

COMBATING BIOPIRACY IN AUSTRALIA: WILL A DISCLOSURE REQUIREMENT IN THE *PATENTS ACT 1990* BE MORE EFFECTIVE THAN THE CURRENT REGULATIONS?

VERITY DAWKINS

I INTRODUCTION

Australia contains approximately 10% of the world's natural genetic and biochemical resources.¹ As a megadiverse country,² Australia could gain considerable economic, social and environmental benefits from effective utilisation of these resources.³ Indigenous Australians' knowledge natural resources and their traditional uses is extensive, and has large potential to be harnessed in the development of future inventions. Further, Aboriginal and Torres Strait Islander peoples own or control access to around 25- 30% of Australian land.⁴ Australia has a well-established system of commercial and intellectual property (IP) law, and a strong scientific and research sector.⁵ This means that there is the ability to utilise and develop these natural resources within Australia.

Protection of Australia's resources and recognition of Indigenous or traditional knowledge is important.⁶ Acknowledgment of traditional knowledge as a contribution to the Australian economy is desired by Indigenous groups. This paper takes the view that it is fundamental that benefits from development of resources and inventions based on traditional knowledge are shared effectively with Indigenous Australians,

¹ Australian Government Department of Environment and Heritage, Parliament of Australia, *Understanding the Nationally Consistent Approach for Access to and the Utilisation of Australia's Native Genetic and Biochemical Resources* (November 2002) 2 ('*Understanding the NCA*').

² There are seventeen megadiverse countries in the world and these countries support more than 70% of the biological diversity on earth.

³ *Understanding the NCA*, above n 1.

⁴ Kylie Lingard, 'The potential of current legal structures to support Aboriginal and Torres Strait Islander interests in the Australian bush food industry' (2016) 23(2) *International Journal of Sustainable Development & World Ecology* 174, 177.

⁵ *Understanding the NCA*, above n 1, 4.

⁶ Traditional knowledge has been defined by the World Intellectual Property Organisation (WIPO) as including 'the intellectual and intangible cultural heritage, practices and knowledge systems of traditional communities, including indigenous and local communities... it is knowledge that is dynamic and evolving, resulting from intellectual activities which is passed on from generation to generation' see: WIPO, *Glossary of Key Terms Related to Intellectual Property and Genetic Resources, Traditional Knowledge and Traditional Cultural Expressions*, WIPO Doc No WIPO/GRTKF/IC/20/INF/13 (7 December 2012)

who face greater disadvantage and economic and social problems. The aim of this paper is to evaluate how best to protect this traditional knowledge and ensure the benefits of inventions based on this knowledge are shared.

Bioprospecting is the exploration of biological diversity for the development of commercially valuable genetic resources. Bio-piracy, however, occurs when commercial actors appropriate traditional knowledge without recognition or benefit-sharing. Despite international condemnation of biopiracy and the creation of the *Convention on Biological Diversity* (CBD), *Bonn Guidelines*, and *Nagoya Protocol* international discussions around the subject have failed to adequately address all concerns. These documents work alongside the *Trade Related Aspects of Intellectual Property* (TRIPS) Agreement. Further, the ‘work in progress’ *Draft Articles* by the World Intellectual Property Office (WIPO) Intergovernmental Committee on Traditional Knowledge and Folklore (IGC) released in September 2016, indicate that the IGC, and indeed the international community, is still divided on how best to combat biopiracy.⁷

In Australia, Pt 8A of the *Environment Protection and Biodiversity Conservation Regulations 2000* (Cth) (*EPBC Regulations*) provides the regulatory framework for encouraging bioprospecting in a way that recognises the contribution of traditional knowledge. However, it is limited as a tool to prevent biopiracy. These regulations provide that access permits must be obtained from the Minister for Environment and Heritage in order to access biological resources of native species in Commonwealth areas. The regulations also require creation of a benefit-sharing contract with Indigenous owners and obtaining their prior informed consent (PIC). This legislative mechanism is unlike other States’ protection for traditional knowledge.⁸ However, for a number of reasons it is argued that an additional disclosure of origin and source requirement within the *Patents Act 1990* (Cth) would assist in better protection of traditional knowledge and promotion of benefit-sharing. This disclosure requirement would require that, for the granting of patent rights, patent applicants would have to

⁷ WIPO IGC *The Protection of Traditional Knowledge: Draft Articles*, WIPO Doc No WIPO/GRTKF/IC/31/FACILITATORS TEXT REV. 2 (30 September 2016) art 4bis (*‘IGC Draft Articles’*).

⁸ WIPO *Technical Study on Disclosure Requirements in Patent Systems Related to Genetic Resources and Traditional Knowledge*, Study No 3, UN Doc UNEP/CBD/COP/7/INF/17 (9 February 2004) 13.

disclose any relevant traditional knowledge, as well as evidence of PIC and benefit-sharing agreements with Indigenous groups.

This paper will explore the adequacy of Australia's approach to combating biopiracy. It is in five parts: First, the global problem of biopiracy is explained. Second, Australia's international obligations are examined.⁹ Third, Pt 8A of the *EPBC Regulations* is explained and critiqued, positing that an additional checkpoint in patent legislation would assist in enforcement of these regulations. Fourth, Australia's strategy is compared with the protections afforded in the United States (US), New Zealand and Brazil. Finally, the benefits and drawbacks of a disclosure requirement are weighed. The paper concludes that including a disclosure requirement in patent legislation would be the optimal strategy for protection of traditional knowledge. It would extend protection to all traditional knowledge, not just that of owners in Commonwealth areas. Tying patent approval to disclosure would also provide an extra checkpoint to ensure benefit-sharing agreements have been made and an additional disincentive for biopiracy.

II BIOPIRACY AND BIOPROSPECTING COMPARED

A Definition

Biopiracy is the 'unauthorized exploitation of traditional knowledge' without obtaining PIC of Indigenous owners'.¹⁰ Biopiracy is typified by individuals or institutions seeking exclusive monopoly control through patents, over traditional resources and knowledge, without having benefit-sharing agreements or consent of Indigenous groups. This paper argues that biopiracy is unfair to traditional communities because companies can earn large profits and fail to share them with the communities from where the resources were originally accessed.¹¹ It can have adverse economic impacts on traditional communities. Although the economic benefits may not have occurred without companies exploiting the resources, biopiracy

⁹ *Convention on Biological Diversity*, opened for signature 5 June 1992, 1760 UNTS 79 (entered into force 29 December 1993) ('*CBD*').

¹⁰ Paul Kuruk, 'Goading a Reluctant Dinosaur: Mutual Recognition Agreements as a Policy Response to the Misappropriation of Foreign Traditional Knowledge in the United States' (2007) 34 *Pepperdine Law Review* 629, 630.

¹¹ Paul Kuruk, 'Regulating Access to Traditional Knowledge and Genetic Resources: The Disclosure Requirement as a Strategy to Combat Biopiracy' (2015) 17(1) *San Diego International Law Journal* 1, 8.

denies source countries or communities the ability to protect and commercially profit from the resources and knowledge themselves. If the pirated material becomes patented this gives further protection and commercial rewards to the pirate, who gains ownership and a monopoly on use of the product.¹² Biopiracy has been viewed as a form of thievery, perpetrated against Indigenous groups and performed at the expense of the resources' source countries and communities.¹³

Biopiracy is contrasted with bioprospecting, which when compliant with internationally recognised requirements for PIC and benefit-sharing, provides a legitimate and acceptable way of accessing resources. Previously, drug discovery involved random or mass collection of plant samples, which are then individually screened.¹⁴ This has a low success rate due to the small chances of finding plants containing therapeutic agents.¹⁵ Therefore in recent years, bioprospecting has become systematic targeted searches for small samples medically useful resources, often conducted with the help of Indigenous groups.¹⁶ Bioprospecting with the assistance of traditional knowledge has been reported to have 'increased the efficiency of screening plants for medical properties by more than 400%.¹⁷ The relevance of traditional knowledge is indicated by the fact that an estimated 74% of modern pharmaceutical products derived from plants have the same or a similar use by Indigenous cultures.¹⁸

B Example of importance of combating biopiracy in Australia

One example of considered misappropriation of Indigenous biodiversity and associated knowledge in Australia was the use of the Smokebush plant. This is outlined in a report 'Our Culture, Our Future' which was developed to inform reform proposals.¹⁹ The Smokebush from Western Australia has traditionally been used by the Nyoongah people for healing. In the 1960s, the Western Australian Government

¹² Ibid 381.

¹³ Katherine A Kelter, 'Pirate Patents: Arguing for Improved Biopiracy Prevention and Protection of Indigenous Rights Through a New Legislative Model' 47 *Suffolk University Law Review* 373, 380.

¹⁴ Petra Ebermann, *Patents as Protection of Traditional Medical Knowledge? A Law and Economics Analysis* (Intersentia, 2012) 20.

¹⁵ Ibid.

¹⁶ Ibid.

¹⁷ Shannon F Smith, 'All Hands on Deck: Biopiracy and the Available Protections for Traditional Knowledge' (2014) 10 *Journal of Animal and Natural Resources Law* 273274.

¹⁸ Ebermann, above n 14, 22.

¹⁹ Terri Janke, *Our Culture: Our Future, Report on Indigenous Cultural and Intellectual Property Rights* (1998) 24.

granted the US National Cancer Institute a licence to collect and screen plants for cancer-fighting properties.²⁰ In 1981 the specimens were found to be ineffective, but in later years were retested in the search to find a cure for AIDS. The Smokebush was one of four plants out of 7 000 screened that contained the active property Conocurovone, which tests showed could destroy the HIV virus in low concentrations.

The US National Cancer Institute awarded Amrad, a Victorian pharmaceutical company, an exclusive worldwide licence to develop the invention.²¹ In the early 1990s, the Western Australian Government awarded Amrad the rights and access to the Smokebush species, for the price of \$1.5 million, to develop an anti-AIDS drug. At the time it was thought that if Conocurovone was successfully commercialised, the WA government would recoup royalties of \$100 million per year. At this time there was no requirement for the government to ensure that these profits were shared with the Nyoongah people.

Although it was not successfully developed (because it was found to have substantial side effects when ingested) there has been no acknowledgement of Indigenous people, financial or otherwise, for their role in having first discovered the healing properties of Smokebush. Whilst developing the product Amrad did not communicate with the Nyoongah people to identify traditional preparation method for preparation and use. As a result Amrad did not discover that traditionally the plant was inhaled not ingested.²² This example indicates the lack of consultation processes between the bioprospectors, government institutions, pharmaceutical representatives and the Indigenous community, and indicates that recognising traditional knowledge may also help with commercialisation.²³ This paper now turns to how the international community has responded to biopiracy.

²⁰ Ibid 25.

²¹ Ibid.

²² John Hunter and Chris Jones, *Bioprospecting and Indigenous Knowledge in Australia: Implications of Valuing Indigenous Spiritual Knowledge* (2006) Bahai Library Online <http://bahai-library.com/hunter_jones_bioprospecting_australia>

²³ Ibid.

III INTERNATIONAL AGREEMENTS

A TRIPS

The TRIPS Agreement provides the international legal framework governing IP rights.²⁴ Administered by the World Trade Organisation, the TRIPS Agreement requires all member countries to provide minimum standards for protection of IP rights.²⁵

For several reasons, traditional knowledge is inadequately protected through TRIPS. First, traditional knowledge is not explicitly mentioned in the TRIPS Agreement, and protection of traditional knowledge is not recognized in its objective.²⁶ Further, there is some international concern that the CBD and TRIPS are incompatible, with the result that consideration is not able to be given to public interests, including the interests of Indigenous peoples. This is because article 27 of the TRIPS agreement only allows for three substantive requirements for patent protection: novelty, inventiveness and industrial application. It is argued that a mandatory disclosure requirement for patent protection is extra to this and incompatible.²⁷ However, Peter Yu states that articles 7 and 8 can act as a bridge between the TRIPS Agreement and the recognition of traditional knowledge in the CBD.²⁸ Article 7 of the TRIPS Agreement sets out the TRIPS objective of ‘promotion of technological innovation... transfer and dissemination of technology’ to the advantage of producers, users and for social and economic welfare.²⁹ Yu argues that article 7 and 8 (which allows for public health and socio-economic development concerns) provide that broader public interest policies are not inconsistent with the TRIPS Agreement.³⁰ Furthermore many States have implemented changes to patent law without viewing CBD and TRIPS as incompatible.

B *Convention on Biological Diversity*

²⁴ *Marrakesh Agreement Establishing the World Trade Organization*, opened for signature 15 April 1994, 1867 UNTS 3 (entered into force 1 January 1995), annex 1C (*‘TRIPS Agreement’*)

²⁵ Kelter, above n 13, 385.

²⁶ Ebermann, above n 14, 61.

²⁷ Nuno Pires de Carvalho, ‘Requiring Disclosure of the Origin of Genetic Resources and Prior Informed Consent in Patent Applications Without Infringing The TRIPS Agreement: The Problem and The Solution’ (2000) 2 *Washington University Journal of Law & Policy* 371, 379.

²⁸ Peter Yu, ‘The Objectives and Principles of the TRIPS Agreement’ (2009) 46(4) *Houston Law Review* 980, 1039.

²⁹ *TRIPS Agreement*, art 7.

³⁰ Yu, above n 298.

In contrast to no express recognition of traditional knowledge in TRIPS, the CBD explicitly deals with protection of traditional knowledge as well as its other objectives.³¹ The Convention has the objectives of conservation of biological diversity, sustainable use of biological resources, and fair and equitable sharing of benefits arising from use of resources.³² It has 196 Parties and 168 Signatories, indicating near universal participation. Australia ratified the CBD on 18 June 1993.³³ However, notably, the US is not a member of the CBD, and is not required to abide by its guidelines.³⁴ There has been much academic discussion on whether the US should ratify the CBD. Those against ratification suggest that complying with the CBD would require significant changes to the patent system and lessen the market advantages given to inventors.³⁵ However, many countries, including Australia, have not changed their patent systems after ratification and have introduced different legislative mechanisms to achieve CBD objectives.

Part of the impetus for the creation of the CBD was the threat to indigenous knowledge caused by the loss of biodiversity.³⁶ The drafters recognized that as habitats are destroyed there are significant effects on Indigenous people because these groups have a close relationship with the environment.³⁷ It was also recognized that because traditional knowledge is influenced by the natural environment, destruction of that environment may result in the complete loss of traditional knowledge.³⁸ Article 8(j) is the key article relating to traditional knowledge. It requires a member state to:

respect, preserve and maintain knowledge, innovations and practices of Indigenous and local communities embodying traditional lifestyles relevant for the conservation and sustainable use of biological diversity and promote their wider application with the approval and involvement of the holders of such knowledge, innovations and

³¹ *CBD*, art 1.

³² *Ibid.*

³³ Australian Government Department of Environment and Energy, *The Nagoya Protocol - Convention on Biological Diversity* <<https://www.environment.gov.au/topics/science-and-research/australias-biological-resources/nagoya-protocol-convention-biological>>.

³⁴ Laura Grebe, 'Requiring Genetic Source Disclosure in the United States' (2011) 44 *Creighton Law Review* 367, 386.

³⁵ *Ibid* 369.

³⁶ Ebermann, above n 14, 26.

³⁷ *Ibid.*

³⁸ *Ibid.*

practices and encourage the equitable sharing of the benefits arising from the utilization of such knowledge, innovations and practices.³⁹

This provision recognises the wider application of traditional knowledge and highlights its value for scientific research.⁴⁰ According to this provision, any use of traditional knowledge in research should be subject to the approval of providers of that knowledge. This is commonly understood to require consent from Indigenous groups for the use of the knowledge.⁴¹

Benefit-sharing with Indigenous groups is also a central requirement of the CBD. Article 15 recognizes ‘the sovereign rights of States over their natural resources’ and that the ‘authority to determine access to genetic resources rests with the national governments’.⁴² It further provides that States must take legislative measures with the ‘aim of sharing in a fair and equitable way the results of research and development and the benefits’ from the use of the resources.⁴³ This provision purports to compensate Indigenous communities for their traditional knowledge contributions. However, what legislative requirements should be taken and how benefits should be shared is not elaborated within article 15.

Although express recognition of traditional knowledge in the CBD is an important step, the Convention itself is not without its flaws. Most relevantly, access regulation of this type seeks to establish incentives to conserve biodiversity and sustainable use by allocating property rights to biological resources, with benefits for resource owners.⁴⁴ The CBD is based on the principle that biological resources are considered to be a State’s property subject to administration by governments.⁴⁵ However, many Indigenous cultures do not consider that biological resources can be owned, and therefore do not accept that resources are owned by a State’s government.⁴⁶

³⁹ *CBD*, art 8 (j).

⁴⁰ Ebermann, above n 14, 35.

⁴¹ *Ibid.*

⁴² *CBD*, art 15.

⁴³ *Ibid* art 15(7).

⁴⁴ Ebermann, above n 14, 30.

⁴⁵ *CBD*, art 3.

⁴⁶ Marcelin Tonye Mahop, *Intellectual Property, Community Rights and Human Rights* (Routledge, 2010) 87.

Articles 8(j) and 15 inadequately protect traditional knowledge because of their lack of specificity, binding force and clarity.⁴⁷ For example, Paul Kuruk states that the three basic principles introduced in the CBD of PIC, fair and equitable sharing of benefits, and mutually agreed terms, are not fully elaborated in the CBD.⁴⁸ He states that this leaves doubt to the precise scope of their application. Further, focus of the CBD is on the national level and therefore the effectiveness of the CBD is limited to whether States themselves implement legislation. These criticisms led to the creation of the *Bonn Guidelines* and *Nagoya Protocol*.

C *Bonn Guidelines*

In 2002 the Conference of Parties to the CBD adopted the *Bonn Guidelines on Access to Genetic Resources and Fair and Equitable Sharing of the Benefits Arising out of their Utilization*.⁴⁹ These voluntary guidelines were created to assist national governments in developing and drafting legislative, administrative or policy measures for access and benefit-sharing.⁵⁰

Under the *Bonn Guidelines*, PIC is required for access to genetic resources.⁵¹ Section 16(a)(iii) of the *Bonn Guidelines* calls on States to take steps ‘to ensure that the commercialization and any other use of genetic resources [does] not prevent traditional use of genetic resources.’⁵² Section 14 requires national competent authorities to advise on mechanisms for effective participation of Indigenous groups in the process of access and benefit-sharing.⁵³ For benefit-sharing, the guidelines require consideration of near, medium, and long term monetary and non-monetary benefits.⁵⁴

Significantly, the *Bonn Guidelines* call on countries to adopt measures ‘to encourage the disclosure of the country of origin of the genetic resources and of the origin of

⁴⁷ Kuruk, above n 11, 21.

⁴⁸ Ibid.

⁴⁹ CBD Conference of the Parties, Decision VI/24 A (2002) (*‘Bonn Guidelines’*).

⁵⁰ Kuruk, above n 11, 21.

⁵¹ *Bonn Guidelines*, arts 14(b), 24.

⁵² Ibid art 16(a)(iii).

⁵³ Ibid art 14(g).

⁵⁴ Ibid art 47.

traditional knowledge... in applications for intellectual property rights.⁵⁵ This is suggested as a tool to track compliance with requirements for gaining PIC and benefit-sharing.⁵⁶ Kuruk states that this requirement could be used to deny or revoke improper patents based on traditional knowledge.⁵⁷

The *Bonn Guidelines* are voluntary and non-binding. They were the first step in articulating the requirements from the CBD. However, the guidelines only encourage implementation of strategies on a national level, which means they do not address problems that have international dimensions or require cross-jurisdiction cooperation.⁵⁸

D *Nagoya Protocol*

This need for cooperation across jurisdictions led to the international community adopting the *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 (the Nagoya Protocol)* in October 2010.⁵⁹ Article 16 provides that States must provide that traditional knowledge associated with genetic resources has been accessed in accordance with PIC from Indigenous groups and that mutually agreed terms have been established.⁶⁰ Article 5 provides each party shall take legislative, administrative or policy measures to ensure that benefits are shared in a fair and equitable way with the communities concerned.⁶¹

Unlike the voluntary *Bonn Guidelines*, the *Nagoya Protocol* is intended to impose binding and enforceable obligations on States.⁶² Its provisions are considered to be enforceable by and against States that ratify or accede to it. However for Indigenous people the benefits of the *Nagoya Protocol* are contingent upon their State's ratification and how that State chooses to implement the protocol in domestic

⁵⁵ Ibid, art 16(d)(ii).

⁵⁶ Ibid.

⁵⁷ Kuruk, above n 11, 25.

⁵⁸ Ibid 26.

⁵⁹ Nagoya Protocol on Access to Genetic Resources and the Fair and Equitable Sharing of Benefits Arising from their Utilization (ABS) to the Convention on Biological Diversity, opened for signature 2 February 2011 (entered into force 12 October 2014) ('*Nagoya Protocol*').

⁶⁰ Ibid art 16(1).

⁶¹ Ibid art 5(2)(5).

⁶² Kuruk, above n 11, 32.

legislation.⁶³ This means that the actual utility of the Protocol will only be visible once implemented in a consistent way.⁶⁴ To this date there are only 78 parties to the Protocol and only 87 countries have ratified it. New Zealand, Australia, Brazil or the US have not ratified or acceded to the Protocol.⁶⁵ However, Australia and Brazil are signatories to it, perhaps indicating an intention that they may ratify in the future.

Whilst this is an improvement on the CBD and *Bonn Guidelines*, the Protocol does not govern some areas. In particular, the Protocol does not require states to implement a disclosure of origin or use of traditional knowledge requirement in patent law. Rather, it simply requires that access to the resource must only be given if there is PIC of Indigenous groups.⁶⁶ The *Nagoya Protocol* omits a disclosure requirement such as that provided in the *Bonn Guidelines*. This is perhaps suggestive of difficulties with reaching an agreement on the disclosure requirement during negotiations leading up to the adoption of the Protocol.⁶⁷ A requirement to include patent offices as checkpoints of access and benefit-sharing was dropped late in negotiations as part of the compromise to pass the Protocol. Daniel Robinson argues that this is a considerable gap in the Protocol because exploitation of traditional knowledge by innovations registered through the patent system is one of the main perceived injustices from biopiracy.⁶⁸

E WIPO Committee

In 2000 WIPO established the IGC to create an international legal instrument to protect traditional knowledge.⁶⁹ Its mandate is to undertake negotiations with the objective of reaching agreement on text of international legal instruments, including one on the effective protection of traditional knowledge.⁷⁰ The Committee's progress has been slow and it has not met its initial deadline of 2008 or its postponed deadline

⁶³ Peter Drahos, *Intellectual Property, Indigenous People and Their Knowledge* (Cambridge University Press, 2014) 83.

⁶⁴ Tania Bubela and E Richard Gold, *Genetic Resources and Traditional Knowledge: Case Studies and Conflicting Interests* (Edward Elgar Publishing, 2012) 12.

⁶⁵ CBD Secretariat, *Parties to the Nagoya Protocol* (August 2016) Convention on Biological Diversity <<https://www.cbd.int/abs/nagoya-protocol/signatories/default.shtml>>

⁶⁶ Kuruk, above n 11, 35.

⁶⁷ *Ibid* 42.

⁶⁸ Daniel F Robinson, 'Biopiracy and the Innovations of Indigenous Peoples and Local Communities' in Peter Drahos and Susy Frankel (eds), *Indigenous Peoples' Innovation Intellectual Property Pathways to Development* (ANU E Press, 2012) 77, 77.

⁶⁹ WIPO General Assembly, *Sept. 25-Oct. 3 2000*, WIPO Doc WO/ GA/26/10 (3 October 2000).

⁷⁰ WIPO, *Intergovernmental Committee (IGC)*, WIPO, <<http://www.wipo.int/tk/en/igc/>>

of 2011.⁷¹ Kuruk attributes this to a lack of interest by the traditional knowledge user countries, and states that there may even be evidence of their efforts to stall and protract the process.⁷² It is clear that some countries are unwilling to participate. The US has only agreed to support the committee to the extent it is not on a ‘norm-setting track’ and would not result in the creation of a treaty or recommendations.⁷³

On the 30th September 2016 the IGC released *Draft Articles* which represent a ‘work in progress’.⁷⁴ Article 4bis provides three alternative disclosure requirements discussed by the IGC: one where patent rights are denied if origin is not disclosed, one where patent rights are not denied but other sanctions are given, and one where there is no mandatory disclosure requirement.⁷⁵ This indicates the continued divide of the international community of whether there should be a mandatory disclosure requirement.

F *Effect On States*

Currently there is the will but no binding international requirements to effectively protect traditional knowledge. Even if parties are signed up to the CBD, *Bonn Guidelines* and *Nagoya Protocol* there is no requirement to have a disclosure requirement in patent law. At a maximum, a member State must only ensure access to resources is with PIC and that there is some benefit-sharing agreement in place. Many member states have not signed these conventions at all, notably the US. Australia’s *EPBC Regulations* meet what is required by the CBD. However they do not follow the *Bonn Guidelines* approach or what may be recommended by the IGC, if article 4bis is incorporated into a final text. Australia has not yet ratified the *Nagoya Protocol*. Robinson states that Australian legislation does not include ‘user measures’, as required by the *Nagoya Protocol*, that ensure researchers are in compliance with foreign bioprospecting regulations, indicating the Australia would have to implement further legislative change to ratify the Protocol.⁷⁶ A patent disclosure requirement would cover ‘user measures’.

⁷¹ Bubela and Gold, above n 64.

⁷² Kuruk, above n 11, 72.

⁷³ Smith, above n 18, 285.

⁷⁴ *IGC Draft Articles*.

⁷⁵ *Ibid* art 4bis.

⁷⁶ Daniel F Robinson, *Biodiversity, Access and Benefit Sharing: Global Case Studies* (Routledge, 2014) 134.

IV CURRENT AUSTRALIAN PROTECTION

A Patents Act 1990

The *Patents Act* provides the framework for patent protection of medical knowledge and innovations in Australia, but includes no reference to traditional knowledge. A patent granted in Australia gives the patentee the exclusive rights, during the term of the patent, to exploit the invention.⁷⁷ The *Patents Act* does not require disclosure of origin or source of materials. Section 40 of the Act only requires the patent applicant to disclose details of the invention in a manner, which is clear enough and complete enough for the invention to be performed by a skilled person, including the best method to perform the invention.⁷⁸

B Nationally Consistent Approach

In response to the CBD, Australia created a *Nationally Consistent Approach for Access to and the Utilisation of Australia's Native Genetic and Biochemical Resources* (NCA) and a *National Strategy for the Conservation of Australia's Biological Diversity* (National Strategy).⁷⁹ The NCA recognises that 'as a megadiverse country, Australia therefore stands to gain considerable economic, social and environmental benefits' from effective use of resources.⁸⁰ One objective of the National Strategy is to 'ensure that the social and economic benefits of the use of genetic material and products derived from Australia's biological diversity accrue to Australia.'⁸¹ The NCA provides that, on principle, governments recognise the need to ensure the use of traditional knowledge is undertaken with the cooperation and approval of the holders of that knowledge and on mutually agreed terms.⁸² In addition, the NCA provides that any legal framework must be developed in consultation with Indigenous peoples.

⁷⁷ *Patents Act 1990* (Cth) s 13.

⁷⁸ *Ibid* s 40.

⁷⁹ Explanatory Statement, *Environment Protection and Biodiversity Conservation Regulations 2000* (Cth), 1.

⁸⁰ *Understanding the NCA*, above n 1, 2.

⁸¹ National Biodiversity Strategy Review Task Group, *National Strategy for the Conservation of Australia's Biological Diversity* (2002) Obj 2.8.

⁸² *Ibid*.

C Pt 8A EPBC Regulations

After an extensive consultation process Part 8A of the *EPBC Regulations* was implemented to give effect to the NCA goals at the Commonwealth level.⁸³ These regulations were introduced under section 301 of the *Environment Protection and Biodiversity Conservation Act 1999*.⁸⁴ The regulations apply to Commonwealth land only. At a state level, Queensland and the Northern Territory have enacted their own legislation for land under state government control.⁸⁵ In the states, access and benefit-sharing is determined as a private unregulated agreement between the land holder and the bioprospector.⁸⁶

Part 8A requires that an access permit must be obtained from the Minister for Environment and Heritage in order to access biological resources of native species in Commonwealth areas.⁸⁷ The Minister can grant the permit if a number of conditions are satisfied. First, the proposed access has to be ecologically sustainable and consistent with the conservation of Australia's biodiversity.⁸⁸ Second, an environmental assessment must have been undertaken.⁸⁹ Third, submissions from interested persons and organisations must be taken into account.⁹⁰ Fourth, there must be a mutually agreed benefit-sharing contract between parties including PIC of any Indigenous owners and full disclosure made of any use of traditional knowledge.⁹¹

PIC is determined by the Minister according to a number of factors.⁹² First, the Minister must consider whether the access provider had adequate knowledge of the regulations and was able to engage in reasonable negotiations about benefit-sharing. Second, the Minister must consider whether the access provider was given adequate time to consider the application for the permit, including time to consult with relevant people, to consult with the traditional owners of the land, and to negotiate the benefit-sharing agreement. Third, if the biological resources are in Indigenous

⁸³ *Environment Protection and Biodiversity Conservation Regulations 2000* (Cth) Pt 8A

⁸⁴ *Understanding The Nationally Consistent Approach*, above n 1, 2.

⁸⁵ *Biodiscovery Act 2004* (Qld); *Biological Resources Act 2006* (NT).

⁸⁶ For discussion see: Charles Lawson, 'Patents and Access and Benefit-sharing Contracts: Conservation or Just More Red Tape?' (2011) 30(2) *Biotechnology Law Report* 197, 206.

⁸⁷ *Environment Protection and Biodiversity Conservation Regulations 2000* (Cth) Pt 8A.06.

⁸⁸ *Ibid* 8A.16.

⁸⁹ *Ibid* 8A.12.

⁹⁰ *Ibid* Pt 8A.15(1)

⁹¹ *Ibid* Pt 8A.2, 8A.07.

⁹² *Ibid* Pt 8A.10 (2)(a)-(e).

peoples' land and there is a land council, the Minister must consider whether the views of the land council have been sought. Fourth, if native title exists in the area, whether the views of any representative Aboriginal/Torres Strait Islander body within the meaning of the *Native Title Act 1993* (Cth) have been sought must be considered. Fifth, the Minister must consider whether the access provider has received independent legal advice.

Non-compliance with the regulations attracts a \$5,500 fine.⁹³ Furthermore, reputational and other legal risks associated with 'biopiracy' provide additional incentive to comply with these legislative requirements.⁹⁴ However, the sanctions in the EPBC Act have also been criticised. Brad Sherman states that while the fine of \$5,500 and any resulting adverse publicity may provide some disincentive against non-compliance, a company could decide this is outweighed by the legal costs and by the moneys that they would have to pay under a benefit-sharing agreement with the access provider.⁹⁵

The regulatory framework itself is not without its critics. Charles Lawson argues that attempts to regulate access and benefit-sharing appear to merely impose additional costs and inefficiencies on the transactions (a regulatory burden) without benefits flowing through to promoting biodiversity conservation.⁹⁶ He further states that the policy shows 'a preference for maintaining existing patent standards irrespective of their consequences for biodiversity conservation.'⁹⁷ This criticism could be extended to the regulations application to traditional knowledge, that pre-existing patent standards are favoured.

The regulations promote commercial negotiations with Indigenous groups. Sherman states that groups are potentially left in a vulnerable position, forced to rely on commercial practices to protect themselves against misuse of their resources.⁹⁸ This

⁹³ Ibid Pt 8A.06.

⁹⁴ Explanatory Statement, *Environment Protection and Biodiversity Conservation Regulations 2000* (Cth), 1.

⁹⁵ Brad Sherman, 'Regulating Access And Use Of Genetic Resources: Intellectual Property Law And Biodiscovery' (2003) 25 (7) *European Intellectual Property Review* 304.

⁹⁶ Lawson, above n 86, 214.

⁹⁷ Ibid 21.

⁹⁸ Sherman, above n 95, 304.

reflects international concerns about the imbalance of power between companies and traditional communities in bioprospecting negotiations.⁹⁹ Kylie Lingard states that access and benefit-sharing regimes ‘simply coerce Indigenous peoples into participation in the economic exploitation of their knowledge and resources’.¹⁰⁰ She further argues that the regulations only support the interest of Indigenous land owners and excludes interests of others holding a cultural stake in the resource.¹⁰¹ Matthew Rimmer states that problems could arise from the regulations heavy dependence on ministerial discretion; if a particular Minister lacked vigilance in enforcing the access regime.¹⁰²

Finally, these protections only apply to traditional knowledge in Australia and do not affect cases where the patent system is used as a tool of misappropriation of foreign traditional knowledge. Sherman states that this concern also applies where Australian plants have already been collected and land owners not compensated by third parties.¹⁰³ Further, Aboriginal and Torres Strait Islander peoples own or control access to around 25- 30% of Australian land.¹⁰⁴ Traditional knowledge from areas outside of this control is not protected through these regulations.

C Queensland and Northern Territory Legislation

The Northern Territory *Biological Resources Act 2006* largely mirrors the *EPBC Regulations* and provides that a researcher must apply for a permit from the CEO of the appropriate authority, currently the Research and Innovation Section of the Department of Business.¹⁰⁵ It has requirements for negotiation of PIC and benefit-sharing with the land holder.¹⁰⁶ Under the Act, agreements must provide for reasonable benefit-sharing arrangements, including the protection, recognition and valuing of traditional knowledge.

⁹⁹ Bubela and Gold, above n 64, 78.

¹⁰⁰ Kylie Lingard, ‘Legal support for the interests of Aboriginal and Torres Strait Islander peoples in the commercial development of new native plant varieties: Current status and future options’ 26 *Australian Intellectual Property Journal* 39, 53.

¹⁰¹ *Ibid.*

¹⁰² Matthew Rimmer, ‘Blame it on Rio: Biodiscovery, Native Title and Traditional Knowledge (2003) 7 *Southern Cross University Review* 1, 19.

¹⁰³ Sherman, above n 95, 304.

¹⁰⁴ Lingard, above n 4, 177.

¹⁰⁵ *Biological Resources Act 2006* (NT).

¹⁰⁶ Robinson, above n 76, 134.

The Queensland *Biodiscovery Act 2004*, however, does not explicitly require benefit-sharing with Aboriginal and Torres Strait Islander people, does not provide any recognition for traditional knowledge and does not require PIC.¹⁰⁷ While some companies do make benefit-sharing agreements, there is no requirement that an agreement be drawn up and the legislation provides no way for communities to control commercial use of their traditional knowledge.¹⁰⁸ Drahos finds that Indigenous groups have not received the benefits from biodiscovery in Queensland and there is few records of benefit-sharing.¹⁰⁹

The inconsistency across Australian states is problematic. Robinson states that lack of consistency between states and territories may lead to the potential for ‘access shopping’ between the states to find the lowest regulatory bar for legal sampling or access.¹¹⁰ Currently southern states have no regulatory hurdles. This criticism is realized when considering the Griffith- AstraZeneca partnership to collect hundreds of samples of biological materials, where care was taken to collect resources from national parks and Crown land (collected before the *EPBC Regulations* came into effect) and not to consult Indigenous groups.¹¹¹ The Federal Government sought to encourage states to introduce legislation through the NCA but there has been little movement from states to follow the *EPBC Regulations*.¹¹² Furthermore, there is also a risk that states will introduce acts that do not adequately protect traditional knowledge or provide benefit-sharing, like the Queensland act.

V DISCLOSURE REQUIREMENTS IN OTHER JURISDICTIONS: US, NZ AND BRAZIL

States have implemented a variety of legislative strategies in the attempt to combat biopiracy. Commitment to effective protection is markedly different between resource-rich developing and least-developed countries, from those with advanced industries and research capacities.¹¹³ This difference is expounded in this section. Australia, however, is both resource-rich and has advanced industries and research

¹⁰⁷ *Biodiscovery Act 2004 (QLD)*.

¹⁰⁸ Neva Collings and Heidi Evans, ‘Access and Benefit Sharing - Protecting Biodiversity and Indigenous Knowledge’ (2009) 7(14) *Indigenous Law Bulletin* 11, 13.

¹⁰⁹ Drahos, above n 82, 138.

¹¹⁰ Robinson, above n 76, 139.

¹¹¹ Drahos, above n 82, 149.

¹¹² Collings and Evans, above n 108, 14.

¹¹³ Bubela and Gold, above n 64, 1.

capacities. Therefore concerns from both sides of this debate are informative. This section will analyse how traditional knowledge is protected in the US, NZ and Brazil. These countries have different protection from Australia and are cited as a comparison. The US has no protection for traditional knowledge and is a worst practice example. NZ has consideration of whether an invention is based on Māori knowledge in built into patent approval. Brazil has an access requirement and a disclosure requirement in their patent application process. New Zealand and Brazil are considered as both assert to be best practice examples but have contrasting ways of tackling biopiracy.

A US

As noted earlier in this paper, the US is not party to the CBD because of perceived negative effects on innovation. US patent law contains no independent requirement of disclosure of the source of genetic resources or PIC.¹¹⁴ As in Australia, and as required by TRIPS, applicants are only required to disclose ‘a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art... to make and use the same.’¹¹⁵

The USPTO has received tens of thousands of patent applications based on traditional knowledge, obtained mostly from resource rich emerging economies, without applicants acknowledging the origin of the resources.¹¹⁶ According to some studies, if the US was forced to pay fair royalties on foreign traditional knowledge currently being used in successful pharmaceutical products, it would owe emerging economies US\$5.1billion dollars annually.¹¹⁷ The profits under the current US system seldom flow to the community upon whose traditional knowledge the product is based.¹¹⁸

¹¹⁴ Grebe, above n 34, 386.

¹¹⁵ *Patent Act*, 35 USC § 112 (1790).

¹¹⁶ Ryan Levy and Spencer Green, ‘Pharmaceuticals and Biopiracy: How the America Invents Act May Reduce the Misappropriation of Traditional Medicine’ 23 *University of Miami Business Law Review* 401.

¹¹⁷ Noah Zerbe, ‘Contested ownership: TRIPS, CBD and implications for Southern African biodiversity’ (2002) 1 *Prospectives on Global Development and Technology* 294.

¹¹⁸ Graham Dutfield, ‘From Traditional Medicine to Modern Drugs’ in Tania Bubela and E Richard Gold, *Genetic Resources and Traditional Knowledge: Case Studies and Conflicting Interests* (Edward Elgar Publishing, 2012) 93, 102.

The US patent system has facilitated this misappropriation, by excluding foreign public use, sale, or knowledge of these traditional remedies in its description of ‘prior art’.¹¹⁹ Although not affecting public use of Native American knowledge, this has meant that undocumented foreign traditional knowledge could not be considered as ‘prior art’ under the novelty requirement, perpetuating biopiracy. An example of this is the Pharmaceutical company Grace’s development of insecticide from the Indian Neem Tree. Despite the patent being revoked in Europe, the US patent was upheld because India was unable to present published evidence of traditional prior use of the Neem Tree as an insecticide.¹²⁰ Graham Dutfield argues that this archaic rule should have been abolished decades ago.¹²¹ However, Ryan Levy and Spencer Green argue the *America Invents Act (AIA)* passed in 2012, which notably changed US patent law from a ‘first to invent’ to a ‘first to file’ system, might now allow ‘public use’ of traditional knowledge from other countries as prior art to invalidate novelty.¹²² Although it is still disputed whether the Act will have this effect, Levy and Green are correct in asserting that this would be an improvement to US patent law and a step towards tackling biopiracy.

US Representatives to the IGC have been resistant to the international proposals of a disclosure requirement. The US has argued that this requirement would fall outside the mandate of the IGC and it would be inappropriate to use the patent system as an enforcement agency.¹²³

The resistance on a government level has not stopped some companies from disclosing source and origin and benefit-sharing agreements. Ecoflora Cares, a Colombian company, was recently granted US patent 9,376,569 B2 and included in their application details of the source of the genetic resources used, and access and benefit-sharing agreement made with the Indigenous communities.¹²⁴ The invention

¹¹⁹ *Patent Act*, 35 USC § 102 (1790).

¹²⁰ Ebermann, above n 14, 101.

¹²¹ Bubela and Gold, above n 64, 102.

¹²² Levy and Green, above n 116, 401.

¹²³ WIPO Secretariat, *Report of the Intergovernmental Committee on Intellectual Property and Genetic Resources, Traditional Knowledge and Folklore*, WIPO Doc WIPO/GRTKF/IC/23/8 Prov 2. (26 April 2013) 35.

¹²⁴ Cano et al, *US Patent No 9,376,569* (issued June 28 2016), USPTO <<http://patft.uspto.gov/netacgi/nph->

was based on the extraction of a natural blue dye with edible properties from the fruit of the *Genipa Americana* tree, growing in Colombia.¹²⁵ To utilise the resource, Ecoflora Cares has secured various permits and agreements in Colombia, based on the legal framework established by Andean Decision 391 and implementing rules.¹²⁶

This disclosure was linked to Ecoflora Cares' membership of the Union for Ethical BioTrade (UEBT), a non-profit association which asks its members in patent applications to disclose the country of origin of the biological resources and include details of agreements on fair and equitable benefit-sharing. The UEBT have these requirements because they recognise broad support for a disclosure requirement.¹²⁷ Here, benefit-sharing was ensured through a shareholding agreement where community-owned suppliers gained a share of the financial benefits of commercialization of the genetic resources.¹²⁸ Further, EcoFlora Cares organised training for local producers on sustainable sourcing in the Pacific rainforest.¹²⁹ This demonstrates both monetary and non-monetary benefits flowing to Indigenous groups. The patent also provides practical proof that a disclosure requirement is not too burdensome.

B *New Zealand*

Māori rights over their Indigenous resources are well recognised in NZ. NZ also provides a good comparison to Australia as a country with biotechnological capabilities and a strong Indigenous culture. Article 2 of the Treaty of Waitangi provides that Māori have 'unqualified exercise of their chieftainship [tino rangātiratanga] over their lands, villages and all their treasures [taonga].'¹³⁰ The Treaty of Waitangi is interpreted chiefly through the *Treaty of Waitangi Act 1975*, by the established Waitangi Tribunal. Whilst the Treaty does not mention IP or cultural

Parser?Sect1=PTO1&Sect2=HITOFF&d=PALL&p=1&u=%2Fnetahhtml%2FPTO%2Fsrchnum.htm&r=1&f=G&l=50&s1=9,376,569.PN.&OS=PN/9,376,569&RS=PN/9,376,569>

¹²⁵ Catherine Saez, *Access And Benefit Sharing Mentioned In US Patent For Natural Dye, Might Be A First*, (1 September 2016) Intellectual Property Watch

<http://www.ip-watch.org/2016/09/01/access-and-benefit-sharing-mentioned-in-us-patent-for-natural-dye-might-be-a-first/?utm_source=IP-Watch+Subscribers&utm_campaign=c02e238522-WEEKLY_SUMMARY&utm_medium=email&utm_term=0_b78685696b-c02e238522-352152757>.

¹²⁶ Ibid.

¹²⁷ Ibid.

¹²⁸ Cano, above n 124.

¹²⁹ Saez, above n 125.

¹³⁰ Ministry for Culture and Heritage, *Differences between the texts* (20 December 2012) New Zealand History <<http://www.nzhistory.net.nz/politics/treaty/read-the-Treaty/differences-between-the-texts>>.

heritage, it is clear that these can be considered taonga.¹³¹ Although encouraged by government, patents over taonga are often not sought by Māori for their traditional knowledge, as they are considered as another way of ‘stealing ownership away from original peoples’.¹³²

The Wai 262 Report by the Waitangi Tribunal, an independent commission of inquiry which considers breaches of the *Treaty of Waitangi* 1840, found that the New Zealand government had breached its obligations to respect the exercise of tino rangātiratanga over taonga and that existing IP law does not adequately protect taonga species.¹³³ The Waitangi tribunal recommended that a Māori Committee with greater powers than the one subsequently introduced by the government, be established to advise the Commissioner of Patents about the use of Māori knowledge or species, including the power to state whether registration should occur. It also proposed that patent applications be required to disclose whether any Māori traditional knowledge was used in research for the invention and ‘the source and country of origin of any genetic or biological resources that contributed to the invention’ with consequences for non-disclosure ranging from sanctions to refusal of a patent.¹³⁴ These recommendations have not been adopted by the NZ Government.

In 2013 the NZ government introduced a new *Patents Act* which was a considerable overhaul to their 1953 *Patents Act* to reflect modernisation of patent law and development of new technologies.¹³⁵ It also brought NZ patent legislation in conformity with Australian patent law as amended by the Australian *Raising the Bar Act*.¹³⁶ However, the New Zealand *Patents Act* also provides that the Commissioner can refuse a patent if it is substantially based on traditional knowledge. If the patent includes traditional knowledge then the Commissioner must seek the advice of the Patents Māori Advisory Committee. The Committee must advise the Commissioner as to whether a claimed invention is derived from Māori traditional knowledge or

¹³¹ Waitangi Tribunal, *Report of the Waitangi Tribunal on Te Roroa* (1992) 21.

¹³² Jessica Lai, ‘Māori Traditional Knowledge and New Zealand Patent Law: The 2013 Act and the Dawn of a New Era?’ 17(1-2) *Journal of World Intellectual Property* (2014) 34, 34.

¹³³ Waitangi Tribunal, *Report of the Waitangi Tribunal on Claims Concerning New Zealand Law and Policy Concerning New Zealand Law and Policy Affecting Māori Culture and Identity* (2011).

¹³⁴ *Ibid* 212.

¹³⁵ *Patents Act 2013 (NZ)*.

¹³⁶ Lai, above n 132, 34.

‘Indigenous plants or animals’ and, if so, whether ‘the commercial exploitation of that invention is likely to be contrary to Māori values’.¹³⁷ The Commissioner can deny the patent if it is against the *ordre public* and is contrary to Māori values. The Commissioner is not bound by the opinion of the Māori Advisory Committee. Justin Graham asserts that this makes sense because the Committee represents only Māori interest and is not comprised of patent law specialists.¹³⁸ However, this falls short of what was lobbied for by the Wai 262 Report. It also means it is likely that the Commissioner may give more weight to public opinion than to the opinion of Committee.¹³⁹

An *ordre public* or morality exception is allowable under art 27.2 of TRIPS.¹⁴⁰ The derivation of this exception is from the European Patent Convention, and it introduces ethical and social considerations into patent law, denying patents if the invention is contrary to public morality. However considering traditional knowledge here is an interesting solution. The other explicit exclusions from patentability in New Zealand under this section are inventions for cloning human beings, modifying germ line genetic identity and using human embryos for commercial purposes, hardly comparable to traditional knowledge.¹⁴¹ Consideration of Māori right to *tinō rangatiratanga* over *taonga* as within *ordre public* was justified by the Waitangi Tribunal in the Wai 262 Report, because the Treaty is a constitutional document, which defines the New Zealand legal and social order.¹⁴²

Although this legislation is thought of as a positive step in the protection of Māori knowledge, it has been criticized. Jessica Lai provides some criticisms.¹⁴³ First, before the Commissioner seeks the advice of the Committee, there needs to be a realisation that the patent application may be derived from Māori traditional knowledge, and may be contrary to Māori values.¹⁴⁴ This is problematic because often Māori traditional knowledge is not published or kept secret. Further, because this

¹³⁷ *Patents Act 2013* (NZ), ss 275-278

¹³⁸ Justin Graham, ‘The Future of Patent Law’ (2008) *New Zealand Law Journal*, 363, 365.

¹³⁹ Lai, above n 132, 45.

¹⁴⁰ *TRIPS Agreement* annex 1C.

¹⁴¹ *Patents Act 2013* (NZ), s 14(1)

¹⁴² Waitangi Tribunal, above n 133, 201,210.

¹⁴³ Lai, above n 132, 45.

¹⁴⁴ *Ibid* 41.

consideration is within the *ordre public*, few patents would be refused on this ground because it is difficult to define what is against the *ordre public*.¹⁴⁵ Graham argues it only ‘dips a toe in the water of a particular view of traditional knowledge’, or is ‘an impuissant nod to lobbyists that will in fact rarely be used’.¹⁴⁶

These criticisms show that a disclosure requirement would also be beneficial in New Zealand, in addition to the current provision.¹⁴⁷ This would address Lai’s concern that for the Commissioner to seek advice of the Committee, it has to be identified that an invention is based on Māori knowledge. It would put a positive obligation on patent applicants to disclose any link to Māori knowledge or species. Further, this Committee only steps in when the knowledge is Māori, and does not cover situations where patents are based on foreign traditional knowledge.

C Brazil

Brazil is the most biologically diverse country in the world, containing 20% of the world’s known species.¹⁴⁸ It provides a good comparison because of large genetic heritage and unique cultural diversity but also widespread social inequity.¹⁴⁹ Brazil does have scientific capacity but there has been a lack of integration between scientific research and the traditional knowledge, meaning the sector has not reached its full potential.¹⁵⁰ Despite being a civil law country, Brazilian patent law is largely consistent with the IP laws of other countries, including Australia. The requirements for patentability in Brazilian law are described in Article 8 of Law Number 9.279 and include novelty, inventive activity, and industrial application.¹⁵¹

¹⁴⁵ Ibid.

¹⁴⁶ Graham, above n 138, 363.

¹⁴⁷ Peter Drahos and Susy Frankel, ‘Indigenous Peoples’ Innovation and Intellectual Property: The Issues’ in Peter Drahos and Susy Frankel (eds), *Indigenous Peoples’ Innovation Intellectual Property Pathways to Development* (ANU E Press, 2012) 1, 57.

¹⁴⁸ John Tustin, ‘Traditional Knowledge and Intellectual Property in Brazilian Biodiversity Law (2006) 14 *Texas Intellectual Property Law Journal* 131, 132.

¹⁴⁹ Edson Beas Roderigues Jr ‘Property Rights, Biocultural Resources and Two Tragedies: Some Lessons From Brazil’ in Tania Bubela and E Richard Gold, *Genetic Resources and Traditional Knowledge: Case Studies and Conflicting Interests* (Edward Elgar Publishing, 2012) 113, 118.

¹⁵⁰ Ibid.

¹⁵¹ Law Number 9.279 (Brazil) art 8.

Brazil was one of the first countries to develop a sui generis legal system specifically for the protection of traditional knowledge in 2001.¹⁵² Provisional Measures number 2.186-16 are aimed at regulating access to genetic heritage and associated traditional knowledge.¹⁵³ These measures grant to Indigenous owners, without prior registration, rights similar to those granted to patent holders, including the right to prevent unauthorised third parties from accessing their traditional knowledge and biological resources.¹⁵⁴ Any organisation that wishes to exploit these resources must apply for an access permit through Genetic Heritage Management Council, obtain their authorisation and show PIC from Indigenous communities and a benefit-sharing agreement.

Article 31 of the Provisional Measures also provide that any application for patent protection of an invention based on genetic resources or traditional knowledge should disclose the origin of the material and the associated traditional knowledge.¹⁵⁵ The award of patents is conditional on compliance with the Provisional Measures access requirements.¹⁵⁶ Further, legislative decree number 5.459/2005 establishes a schedule of fines and penalties for the unauthorised access to and disclosure of traditional knowledge and omission of origin from any publication referring to traditional knowledge.¹⁵⁷

The Brazilian access scheme has been criticised by the Brazilian scientific sector for being over bureaucratic and hindering the study of biodiversity and traditional knowledge, because of long delays with granting access permits.¹⁵⁸ This in part stems from the sui generis rights given to the Indigenous Groups, and that a number of Indigenous groups have claims over land areas. Edson Beas Roderigues Jr also states that the Measures provide no guidance in identifying whether benefit-sharing

¹⁵² Kanchana Kariyawasam and Scott Guy 'Intellectual Property Protection of Indigenous Knowledge: Implementing Initiatives at National and Regional Levels' (2007) 12(2) *Deakin Law Review* 105, 107.

¹⁵³ *Provisional Measures No. 2.186-16* (Brazil) 23 August 2001.

¹⁵⁴ *Ibid* arts 7 and 9.

¹⁵⁵ *Ibid* art 31.

¹⁵⁶ Tustin, above n 148, 148.

¹⁵⁷ *Ibid*.

¹⁵⁸ Roderigues, above n 19, 161.

agreements are fair and equitable and that guidelines should be introduced.¹⁵⁹ He also states that in practice few patent applications reference traditional knowledge.¹⁶⁰

Despite these criticisms, the disclosure requirement and associated sanctions are an effective way of protecting traditional knowledge from biopiracy. Kanchana Kariyawasam and Scott Guy state that Brazil has taken all possible measures to prevent unauthorised third parties from misappropriating traditional knowledge.¹⁶¹ Although Brazil may need legislative amendment to address bureaucracy around the access requirements and ensure innovation isn't impeded, the patent disclosure requirement provides an effective checkpoint to consider whether traditional knowledge has been obtained with PIC and benefit-sharing. Brazil's protection is thought to follow the *Bonn Guidelines* approach and be compliant with the CBD and *Nagoya Protocol*.¹⁶²

VI BENEFITS OF A DISCLOSURE REQUIREMENT

Although the *EPBC* Regulations are an important step towards the protection of traditional knowledge, tying them to the granting of patent rights would be an effective checkpoint to ensure compliance. There are many advantages to having a disclosure requirement in the *Patents Act*. A disclosure requirement would directly and effectively ensure compliance with the PIC and fair and equitable benefit-sharing obligations of Article 8(j) of the CBD.¹⁶³ In an early proposal for a disclosure requirement to the IGC, Switzerland provided four reasons for its inclusion – transparency, traceability, technical prior art and mutual trust.¹⁶⁴ Including a disclosure requirement creates more transparency around the process of patent application and pharmaceutical development. It would allow the 'providers of ... traditional knowledge to keep track of the use of their resources or knowledge.'¹⁶⁵

¹⁵⁹ Ibid 160.

¹⁶⁰ Ibid 156.

¹⁶¹ Kariyawasam and Guy, above n 152, 108.

¹⁶² Tustin, above n 148, 188.

¹⁶³ WIPO Secretariat, *Report of the Intergovernmental Committee on Intellectual Property and Genetic Resources, Traditional Knowledge and Folklore*, WIPO Doc No WIPO/GRTKF/IC/23/8 Prov 2 (26 April 2013) 35.

¹⁶⁴ WIPO Intergovernmental Committee on Intellectual Property and Genetic Resources, Traditional Knowledge and Folklore, *Proposals by Switzerland regarding the Declaration of the Source of Genetic Resources and Traditional Knowledge in Patent Applications* WIPO Doc WIPO/GRTKF/IC/10 (6 June 2007).

¹⁶⁵ Ibid 12(b).

Determination of prior art would be made easier by creating a record of traditional knowledge on the database. Finally, it encourages greater trust between companies and communities through acknowledgement and recorded details of benefit-sharing.

Laura Grebe describes three major benefits of having a disclosure requirement. First, disclosures will help to enforce the novelty requirement. The novelty requirement is undermined when patents are applied for based on traditional knowledge without acknowledging the knowledge as prior art.¹⁶⁶ Second, she argues that patenting biological resources causes definite economic harm to the source countries and communities. Depending on the scope of the patent, when companies gain patents over the resources, these countries and communities may be prevented from using their own resources for economic advancement. A disclosure requirement would alert source countries that some resources may have medical benefits and the countries would be able to use, develop and monitor their resources appropriately.¹⁶⁷ Third, a source and PIC disclosure requirement will encourage conservation of resources and ethical treatment of communities.¹⁶⁸

Conservation is achieved because requiring researchers to disclose PIC will mean that governments can turn their attention to conserving the resources.¹⁶⁹ Further, a disclosure requirement that turns on whether a community has given PIC renders local communities in charge of their resources. These communities most likely know the most appropriate ways to conserve the resources. Ethical treatment of communities is encouraged because the disclosure requirement may also influence researchers to obtain their resources from reliable and reputable handlers. Further, a disclosure requirement that requires companies to provide details of benefit-sharing agreements provides an extra checkpoint as to whether the access has been on acceptable terms. Peter Drahos argues that building a disclosure requirement into IP law means that real risks, including patent revocation, attach to not entering into a process of negotiation with Indigenous groups.¹⁷⁰

¹⁶⁶ Grebe, above n 34, 393.

¹⁶⁷ Ibid 394.

¹⁶⁸ Ibid.

¹⁶⁹ Ibid.

¹⁷⁰ Drahos and Frankel, above n 147, 26.

From an Indigenous perspective, a disclosure requirement would give recognition of the value of traditional knowledge and ensure the continued existence of traditional knowledge into the future by providing formal record.¹⁷¹ Further, a disclosure requirement would assist Indigenous and local communities to monitor potential misappropriation of their knowledge and affirm their rights over developed traditional knowledge.¹⁷²

Countries including Brazil, Peru, India, China, Namibia and South Africa have emerged as very strong advocates for a mandatory disclosure requirement.¹⁷³ These countries envisage patent offices serving as a checkpoint on whether a particular product has misappropriated traditional knowledge.¹⁷⁴ Brazil supports the disclosure requirement as ‘the most effective solution’ to the problem of the misappropriation of genetic resources and proposes sanctions for non-compliance.¹⁷⁵

A Arguments against disclosure

There are a number of arguments posed by states such as the US and Japan against a disclosure requirement. One argument is that an obligation to disclose will place too large a burden on patent applicants.¹⁷⁶ This is especially the case when patent applicants do not know all the details of the source and origin of the resources. However, Petra Ebermann states that these situations can be avoided if the extent of the required disclosure is precisely defined and governments are cautious to avoid putting an undue burden on the applicants.¹⁷⁷

¹⁷¹ Kelter, above n 13, 396.

¹⁷² Chidi Oguamanam, ‘Pressuring ‘suspect orthodoxy’: traditional knowledge and the patent system’ in Matthew Rimmer (ed) *Indigenous Intellectual Property: A Handbook of Contemporary Research* (Edward Elgar Publishing, 2015) 313, 323.

¹⁷³ Kuruk, above n 11, 59.

¹⁷⁴ Ibid.

¹⁷⁵ WIPO Intergovernmental Committee on Intellectual Property and Genetic Resources, Traditional Knowledge and Folklore, *Proposals by Switzerland Regarding Declaration of the Source of Genetic Resources and Traditional Knowledge, Communication from Switzerland* WIPO Doc IP/C/W/400/Rev.1 (18 June 2003).

¹⁷⁶ WIPO Secretariat, *Report of the Intergovernmental Committee on Intellectual Property and Genetic Resources, Traditional Knowledge and Folklore*, WIPO Doc WIPO/GRTKF/IC/23/8 Prov 2 (26 April 2013) 62.

¹⁷⁷ Ebermann, above n 14, 174.

US Representatives to the IGC consistently represent that a disclosure requirement would add uncertainties to the patent system and negatively affect innovation.¹⁷⁸ Other supporters of this argument have suggested that having a disclosure requirement is contrary to the objectives of the TRIPS agreement and would work against incentivizing inventions.¹⁷⁹ However Brazil, India and many other countries have interpreted TRIPS in a way that it is consistent with a disclosure requirement.¹⁸⁰

As well as deterring innovation it may be argued that a disclosure requirement may deter bioprospectors from negotiating access and encourage them to look elsewhere for the resources or not develop the product. As noted above, this was a real occurrence with the Griffith-AstraZeneca partnership in Queensland. Further, many companies may then decide to forego patent protection altogether, if they are unwilling to disclose the source of resources or do not weigh the benefits against the cost of a benefit-sharing agreement.

B *Why Can't We Have Both?*

The *EPBC Regulations* provide some protection against biopiracy in Australia. However, a disclosure requirement within the *Patents Act* would provide an additional checkpoint to ensure biopiracy does not occur, and that traditional knowledge is not being misappropriated without recognition or benefit-sharing.

Compliance with the *EPBC Regulations* should be made a condition for patent approval as suggested by Sherman.¹⁸¹ He suggests that this would be an easy way to protect traditional knowledge from exploitation. Jacques De Werra argues that a disclosure of origin requirement will increase transparency in the patent process but may not alone be sufficient to ensure benefit-sharing for communities.¹⁸² However if there is additional protective measures for benefit-sharing, a disclosure requirement will lead to effective protection of traditional knowledge.

¹⁷⁸ Jon Santamauro, 'Reducing the Rhetoric: Reconsidering the Relationship of the TRIPS Agreement, CBD and Proposed New Patent Disclosure Requirements Relating to Genetic Resources and Traditional Knowledge' (2007) *European Intellectual Property Report* 91, 91.

¹⁷⁹ Kuruk, above n 11.

¹⁸⁰ Sherman, above n 95, 307.

¹⁸¹ *Ibid.*

¹⁸² Jacques de Werra, 'Fighting Against Biopiracy: Does the Obligation to Disclose in Patent Applications Truly Help' (2009) 42 *Vanderbilt Journal of Transnational Law* 143, 178.

A disclosure requirement would bridge the current gap in protection that exists when resources are obtained from other countries or from areas not covered by the *EPBC Regulations*. As indicated, cross-jurisdictional biopiracy is problematic and has drawn the attention of the international community, as it benefits biotechnology-capable countries at the expense of resource-rich emerging economies. Grebe argues that requiring applicants to disclose details of source countries and whether PIC has been obtained would be an effective way to tackle biopiracy across States.¹⁸³

Introducing a disclosure requirement would be in Australia's interest. Firstly it would bring our protection into line with a number of different jurisdictions such as the EU, Brazil, Denmark, Switzerland and India, who also have disclosure requirements similar to that in Brazil.¹⁸⁴ The Federal Government may be reluctant to take this step before it is required or encouraged at an international level. However, the international discussions at the IGC may lead to a mandatory disclosure requirement. Further, as Australia moves forward with its goal of constitutional recognition of Aboriginal people it should take steps to ensure their knowledge is adequately protected. A requirement would encourage preservation and records of traditional knowledge. Further, benefit-sharing agreements would provide benefits to often isolated Indigenous communities. Finally, it would be a simple additional requirement, as it would not place undue burden on applicants who have already complied with the *EPBC Regulations*. The disclosure requirement would extend the obligations in the Regulations to knowledge from the rest of Australia and overseas.

VII CONCLUSION

An amendment to the *Patents Act* to require disclosure of the source and origin of traditional knowledge and details of any benefit-sharing agreements with Indigenous group would provide additional and necessary protection against biopiracy. The *EPBC Regulations* only apply to Commonwealth land, and Australian traditional knowledge. A disclosure requirement would provide an additional checkpoint that the regulations have been complied with and benefit-sharing agreements are adequate. It may be unlikely that Australia would take this step before it is required or encouraged

¹⁸³ Grebe, above n 34.

¹⁸⁴ Sherman, above n 95, 306.

at an international level. However Australia should follow the example of the EU, Brazil and others and incorporate a disclosure requirement into the *Patents Act*. As Australia moves forward in its path to constitutional recognition of Indigenous peoples it should also provide additional safeguards for traditional knowledge.