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Review of the Plant Variety Rights Act 1987; Disclosure of origin of genetic resources and traditional knowledge in the patents regime

Dear Carolyn,

Auckland UniServices Limited (**UniServices**) welcomes the opportunity to respond to the September 2018 issues papers on the *Review of the Plant Variety Rights Act 1987* (**PVR Review**) and *Disclosure of origin of genetic resources and traditional knowledge in the patents regime* (**Disclosure of Origin Review**).

PVR Review

UniServices supports:

1. the implementation of a *sui generis* PVR regime that gives effect to the 1991 version of the International Convention on the Protection of New Varieties of Plants (**UPOV 91**). The *sui generis* approach is preferable to direct ratification of UPOV 91 as it allows the New Zealand government to meet its obligations under the Comprehensive and Progressive Agreement for Trans-Pacific Partnership (**CPTPP**) whilst also meeting its Te Tiriti o Waitangi obligations to Māori by incorporating the Ko Aotearoa Tēnei (**Wai 262**) recommendations and recognising kaitiaki relationships with taonga species and mātauranga Māori;

2. the inclusion of explicit provisions in the *sui generis* PVR regime to enable the Commissioner of PVRs to refuse a PVR that would adversely affect a kaitiaki relationship and also refuse a PVR name that would be likely to offend a significant section of the community, including Māori; and

3. the expansion of the role of the Māori Advisory Committee for patents and trademarks to include PVRs and for the committee to be empowered (and appropriately resourced) to advise the Commissioner on the existence and scope of kaitiaki relationships, and to publish guidelines and codes of conduct for those working in research and development.

Disclosure of Origin Review

In summary, UniServices recommends that MBIE revise the Discussion Paper to more carefully consider the stated Objectives and proposed Options. Below we have proposed a further Option (2A) which would require:

a. disclosure of the origin of genetic resources and traditional knowledge (GR/TK) for all applicants; and

b. compliance with Access and Benefit Sharing (ABS) guidelines for GR/TK **originating in New Zealand**; and

c. **for GR/TK originating outside New Zealand**, a declaration that ABS guidelines for the originator country from the country of origin have been complied with.

The current government has an opportunity to respond in good faith to the Wai 262 report through the adoption of a disclosure of origin **and** ABS system. Many of New Zealand's trading partners have already adopted these policies. ABS guidelines and disclosure of origin in patent applications are becoming the international norm. New Zealand, with its progressive history of civil and human rights, has the opportunity to position itself as a global leader for the promotion of indigenous knowledge, research and scholarship, and should carefully consider how to implement these policies for mutual benefit to commerce and culture.

Do you have any comments on the problem definition?

The problem definition is currently too narrow. The principle of Disclosure of Origin is internationally recognised and already adopted by many countries both with and without indigenous populations[1]. The suggestion that the only Problems addressed by Disclosure of Origin are addressing Patents Māori Advisory Committee (PMAC) referrals and a lack of information about the use of genetic resources (GR) and mātauranga Māori (MM) in research is misinformed.

The current narrowly-defined problems unfortunately lead to an equally narrowly-defined solution. In summary, we believe the Problem section should be revised to consider the international discussion of this topic that has been going on for over two decades. There is a substantial international body of work that should not be ignored when considering the path that New Zealand should follow for this legislation. This body of work includes Technical Studies, Questionnaires and Studies on existing law in other countries. The "Context and Purpose" section of the Discussion Paper recognises the background to the principle of Disclosure of Origin but this is omitted when the Problem is defined. Outlined below are some key documents which set out the background and discussion regarding the Disclosure of Origin principle:

D1 - Technical Study On Disclosure Requirements In Patent Systems Related To Genetic Resources And Traditional Knowledge

The World Intellectual Property Organisation (WIPO) published a 72 page study on this exact topic in 2004 entitled: Technical Study On Disclosure Requirements In Patent Systems Related To Genetic Resources And Traditional Knowledge.[2] One does not have to read far to understand that the principle of Disclosure of Origin in intrinsically linked to the Convention on Biological Diversity (CBD). In the Executive Summary of the WIPO Study it states:

"One widely discussed possible approach to enhancing the relationship between the IP system and the CBD has been to strengthen or broaden disclosure obligations in the patent system so that information is specifically required about genetic resources or traditional knowledge used in the claimed invention"

The CBD provides that each Contracting Party:

"shall endeavour to develop and carry out scientific research based on genetic resources provided by other Contracting Parties with the full participation of, and where possible in, such Contracting Parties"

and

[1] WIPO 2017 table of countries and requirements:https://www.wipo.int/export/sites/www/tk/en/documents/pdf/genetic_resources_disclosure.pdf
[2] https://www.wipo.int/edocs/pubdocs/en/tk/786/wipo_pub_786.pdf accessed 11 December 2018

"shall take legislative, administrative or policy measures, as appropriate [and subject to certain conditions] with the aim of sharing in a fair and equitable way the results of research and development and the benefits arising from the commercial and other utilization of genetic resources with the Contracting Party providing such resources"

The problem addressed by the Disclosure of Origin principle is therefore broader than simply PMAC referrals and a lack of information about the use of GR/traditional knowledge (TK) in research. In fact, the principle originated from a consensus to address:

a. unregulated bioprospecting that may exploit or offend communities or countries; and

b. sharing of benefits from commercialisation of genetic resources and traditional knowledge.

New Zealand is a signatory to the CBD. Therefore legislation enacted by the government should consider the international context of the Disclosure of Origin principle. The international context is that:

a. many countries have already adopted Disclosure of Origin obligations;

b. Disclosure of Origin requirements are related to the CBD which requires signatories to comply with the CBD's access and benefit sharing (ABS) provisions; and

c. many countries have signed and ratified the Nagoya Protocol (which is a supplementary agreement to the CBD) which obliges them to aim to recognise the use of genetic resources and traditional knowledge, and share the benefits arising from their use in a fair and equitable way. New Zealand deferred signing the Nagoya Protocol until *"domestic policy issues relating to the Wai 262 claim, and ambiguity regarding the application of the Protocol to certain sectors (e.g. agriculture), are resolved or clarified"* [3]

The Wai 262 report was issued in 2011 and the government is yet to respond to the report or sign the Protocol.

As recognised in the Discussion Paper, the Disclosure of Origin principle has particular relevance to New Zealand following the 2011 publication of the Wai262 report.

D2 - Report on Disclosure of Origin in Patent Applications. Prepared by Queen Mary Intellectual Property Research Institute for the European Commission[4]

This 2004 document also states the purpose of the Disclosure of Origin principle as being:

"...intended to help realise fair and equitable benefit sharing as required by the Convention on Biological Diversity. It is supposed to do this by ensuring that the resources and, in some cases, TK, were acquired in accordance with biodiversity access and benefit sharing regulations in the provider countries, and other provisions of the Convention on Biological Diversity relating to national sovereignty, technology transfer and the knowledge, innovations and practices of indigenous and local communities embodying traditional lifestyles"

Chapter 2 of this document provides some commercial and political context in order to understand why the disclosure of origin proposal was formed and to explain the problems it is intended to solve. In summary, the proposal was formed to address perceived or actual misappropriation and monopolisation of genetic resources and traditional knowledge without benefit sharing, alleged to be mainly by Western corporates or governments.

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[3] MFAT archived website https://web.archive.org/web/20120812102259/http:/mfat.govt.nz/Foreign-Relations/1-Global-Issues/Environment/7-Species-Conservation/geneticres.php accessed 12 December 2018

[4] http://trade.ec.europa.eu/doclib/docs/2005/june/tradoc_123533.pdf accessed 11 December 2018

A similar problem exists in New Zealand where Māori communities often mistrust the government and researchers seeking to study or commercialise genetic resources. Therefore the problems that the Disclosure of Origin principle seeks to address are ultimately ones of transparency, trust and respect.

D3 - Disclosure of Origin in Patent Law: How to Enforce it Best?[5]

This 2015 paper discusses the origin of the Disclosure of Origin principle and how best to enforce it. It states:

"Making it [the Disclosure Requirement] an internationally legally binding requirement is controversial and subject to spirited debates; but it will enhance the transparency of the system as well as legal certainty and foster legal economy by settling down allegations of unjust enrichment and endless commentaries on improper behaviour. Most importantly, it will improve the quality of the granted patents, as their substantive examination will be more informed and complete. This is because the leads obtained by the DR information will guide the patent examiner to closer prior art to the invention"

The DR will enhance the public image and the marketing strategies of companies who comply with it as good business practice. It will also accommodate the fact that several countries around the world have already implemented a version of it and hence harmonise these approaches.

This paper also outlines Switzerland's approach to the Disclosure of Origin requirement (DR) which it believes would enable four policy objectives to be achieved:

"...which consist of the "four T's". These are:

transparency *in the ABS framework and enhanced* ***traceability*** *in the end product/patentable invention, as the DR allows provider communities to monitor the use and development of their GR.*

Also, the breadth of the ***technical*** *prior art is better identified; this improves the integrity of patents and thus decreases litigation and post-grant opposition costs. It also enhances legal certainty and confidence in the strength of the patents, thus reducing transaction costs.*

Finally, mutual ***trust*** *among the various stakeholders is increased"*

It is disingenuous to try to disconnect the New Zealand context for Disclosure of Origin from the International context from which the principle arose. Therefore, we urge the Ministry to revise the "Problem definition" to consider the international context. We propose the "four T's" as a considered approach that fairly reflects the international consensus on the problems. This approach also provides a framework applicable to the New Zealand context that could guide the discussion on how to implement the principle in New Zealand.

In summary, New Zealand has a unique cultural history and a historically progressive government with respect for human and civil rights. Any legislation that seeks to provide a solution arising from the Disclosure of Origin proposal should broadly consider the international, cultural and historical context of the principle and how it applies to New Zealand.

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[5] Kollia, Paraskevi, Disclosure of Origin in Patent Law: How to Enforce it Best? (September 13, 2013). MIPLC Master Thesis Series (2012/2013). Available at SSRN: https://ssrn.com/abstract=2407321

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

Page 12 of the Discussion Paper states that the objectives take into account the broader objectives of the Patent's Act, and the Problems identified in section 2. As discussed above, the Problems do not fairly reflect the international context and nor do they fairly reflect the New Zealand context pertaining to the government's obligations under the Treaty of Waitangi.

There is a movement by many developed and developing countries to ratify the Nagoya Protocol, and enact legislation which provides protections to genetic resources and traditional knowledge. Importantly, such actions are **seen** to provide protections and acknowledge current and historical grievances.

Unfortunately, the current objectives do not include an aim to acknowledge Māori claims such as the Wai262 claim, nor address past and present grievances by Māori relating to GR/TK. They ignore the politically sensitive issues and follow the path of least resistance.

The Castalia report entitled "Economic Evaluation of Disclosure of Origin Requirements" states:

"Some possible objectives for the introduction of further DoO requirements have been identified as:

- *To obtain more information about the use and potential misuse of New Zealand GR and TK (known as matauranga Maori)*
- *To be consistent with the Treaty of Waitangi*
- *To inform New Zealand's position on Disclosure of Origin at international negotiations"*

We question why the two latter objectives have been omitted.

The Problem Definition, Objectives and Options are consistent with each other but only because they omit reference to the international context and the national relevance for the Disclosure of Origin principle. As such they appear to follow a pre-determined path and achieve a predictable policy outcome.

While we agree with the existing objectives, we believe that they should be expanded to take into account the four policy objectives identified by Switzerland - transparency, traceability, technical prior art and mutual trust. Developing these further objectives for the New Zealand context would make the most of the legislative opportunity to ensure protection for Māori GR/TK in the future.

An important point to note is that Option 2 does not meet with the expressed Objective D – "Align with international obligations and interests". This is because Option 2 does not give effect to the Convention on Biological Diversity requirement to:

> *"...take legislative, administrative or policy measures, as appropriate [and subject to certain conditions] with the aim of sharing in a fair and equitable way the results of research and development and the benefits arising from the commercial and other utilization of genetic resources with the Contracting Party providing such resources"*

Do you have any comments on the preliminary assessment of the options?

We agree with proposed Option 2 to require the disclosure of:

a. Country of origin for genetic resources; and

b. The indigenous or local community who supplied the traditional knowledge.

However, while the proposed Option 2 is certainly better than the status quo, it fails to address the question of consistency with the Treaty of Waitangi as clarified in the Wai262 report.

Option 3 requires the additional step of provision of evidence of compliance with the ABS legislation in the country of origin of GR/TK. Clearly, this requirement places a high burden on IPONZ to understand the abundance of ABS legislation around the world. It also requires them to assess the patent application/declarations made about ABS and make a justifiable decision in relation to the patent. The Castalia report notes that the overall compliance costs for IPONZ and the patent applicants (domestic and overseas) is likely to be "high" for this option. However, from a New Zealand perspective Option 3 makes no sense because there is currently no ABS legislation to comply with.

Therefore, we propose an Option 2A, which also requires some elements of Option 3. For option 2A we propose the existing requirements of Option 2 (i.e. a. and b. above) as well as requiring that ABS requirements apply to GR/TK where the indicated country of origin is New Zealand.

This proposal is similar to the current law in China which requires:

a. *the disclosure of direct and original sources of the genetic resources in patent applications; and*

b. *if the acquisition or use of genetic resources violates relevant laws and regulations of China, then no patent will be granted for any invention that relies upon such genetic resources.*

Option 2A is a more viable option than option 3 for New Zealand, and one that significantly reduces the burden for overseas applicants and IPONZ.

GR/TK originating in New Zealand

From a legislative point of view, option 2A would require the establishment of ABS guidelines/regulations in New Zealand. However, there is ample international precedent for such guidelines as exemplified by the 111 countries[6] that have ratified the Nagoya Protocol. The Nagoya Protocol also provides a framework and assistance with which to implement an ABS system.

On the international stage, the proposal to implement guidelines around access and benefit sharing from GR/TK is not a radical move. Many countries have ratified the Nagoya Protocol for example these include the European Union, India, China and Japan. New Zealand often holds itself out to be an enlightened and civil-minded nation and is often lauded as having progressive policies towards the indigenous Māori population. However, it is lagging with the likes of Australia and the USA in its legislative recognition of indigenous claims to GR/TK.

In reality, the number of cases which would require evidence of ABS is likely to be negligible. Evidence for this can be seen in the lack of any voluntary disclosures in patent applications that they relate to Māori GR/TK, and the lack of referrals to the PMAC.

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[6] https://www.cbd.int/abs/nagoya-protocol/signatories/default.shtml accessed 13 December 2018

If cases of use of GR/TK use become known following the implementation of option 2A, then this will require patent applicants to implement ABS agreements or forego patent protection in New Zealand. Therefore a possible outcome of implementing option 2A is an increase in understanding, trust and collaboration between researchers on GR/TK and Māori.

Regardless of the number of cases that require ABS evidence, the process will increase trust, transparency and traceability, and likely increase the technical prior art that is provided to IPONZ. It will also go some way towards addressing grievances by Māori and protecting mātauranga Māori, as recommended by the Wai262 report.

If consistency with the Treaty of Waitangi is taken to be an objective of the proposal to implement Disclosure of Origin requirements, the mere disclosure of a specific source of mātauranga Māori does not impose any obligation on the applicant to adhere to ABS best practice. Best practice in this context will be to secure Prior Informed Consent (PIC) on Mutually Agreed Terms (MAT) and with equitable sharing of benefits.

GR/TK originating overseas

Where GR/TK is disclosed that does not originate in New Zealand, we propose that a modified Option 3 requirement should take effect. This would consist of a Declaration by the Applicant that any relevant ABS laws in the country of origin had been complied with. IPONZ would not conduct a substantive examination of this requirement but if a false declaration was made, the application would be potentially invalid under the ground of fraud, false suggestion, or misrepresentation (Opposition ground 92(1)(d); Revocation ground 114(1)(d)).

By analogy with other areas of patent procedure, it may also be possible for a requirement involving the submission of detailed evidence to be imposed only in cases of reasonable doubt, rather than as an *a priori* requirement for all patent applications. For example the PCT Regulations (Rule 51bis.2) provide that (subject to various conditions) a patent office may require documents or evidence if it reasonably doubts the veracity of any declaration by the applicant. Examples given are declarations concerning the identity of the inventor and the entitlement of the applicant to apply or to claim priority from another application.

Do you have any comments on how New Zealand should approach international discussions relating to disclosure of origin requirements?

New Zealand has thus far failed to engage with international discussions on this issue. As such, there is now an opportunity to demonstrate global leadership in implementing a system which not only requires disclosure but also encourages patent applicants to engage with GR/TK providers.

The main international discussions relating to Disclosure of Origin are carried out at the WIPO Intergovernmental Committee (IGC)[7]. New Zealand should engage with the WIPO IGC to understand the issues in more depth. New Zealand has experience with similar negotiations and discussions on a national level with the Waitangi Tribunal and these learnings could assist the IGC with international initiatives and decision-making.

What are your views on the design features of a potential disclosure of origin requirement?

There are already internationally accepted norms for subject matter, trigger and sanctions and remedies. This area of law is well developed in countries such as China, Brazil, South Africa and many European countries. New Zealand should look to those countries and WIPO for definitions and norms to deliver legislation that balances commercial and cultural interests.

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[7] https://www.wipo.int/tk/en/igc/ Accessed 21 December 2018

General comments

At an Auckland hui to discuss the PVR review and Disclosure of Origin proposal, the MBIE representatives noted that Minister Kris Faafoi was very keen to implement legislation and guidelines which give effect to the recommendations of the Wai 262 report. We welcome this commitment, but are concerned that the preferred Option 2 will only create the appearance of action, but without any meaningful commitment to ensure equitable access and benefit sharing arrangements. Contained in this response is a modified Option 2A that would ensure greater consistency with Wai 262 and international ABS norms.

If MBIE is concerned that an access and benefit sharing arrangement for GR/TK originating in New Zealand will be viewed as too difficult or controversial, we propose that a phased approach is adopted. This could involve adoption of Option 2 immediately then move towards the modified Option 2A (as outlined above) in 2–3 years once guidelines have been developed. Such guidelines could be developed based on international and domestic consultation and the experience of partner jurisdictions such as the UK, European Union, South Africa and Brazil. This would provide industry and research institutions (such as the University of Auckland) the time that they need to start developing a reciprocal, early stage ABS approach with Māori, rather than entrenching a compliance-focused "after the fact" mentality.

The above phased approach would also enable constructive engagement with iwi. Our initial consultations with iwi representatives at the University indicate an awareness of the issues and a desire to be included in these conversations

In summary, we recommend that MBIE invite genuine informed debate on the broader policy and cultural issues that go with a formal ABS system. The economic downside of such a system would likely be negligible and the cultural benefits and settlement of grievances would be a lasting legacy. The government should not be afraid to tread a new policy path that balances and promotes both cultural and commercial interests, while continuing the generational shift in understanding and respect for the Māori culture.

Yours Sincerely

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