

## **Responses to questions in discussion paper: *Disclosure of origin of genetic resources and traditional knowledge in the patents regime***

### **1. Do you have any comments on the problem definition?**

The problem definition appears to be based on suppositions rather than evidence. The word “may” qualifies both issues in paragraph 52 as well as in the examples in paragraphs 53 to 56. Unless a problem is properly quantified, there may not be a problem at all, or that it may be so minor as not to require parliamentary attention. Proposing a new policy without evidence of a need for that policy is bad policy.

In addition, the second issue (lack of information available) is open to serious doubt. A starting point would be Murdock Riley’s 1994 book “**Māori Healing and Herbal**”. A brief synopsis of the book reads:

First section of this book surveys Māori health and healing from the pre-contact period with Europeans to the present time. It itemises individual ailments and subjects, discussing the spiritual and herbal healing needed. The second section contains information on some 200 plants with colour photographs of each. This book details New Zealand and world medicinal information according to the particular botanical family. Award winning book with wide appeal, also a recommended textbook for students.<sup>1</sup>

A University of Auckland research team analysed 396 compounds from New Zealand flora with medicinal properties. The results were published<sup>2</sup> in the journal **Chemistry, an Asian Journal**. The results of the research were reviewed<sup>3</sup> on the website *Stuff*. The review also refers to a classic book, *New Zealand Medicinal Plants*.

A research study<sup>4</sup> co-funded by University of New South Wales and Victoria University identified 77 patent families for inventions using plant species connected to traditional Māori knowledge. Of these, 33 covered some aspect of mānuka, either the plant, isolates of the plant, or honey made from it.

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<sup>1</sup> *Maori Healing and Herbal*: <https://www.wheelers.co.nz/books/9780854670956-maori-healing-and-herbal/#desc>

<sup>2</sup> Pilkington, Lisa I., et al., *A Chemometric Analysis of Compounds from Native New Zealand Medicinal Flora*: <https://onlinelibrary.wiley.com/doi/full/10.1002/asia.201800803> (Paywall protected.)

<sup>3</sup> *Native plants rich source of potential drugs, new analysis finds*: <https://www.stuff.co.nz/science/106716402/natives-rich-source-of-potential-drugs>

<sup>4</sup> *Patents threaten to misappropriate Māori knowledge*, Newsroom, 10 July 2018: <https://www.newsroom.co.nz/2018/07/09/145825/patents-raise-concern-over-threat-to-maori-knowledge>

There is an entire chapter in *Te Ara, the Encyclopedia of New Zealand* on Rongoā medicinal use of plants.<sup>5</sup>

It is submitted that the assertion that there is a lack of information available in research seems to be based on an assumption without having looked for evidence. Patent examiners and patent attorneys are trained to search in the almost unlimited online resources. If examiners do not include such sources in their searches then they should.

The problem identified in chapter 2 of the Wai 262 report<sup>6</sup> was that in the continuum from bioprospecting to commercialisation of product derived from taonga species there was little if any recognition of and protection for kaitiaki relationships. This should be addressed across the entire continuum - starting with a bioprospecting policy. The problem definition in the discussion paper does no more than state that there **may** be a lack of identification that an invention has been derived from a taonga species. That is far narrower than the problem definition in the Wai 262 Report, which should have formed the problem definition of this discussion paper. (Please also refer to the answer to question 4 below.)

## **2. Do you agree with the objectives we have identified? Do you agree with the weighting we have given the objectives?**

**Objective A:** This objective would be better stated as “better informed decision-making”. The quality of decision-making depends on how well examiners apply the law in examining patent applications. Being better informed is a part of making better decisions, but not the most important part.

On the other hand, better quality decision-making might result if the law in respect of section 15 of the Patents Act 2013 and its relationship to section 226 (b) were made clearer. By section 226 (b) the Māori advisory committee is to advise if the commercial exploitation of an invention is *likely to be contrary to Māori values*. But the Commissioner (for that, read “the examiners”) are then to determine whether or not being contrary to Māori values is contrary to *public order* or morality with no case law for guidance. Is “contrary to Māori values” the same as contrary to public order or morality? Or is “contrary to Māori values” a threshold after which examiners have to decide whether the commercial exploitation identified is also contrary to public order or morality. The only guidance to be found is in the Examination manual, which states:

*The concept of public order covers the protection of public security and the physical integrity of individuals as part of society, and encompasses the protection of the environment. With respect to morality, the culture inherent in New Zealand society as a whole or a significant section of the community should form the basis for determining what behaviour is right and acceptable, and what behaviour is*

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<sup>5</sup> *Te Ara, Rongoā medicinal use of plants*: <https://teara.govt.nz/en/rongoa-medicinal-use-of-plants/page-1>

<sup>6</sup> *Ko AoteAroA tēnei. A Report into Claims Concerning New Zealand Law and Policy Affecting Māori Culture and Identity. Te Taumata Tuarua*, Volume 1, pp 210 - 212

*wrong or immoral. The concerns of interest groups, evidence including appropriate public polls and research, corresponding foreign legislation, caselaw and guidelines may be taken into consideration.<sup>7</sup>*

It is submitted that better quality decision-making would be achieved by clarifying what sections 226(a) and 15(1) actually mean. Inserting a disclosure of origin (DoO) requirement would do nothing to clarify the meaning of the two sections.

**Objective B:** For all the reasons pointed out in the answer to question 1, “quality” information about the use of traditional knowledge in New Zealand is already available to anyone who goes looking for it.

**Objective C:** Any proposal to add an additional procedural requirement would inevitably add some cost. The objective would be better stated as seeking to minimise additional compliance and administrative costs inherent in adding a new requirement.

The Castalia report, on pages 22 and 23, states that in calculating the additional costs “We use the average of an additional [number] of hours.” Where that number came from is not disclosed. How many applications by New Zealand based applicants were considered relevant (and used as a multiplier in their calculations) is not disclosed. It then (on page 23) assumes that 5% of all New Zealand applications would be based on GR or TK without stating the basis for that assumption. Castalia then did a lot of number crunching and sensitivity analyses to come up with the figures that are quoted on page 16 of the discussion paper. But that final calculation is no better than the accuracy of the guesses as to how much time each application would take and how many applications there would be. The cost benefit analysis ends with the conclusion: **if** the benefits (which we cannot estimate) outweigh the costs, then the policy is beneficial. That statement of the obvious does not give much confidence for concluding that the net value of the DoO proposal is positive.

**Objective D:** Objective D is to align our law with New Zealand’s international obligations and interests. But paragraph 108 of the discussion document states that if a DoO requirement were adopted in New Zealand we “would need to consider whether, how and in what contexts we might support the introduction of an international patent disclosure of origin requirement.” How can the DoO proposal align our law with our international obligations and interests when those obligations and interests do not yet exist?

### **3. Do you have any comments on our preliminary assessment of the options?**

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<sup>7</sup> *The Patent Examination Manual, Section 15, paragraph 5:*  
<https://www.iponz.govt.nz/about-ip/patents/examination-manual/>

Please refer to the answer to question 4.

#### **4. What is your preferred option? Why?**

I do not prefer any of the listed three options. This discussion paper and the workshop in Wellington on 22 November were all directed to considering **how** a DoO requirement should be put in place – not **whether** there should be a DoO requirement in the Patents Act 2013. This is not proper consultation – it is coercion under the guise of consultation.

The Wai 262 Report was published in 2011. So far there has been no government response. It is not stated whether the DoO proposal is a partial response, a total response or not at all a response to the Wai 262 report.

The Wai 262 Report noted:

We have said throughout this chapter that bioprospecting, GM, and IP are not isolated subjects but points along a single path from discovery to exploitation of commercially valuable biological material. IP rights, particularly patents, are both the culmination of the research process and the starting point for commercial development.

**If the kaitiaki interest is not protected in the entire research continuum from bioprospecting to the commercialisation phase, there is a real and demonstrable risk that commercial interests will always override the kaitiaki interest.** We are not suggesting the proposed disclosure requirement is the whole answer to the issue, but it provides an effective mechanism to ensure that kaitiaki interests are at the table when patent decisions are made. [Emphasis added.]<sup>8</sup>

The DoO proposal is ignoring an important point made in the Wai 262 Report – that the kaitiaki interest should be protected along the entire research continuum. The DoO proposal would only engage kaitiaki interests near at the patenting end of the continuum - where “there is a real and demonstrable risk that commercial interests will always override the kaitiaki interest.” There is no bioprospecting regime in place or proposed that would provide a mechanism for early engagement of kaitiaki, before commercial interests have overridden kaitiaki interest. A standalone DoO requirement is the worst possible response to the Wai 262 recommendations. It would create uncertainties for applicants and it would create false hope for kaitiaki who would have no legal power to enforce a kaitiaki relationship. (Please also refer to the answer to question 7 as to why a DoO requirement would be ineffective in protecting the kaitiaki relationship.)

#### **5. Do you have any comments about how New Zealand should approach international discussions relating to disclosure of origin requirements?**

The WIPO IGC discussions on access to genetic resources have been going on since 2000. The 38<sup>th</sup> session was held in Geneva in December 2018. At least one

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<sup>8</sup> *Te Taumata Tuarua*, Volume 1, p206

New Zealand representative has attended many of those sessions. This begs the question, what has been the New Zealand approach up until now? That should have been explained in the discussion paper and the question that should have been asked was whether that approach was the correct one and/or whether it should be changed.

It has become apparent that the IGC discussions have become institutionalised – with no end point in sight. The WIPO general assembly in 2017 agreed to renew to IGC’s mandate<sup>9</sup> for 2018/19. All of the current work is focused on reaching some agreement on traditional knowledge (TK) and traditional cultural expressions (TCE). The only mention of genetic resources (GR) and TK is in paragraph 8 of the mandate: “The Secretariat is also requested to produce a report(s) compiling and updating studies, proposals and other materials relating to tools and activities on databases and on existing disclosure regimes relating to GR and associated TK, with a view to identify any gaps.” There will not even be negotiations on an international regime for GR and associated TK before 2020/21 - if the WIPO general assembly agrees to continue to fund the negotiations. Until a New Zealand government response has been made to the Wai 262 report and put in place there does not appear to be much that New Zealand can add to “identify any gaps” in the vast amount of material that has already been generated in the IGC discussions.

Also, there is an inherent tension between the objective of establishing and maintaining kaitiaki relationships in New Zealand and the emphasis internationally on access and benefit sharing. The former may mean that a resource should not be exploited at all, or, if it is, exploited in a limited way. In the latter the emphasis is on exploitation under an ABS agreement. New Zealand should consider whether it should have a Treaty exclusion clause (similar to Annex 18-A of the TPP Agreement) in any other international agreement it enters into.

## **6. What are your views on the design features of a potential disclosure of origin requirement?**

If any DoO requirement is to be consistent with the Patents Act section 226 (b) wording of “contrary to Māori values” then there must be some link between the genetic resource and traditional knowledge. This was tacitly acknowledged in the Wai 262 Report:

While Māori can say they created taonga works and mātauranga Māori, they did not create taonga species. In fact, at a cultural level at least, the relationship is the reverse – the taonga species created Māori culture. A general case for exclusive proprietary rights in the genetic and biological resources of taonga species cannot be justified by reason only of cultural association.<sup>10</sup>

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<sup>9</sup> *Matters Concerning the Intergovernmental Committee on Intellectual Property and Genetic Resources, Traditional Knowledge and Folklore*:  
[https://www.wipo.int/export/sites/www/tk/en/igc/pdf/igc\\_mandate\\_2018-2019.pdf](https://www.wipo.int/export/sites/www/tk/en/igc/pdf/igc_mandate_2018-2019.pdf)

<sup>10</sup> *Te Taumata Tuarua*, Volume 1, pp192,193

Paragraph 126 of the discussion paper suggests that an applicant would be required to disclose if genetic resources were used - even if there was no associated traditional knowledge. It is not clear that this would serve any purpose because it would be asserting that there is proprietary right in a genetic resource per se (a taonga species) which the Wai 262 Report says there isn't.

For practical reasons biological resources should not include microorganisms. Microorganisms are ubiquitous<sup>11</sup> and their source could be anywhere.

Paragraph 129 suggests that there should be financial penalties for a false declaration. This would presumably mean creating a new offence provision. None of the offence provisions of the Patents Act 1953<sup>12</sup> were carried forward into the 2013 Act. It is not seen why a threat of a fine would be more of a deterrent than the loss of rights that would result from a false declaration.

## **7. Are there other design considerations that we should consider?**

The Wai 262 report recommended:

Before a matter reaches the IPONZ decision-making process, there are mechanisms which can be used to ensure that applicants and kaitiaki have early notice of each other, and to enable kaitiaki to participate in an application for registration if they have concerns. The goal is that notice of competing interests should be given as soon as possible so that concerns may be resolved early.<sup>13</sup>

However, this early notice is not achievable through a DoO requirement because of patenting procedures. A typical patent procedure for a New Zealand invention involves the filing of a provisional patent application followed 12 months later with the filing of a PCT international application. If New Zealand is considered of sufficient commercial interest the applicant might then enter the national phase in New Zealand 31 months after the original provisional filing date. The applicant has until 5 years from the international filing date to request examination of the application and then has to wait until the application reaches its turn in the queue before it "reaches the decision making process". If examination determines it should have had a disclosure of origin statement, or that the statement is inadequate the "early" notice sought by the Wai 262 report would only happen some 6+ years after a provisional specification was filed. PCT international applications are published 18 months from their priority date. But there are 240,000+ PCT international applications filed annually. It would be a mammoth task to try to monitor each application to have notice that an application might contain an invention derived from a taonga species or mātauranga Māori.

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<sup>11</sup> *Scientists identify vast underground ecosystem containing billions of micro-organisms*: <https://www.theguardian.com/science/2018/dec/10/tread-softly-because-you-tread-on-23bn-tonnes-of-micro-organisms>

<sup>12</sup> Patents Act 1953, ss 105 to 108

<sup>13</sup> *Te Taumata Tuarua*, Volume 1, p 202

The other mechanism recommended in the Wai 262 report for giving early notice was a register of kaitiaki interests:

... [W]e see considerable value in kaitiaki being able to register their interest in taonga species and mātauranga Māori. First, it provides a clear statement of the Māori interest. It also gives kaitiaki the opportunity to demonstrate the depth of their commitment to safeguarding their relationship with particular mātauranga Māori or taonga species. This proactive approach means kaitiaki can register their interest only when they think it is essential to do so. Secondly, a register gives patent applicants fair warning of the kaitiaki interest and of the need to engage with them, and in this way provides applicants with the level of certainty required to protect their economic interests. Certainty and transparency are fundamental to successful engagement between the parties.<sup>14</sup>

If the intention is to follow the early engagement recommendation of the Wai 262 report, a disclosure of origin requirement is not the mechanism for doing so. The register of kaitiaki interests recommended in the Wai 262 Report would be available to all stakeholders **before** a patent application was filed and would be better suited to the recommendation than a DoO requirement.

## **8. Are there additional comments that you wish to make about the Disclosure of Origin paper?**

The Wai 262 Report noted that its recommendations should not be applied retrospectively. It went on to say:

Having said that it is unrealistic to attempt to claw back exclusive and undisturbed possession of this knowledge, there remains a just claim against those who would seek to exploit that knowledge for commercial gain without proper acknowledgement of the prior rights of kaitiaki. After all, the relevant mātauranga Māori will always be a creation of the relevant kaitiaki community, and it would be most unfair to deprive that community of a say in its commercial exploitation.

Thus, what can be amply justified are three rights. First, the right of kaitiaki to acknowledgement, secondly, their right to have a reasonable degree of control over the use of mātauranga Māori, thirdly, any commercial use of mātauranga Māori in respect of taonga species must give proper recognition to the interests of kaitiaki. Just what is 'proper recognition' must depend on the circumstances. Kaitiaki relationships with their mātauranga will all be different, just as they often are with taonga species. There will be cases where a consent requirement is appropriate. In others, disclosure or consultation will be sufficient. The answer will depend on the balancing process in which the importance of the relationship will be weighed against the interests of researchers or the holders of IP rights on a case-by-case basis.<sup>15</sup>

There is a disconnect between these three rights and the patents regime – even if that regime were amended to include a DoO requirement. At best the requirement would only oblige an *acknowledgement* of the rights of kaitiaki.

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<sup>14</sup> *Te Taumata Tuarua*, Volume 1, p 202

<sup>15</sup> *Te Taumata Tuarua*, Volume 1, p 195



There is no nexus between the legal concepts of “contrary to Māori values”, “contrary to public order or morality” in the Patents Act and control over the use of mātauranga Māori. The Patents Act has no mechanism for requiring proper recognition. It only provides a mechanism for refusing an application or revoking a patent if the commercial exploitation of the invention claimed is contrary to public order or morality.

The patent right is only a right to exclude others from exploiting an invention. It is not a licence to exploit the invention. Therefore a patent owner may exploit an invention without any proper recognition of the interests of kaitiaki even if the patent is not granted or revoked. And because patent laws are national, the owner would be able to obtain patents in other countries where patent laws disregard kaitiaki relationships.

The three Wai 262 rights are already, in substance, recognised and made compulsory in the Code of Professional Standards and Ethics in Science, Technology, and the Humanities of the New Zealand Royal Society.<sup>16</sup> The interpretation document of the code provides in clause 5:

*Members are obliged:*

***5. In undertaking their activities, to endeavour, where practicable, to partner with those communities and mana whenua for whom there are reasonably foreseeable direct impacts and to meet any obligations arising from the Treaty of Waitangi.***

To meet this standard, Members should —

- a. endeavour to identify potentially affected communities, hapū or iwi prior to commencement of the activity and, where practicable, ascertain whether they wish to participate; and
- b. where practicable and appropriate, involve any participating community, hapū or iwi in the development of the aims, design of the activity and the selection of means for its execution; and
- c. where practicable and appropriate, both involve and adequately resource participating communities, hapū and iwi as partners in the activity and respect their rights and cultural practices; and
- d. recognise and respect any established rights and interests of participating or affected communities, hapū or iwi, in intellectual property, mātauranga,<sup>17</sup> or of

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<sup>16</sup> *Code of Professional Standards and Ethics in Science, Technology, and the Humanities*: <https://royalsociety.org.nz/assets/Uploads/Code-Overview-A3-web3.pdf>

<sup>17</sup> Mātauranga Māori is the intellectual capital generated by whānau, hapū and iwi over multiple generations. It is a shared-community knowledge that is embedded in lived experience and carried in stories, song, place names, dance, ceremonies, genealogies, memories, visions, prophesies, teachings and original instructions, as learnt through observation and copying of other community members. It is a holistic system of orally passed knowledge, concepts, beliefs and practice. Mātauranga Māori, mātauranga ā-iwi,



materials, samples, data or information gathered or developed during the research, including obtaining necessary permissions to use existing mātauranga and giving effect to any established right to participating or affected community, hapū or iwi ownership of new knowledge created during the activity; and

e. endeavour, where practicable, to share those results and findings that are specific to the participating or affected community, hapū or iwi with them in advance of publishing or otherwise communicating the results and findings to others.

Most professional scientists in New Zealand are members of the Royal Society.<sup>18</sup> All members will be bound by the code when it comes into force on 1 January 2019. Making this code a part of a bioprospecting regime would be a far more effective means of assuring the three rights sought by the Wai 262 Report than would a DoO requirement in the Patents Act. And the primary requirement of the code is early engagement.

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mātauranga ā-hapū, and mātauranga ā-whānau are dynamic, innovative, and generative systems of knowledge.

<sup>18</sup> *List of Members of the Royal Society of New Zealand*: <https://royalsociety.org.nz/who-we-are/our-people/our-members/view-our-members/>