: Obtain quality information about the use of genetic resources and traditional knowledge

83. Though Option 3 requires patent applicants to provide more information than Options 1 and 2, this option may not result in the provision of more information on genetic resources and traditional knowledge than Options 1 and 2, if it is considered too burdensome.

84. Option 3's requirement that applicants both know the country of origin/indigenous people or local community for genetic resources and/or traditional knowledge used respectively and provide evidence of compliance with ABS regulation is uncommon among developed countries. It is likely to require significant extra effort from prospective patent applicants. If the cost of providing that information is perceived to outweigh the benefits of patent protection, applicants are likely to be deterred from applying for patents over inventions based on genetic resources and/or traditional knowledge in New Zealand. They may choose to forego protection in New Zealand altogether, given the comparatively small size of our economy. In terms of provision of information, this may be worse than the status quo. Information that would have otherwise been made available for the possibility of

investigation by interested parties may not be made available in New Zealand at all (though it may be made available through other countries' patent registers).

85. The ability to declare lack of knowledge under Options 1 and 2 may allay some compliance concerns. Under Option 2, patent applicants would be required to provide information about their direct source of genetic resources or traditional knowledge. This would provide at least some information to allow IPONZ, or interested parties, to enquire into further should they wish to. On this basis, we consider Option 2 would be more likely to result in more information on the use of genetic resources and traditional knowledge, than the other options and the status quo.

Objective C: Minimise compliance and administration costs

86. In November 2017, MBIE commissioned Castalia to undertake an economic analysis of the impacts associated with the introduction of a mandatory disclosure of origin requirement in the patents regime. Castalia considered whether any of the proposed options would provide a net benefit or cost and what the value of the costs or benefits would be. Below we outline the compliance costs for New Zealand patent applicants specifically, and the direct costs to New Zealand's economy overall. Castalia's report can be found here: ***https://www.mbie.govt.nz/info-services/business/intellectual-property/patents/document-library/castalia-economic-assessment.pdf***

Compliance costs for New Zealand patent applicants

87. In considering the compliance costs of the options for New Zealand patent applicants,[19] Castalia quantified:

    a. the additional time that it would take for New Zealand patent and PVR applicants to submit an application;

    b. the additional legal fees associated with the options; and

    c. the cost of compliance with ABS schemes (for Option 3 specifically).

88. It estimated the costs as follows:

Table 6.1: Compliance cost estimation over 30 years (present value) for patents

Cost Type	Option 1	Option 2	Option 3
NZ Applicants Additional Time to Submit	$162,000	$203,000	$649,000
NZ Applicants Additional Legal Fees	$360,000	$360,000	$721,000
NZ Applicants Compliance with International ABS	Nil	Nil	$492,000
Total Present Value	$522,000	$563,000	$1,862,000

[19] As Castalia's economic assessment only includes the costs and benefits affecting the New Zealand economy, increased compliance costs for foreign applicants were not included in the study.

89. The additional compliance costs for New Zealand applicants under Options 1 and 2 as compared to the status quo are comparable, and low (given they are spread over 30 years)[20]. In contrast, Option 3 would have significantly higher costs for New Zealand applicants than Options 1 and 2, across every category. Castalia considered that the requirement of compliance with ABS laws in other countries would require patent applicants to invest significant extra time to comply, obtain additional legal advice, and share the benefits from the invention with the country of origin and/or indigenous people or local community.

90. In addition to quantifying the compliance costs to New Zealand patent applicants, Castalia also quantified material administrative costs to IPONZ. These were:

    a. Implementation;
    b. updating internal guidance procedures;
    c. additional training; and
    d. additional application processing time.

91. The administrative costs for Options 1 and 2 were equal at $250,000. The cost for Option 3 was $2,704,000. The difference in cost is attributable to the additional application processing time required under Option 3. Castalia assessed that IPONZ's role under Option 3 of confirming ABS compliance would take an average of four hours per patent application and quantified this cost accordingly.

Overall economic evaluation

92. Adding both the compliance and administrative costs, Castalia found that the present value[21] of the direct costs associated with the options across a 30-year period were as follows:

    a. Option 1: $772,000.
    b. Option 2: $813,000.
    c. Option 3: $4,556,000.

93. Altering key assumptions (such as discount rate, growth rate of applications, or the percentage of patents affected) did not alter Castalia's overall conclusion.

94. There are small administrative and compliance costs for Options 1 and 2. Though the cost of Option 3 is appreciably higher than Options 1 and 2, as Castalia identifies in its report, the cost is relatively small considered against the present value of a typical regulatory change over a long period, and the uncertainty surrounding this study. To put the cost of Option 3 in perspective, the present value additional cost per patent application over the next 30 years was found to be only $19.85. This would be $3.36 for Option 1 and $3.54 for Option 2.

[20] Thirty years is a standard period of time for evaluating the economic impacts of a regulatory change. There is no relationship between this assessment period and the period of patent protection (20 years).
[21] 'Present value' is the value in the present of a sum of money, in contrast to some future value it will have when it has been invested at a specified rate of return.

95. Analysis of the intangible benefits of a disclosure of origin requirement was not included in the scope of Castalia's brief. The intangible benefits identified by Castalia align with the objectives. They are:

    a. an increase in the volume and quality of information regarding the use of genetic resources and traditional knowledge in New Zealand patent applications;

    b. compliance with Treaty of Waitangi considerations; and

    c. a clearer international position on the issue of the use of other countries' genetic resources that could potentially lead to value to New Zealand through reciprocal international relationships.

96. Castalia considered that if the value of these benefits was considered to be greater than the direct costs identified in this study, all of the proposed options for change would be beneficial (i.e. the benefits would outweigh the costs).

Objective D: Aligns with international obligations and interests

International intellectual property law

97. The most comprehensive international intellectual property agreement is the TRIPS Agreement. TRIPS sets out minimum standards for intellectual property protection, including copyright, trade marks, patents, industrial designs, trade secrets and geographical indications. It is one of the mandatory agreements at the WTO. As a member of the WTO, New Zealand is party to TRIPS.

98. While TRIPS does not require member states to implement formal disclosure of origin requirements, it is generally accepted to be flexible enough to permit them. Article 29(1) of TRIPS outlines mandatory and optional patent application disclosure requirements. It does not prohibit countries from imposing additional disclosure requirements.

99. Other relevant treaties include:

    a. the Patent Co-operation Treaty (**PCT**), which allows patent applicants to use a unified process to seek patent protection across PCT's 150 contracting states; and

    b. the Paris Convention for the Protection of Intellectual Property, which facilitates patent applicants' ability to gain international intellectual property protection and establishes national treatment, right of priority and common rules for the different intellectual property regimes.

100. We consider that the options are also consistent with these treaties.

International biodiversity law

101. We consider that all of the options would support New Zealand's ability to meet its obligations under the CBD better than the status quo. Option 3 would provide the clearest link between the patents regime and the CBD as it requires evidence of ABS compliance with a foreign ABS regime before a patent based on genetic resources and/or traditional knowledge can be granted.

Free trade agreements

102. We also consider that the options are consistent with New Zealand's commitments under free trade agreements (**FTAs**). Under the majority of FTAs that New Zealand is a party to, there is specific recognition of the ability of parties' policy space to establish appropriate measures to protect traditional knowledge.

103. The Comprehensive and Progressive Agreement for Trans-Pacific Partnership (**CPTPP**), which has not yet come into force, contains specific recognition of the "relevance of intellectual property systems and traditional knowledge associated with genetic resources to each other". The Agreement states that Parties to the CPTPP shall endeavour to cooperate to "enhance the understanding of issues connected with traditional knowledge associated with genetic resources" and "pursue quality patent examination".[22]

Summary of options analysis

104. Table 2 provides a summary of our preliminary assessment of the options against the objectives. More weighting is given to objectives A and B.

Table 2: Summary of assessment of the options against the objectives

Objective	Status quo	Option 1	Option 2	Option 3
A: Aid better quality decision-making in the patents regime	0	+	+	++
B: Obtain quality information about the use of genetic resources and traditional knowledge	0	+	++	+
C: Minimise compliance and administrative costs	0	-	-	--
D: Aligns with New Zealand's international obligations/interests	0	+	+	+

Key:

++ much better than status quo

+ better than status quo

0 about the same as status quo

- worse than status quo

-- much worse than status quo

Preferred option

105. On the basis of the work done so far, MBIE's preferred option is Option 2. In our view, Option 2 would achieve a good balance to ensure the provision of quality information about the use of genetic resources and traditional knowledge through the patents regime, while not creating a significant deterrent or burden for patent applicants. The costs of this option over 30 years are relatively low, and we consider that the intangible benefits discussed above would be likely to outweigh them.

[22] Comprehensive and Progressive Agreement for Trans-Pacific Partnership, Article 18.16.

106. Current regulatory arrangements in New Zealand on bioprospecting and the state of international discussions on disclosure of origin also inform our assessment. If New Zealand were to implement an ABS regime for the use of its genetic resources and Māori traditional knowledge, Option 3 would allow the patents regime to serve as a checking system for compliance with that regime. This would likely affect our analysis. Should the government develop a bioprospecting regime, MBIE could review any disclosure of origin requirement that may result from this process. Without this, introducing an "evidence of ABS compliance" requirement would primarily benefit foreign countries (and indigenous people or local communities) with ABS regimes, not New Zealand or kaitiaki. We understand that bioprospecting policy is not under consideration at this time.

Implications of the preferred option on our international approach

107. New Zealand may gain more economic benefits from the introduction of a disclosure of origin requirement in major economies with high volumes of pharmaceutical and biotechnology patents (such as the United States of America) than it would from introducing a disclosure requirement domestically. The introduction of a disclosure requirement in such jurisdictions could incentivise researchers to seek prior informed consent of, and share benefits with, the states, indigenous peoples or local communities (including iwi and hapū), that hold an interest in the genetic resources and traditional knowledge that they use.

108. If the Government decided to implement a disclosure of origin requirement in our domestic patents regime, New Zealand would need to consider whether, how and in what contexts we might support the introduction of an international patent disclosure of origin requirement.

Questions

3	Do you have any comments on our preliminary assessment of the options?
4	What is your preferred option? Why?
5	Do you have any comments on how New Zealand should approach international discussions relating to disclosure of origin requirements?

4 Key design features

109. Below, we seek your feedback on some of the key design features that could be applied to the options set out in section 3.

110. The design features discussed are:

   a. subject matter;

   b. trigger; and

   c. sanctions and remedies.

Subject matter

111. The options tested above refer to the subject matter of the disclosure as genetic resources and traditional knowledge. However, the exact scope of these terms will need to be clarified further.

Genetic resources

112. Internationally, there is a broad range of concepts used in disclosure requirements, including "biological material", "biological material of plant or animal origin", "elements of biodiversity" and "genetic resources". The Tribunal recommended the subject matter be "any genetic or biological resource". "Biological resources" is defined in the CBD as including "genetic resources, organisms or parts thereof, populations or any biotic component of ecosystems with actual or potential use or value for humanity".[23] This definition is not entirely clear.

113. Another relevant concept in this area is "derivatives" of genetic resources. The Nagoya Protocol defines derivatives as "a naturally occurring biochemical compound resulting from the genetic expression or metabolism of biological or genetic resources".[24] Examples are plant resin or snake venom. While derivatives do not contain "functional units of heredity", some have interpreted their inclusion in the Nagoya Protocol to require ABS requirements to extend to them. While New Zealand is not a member of the Nagoya Protocol, these considerations are relevant to the scope of the subject matter for which disclosure of origin might be sought. We seek your views.

[23] Convention on Biological Diversity, article 2.
[24] Nagoya Protocol, article 2.

114. Finally, we are also interested in submitters' views on whether genetic sequence data should be within the scope of the subject matter that triggers disclosure of origin obligations. The World Health Organization has defined "genetic sequences" as "the order of nucleotides found in a molecule of DNA or RNA… contain[ing] the genetic information that determines the biological characteristics of an organism or virus".[25] The use of genetic sequence data, rather than physical genetic material, may facilitate cheaper and quicker research and development processes.

115. Whether genetic sequence data – also referred to as digital sequencing information or digital DNA – is covered by the concept of "genetic resources" in the CBD and Nagoya Protocol is contested. States have taken different approaches to this issue. Some states assert that genetic sequence data does fall under the CBD and Nagoya Protocol and consequently should be subject to ABS requirements. Most developed countries, however, consider that the CBD and Nagoya Protocol should apply to physical genetic material only, citing a possible chilling effect on research using genetic sequence data if researchers are required to pay countries of origin for access. We are interested in your views on whether the use of genetic sequence data should trigger disclosure of origin obligations.

Traditional knowledge

116. In the Wai 262 report, the Tribunal endorsed a WIPO definition of "traditional knowledge", as follows:[26]

> *the term 'traditional knowledge' refers to the content or substance of knowledge resulting from intellectual activity in a traditional context, and includes the know-how, skills, innovations, practices and learning that form part of traditional knowledge systems, and knowledge embodying traditional lifestyles of indigenous and local communities, or contained in codified knowledge systems passed between generations. It is not limited to any specific technical field, and may include agricultural, environmental and medicinal knowledge, and knowledge associated with genetic resources.*

117. The *Patents Act* currently refers to "Māori traditional knowledge" in relation to the role of the PMAC, though this is not defined. We seek your feedback on whether a definition of traditional knowledge would be helpful as part of any new disclosure of origin requirement.

Trigger

118. Whether patent applicants using genetic resources or traditional knowledge in a claimed invention would be required to comply with any new disclosure requirement will depend on the relationship between the relevant genetic resources or traditional knowledge, and the claimed invention. This relationship is referred to as the "trigger".

[25] World Health Organization *Pandemic influenza preparedness Framework* (2011) at 8.
[26] Waitangi Tribunal *Ko Aotearoa Tēnei: A Report into Claims Concerning New Zealand Law and Policy Affecting Māori Culture and Identity: Te Taumata Tuarua* (Wai 262, 2011) vol 1 at 204.

Genetic resources

119. In other countries, triggers for disclosure of origin for genetic resources vary, including:

    a. "utilisation of genetic resources," consistent with the Nagoya Protocol definition;[27]

    b. "where the invention is derived from genetic resources" (which could encompass anything from direct physical derivation from a genetic resource, to something created from derivation from genetic sequence data); and

    c. "where the invention is based or directly based on genetic resources," which requires the invention to make immediate use of, and depend on the specific properties of, the genetic resources.

120. The Tribunal recommended that the disclosure requirement be triggered where genetic resources "contributed in any material way to the invention". This seems aligned with the "based on" formulation. We seek your feedback on whether this is the appropriate trigger for disclosure of origin for the use of genetic resources.

Traditional knowledge

121. The "utilisation", "derivation" and "based on" triggers can also be used for traditional knowledge. The inventor must have had knowledge of the traditional knowledge and used it to develop their invention.

122. The Tribunal required disclosure where mātauranga Māori was "used in the course of research, including traditional knowledge that is not integral to the invention but that prompted the inventor to take the course of research that led to the relevant patent application".[28] This seems aligned with the "utilisation" or "derivation" trigger.

123. We seek your feedback on the appropriate trigger for traditional knowledge. We also seek your feedback as to whether the triggers for genetic resources and traditional knowledge should be aligned.

Sanctions and remedies

124. The consequences of non-compliance are an important aspect of disclosure requirements at the national level. Examples include:

    a. halting proceedings under the *Patents Act*;

    b. invalidation of the patent; and

    c. civil, administrative and criminal remedies and sanctions.

[27] This is conducting "research and development on the genetic and/or biochemical composition of genetic resources, including through the application of biotechnology", Nagoya Protocol, article 2.

[28] Waitangi Tribunal *Ko Aotearoa Tēnei: A Report into Claims Concerning New Zealand Law and Policy Affecting Māori Culture and Identity: Te Taumata Tuarua* (Wai 262, 2011) vol 1 at 204.

125. The Tribunal recommended that the consequences of failure to disclose would be a "matter of discretion for the Commissioner [of Patents], sitting with the chair of the [PMAC]". It explained further, as follows:[29]

> *...in some cases, there will be no sanction at all, because the effects on the relationship are limited or the parties have found ways to mitigate possible detrimental effects. In other cases, a patent will be revoked or refused – but only when the merits of the case justify it.*
>
> *We consider this approach desirable because it is likely to have a proportionate impact on research and patenting behaviour.*

126. We consider that the Tribunal's proposed approach may not provide sufficient certainty for patent applicants. Our proposed approach under Option 2 would be to require patent applicants to disclose whether genetic resources or traditional knowledge are used in their invention. These applications would not be considered complete unless the relevant origin/source disclosure and/or declaration had been provided.

127. As we have mentioned above, we recommend a formal disclosure of origin requirement. Information disclosed would generally not be examined for accuracy by IPONZ unless this was considered to be relevant to patentability.

128. If an incomplete or false declaration and/or disclosure became known to IPONZ, the consequences would be as follows:

a. If pre-grant, IPONZ would not progress the relevant application until the correct information was provided.

b. If post-grant, the scope of the patent could be narrowed, or the patent could be revoked, but only if the provision of accurate information would have meant the patent would not have been granted as it was.

129. If the patent applicant has knowingly made a false declaration or disclosure, there would be financial penalties.

130. We consider that this approach balances the need for proportionate sanctions and legal certainty. We welcome submitters' views.

Questions

6	What are your views on the design features of a potential disclosure of origin requirement?
7	Are there other design considerations that we should consider?

[29] Ibid.