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Opportunities and barriers to commercialisation of Indigenous medicines

My PhD research at ANU is investigating the opportunities and barriers facing Aboriginal traditional owners/knowledge holders who seek commercial development of traditional medicines, and examines the extent to which Australian regulatory frameworks operated by IP Australia and the Therapeutic Goods Administration provide support for them. In addition to my PhD research I have had extensive engagement over several decades coordinating research and development efforts on behalf of Traditional Owners who wish to commercialise a traditional medicine, referred to by Blackwell et al. (2019)[1]; a project which Janke and Sentina (2018) note is 'recognised as a leading Indigenous medicine patent project in Australia'.[2] This has provided me with many insights into both the opportunities and barriers such efforts face. The potential economic opportunities for both Indigenous Australians and for the Australian economy as a whole could be enormous if appropriate steps are taken.

I welcome the opportunity to make a submission to this inquiry.

The central importance of UNDRIP and the Nagoya Protocol

The international standards established under the *UN Declaration on the Rights of Indigenous Peoples* (UNDRIP), and by the Nagoya Protocol to the Convention on Biological Diversity (CBD), affirm the legitimate aspirations of Indigenous peoples to benefit from their biocultural resources. In particular, where Indigenous people have aspirations for the commercial development of their traditional knowledge of biocultural resources there is an internationally endorsed rights framework relating to the Free Prior Informed Consent of Indigenous knowledge holders and for Access and Benefit Sharing arrangements on Mutually Agreed Terms.

It is noteworthy that the 2019 IP Australia report on the protection of Indigenous Knowledge in Australia's intellectual property system reported that the stakeholders identified the ratification of the Nagoya Protocol and implementing obligations under UNDRIP as important issues and concerns.[3]

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[1] Blackwell, B.D. Bodle, K. Hunt, J. Hunter, B. Stratton, J. and Woods, K. (2019). *Methods for Estimating the Market Value of Indigenous Knowledge*, report commissioned by IP Australia, Canberra: 49.

[2] Terri Janke and Maiko Sentina, *Indigenous Knowledge: Issues for Protection and Management,* IP Australia, Commonwealth of Australia, 2018, case study p. 102; See also Virginia Marshall, Terri Janke and Anthony Watson, 'Community Economic Developments in patenting Traditional Knowledge: a Case Study of the Mudjala TK Project in the Kimberley Region of Western Australia, (2013) 8(6) *Indigenous Law Bulletin* 17: 19.

[3] IP Australia 2019, 'Protection of Indigenous Knowledge in the Intellectual Property System – Consultation Report', August 2019: 19, <https://www.ipaustralia.gov.au/sites/default/files/reports_publications/indigenous_knowledge_consultation_report.pdf>, accessed 8 July 2020.

Human rights advocates welcomed UNDRIP as a symbol of hope for Indigenous Peoples[4] and Rimmer[5] observed that UNDRIP 'provides a framework for the protection of Indigenous intellectual property'. Former UN Secretary-General Ban Ki-Moon stated that UNDRIP 'should inform future developments in international law'.[6] Drahos (2014) asserts that:

> How individual states respond at the individual property systems level will determine whether UNDRIP's recognition of the inherent rights of indigenous peoples will see for them a new development dawn. Australia along with Canada, New Zealand and the United States voted against UNDRIP's adoption, although all four states have since endorsed it. Whether these states reform their intellectual property systems in ways that are developmental for their indigenous peoples remains to be seen.[7]

Indigenous peoples' rights to biocultural resources have been acknowledged by the UN Conference on Trade and Development (UNCTAD), which incorporated Access and Benefit Sharing Rules[8]; by the UN Food and Agriculture Organization (FAO) *International Treaty on Plant Genetic Resources for Food and Agriculture* which includes Free, Prior and Informed Consent guidelines[9]; the World Intellectual Property Organization *(*WIPO)[10] *Trade-related Aspects of Intellectual Property Rights (TRIPS* and *TRIPS+)* agreements, the Intergovernmental Committee on Intellectual Property and Genetic Resources, Traditional Knowledge and Folklore[11] and the World Health Organisation (WHO) *Traditional Medicine Strategy 2002-2005* and *Traditional Medicine Strategy 2014-2023.*[12]

Although the Australian Government reiterated its support for UNDRIP[13] as recently as 2020, progress towards domestic implementation remains extremely slow. In March last

[4] Hartley J, Joffe P and Preston J, 2010, 'From Development to Implementation: An Ongoing Journey', in Jackie Hartley, Paul Joffe and Jennifer Preston (eds) *Realizing the UN Declaration on the Rights of Indigenous Peoples: Triumph, Hope, and Action*, Saskatoon (SK): Purich Publishing Limited, 2010.
[5] Rimmer M 2015, 'Introduction: mapping Indigenous intellectual property' in Matthew Rimmer 2015: 34 (ed), *Indigenous Intellectual Property A Handbook of Contemporary Research*, Elgar.
[6] Ban Ki-Moon, 'Post-2015 Agenda Must Incorporate Rights, Perspectives, Needs of Indigenous Peoples', International Day of the World's Indigenous Peoples, 9 August 2013, <http://www.un.org/News/Press/docs/2013/sgsm15203.doc.htm> in Rimmer M 2015 *Introduction: mapping Indigenous intellectual property* in Matthew Rimmer 2015 (ed) *Indigenous Intellectual Property: A Handbook of Contemporary Research*, Elgar, p. 34.
[7] Peter Drahos 2014 *Intellectual Property, Indigenous People and their Knowledge*, Cambridge University Press: 93. Note that Australia endorsed UNDRIP in April 2009.
[8] UNCTAD 2014, '*The Convention on Biological Diversity and the Nagoya Protocol: Intellectual Property Implications: A Handbook on the Interface between Global Access and Benefit Sharing Rules and Intellectual Property*, United Nations Conference on Trade and Development
[9] FAO 2016, F*ree, Prior and Informed Consent (FPIC) Manual',* <http://www.fao.org/3/a-i6190e.pdf>
[10]WIPO <https://www.wipo.int/treaties/en/>
[11] WIPO <https://www.wipo.int/export/sites/www/tk/en/igc/pdf/igc_mandate_2018-2019.pdf>
[12] WHO <https://apps.who.int/medicinedocs/en/d/Js2297e/>
[13] Australian Government 2020, 'National report to be submitted in accordance with paragraph 5 of the annex to Human Rights Council resolution 16/21', Consultation draft as at 30 June 2020: 12, <https://www.ag.gov.au/integrity/publications/universal-periodic-review-upr-national-report-australia-draft> accessed 1 July 2020>.

year a broad coalition of NGOs called on the Australian government to take steps to incorporate UNDRIP into Australian domestic law and to appoint an independent body to oversee its implementation.[14]

The Nagoya Protocol[15] affirms UNDRIP as 'a standard of achievement to be pursued in a spirit of partnership and mutual respect'. The Protocol's provisions strengthen Indigenous rights to benefit from, among other things, their traditional knowledge associated with genetic resources. In particular Article 24 deals with Indigenous people's rights to their traditional medicines, including the conservation of their vital medicinal plants, and Article 31(1) deals with Indigenous rights 'to maintain, control, protect and develop *[emphasis added]* their … genetic resources, seeds and medicines'.

In 2013 the National Congress of Australia's First Peoples called for the incorporation of the Nagoya Protocols into the legal framework of all Nation States[16] and Marshall (2013) states that 'the lens of human rights must remain the focus for restoring the control and management of Indigenous peoples over their inherent resources on land or in the waters'.[17] I note that the IP Australia consultation Discussion Paper on Nagoya Protocol implementation states that 'much work needs to be done to make protocols widely used and accepted'.[18]

The desire to align with the Nagoya Protocol is behind the Queensland Government's current review of the *Biodiscovery Act* 2004[19] in light of the valuable contribution to the State's economy made by the biodiscovery sector and the government's commitment to 'streamlining biodiscovery in Queensland and encouraging investment'. The Options Paper into reform of Queensland's *Biodiversity Act* 2004 states that:

> It is also a critical step towards recognising the rights that Aboriginal and Torres Strait Islander people hold in relation to their traditional knowledge, and ensuring

[14] Human Rights Law Centre 2020, Australia's 3rd Universal Periodic Review: Joint NGO Submission on behalf of the Australian NGO Coalition, March 2020: 1, <https://www.hrlc.org.au/universal-periodic-review> accessed 29 March 2020.
[15] United Nations 2010, *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,* COP 10 Decision, adopted 29 Oct 2010.
[16] National Congress of Australia's First Peoples, *Agenda Item 3: Follow up to the Recommendations of the Permanent Forum* (18-23 May 2013) <https://www.nationalcongress.com.au/wp-content/uploads/2013/05/UNPFIICongressStatementHealthEducationCulture.pdf> in Marshall V 2013, 'Negotiating Indigenous access and benefit sharing agreements in genetic resources and scientific research', 2013 8(8) Indigenous Law Bulletin.
[17] Ibid.
[18] Janke T and Sentina M 2018, *Indigenous Knowledge: Issues for Protection and Management,* IP Australia, Commonwealth of Australia.
[19] Queensland Government 2018, Pathways to reform: Biodiscovery Act 2004: Options Paper: 5 <https://environment.des.qld.gov.au/licences-permits/plants-animals/documents/biodiscovery-reform-options-paper.pdf>, accessed 9/4/19.

> biodiscovery entities are able to meet international obligations regarding access to genetic resources and the sharing of benefits resulting from their use.[20]

Drahos (2014) states that the introduction, during the WTO's Doha Round, of a proposal for mandatory disclosure obligations on patent applicants seeking patents involving biological resources associated with TK as a significant development which, if incorporated into TRIPS, would 'represent an important linkage between the CBD's principles of prior informed consent and benefit sharing, the requirement of the Nagoya Protocol and the obligations of patentees in the world's major patenting jurisdictions'.[21]

Rimmer (2015) asserts that 'International law in respect of Indigenous intellectual property law has been fragmented and fractured',[22] and cites Bowrey (2011) who contends '… the major obstacle to better protection of Indigenous intellectual property has not been a lack of interest, or disagreement about the need for reform, but the considerable uncertainty about *how* to achieve this objective'.[23] I believe it is imperative that the 2021 Indigenous Knowledge Consultation by IP Australia makes significant strides in progressing recognition of TK within Australia's IP system.

Commercialisation of Indigenous biocultural resources

Globally, Indigenous peoples manage a large proportion of the world's natural estate, including vast areas with very high biodiversity values[24,25] and Indigenous Traditional Knowledge (TK) has gained increased recognition. International attention is being given to developing frameworks and mechanisms for the protection of this TK from biopiracy activity.[26] As a global biodiversity hotspot with a significant Indigenous estate it is vital that Australia gives a high priority to developing culturally-appropriate frameworks to both protect TK from unscrupulous exploitation, and to support and facilitate Traditional Owners who might seek commercial development of their biocultural resources.

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[20] Ibid: 4.
[21] Drahos P 2014, Op. Cit., p. 89.
[22] Rimmer M 2015 Op Cit., p. 32.
[23] Bowrey K 2011 'Indigenous Culture, Knowledge and Intellectual Property: The Need for a New Category of Rights', in Kathy Bowrey, Michael Handler and Dianne Nical (eds) Emerging Challenges in Intellectual Property, Oxford University Press 2011, p. 46 in Matthew Rimmer, 'Introduction: mapping Indigenous intellectual property' in Matthew Rimmer 2015 (ed), *Indigenous Intellectual Property A Handbook of Contemporary Research*, Elgar, p. 4.
[24] Wildlife Conservation Society 2018 "Indigenous peoples own or manage at least one quarter of world's land surface: Authors say Indigenous Peoples are key to maintaining biodiversity and ecologically valuable landscapes". *ScienceDaily*, 16 July 2018. <www.sciencedaily.com/releases/2018/07/180716130732.htm>.
[25] Sobrevila C 2008 *The Role of Indigenous Peoples in Biodiversity Conservation The Natural but Often Forgotten Partners,* The World Bank, Washington, D.C. <http://documents.worldbank.org/curated/en/995271468177530126/pdf/443000WP0BOX321onservation01PUBLIC1.pdf>
[26] Brand et. al. 2008 'Conflicts in Environmental Regulation and the Internationalisation of the State' Routledge, p. 24, p. 26.

The pharmaceutical industry is increasing the pace of its biodiscovery activity and has expanded greatly its size, reach, power and influence.[27] In the absence of appropriate regulation, the power imbalance in commercial negotiations between pharmaceutical industry players and Indigenous TK holders is significant. Blackwell et al. (2019) cite Posey (1990) who estimates that '0.001 percent of profits from drugs derived from traditional medicine have flowed to Indigenous Peoples'[28]. While one group of Traditional Owners have successfully defended their intellectual property rights in biocultural resources[29] from being usurped by a small non-Indigenous business, biopiracy remains a serious concern until Australia incorporates UNDRIP and the Nagoya Protocol into its domestic laws.

The Australian government has stated that it 'can only ratify the Protocol when it is confident that all obligations are being met – this requires changes to domestic law'.[30] Until Australia does ratify the Nagoya Protocol and establish a national framework for issuing International Certificates of Compliance, biodiscovery entities will continue to face restrictions on export into important markets such as the EU of any biodiscovery products which utilise Traditional Knowledge in their development.[31] This puts the Australian biodiscovery sector at a significant disadvantage. Many widely used products in the global marketplace, such as plant-based medicines and cosmetics, were derived from Traditional Knowledge. In some Asian and African countries, 80% of the population depend on traditional medicine for primary healthcare, and medical treatments derived from TK have frequently been adopted by populations outside the Indigenous culture that was the source of the knowledge.[32]

Although some universities and research institutes have developed impressive technological capacity in biodiscovery[33, 34] most face significant financial constraints when it comes to commercialisation activities, generally relying on intermittent government grants and philanthropy to advance their patents or, in some cases, on strategic industry partnerships. Indigenous TK holders who have formed partnerships with universities/research institutes to advance R&D of their biocultural resource can find themselves on a frustratingly slow development pathway, watching the patent life of their IP assets inexorably ticking away.

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[27] Ibid.
[28] Blackwell et al. 2019, Op Cit.: 50.
[29] See for example 'Non-Indigenous business fails in bid to trademark Aboriginal bush medicine' <https://www.abc.net.au/news/2020-01-24/gumby-gumby-trademark-fails/11890218>
[30] Australian Government Factsheet: The Nagoya Protocol in Australia, accessed 20 Aug 2019
[31] Queensland Government 2018, Pathways to reform: Biodiscovery Act 2004 Options Paper: 4 <https://environment.des.qld.gov.au/licences-permits/plants-animals/documents/biodiscovery-reform-options-paper.pdf>, accessed 9/4/19.
[32] World Health Organisation Fact Sheet No. 134. *Traditional Medicine.* Published by WHO, revised Dec 2008.
[33] See for example the Griffith Institute for Drug Discovery <https://www.griffith.edu.au/institute-drug-discovery/our-institute>.
[34] See also Institute of Applied Sciences, University of South Pacific <https://www.usp.ac.fj/index.php?id=6380&tx_ttnews[tt_news]=461&cHash=4599b909bbc095766b8452b63df631b6>.

This raises the question of the term of patents lodged by Indigenous Traditional Owners (or by TOs in an equitable partnership with a research institution) is adequate to the circumstances and whether consideration might be given to providing such patents with an extended patent life.

It is worth noting that leading Maori academic Prof Linda Tuhiwai-Smith, in pointing to the flaws in how the international IP system deals with Indigenous Traditional Knowledge, argues that the language of imperialism and colonialism impacts the Indigenous struggle for the validity of their knowledges and control over Indigenous forms of knowledge:

> The commodification of knowledge as intellectual property, of collective knowledge as public knowledge, and of knowledge as value-added takes the struggle into another set if cultural interpretations. Now indigenous people have to prove that what was used for centuries to heal an illness was something which was 'discovered' and then had a value added to that discovery through some sort of scientific process.[35]

AIATSIS (2016) also points to the tension that exists between Indigenous Knowledges, including ethno-biological knowledge and the medicinal use of plants, and the prescriptions of Australian law regarding the ownership of materials and the IP contained in those materials, which 'at times conflicts with expectations or cultural obligations of traditional owners'.[36]

Some key questions

I would like to advance some key questions that the IP Australia Indigenous Knowledge consultation might seek to address. These are questions that my PhD research will also seek to answer.

- How can Australia advance domestic implementation of UNDRIP and Nagoya Protocol standards relating to Indigenous genetic resources, and what can Australia learn from the progress made by Canada, New Zealand and the United States?
- What policies and strategies have been adopted by IP Australia in relation to domestic implementation of UNDRIP and the Nagoya Protocol standards?
- In what ways does Australia's IP system support or impede Indigenous knowledge holders who seek to commercialise their traditional medicines / medicinal products?
- What policy frameworks, strategies and protocols have been developed and implemented to reduce regulatory impediments to Indigenous stakeholders seeking to commercialise traditional medicines?

[35] Tuhiwai-Smith L. 2006, Decolonizing Methodologies: Research and Indigenous Peoples, rev ed, 2006: 104, Zed Books and University of Otago Press, Dunedin.
[36] AIATSIS 2016, 'How Indigenous Knowledge can work with the intellectual property (IP) system?' Submission to IP Australia, Trade and Policy Projects, 4 March 2016: 3.

- What is the nature and form of any guidance or assistance provided to TOs for the development /commercialisation of their traditional medicines or bush food resources?
- How do TOs understand the potential benefits and risks of commercialising their Traditional Knowledge (TK) and what are their expectations for IP protection over their TK in both the short and long-term?
- To what extent are TOs concerned about biopiracy of their traditional medicines and foods, and do they believe federal and state governments have provided adequate assistance for the protection of TK and traditional genetic resources from unscrupulous exploitation, as foreshadowed by the Nagoya Protocol and UNDRIP?
- What level of interest do TOs and TK holders have for developing and/or commercialising traditional medicines or food plants from their traditional country, and what views do they hold on potential benefits and risks to their communities?
- What type of support would TOs like to see from government (federal and state) agencies to assist them to develop and/or commercialise their traditional medicines?
- What pathways exist for traditional owners to undertake commercial development of their TK in genetic resources?