FNI Report 1/2014

The Australian ABS Framework

A Model Case for Bioprospecting?

Christian Prip, G. Kristin Rosendal, Steinar Andresen and Morten Walløe Tvedt

Access and Benefit Sharing
The ABS Capacity Development Initiative

FRIDTJOF NANSENS INSTITUTT
FRIDTJOF NANSEN INSTITUTE

The Australian ABS Framework

A Model Case for Bioprospecting?

Christian Prip, G. Kristin Rosendal, Steinar Andresen

and Morten Walløe Tvedt

March 2014

This report is a contribution from the Fridtjof Nansen Institute (FNI), Norway, as part of a research project on Access and Benefit Sharing carried out in co-operation with the multi-donor ABS Capacity Development Initiative. The Initiative is supported by the Norwegian Ministry of Foreign Affairs, the Danish Ministry of Environment, the German Federal Ministry for Economic Cooperation and Development (BMZ), the Institut de la Francophonie pour développement durable (IFDD) and the European Union, and is carried out in partnership with the United Nations Environment Programme and the Secretariat of the Convention on Biological Diversity. The implementation of the Initiative is commissioned by BMZ to the Deutsche Gesellschaft für Internationale Zusammenarbeit (GIZ) GmbH. Starting in 2009, the FNI research project is aimed at improving the knowledge foundation and management related to working on ABS in Africa and internationally. See: www.fni.no/abs

funded by
BMZ Federal Ministry for Economic Cooperation and Development
Organisation internationale de la francophonie
Institut de la Francophonie pour le développement durable IFDD
Norwegian Ministry of Foreign Affairs
Danish Ministry of the Environment
European Commission
implemented by
giz Programme Implementing the Biodiversity Convention

FRIDTJOF NANSENS INSTITUTT
FRIDTJOF NANSEN INSTITUTE

Title: The Australian ABS Framework: A Model Case for Bioprospecting?

Publication Type and Number
FNI Report 1/2014

Pages
42

Author
Christian Prip, G. Kristin Rosendal, Steinar Andresen and Morten Walløe Tvedt

ISBN
978-82-7613-674-6

ISSN
1893-5486

Abstract

Australian ABS legislation is advanced and pioneering in giving national effect to the third objective of the CBD with mandatory permits for all biodiscovery and mandatory benefit sharing agreements for biodiscovery with a commercial intent. Nevertheless, under Commonwealth legislation there is still only one biodiscovery case involving commercial benefit sharing. This is spite of persistent interest in biodiscovery.

One lesson is the need for improving the dynamic element in ABS contracts, building in a clearer trigger point for when the obligations to share are actualized and to reverse the burden of tracking and follow-up to the user rather than leaving it to the provider. If a rich country like Australia lacks sufficient resources to follow the future development based on its material, this speaks volumes for poor provider countries. Linking the ABS and IPR legislation through disclosure of the source of biological resources in patent applications can be an appropriate legal measure to track compliance. Also, the statutory declaration in Commonwealth legislation is a legal instrument that could bind the user to Australian criminal law, although this holds a more limited prospect for following and tracking genetic material if it is transferred to third parties. This indicates that using the general legal means for making ABS work is a fruitful way forward.

Australia played an important role in the negotiations leading to the Nagoya Protocol (NP), and its legislation inspired some of the Protocol's provisions. On that basis and being a megadiversity country with extensive ABS experience and wide support by the biodiscovery stakeholders to the NP, it would seem obvious and in the interest of the country to become a party to the NP. The outside world would also benefit from Australia being a party because Australia has learned many ABS lessons to be shared with other parties of which many will not have come nearly as far in their ABS experience. Among others, there are lessons about drawing up an effective regulatory system, but also about legal challenges for federal nations with mixed jurisdictions between the federal and state level. These lessons concern partnerships between public academic institutions and the private sector with great benefits for both parties, as well as difficulties in distinguishing scientific from commercial biodiscovery and defining roles

Key Words

biodiversity, Australia, access and benefit sharing, legislation, institution

Orders to:

Fridtjof Nansen Institute
Postboks 326
N-1326 Lysaker, Norway.

Tel: (47) 6711 1900
Fax: (47) 6711 1910
Email: post@fni.no
Internet: www.fni.no

Contents

1 Introduction

The aim of this study is to explore elements in Access and Benefit Sharing legislation in Australia for the purpose of drawing lessons that other countries can learn from in their management of genetic resources.

Australia is one of the 17 megadiverse countries with an estimated 10 per cent of the world's biodiversity. Of that biodiversity 80 per cent is endemic to Australia, and Australia is possibly the country with the highest rate of endemism (Mittermeier and Mittermeier, 1997). A significant proportion of its great biodiversity, especially in the marine ecosystem, remains to be identified. As such, Australia is also rich in genetic resources for potential use in research and development of new products. The country sees great opportunities and seeks to be a leader in bioprospecting (mostly referred to as 'biodiscovery' in Australia and therefore this term is used in the following) in collaboration with indigenous peoples, biotech companies, research scientists and managers of biodiversity.[1]

Australia has come a long way in implementing the three-fold objective of the Convention on Biological Diversity (CBD, 1992), namely conservation and sustainable use of biodiversity and equitable sharing of benefits derived from utilization of genetic resources (GR). With regard to the latter objective, Australia probably has one of the most advanced regulatory systems in the world for regulating access to genetic resources and sharing of benefits (ABS). The Australian government ties its legislation closely with the CBD ABS provisions affirming the sovereign rights of a state to its biological resources.[2]

Due to the complexity of the issue and the many years of ongoing politicized negotiations in the CBD on developing the ABS regime further, a large number of countries have still not enacted national legislation to comply with the regime. The long negotiation round leading to the NP probably also slowed down the initial implementation phase for ABS implementation, as countries awaited the conclusion of the negotiations. An increasing number of developing countries have enacted or are in the process of developing access legislation as providers of genetic resources. However, since the number is still limited and without compatible legislation in user countries to support compliance with access regulations, there is still some way to go before the regime can effectively work (Tvedt and Young 2007, Tvedt and Rokundo 2009 and Tvedt 2014). ABS legislation in developing countries is often criticized for being cumbersome with a view to access as well as being futile with a view to benefit sharing (Morgera et al., 2013; Fowler, 2001; Grajal, 1999). Australia's ABS legislation, in contrast, has not been subject to similar objections; it seems to be regarded as successful in terms of

[1] Australian Government, Department of the Environment and Heritage. 'Genetic Resources Management in Commonwealth Areas. Sustainable Access > Shared Benefits. Understanding the new Australian regulations for access to genetic and biochemical resources found in native species in Commonwealth areas.' An undated information publication.
[2] Ibid.

handling access issues, although verdicts are varied regarding its provision of benefits to Australia from utilization of genetic resources (Burton, 2013); Siswandi, undated). Since the Australian legal framework for ABS was developed, internationally the CBD principles on Access and Benefit Sharing (ABS) have been sought reinforced through the Nagoya Protocol (NP, 2010). In light of the NP, Australia currently considers a number of aspects on strengthening its ABS legislation, including disclosure of source in patent applications including associated traditional knowledge (TK), penalties for non-compliance (unlawful sourcing of biological resources in Australia) and for use of TK (without Prior Informed Consent (PIC) and Mutually Agreed Terms (MAT), and requirement for researchers and other user of genetic resources to comply with ABS legislation in provider countries (Burton, 2013).

These are also items that remain controversial between users and providers in the global ABS negotiations and as such they have a wider interest. The evolving ABS legislation makes Australia an interesting model case, as Australia recognises its strengths the two roles of user and provider: it is a developed country with an ambitious and advanced biotechnology sector (user) and a megadiverse country in terms of species and genetic resources (provider). Also, Australian institutions keep genetic resources from other countries in their collections, making Australian actors potentially strong as middlemen in access to other countries' genetic resources. The bulk of terrestrial species diversity is found in the tropical South (UNEP, 1995, p.749), while developed countries are mostly in the position to reap the biotechnological revenues from utilization of genetic resources (GR). This North–South controversy still colours the ABS conflict, even though the negotiating coalitions in the CBD are changing along with the picture of providers and users. Throughout, Australia has embodied a cross-cutting role: it has generally pursued developed countries' interests (as a user) in the international negotiations while at the same time having established pioneering ABS legislation domestically (as a large-scale provider of genetic resources).

This makes Australia an interesting case to study in order to draw potential lessons for ABS legislation in other (and poorer) provider countries. The task here is to study aspects of the situation in Australia for the purpose of understanding the conditions for ABS. What also makes Australia an interesting case in this context, is the large presence of indigenous peoples (in Australia mainly referred to as Aboriginal and Torres Strait Islanders) as providers of genetic resources and associated traditional knowledge.

In this study we pose three core questions:

i) How well does Australia's legal and institutional ABS system achieve the aims of the CBD/NP ABS regime?

ii) How well does the Australian system provide benefits for Australia and its providers of biological resources?[3]

[3] 'Biological resources' including but not limited to genetic resources is the subject of ABS legislation in Australia and therefore the term used here and throughout the text.

iii) To what extent is Australia ready to ratify and implement the Nagoya Protocol?

Towards the end of this report, we discuss these experiences and suggest ways of making them available for more countries as they enter into a phase of NP implementation.

2 Approach and Method

Our methodological approach is to examine the relevant legislation and institutions relating to ABS (biodiscovery) in Australia, as well as how this system functions in practice. To this are added literature reviews and interviews with fifteen key actors. Interviewees came from the Department of the Environment with its focal point and competent national authority on ABS; the Department of Agriculture; and the Intellectual Property Authority at the Federal (Commonwealth) level. At State level we interviewed key actors from the Queensland Government ABS / biodiscovery focal point and from the academic / research sector from Griffith University (Eskitis Institute), the Australian Institute of Marine Science (AIMS), the Tropical Herbarium of Cairns, the James Cook University and the United Nations University.

A potential weakness in our case study is the lack of interviews with the biotechnology industry and with government representatives from the Northern Territory, the only other State/Territory with legislation to regulate biodiscovery. Still, in total the selection has secured a quite high level of representation at different levels of governance and has brought out a range of opinions about the strengths and weaknesses of the legal and institutional framework on ABS and what factors are seen as conducive or as barriers to further development of the framework.

In our interviews we asked key actors to pinpoint specific barriers to ABS policy and legislation and their implementation. Institutional factors could involve harmonization between various sector ministries and other interests, and the distribution of authority between Federal and State/ Territory levels. Moreover, we asked whether the actors saw established institutions as being able to monitor permits to prospect biological resources as well as to develop taxonomic studies and inventories to increase knowledge about the country's biodiversity. This latter aspect relates to how science and policy interact in the decision-making process on ABS. We asked what strategies are best suited for achieving national interests and for overall goal achievement in line with the international regime. Also, we assessed the extent to which Australia is ready to ratify and implement the Nagoya Protocol.

In other country studies under the collaboration with the multidonor ABS Capacity Building Initiative (Rosendal, 2010; et al., 2011; et al. 2012; Andresen and Winge, 2012), we examined cases from medicine, agriculture and aquaculture.

3 Global ABS Governance: Key Actors, Arenas and Conflicts

Developed and developing countries came to the CBD negotiation with widely different agendas and largely incompatible interests. Many developed countries wanted a straightforward treaty to protect wildlife fauna, flora and habitats. They considered genetic resources as unregulated allowing them to enjoy free access to the resources in countries in the South. In contrast, developing countries wanted recognition of national sovereignty to genetic resources and genetic material from both wild and cultivated/agricultural species to be included in the convention. This way, they sought to ensure that they would receive a fair share of the proceeds from the use of the genetic resources. In response, developed countries insisted that focusing on the value of genetic resources politicized the negotiations. Speaking for the interests of the biotechnology sector, developed countries wanted the traditional conservation strategy to continue (the establishment of wildlife reserves and protection of endangered species) and did not want to link conservation with economic obligations in developed countries, nor link the use of genetic resources to benefit sharing.

In addition to the demand for a fair sharing of the benefits, the developing countries wanted compensation and incentives to preserve their biological diversity, thus avoiding having to shoulder the greatest burden. How to parcel out the economic responsibility for preserving diversity has been one of the hardest topics at the negotiations.

A key contentious issue between developed and developing countries was the extent to which ‘user’ (mainly developed) countries should assist ‘provider’ (mainly developing) countries in ensuring that benefits from the use of genetic resources were equitably shared and that users complied with provider countries’ access legislation. This is central as access often happens under the jurisdiction of one country and use under the jurisdiction of another; and the laws of the former are not automatically applicable in the latter.

The focus of this discussion was the relation between the CBD ABS provisions and the international regulation of Intellectual Property Rights (IPRs) in the WTO TRIPS Agreement. This Agreement was perceived by developing countries to disrupt the objectives sought within the CBD negotiations; in both arenas developing country were making efforts to counter the increased strength and scope of patent protection within the biotechnological sector. The North–South divide arose to a large extent because patenting is a long and costly business and primarily employed by large corporations to establish exclusive rights to inventions. The Nagoya Protocol did not resolve this perceived conflict (Pavoni, 2013). There is an unused potential for synergy with the WTO, but not sufficient political willingness to use the patent system as a tool for making benefit sharing workable (Kamau and Winter, 2009; Pavoni, 2013). The great imbalance between the patent system and ABS is that the institutions of the patent system are already in place and working, whereas ABS is a new legal concept in the CBD and requires the establishment of new

institutions. There are also crucial differences in how these two systems define their respective objects that add to the imbalance in their functional implementation (Tvedt 2013).

The current controversy with the patent system mainly concerns whether to make disclosure mandatory in domestic patent legislation. Disclosure could imply that all patent applications involving genetic material should provide information about the origin of the material used and whether prior informed consent (PIC) and mutually agreed terms (MAT) have been obtained. Provider countries lost their attempt to have mandatory disclosure requirements included in the NP. This discussion is mainly going on in the Intergovernmental Committee on Genetic Resources, Traditional Knowledge and Folklore (IGC) in the WIPO. As the patent system has a much stronger legal clout compared to the ABS system, using it as a mechanism for enforcing ABS might enhance the strength of ABS, improve transparency and help trace genetic material into a final patented product. Nevertheless, among the OECD (primarily users) countries, the most significant ABS measures are the legal amendments in patent legislation towards *disclosure of origin of genetic resources in patent applications*: Norway, Belgium, Denmark, Germany, Italy, Portugal, Romania, Sweden, and Switzerland have all provided for this quite far-reaching legislation.

Since the entering into force of the CBD in 1993, seven regions[4] and 57 countries (40 developing/provider countries and 17 industrialized/user countries) have formulated domestic legal ABS measures.[5] The emerging economies of Brazil, China, India and South Africa have all enacted fully fledged ABS legislation. Other user country measures relate to legal language demanding compliance with *PIC and MAT,* and this is found in Norway, Croatia, Denmark, France, Malta, and Portugal. A third significant legal activity in terms of compliance measures in user countries is the introduction of *penalties/sanctions for non-compliance*, which have been enacted in Norway, Australia, Bulgaria, Denmark, Malta, Portugal, and Switzerland. Australia has elaborate ABS legislation aimed at regulating biodiscovery (their concept for bioprospecting) activities by external actors within their borders, in other words their legislation is that of a provider country, and there are still no legal measures to regulate Australian activities abroad. In the others it is the other way around: e.g. in Norway, the legislation on PIC and MAT aims at Norwegian activities abroad, while there is still very little in terms of ABS permits regulating bioprospecting within Norwegian borders.

Although the fronts between North and South became less clear cut during the many years of negotiations leading up to the Nagoya Protocol, the core contentious issues still persist (Wallbott et al., 2013). The ABS regime of the CBD/NP faces several implementation challenges, not least in terms of competing approaches to governing genetic resources in a

[4] Regions are African Regional Intellectual Property Organization, African Union, Andean Pact, Central American countries, Commission des Forets d'Afrique Centrale, the European Union, and the Nordic region.
[5] www.cbd.int/abs/measures/groups.shtml Accessed 30.09.2013.

number of related international forums (Tvedt, 2014; Medaglia et al, 2013). These alternative approaches were among the contested issues during the NP negotiations, where user countries successfully advocated that the NP should be open for sectoral approaches to GR (Art 4.3, 8.b). Several arenas, including the Food and Agricultural Organization (FAO) and the World Health Organization (WHO), have opened discussions on sectoral approaches to governing GR. This could be interpreted as necessary fine-tuning of governance within specific areas in order to enhance access and as a sign that the CBD/NP regime has influenced a wide range of forums associated with GR (Morgera et al, 2013). Alternatively, it could be seen as forum shopping by more powerful actors to sidestep benefit sharing and as an illustration of persistent turf wars between international organizations.

Since the entering into force of the CBD in 1993, more than 50 developing countries have enacted national laws regulating access to genetic resources and to secure a share of the benefits from their utilization. Only a very few developed countries have introduced corresponding legislation to support compliance with access legislation.

As mentioned above, Australia is atypical of OECD countries by being megadiverse and both a major provider and user of genetic resources.

4 Legal and Institutional ABS Framework in Australia

Australia is a constitutional federation of six sovereign states, two self-governing territories and a national government. Genetic resources management in Australia falls within the competence of each State and Territory government. Based on the CBD Bonn Guidelines on Access to Genetic Resources and Fair and Equitable Sharing of the Benefits Arising out of their Utilization adopted in 2002,[6] the Commonwealth, State and Territory Governments of Australia agreed on a 'National Consistent Approach for Access to and the Utilization of Australia's Native Genetic and Biochemical Resources' to promote consistency in the regulation and management of access to genetic resources in conformity with the CBD and the Guidelines.[7] Its overall goal is to maximize the economic, social and environmental benefits from the ecologically sustainable use of its genetic and biochemical resources while protecting biodiversity and its natural capital.[8] The document includes 14 general policy principles on which to build legislative, administrative or policy frameworks in the ABS field and a further 11 elements to be considered.[9]

4.1 The Commonwealth (federal) level

The federal ABS system builds on the assumption that research and development on genetic resources are a significant ecosystem service to produce economic outcomes that value biodiversity and contribute to its conservation (Burton, 2013).

The basis to regulate access at the federal level to Australia's biological resources is the *Environment Protection and Biodiversity Conservation Act 1999, section 301.* Under this the *EPBC Regulations* 2000 Part 8A 'Access to biological resources in Commonwealth areas' provides the legal framework.

The provisions cover access to native biological resources which include genetic resources, organisms, parts of organisms, populations, and other biotic components of an ecosystem with actual or potential us of value for humanity.[10] Hence, the scope is wider than the CBD provisions on ABS, which cover only genetic resources. The broad scope gives the authorities wide discretion when they are considering an ABS contract. Leaving the discretion broad for the authorities will probably put them in a better position when negotiating an ABS agreement with a user, as the argument that a company is not really using the genetic resources will be less easy to invoke.

The geographical scope is Commonwealth Areas. These comprise land owned or leased by the Commonwealth or a Commonwealth agency and

[6] www.cbd.int/doc/publications/cbd-bonn-gdls-en.pdf
[7] www.environment.gov.au/biodiversity/publications/access/nca/pubs/nca.pdf
[8] Ibid.
[9] Principle 7.
[10] EPBC Regulation Part 8A.

the Territorial Sea and Exclusive Economic Zone of Australia;[11] including defence lands, Commonwealth reserves, Australia's external territories and 10 million square kilometres of marine areas.[12] Six objectives are set out in the EPBC Regulation for governing access to biological resources consistent with the CBD's ABS provisions and the Bonn Guidelines:[13]

(a) promoting the conservation of biological resources in those Commonwealth areas, including the ecologically sustainable use of those biological resources;

(b) ensuring the equitable sharing of the benefits arising from the use of biological resources in those Commonwealth areas;

(c) recognising the special knowledge held by Indigenous persons about biological resources;

(d) establishing an access regime designed to provide certainty, and minimize administrative cost, for people seeking access to biological resources;

(e) seeking to ensure that the social, economic and environmental benefits arising from the use of biological resources in those Commonwealth areas accrue to Australia; and

(f) contributing to a nationally consistent approach to access to Australia's biological resources.

Permits

Those seeking access to biological resources of native species for research and development must apply for a permit from the responsible Commonwealth Minister.[14] Such a permit is considered as the prior informed consent in accordance with Article 15.5 of the CBD.

Permits are available for either commercial/potentially commercial or non-commercial purposes, and all permit applications must demonstrate that the applied access is ecologically sustainable and consistent with the conservation of Australia's biodiversity on the basis of the precautionary principle. A large number of access permits pertain to biological resources in protected areas managed by the Commonwealth (Commonwealth reserves). Conditions can be attached to the permit for that purpose.

If access is sought for a commercial purpose there is permit fee of 50 AUD. Access for non-commercial purposes such as taxonomy is free.

For commercial or potentially commercial purposes the permit requires a benefit sharing agreement with the access provider of the biological resources.[15] In most cases this would be the Commonwealth as such, but

[11] EPBC Act, Section 525.
[12] Excluding State and Northern Territory coastal waters within 3 nautical miles from the shore.
[13] EPBC Regulations Part 8A.01
[14] EPBC Regulations Part 8A.06. This responsible Minister is now the Minister for the Environment.
[15] Ibid. 8A.07.

could also be special Commonwealth agencies, and indigenous communities.[16] While one of the overall purposes of the EPBC regulation's provisions on biological resources is to ensure equitable benefit sharing,[17] the more detailed provision on benefit sharing agreements[18] requires an agreement to provide only for 'reasonable' benefit sharing. The Competent Authority has developed model contracts to assist developing benefit-sharing agreements in case of the Commonwealth being the access provider and where others are the access providers.[19]

Access for non-commercial purposes does not require such an agreement, but applicants must provide a statutory declaration stating that the applicant will not conduct, or allow others to conduct commercial research without agreeing on appropriate benefit sharing arrangements.[20] Through this declaration, the applicant further commits to

- give a written report on the results of any research on the biological resources to the access provider(s);
- offer a taxonomic duplicate of each sample to an Australian institution that is a repository of taxonomic specimens;
- seek permission from the access provider(s) to transfer the material to any other than this institution.

The statutory declaration in Australia is a general means of declaring that the signatory undertakes the responsibility for the statement. This system applies to the Commonwealth competence, and the states have similar system for state-matters. It includes a reference to the signatory to understanding the character of the statement, and that he explicitly undertakes and accepts criminal sanctions in cases of non-compliance. The statement reads: 'I understand that a person who intentionally makes a false statement in a statutory declaration is guilty of an offence under section 11 of the Statutory Declarations Act 1959, and I believe that the statements in this declaration are true in every particular.'[21] If the declaration is false the signatory can risk 'imprisonment of up to four years. Being convicted of such a crime will likely be registered and may cause problems when applying for visa at a later stage. As this is a well-functioning system which is more general in application than ABS, it is a good example of using established legal institutional structures to make ABS functional. One great advantage of applying well-established general principles is that it might add to the functionality of the system. It also provides the necessary flexibility by leaving the Commonwealth authority with the discretion to fill in what they need the signatory to confirm in the statutory declaration. This system can thus be tailor-made for the particular use theABS authority.

[16] Ibid 8A.04.
[17] Ibid.8A.01.
[18] Ibid. 8A.08.
[19] Australian Government Response to CBD Notification 2011-216. Access to Genetic Resources and Benefit Sharing. Ref: SCBD/ABS/VNSG/74553.
[20] www.environment.gov.au/biodiversity/science/access/permits/index.html
[21] Quoted from www.ag.gov.au/Publications/Pages/Statutorydeclarations.aspx

One could ask whether the same could not be achieved by the ABS permit or a contract. Both these legal documents would be binding. One core difference could be that for breach of them to be linked to criminal sanctions the legislator would have needed to pass a specific prohibition making ABS illegal without PIC or MAT. The political willingness to pass such an act could easily be perceived as too restrictive for the bioprospector. Thus, linking the permit system to this existing structure of law might prove useful. However, as for other parts of criminal law, the effect will correlate with efforts to prosecute breaches of the prohibition.

Use of indigenous land and traditional knowledge

Where access to biological resources is applied on indigenous peoples' land, the Regulation requires prior informed consent of the indigenous land owner or the native title holder of the land.[22] 'Native title' is regulated by *the Native Title Act* 2003 and describes the recognition by the Australian legal system of rights and interests of Aboriginal and Torres Strait Islander peoples to land and waters according to their traditional laws and customs.

To support indigenous owners of biological resources and safeguard their rights, the Regulation requires the Minister to be satisfied that the conditions for prior informed consent and mutually agreed terms in a benefit sharing agreement have been met. Only then can a permit be issued. This control system is in recognition of the fact that not all indigenous owners have the resources to negotiate with applicants on equal terms (Burton, 2009: 97).

According to interviewees, most cases implying prior informed consent of indigenous people have pertained to access to biological resources in the national parks Kakadu and Uluru-Kata Tjuta. Both parks are located on indigenous people's land in Northern Territory and co-managed by the indigenous owners and the Commonwealth National Parks Authority. These two national parks have an aggregated size of more than 21.000 square kilometres and both been designated UNESCO World Heritage Sites due to their extraordinary natural beauty and ancient cultural heritage.

As mentioned above, a permit for the commercial or potential commercial use of biological resources can only be issued after a benefit sharing agreement between the applicant and the access provider(s) has been reached. Regulation 8A.08 sets out the requirements for such agreements, and these include as the most detailed requirements safeguards for indigenous peoples when their knowledge of biological resources is used. Consistent with CBD Article 8(j) benefit sharing arrangements involving traditional knowledge must include:

- recognition of and valuing of indigenous people's knowledge to be used;

[22] EPBC Regulation Part 8A.10.

- a statement regarding any use of such knowledge including details of the source;
- a statement regarding benefits to be provided or any agreed commitments given in return for the use of the indigenous peoples' knowledge;
- a copy of the agreement regarding use of the knowledge (if there is a written document), or the terms of any oral agreement, regarding the use of the knowledge.

Registration

Permits granted are kept in a register, the Genetic Resource Information Data Base (GRID), which is available for public viewing.[23] As of 1 March 2014, 237 permits have been issued since December 2005, when the regulations came in force, of which all but one have been for non-commercial purposes.[24]

Exemptions/accreditation

EPBC regulation 8A.05 provides for a mechanism to exempt specific biological resources or collections of such from the provisions referred to above. The exemptions may include collections which are administered in a manner consistent with the stated access and benefit sharing purposes of EPBS regulations. In effect, this implies an accreditation system for certain ex-situ collections of biological resources. Agreements of such accreditations have been made with the Great Barrier Reef Marine Park Authority, the Australian National Botanic Gardens, the Australian Institute of Marine Sciences (AIMS), and the Australian Antarctic Division.[25] While only one permit has been granted for commercial purposes, several commercial benefit sharing agreements have been negotiated under this accreditation system. There are also a growing number of cases where the conditions of use agreed to under the Statutory Declaration have resulted in researchers interested in previously unforeseen commercial potential returning to the Competent National Authority to renegotiate terms.

Compliance and awareness raising

A fine may be imposed for access without a permit or for breach of conditions stipulated in a permit.[26] Civil remedies are possible in cases of breach of the terms set out in benefit sharing agreements.

The introduction of the Genetic Resources Data Base (GRID), with which all permits and associated information are published, has been highlighted as an important mechanism for open verification of compliance with Australian ABS legislation (Burton, 2009). It is anticipated that the ABS-CHM will supersede the need for this task at the domestic level.

[23] www.envrionment.gov.au/grid/public//perrep/jsp
[24] Australian Government Response to CBD Notification 2011-216.
[25] Ibid.
[26] EPBC Regulation 8A.06.

In the opinion of Australia's Government, an educative and consultative approach to compliance has had very positive results. To build awareness of the Australian ABS framework, a number of consultative forums have been established, including the Biodiscovery Industry Panel, a forum for biodiscovery practitioners such as universities, research institutions and private sector firms. The Panel has made it possible to build an understanding of the regulatory requirements and minimize the need for compliance actions.[27]

4.2 The State and Territory level

Queensland legislation

Queensland in 2004 enacted the Biodiscovery Act, the first piece of ABS legislation in Australia. According to interviewees the Act was essentially developed as a response to the extensive Natural Product Discovery Partnership established in the late Nineties between the Queensland-based Griffith University and the pharmaceutical company Astra Zeneca further described below. The Queensland Government wished to create legal clarity and regulate biodiscovery activities under this partnership in accordance with the CBD regulatory framework on ABS. At the same time, the Government saw the partnership as an indication that great benefits for the State could be reaped from biodiscovery and thus wished to develop a legal framework to ensure such benefits.

According to the Act biodiscovery means 'biodiscovery research; or the commercialization of native biological material, or a product of biodiscovery research'.[28] In a Queensland Government web portal for business and industry, it is further explained that biodiscovery involves collecting samples of native biological materials such as plants, animals, fungi and microorganisms to test for compounds that may have commercial applications (e.g. pharmaceuticals and insecticides).[29] Thus, the definition of the material to be discovered is less precise than the definition of 'biological resources' in part 8A of the Commonwealth EPBC Regulations referred to above, but, as is the case of the EPBC, the definition goes beyond the definition of 'genetic resources' in the CBD.

The Biodiscovery Act does not apply to biodiscovery on private land. The Act, however, applies both within and outside Queensland subject to the Commonwealth Constitution and the full extent of the extraterritorial legislative power of the Queensland Parliament.[30]

In its introductory part, the Act refers to the CBD and states as one of its purposes to give effect to CBD Article 15.

The Act establishes a permit system in which applicants before engaging in biodiscovery must enter into a benefit sharing agreement with the State that regulates the use of the biological material for biodiscovery. The

[27] Australian Government Response to CBD Notification 2011-216.
[28] Biodiscovery Act, Schedule.
[29] http://www.business.qld.gov.au/industry/science/biodiscovery-business
[30] Biodiscovery Act, Section 9.

applicant must also present a 'Biodiscovery Plan' with information on matters such as proposed commercialization activities, timetable and benefits expected from the activity. Collectors must appropriately identify the material and provide a sample of the material for a museum, herbarium or another 'receiving agency' as specified in the benefit sharing agreement.

The permit is referred to as a 'collection authority' which can be granted on conditions e.g. to ensure that collections are carried out in an ecologically sustainable way. Penalties may be imposed for non-compliance.

The Act differs from the Commonwealth ABS regulations by not having two types of permits for respectively non-commercial and commercial/ potentially commercial biodiscovery. This is interesting as the industry acted as advocates in the process of the Queensland legislation.

The Act does not include provisions for biodiscovery on indigenous people's lands or for making use of indigenous, traditional knowledge, but it is supplemented by the Queensland Biotechnology Code of Ethics which, among other things, covers these aspects in a special section on biodiscovery.[31] The code is not legally binding, but it is considered mandatory for all organizations undertaking biotechnology activities, including biodiscovery, who receive state funding or assistance. Others may sign a statement of intent.

The biodiscovery part of the Code refers to obligations under the CBD and those signing a statement of intent commit to:

- comply with the Biodiscovery Act 2004;
- collect native biological material from state land and Queensland waters only with the prior informed consent of the state;
- Before collecting samples from privately owned land, ensure that the prior informed consent of the landowner is obtained and that there will be the negotiation of reasonable benefit sharing arrangements with the landowner in return for access to the samples;
- Recognizing that there may be culturally significant aspects of the knowledge of Aboriginal and Torres Strait Islander people, treat this in a sensitive and respectful manner if used in the course of biotechnology:
- Where in the course of biodiscovery, traditional knowledge from indigenous persons is obtained and used, negotiate reasonable benefit sharing arrangements with these persons or communities;
- Comply with the Native Title Act 1993;
- Not commit acts of biopiracy and not assist a third party to commit such acts.

[31] http://203.210.126.185/dsdweb/v4/apps/web/secure/docs/4342.pdf

According to interviewees only very few collection authorizations have been issued indicating that the Act has so far has had limited practical effect.

Northern Territory legislation

In the Northern Territory access to biological resources and benefit sharing is regulated by the Biological Resources Act 2006. The principles and procedures are broadly similar to those of the Commonwealth Regulation 8.A with the notable difference that the Northern Territory Act, like the Queensland Act, does not have two types of permits for non-commercial and commercial/potentially commercial use. Also, the Act, unlike the Commonwealth legislation, applies to private land and makes use of the internationally established term 'bioprospecting' as object of the permit.[32]

Another notable difference from the Queensland Act is that the NT Act covers aboriginal controlled land. The latter includes three types of land: aboriginal land; aboriginal community living area; and land subject to native title.[33]

Bioprospecting is subject to a permit, and bioprospectors must enter into benefit sharing agreements with the access providers.[34] Like in the Commonwealth EPBC Regulation the agreements must provide for 'reasonable' benefit sharing arrangements 'including protection for, recognition of and valuing of any indigenous people's knowledge to be used'.[35]

Prior informed consent is required if an access provider is not the Territory. The PIC is overseen by the Chief Executive Officer (CEO) of the Territory who among other things must be satisfied that the access provider has had adequate knowledge of the Act and was able to engage in reasonable negotiations, on the benefit sharing agreements, including whether adequate time was given.[36]

ABS measures in other Australian States

No other states have enacted legislation in this field, but it should be noted that they all have permit systems for collection of biological resources regardless of whether the application is for biodiscovery or not. Broad policy statements on access to biological resources and benefit sharing from their use have been issued by the states of Tasmania and

[32] Defined in the Biological Resources Act Section 5 as 'the taking of samples of biological resources, existing *in situ* or maintained in an *ex situ* collection of such resources, for research in relation to any genetic resources, or biochemical compounds, comprising or contained in the biological resources.' The term 'biodiscovery' is also used here meaning 'research on samples of biological resources, or extracts from those samples, to discover and exploit genetic resources of actual and potential value for humanity' (Section 4.1).
[33] NT Biological Resources Act 2006, Section 6.1.
[34] Ibid, Section 27.
[35] Ibid, Section 29.
[36] Ibid, Section 28.

Victoria, both expressing support for the nationally consistent approach of 2002.[37]

According to interviewees initial steps have been taken by the Government of Western Australia to develop ABS measures. We are not aware of activities in other States.

In summary, the Commonwealth, Queensland and the Northern territory have enacted legislation to implement the ABS provisions of the CBD. However, these pieces of legislation are not fully consistent, and ABS legislation lacks in the other States and Territories. These sections have described how the laws and systems are set up and the next task is to explore how these pieces of ABS legislation and policies have worked in practice.

[37] 'Biodiscovery in Victoria – framework for managing access to and use of our native biological resources. 'Biovision Tasmania 2005–2015: Tasmania's Biotechnology Strategy'.

5 Australian ABS Legislation and Policies in Practice: Perceptions and Lessons

5.1 Actors and activities involved in biodiscovery

Actors on the provider side: States and the Commonwealth

The provider is most commonly the Commonwealth or the State/ Territory, but it could also be agencies thereunder and indigenous communities, or private land owners. In most cases of biodiscovery agreements there will be a research institute, often a university, that signs the agreement as a kind of intermediary between the public provider and the private user, most often a company.

In Commonwealth areas, collection of biological material may require different types of permits for the same material. Besides the permit for biodiscovery, there could be permits for e.g. collection in protected areas and of species listed as endangered. The Commonwealth administration is in the process of streamlining and simplifying the permit procedures thereby making them more user friendly for biodiscoverers.

Approximately 230 biodiscovery permits for biodiscovery in Commonwealth areas have been granted in all, but only five in Queensland. This seems to imply a significant difference between the impact of the Commonwealth and the State/Territory biodiscovery permit systems. This might be due to the differences in permits for non-commercial and commercial activities.

Actors on the provider side: Researchers / academia as intermediaries

Large collections of genetic material (samples) can be found within academic institutions and a great deal of this material has already been made ready for further examination of their active compounds. We looked into biodiscovery activities of three of the most central ones, all in the biodiversity rich State of Queensland.

THE ESKITIS INSTITUTE, GRIFFITH UNIVERSITY

The Eskitis Institute for Cell and Molecular Therapies, under Griffith University, Brisbane, is a drug discovery research centre searching for and developing new drug and cell-based therapies in areas such as cancer, infectious diseases, neurological diseases, and global health. Eskitis' research is supported by the Nature Bank, an integrated drug discovery platform encompassing a library of over 200,000 optimized natural product fractions derived from a diverse collection of over 45,000 samples of plants and marine invertebrates. Eskitis is also home to the Queensland Compound Library (QCL), an automated library of nearly 400,000 pure compounds from samples. The Eskitis institute encourages researchers to send their molecules to the QCL and/or to select screening tests from the compounds there. QCL provides automated retrieval of the requested samples and supervises the formatting into the preferred micro plate format. When screening hits are identified, contact is enabled between chemists and biologists in Australia and abroad for potential collaboration.

Samples for Eskitis' Nature Bank have been collected in Australia, Indonesia, China, and Papua New Guinea and are ready for analysis to determine whether novel bioactive compounds could hit a particular target or bind to a specific protein. Nature Bank fractions can be accessed for screening on assay systems, with follow-up isolation chemistry at Eskitis. The Nature Bank thus provides the service of processing natural products of biota or crude extracts into fractions to create assay-ready screening sets. The next step of the biodiscovery process is to set up the assay properly, i.e. devise the method or 'how to pose the research question practically', which is scientifically more challenging than making the fractions. The Bank stores, reformats and dispatches fractions around the world. Samples are sent to i.a. the UK, the USA, Canada, China, and Denmark in collaboration with Eskitis scientists.

In 1993, the Griffith University entered into a National Product Discovery partnership with Astra Pharmaceuticals (later AstraZeneca, AZ), one of the world's leading pharmaceutical companies.[38] Advances in science at that time had made it possible to research natural products more quickly, inexpensively and efficiently, and incentives had been created for this kind of public-private scientific cooperation (Laird et al. 2008).

As part of the partnership, Griffith University through domestic and overseas partners collected biota, made extracts of samples and ran these through high throughput screens (HTS) against targets provided by and of specific interest to AZ which considered the partnership as an extension of its R&D programme (Laird et al. 2008). The extent of integration of the university's work into AZ meant that it could not collaborate with other researchers, decide on research goals or get ownership to research results. AZ had exclusive rights to the samples. This exclusivity for AZ led to certain criticism of the partnership in Australia media for the 'locking up' of Australia's resources by multinational companies (Laird et al. 2008). According to interviewees it is very unlikely that Griffith University would again enter into an exclusive agreement with one company.

The AstraZeneca/Griffith University collaboration preceded both the Federal and Queensland State biodiscovery legislation, but biodiscovery under the collaboration was subject to these pieces of legislation after they came into force. A Biodiscovery Plan was approved under the Queensland Biodiscovery Act 2004 (Laird et al. 2008).

AstraZeneca invested more than 100 million AUD in the collaboration. This was crucial for the foundation of the Eskitis Institute and the collection of samples, which now represents the biological basis of their biodiscovery activities.[39] It also laid the foundation for the following non-exclusive era with collaboration with a wide range of public and private partners.

[38] The collaboration has been described in a report from the United Nations University – Institute of Advanced Studies: Sarah Laird, Catherine Monagle, Sam Johnston: Queensland Biodiscovery Collaboration. The Griffith University AstraZeneca Partnership for Natural Product Discovery. An Access and Benefit Sharing Case Study. 2008.

[39] The collaboration was referred to as the «golden handcuffs» by interviewees.

It should be noted that the Griffith University/Astra Zeneca partnership has still not lead to commercialization of any product. However, given the often lengthy time it takes to develop drugs from natural products, commercial products can still be developed as a result of the partnership. In that case, Griffith University will receive a royalty to be shared with the collecting institutions and the Queensland Government if the material originated from Queensland public lands.

Since the end of the deal in 2007, the Queensland State as well as the Federal Government have helped finance building the laboratory – the Queensland Compound Library (QCL) that contains and 'manages' the samples, integrating tube and plate storage with sample processing. QCL has considerable technological capacity to control and trace samples.

THE AUSTRALIAN INSTITUTE FOR MARINE SCIENCE (AIMS)

Another major academic intermediary in biodiscovery is the Australian Institute for Marine Science (AIMS), a federally funded research institute established in 1979 in response to environmental concerns about the Great Barrier Reef. Its research activities have subsequently spread to all Australia's marine and tropical areas, accompanied by the largest Australian research institution, the *Commonwealth Scientific and Industrial Research Organisation* (CSIRO). In 1987, there was a great number of bioprospecting expeditions in Australia involving AIMS, funded primarily by the US National Cancer Institute (NCI), as part of the NCI large anticancer programme.

According to biodiscovery professionals we interviewed, the interest and demand is higher for marine than for terrestrial biological resources, and AIMS is involved in a large number of activities in the sea all around Australia: AIMS has a huge collection with taxonomically identified samples, all providing screening results and geographical identification. Like the Eskitis Institute, they also send samples from all over Australia to partners with ready assays. Up until recently, activities have been rather old fashioned at AIMS with collection of samples, chemistry screening of material for active compounds and identification of fractions. Its activities and facilities for processing samples are less modern than those of Eskitis. This could imply a smaller outreach, but more importantly, it could mean that their technological capacity to monitor and trace samples would be lesser.

AIMS has obtained biodiscovery permits from the Northern Territories, Queensland, and the Commonwealth. Western Australia is also active in marine biodiscovery, but still lacks legislation that provides for ABS permits. As a result of this, AIMS has sent all its collected samples from Western Australia to a museum there, which means that those samples can be accessed but not used commercially. In Western Australia a collaborative body, the Western Australian Marine Science Institution (WAMSI), has been established made up of other marine research institutions including AIMS to foster marine science. In part WAMSI addresses difficulties otherwise created by the absence of ABS legislation in Western Australia.

On applications under Commonwealth legislation AIMS always applies for non-commercial, scientific permits while being prepared to apply for another permit if the research is leading towards commercialization. This has happened once for AIMS (and for the Commonwealth). Already in 2000 AIMS signed the first biodiscovery agreement with Queensland four years prior to the Queensland Biodiscovery Act. This was due to requests from the biotechnology industry, who demanded that access to genetic material should be in compliance with the CBD. This is early concrete evidence of the importance of legal certainty to industry and the need to avoid of reputational risk.

Another aspect of the intermediary role is that of an approved source for samples. AIMS is registered as a Wildlife Trade Operation and accredited in accordance with the Commonwealth EPBC regulation 8A.05 thereby authorized to grant its own permits and to enter into agreements on benefit sharing.

TROPICAL INDIGENOUS ETHNOBOTANIC CENTRE (TIEC)

A third important intermediary is the Tropical Indigenous Ethnobotanic Centre (TIEC) which is part of the Australian Tropical Herbarium based at James Cook University, Cairns, and has been in operation since 2009. TIEC is an Indigenous driven initiative, the first of its kind in Australia dedicated to Indigenous ecological knowledge of plants.

TIEC records, documents and researches cultural plant use knowledge, which could be of mutual benefit to traditional owners and their partners and aims to empower Indigenous people to renew and strengthen their cultural knowledge and practices about plants.

Functions of TIEC include:

- Supporting Indigenous decision-making about plants and plant knowledge
- Keeping traditional and cultural knowledge alive
- Protection of Indigenous intellectual and cultural property rights over plants
- Passing it on the younger generation
- Focusing on building up trust with Traditional Owners before involving other agencies
- Getting information back into the community.[40]

According to interviewees, none of TIEC's research has so far triggered commercialization. TIEC's experience with the biodiscovery permit system is limited, even though the system is considered quite complex.

[40] www-public.jcu.edu.au/fmhms/JCU_077417

INDIGENOUS PEOPLES AND TRADITIONAL KNOWLEDGE

One of many controversial issues on ABS throughout the CBD history has been whether prior informed consent and benefit sharing should extend to indigenous and local communities in case of collection on their land and/or making use of their associated traditional knowledge. The Nagoya Protocol was quite innovative in this area *inter alia* by recognising new procedures for establishing a system for Biocultural Protocol. Legal protection of traditional knowledge has been another controversial issue on the international agenda.

At an early stage compared to many other countries, Australia committed to ensure prior informed consent from biodiscovery on indigenous people's land and benefit sharing in any case of using traditional knowledge for commercial biodiscovery. This happened first through the Nationally Consistent Approach from 2002 and later through Commonwealth and Northern Territory legislation. As described above, the legislation quite uniquely provides a government safeguard to control that the conditions for PIC and mutually agreed terms meet certain minimum standards. Also, there are minimum requirements for benefit sharing agreements in cases where traditional knowledge has been used.

In spite of the advanced stage of protection, observers identify inadequacies. Firstly, the geographical scope through legal coverage of only the Commonwealth and the Northern Territory is a limitation in protection.

While prior informed consent and benefit sharing arrangements are mostly relevant for areas under native title, it has been argued that rights should be strengthened for indigenous peoples that are not native title holders but who nevertheless consider themselves as traditional owners of land subject to biodiscovery (Laird et al. 2007). Importantly, traditional knowledge related to marine biodiscovery is largely uncovered. This does not mean that Australian institutions ignore this. AIMS has a policy of recognising indigenous traditional knowledge relating to the marine environment and has undertaken extensive collaborative work with maritime indigenous communities including the establishment of scientific and commercial aquaculture, most notably the cultivation of sea sponges employing techniques arising out of AIMS biodiscovery research into the properties of sea sponges as sources of drug candidates.

Furthermore, in the context of indigenous peoples it has been criticized that the Commonwealth EPBC Regulation in cases of biodiscovery for commercial or potential commercial purposes provides for only 'reasonable' and not CBD consistent 'equitable' benefit sharing[41] and that consent from indigenous knowledge holders is not required when traditional knowledge has been accessed under a non-commercial permit and not in relation to biological resources accessed on indigenous peoples lands (Hawke, 2009 Chapter 5).

On the question of whether there is a demand by industry for traditional knowledge in biodiscovery, it is noteworthy that traditional knowledge

[41] EPBC Regulation 8A.08.

was not seen as important and therefore not collected under the AstraZeneca/Griffith University partnership described above (Laird et al. 2007). Conversely, the establishment of the Tropical Indigenous Ethno-botany Centre (TIEC) under the James Cook University (also described above) is a clear indication of will and demand to stop the loss and make use of TK. The Centre is quite busy in providing assistance to traditional owners in recording, documenting, protecting, managing and maintaining their cultural knowledge on the use of plants. Some promising traits and compounds have been identified and the Centre Manager ethno-botanist, Gerry Turpin has received awards for his work. However, the fact that he is the only employee to do the work is an indication of limited political prioritization of the area.

Australian law does not provide for special intellectual property right protection of traditional knowledge, but IP Australia has initiated a consultative process with indigenous peoples to examine whether the current IPR system is sufficient to protect traditional knowledge, or there should be new initiatives.[42] Developing such a national system for protection of TK would be of interest for the ongoing process in the IGC in WIPO as it could inform the global discussion on the matter with an example.

There are great differences among indigenous communities on the perception of IPRs and sharing of TK. Some are very protective of their TK assuming that publishing TK could lead to misuse and hinder them from getting exclusive rights on the knowledge and the related genetic material. This idea seems to originate from WIPO discussions and an assumption that it will be possible to develop some kind of exclusive right on TK and associated genetic material by sharing it. In practice, however, this avoidance of publishing would arguably be much more likely to keep TK out of 'prior art' and hence make TK more vulnerable to IPR and patenting by others. Whether indigenous knowledge is regarded as prior art or not wholly depends on publicly available documentation of the TK. Hence, if TK is published, there is a need for an institutional structure to safeguard first its inclusion in prior art, and second that the patent criteria of novelty and inventiveness are practices in a manner, which does not allow for appropriation thereof.

Another reason for indigenous peoples being protective of TK is culturally based: To many communities, the idea that others outside the group should utilize the TK is akin to taboo. The expressions are closely linked to identity and may be performed only by specific persons within the community. There are also strong views that TK cannot be owned by one person and sometimes this has led to rivalry and conflicts within groups. Hence, it might be better to document the TK through databases in order to stop others from patenting it – which is not always recognized by indigenous peoples. Some indigenous communities refuse research altogether and yet others demand that it must suit their priorities, such as focusing on threatened species.

[42] www.ipaustralia.gov.au/about-us/public-consultations/indigenous-knowledge-consultation/have-your-say/

Other indigenous communities have an opposite approach and are willing to cooperate with research institutions to develop new pharmaceutical products based on traditional knowledge for commercialization and benefit sharing. In these cases, the communities and the research institutions have jointly filed patent applications. One example is collaboration between the Eskitis Institute, Griffith University and the Jarlmadangah Burru Aboriginal Community in Western Australia on developing a remedy for pain based on an extract from a bark. Another example is the collaboration between Chuulangum Aboriginal Cooperation in Cape York, Queensland and the University of South Australia to develop new plant based treatments for skin conditions such as psoriasis and dermatitis (Simpson et al. 2013). This trend of creating collaborative research initiatives with indigenous communities is increasing (Simpson et al. 2013).

Acknowledging that the CBD and the Nagoya Protocol have provided new opportunities and incentives for collaboration between the research community and indigenous peoples, our interviewees widely agree on a need for improved protection of indigenous rights to biological resources and associated traditional knowledge. It was, however, generally believed that this is not a high political priority for the moment either at the Commonwealth or – and even less – at the State/Territory level. The ongoing national process of assessing ratification of the Nagoya Protocol with stronger provisions on indigenous issues might trigger renewed attention to this subject in Australia.

USERS

Although biodiscovery by external actors is encouraged by the Australian Government, biodiscovery permits have mainly been granted to domestic biodiscoverers. The government sources believe that European firms mostly go to Africa and US firms mostly to Latin America to do biodiscovery. The academic sources describe, however, how Australian samples from university collections often find their way all over the world. Moreover, there are several examples of large US and European based companies and institutions such as the NCI, AstraZeneca (described above), the J. Craig Venter Institute, Leo Pharma and the Max Plank Institute all being involved in biodiscovery in Australia. The role of Australia as a provider is therefore potentially large.

5.2 Opportunities and barriers for ABS in Australia

As has often been discussed in the ABS context, there are different types of benefits to be generated from bioprospecting/biodiscovery. In general Australia has reaped many benefits from its biodiscovery activities mainly in the form of improved knowledge of the examined biological resources and their properties.

The Griffith University partnership with AstraZeneca is in a category of its own in terms of generating and sharing non-monetary benefits. As described by Laird et al. (2008) the partnership provided a multitude of benefits in the form of e.g. increased knowledge, training, equipment, technology, infrastructure, and direct payments not only for Griffith University and its Eskitis Institute but also for other institutions in and

outside Australia. Further benefits may materialize if drugs are developed and placed on the market as a result of the partnership.

After the end of the partnership, the public sector (the Queensland and to some extent the Commonwealth government) provided considerable financial support to the Eskitis Institute. Therefore, the State feels entitled to a share of benefits that may be a result of Eskitis research. However, the most wanted type of benefit sharing and with the biggest impact, sharing of commercial earnings of the product developed, seems to have been very limited so far. As mentioned above and puzzling, there is only one biodiscovery case under the Commonwealth legislation on commercial use with benefit sharing likely to come up. The case involves a large study of sponges with anti-cancer compounds and is based on collaboration between AIMS and the National Cancer Institute (NCI) of the USA (further described below).

Our interviewees mentioned a number of possible reasons: First, this could be linked to a dwindling interest and demand for biodiscovery. Second, biodiscovery activities leading to commercialization could actually take place, but are falling outside the regulatory system due loopholes and weaknesses in the system. A third explanation and related to the second could be a lack of compliance by users – intentionally or non-intentionally – with the existing legislation. The three explanations are hard to keep apart and not necessarily mutually exclusive. In the following we will discuss what may be the reasons for the apparent lack of commercial benefit sharing on the basis of these perceptions thereby also seeking to answer our two first research questions on how the legal and institutional system performs and to what extent it provides benefits.

Is there an interest in and demand for biodiscovery?

It was pointed out that public as well as private funding for biodiscovery was reduced. Only ten years ago, funding was available throughout the biodiscovery process while it is currently aimed at the very early phases and for the very last stages prior to a useful product. Government research priorities no longer include biotechnology except when relating to food security, energy, climate, and welfare issues. Attention was also drawn to the lack of replacement by young researchers when older natural products researchers have retired.

At the same time it was pointed out that although there appears to be a decline in biodiscovery activity, the pharmaceutical industry for the moment has more confidence in natural products than in synthetic and therefore is likely to still be in demand of biodiscovery. This demand is underlined by a couple of commercial biodiscovery cases in the pipeline, including a Danish company involved in a study of krill and the recent acquisition of a Queensland biodiscovery company by the Danish company Leo Pharma and its subsequent marketing of a gel to treat actinic keratosis. The drug has been approved by the US FDA and is derived from molecules found in the Euphorbia peplus plant.[43] [44]

[43] www.prnewswire.com/news-releases/leo-pharma-announces-that-picato-ingenol-mebutate-gel-has-been-approved-by-us-fda-for-once-daily-2-or-3-day-treatment-of-actinic-keratoses-138107063.html

'Traditional' biodiscovery on the basis of collection of wild biological resources has been reduced since biodiscovery increasingly is being carried out through ex situ collections. These are regulated in the same way as wild species although sometimes exempted from the Commonwealth regulations when the institutions holding the collections are accredited and thereby authorized to grant permits and enter into benefit sharing agreements. Importantly, those collections that guarantee Nagoya Protocol compliance seem to be most likely to attract 'customers' which again emphasizes the apparent awareness and wishes of users of biological resources to act responsibly.

Finally, as discussed further below, the apparent discrepancy between dwindling biodiscovery activity and a continuing need in industry for biological resources indicates that a certain degree of biodiscovery is likely to take place unreported and/or uncontrolled.

Summing up on this part, the limited presence of commercial benefit sharing does not appear to be a result of declining demand for commercially intended biodiscovery. Rather, it could be a result of the regulatory and institutional system and the way biodiscovery is done not being sufficiently capable to provide this type of benefit sharing. This will be further discussed below.

Is the ABS legal framework adequate and effective?

Australia is legally advanced in giving national effect to the ABS provisions of the CBD in particular with regard to the Commonwealth legislation. Our interviewees agree that the legislation is functioning well and is generally user friendly. It has inspired the design of the Nagoya Protocol especially in the areas of simplified procedures, certificates of origin and focus on the intent of the utilization of genetic resources rather than on the nature of the material to be utilized (derivatives) (Burton, 2013).

The central feature of the Commonwealth legislation is that the range of activities from non-commercial to commercial is covered at the point of access. The rationale is that it is never possible to link legal consequences to intent as a criterion and that any scientific activity might have a commercial application. Hence, the user must come back to the authorities in the event of commercialization, which also enhances transparency.

We cannot control the derivatives, but we can control the point of access – the point where you actually get the physical thing – that is the only time you can regulate and then you can make it impossible to use it without a permit. This is what the NP does – make it easy to do the right thing: just get a permit.[45]

[44] As the Euphobia peplus plant is not a native Australian species the process to develop the gel was not subject to a biodiscovery permit.
[45] Interview with Ben Phillips, Federal Department of Environment.

It is problematic to link legal consequences to the 'intended use' at the point of time of access to the accession. At the point of time of access, the intent of the collector is not always manifest and thus not externally verifiable. Thus, putting too much emphasis of the regulatory burden on the assessment of the intent of the user at the moment of collecting and taking samples might become an obstacle to making ABS functional on the ground. Australia seeks to clarify this distinction in its definition of 'access' at regulations in 8A.03 by saying, in effect, that a biological resource is covered by its ABS law only if it is taken for the purpose of research and development on its genetic and biochemical make-up. Regulation 8A.03 goes on to explicitly exclude the elements of commodity trade by citing examples of excluded material.

Together with Queensland and the Northern Territory legislation, the Commonwealth legislation has provided coverage of large and biodiversity rich parts of Australia of particular interest to biodiscovery including a large variety of forested areas along the east and north-east coast as well as the huge marine diversity of the Great Barrier Reef. ABS legislation in Australia in line with the CBD has been supported by the pharmaceutical industry eager to act responsibly. However, as already stated it appears as if the legislation has had very limited application or effect in terms of biodiscovery for commercial purposes and thereby as a trigger for ABS and monetary benefit sharing.

The fact that ABS legislation is only in place in three of Australia's many ABS jurisdictions shows that the Nationally Consistent Approach to which the Commonwealth and the State and Territory governments committed in 2002, is still to be fulfilled, and that large parts of Australia remain uncovered by ABS legislation. This includes not least coastal waters within three nautical miles outside other States/Territories than Queensland and Northern Territory which are under State/Territory jurisdiction. Moreover, ABS legislation of the Commonwealth, Queensland and the Northern Territory are only partly consistent and differ in important areas such as distinction between commercial and non-commercial use, coverage of use of indigenous lands and traditional knowledge and coverage of private lands. Our interviewees generally see a great need for further consistency to get better legal certainty using the Commonwealth legislation as the basis. This is particularly important in relation to foreign users of biological resources However, as discussed further below, the declining political attention to ABS matters in Australia makes it difficult to predict if and when the necessary legal action will take place in the States and Territories.

As Commonwealth Competent Authority for ABS, the Department of Environment has served as sparring partner and adviser for the parallel State/Territory authorities. However, due to administrative cuts in the Department and changing political priorities, it has had fewer resources for interaction with State/Territory competent authorities and thereby also seems to have lost track of possible ABS related activities there.

A general lesson to be drawn from this is that a country with different jurisdictions probably wants to include some mechanism for how to fill the gaps, so that parts of the territory do not fall outside the scope of the

legislation. The need for consistency is reinforced by the Nagoya Protocol. The national ratification process may trigger further action at the State/Territory level. However, the Queensland State government officials we interviewed doubted that even the NP would create enough political will for action. In any case, a push from the federal government would seem helpful maybe through initiating a renewed National Consistency Approach.

A second aspect concerning the stringency and enforceability of the ABS legislation concerns its relationship with IPR legislation which also in Australia is a debatable issue. Bioinventions are generally patentable in Australia, provided they meet the patent criteria. Also, Australia has not used the discretion provided by TRIPS Art 27(3) to exclude plants and animals from patentability. The Australian patent system does not require disclosure of origin of biological/genetic resources in patent applications. Here Australian legislation differs from other providing countries and is in line with most user countries. Generally patent law requires the applicant to describe the best mode of carrying out the invention. In these written descriptions information about the origin of the genetic material is sporadically included.

Most of our interviewees see great opportunities in linking the ABS and IPR systems through a disclosure requirement since the IPR system is a functional and strong system that would make it realistic to keep track of genetic material to be commercialized. It was pointed out that when biodiscovery activities turn from non-commercial to commercial, the Intellectual Property Authority would often be the first public authority to deal with the commercial steps, and that the current missing link could be seen as a missed opportunity for strengthening transparency in the ABS system. However some interviewees also point out that the growing number of countries with disclosure requirements (18 to date) helps considerably to meet the acknowledged international need to disclose the origin of genetic resources in patent application and making it less necessary for Australia to introduce such a requirement. Attention was also drawn to the possibility of including a disclosure requirement in benefit sharing agreements between users and providers of biological resources.

Interestingly, the IP Authority is now conducting a study on genetic resources' role in biotechnology patents and the share of Australian actors compared to foreign patent holders. In other words, there is a growing interest in trying to find out whether Australia actually benefits from IP in this sector.

Federal government representatives believe it to be unlikely that Australia will introduce mandatory disclosure and thereby deviate from its present strong position shared by most OECD countries that the ABS and IPR legal systems should not be confused. In any case, this would have to await the outcome of the current negotiating process in World Intellectual Property Rights Organisation's (WIPO's) Intergovernmental Committee on Intellectual Property and Genetic Resources.

Summing up, there is general satisfaction among stakeholders with the ABS legislation, especially legislation covering the Commonwealth. Still, there is room for improvement and with that greater sharing of benefits through creation of legal consistency between State/Territory and federal levels thereby filling the legal gaps. Also, the relationship between IPR and ABS legislation through a disclosure requirement in patent applications was widely seen as a useful tool to measure compliance with benefit sharing agreements.

Is the ABS legal framework complied with and enforced?

Our third question is based on an impression that, despite the low number of biodiscovery permits with a commercial intent and associated benefit sharing, there are quite a lot of activities pointing in the direction of pharmaceutical and other products based on biological resources being developed. A number of our interviewees believed that more biodiscovery is taking place with a commercial intent than what is actually applied for through ABS permits.

With regard to Queensland, its Biodiscovery Act does not distinguish between commercial and non-commercial use, and it was identified as a major problem to pinpoint when biodiscovery activities go from non-commercial to commercial. At the point of issuing a permit, the scientific activity is usually described as non-commercial. These activities are, however, often believed to become commercial down the line and this change of intent is very hard to control. This also applies to scientific purpose permits given to universities that increasingly are partnering with private companies and involved in commercial activities.

Regarding these university – private partnerships, some interviewees believe that public institutions take a disproportionate level of risk in biodiscovery innovation through universities often doing basic research, which is then accessed and later commercialized by private companies if found profitable.

The difficulty expressed by the Queensland government to draw a line when biodiscovery moves from a scientific to a commercial purpose suggests bringing the State legislation in line with the Commonwealth legislation. As we know, this legislation distinguishes between the two and obliges biodiscoverers to apply for a new permit when the purpose of biodiscovery changes. However, this may not be sufficient to solve the problem. As we also know, only one biodiscovery permit has been granted for commercial use under Commonwealth legislation, and it is doubtful whether this one permit accurately reflects the full range of biodiscovery activities under Commonwealth jurisdiction with a commercial intent.

The clear acknowledgement by a wide range of Australian ABS stakeholders that biodiscovery with a scientific intent is difficult to distinguish from commercial intent, and that this may cause problems in terms of compliance and benefit sharing, is interesting in an international context. In international ABS negotiations, developed countries including Australia have been advocating for drawing a sharp line between

commercial and non-commercial activities as a pretext for introducing simplified procedures for the latter. This sharp division found its way into the Nagoya Protocol Art 8 about special concerns. Countries, when implementing ABS, need to decide how to deal with the blurred categories of academic (often classified non-commercial) and commercial use of genetic resources. For allowing an easy access-system for non-commercial uses, two topics need to be clarified: how can it be trusted that the material is not transferred; and in case the non-commercial user identifies something useful, what should then be the legal situation. Typically, the user is outside the jurisdiction of the providing country at that point of time, and can decide whether to come back or not. This could forfeit ABS.

Looking more closely at previous biodiscovery collections and agreements between academia and the big companies, we inquired into the ABS situation for samples acquired during the Griffith University/ AstraZeneca deal. According to scientists at the Eskitis Institute, it was confirmed that the samples and the genetic resources still belonged to the Griffith University after the deal ended, while the knowledge associated with the resources (accessed by screening the material) did not. This was the foundation for further scientific work at Eskitis. As mentioned above, monetary benefits will be provided in case of commercialization of products generated from material under the agreement, and such benefit sharing will apply even when samples were collected prior to Queensland biodiscovery legislation. As far as Eskitis scientists know, there have been no commercial outputs resulting from the agreement so far. It was, however, admitted that there is no way that Eskitis can know this for sure, as it is not possible to trace the process and what compounds have been used. Following up on this line of argument, Eskitis scientists pointed to how their collections have samples that have already been shown to have active compounds (such as medicinal effects). It was explained that it is common that industry follows academia in this manner and that the business sector relies on the work done at universities. By some public authority interviewees it was felt that industry was reaping the benefits from work done by publicly funded universities. Similar experiences and perceptions can be found at the Tropical Indigenous Ethnobotany Centre (TIEC). Even though researchers at TIEC believe that the screening has not led to commercialization yet, they stress that they do not actually know this. The view is that the process is obscure and that compounds could well be extracted and analysed and variants could be synthesized and used by companies to commercialize and take out IP down the road. ('It is all very opaque and at the phase of synthesizing is where you lose track of the material.'[46])

As mentioned before, the one permit granted for biodiscovery for commercial use is that of marine sponges used to develop new drugs to treat conditions such as cancer and bone disease.[47] The compounds were

[46] 19 November 2013. Cairns. Interview with Darren Crayn (Australian Tropical Herbarium) and Gerry Turpin (Tropical Indigenous Ethnobotany Centre).

[47] www.aims.gov.au/latest-news/-/asset_publisher/MlU7/content/drug-potential-from-great-barrier-reef-sea-sponges-ready-for-commercial-development

discovered in collaboration between the Australian Institute for Marine Science (AIMS) and the United States National Cancer Institute (NCI). It is hence interesting to look further into this case and the role and views of AIMS.

Our interviewee at AIMS maintains that the role of the institute is purely scientific and not commercial and stresses that research publication is the main goal; it was also stressed that publication would add to transparency about the use of the biological material. The Eskitis Institute expressed the same thinking with regard to publishing scientific results from biodiscovery. We asked how such scientific publishing would relate to companies' need for patenting biodiscovery inventions, and we were then told that publishing will have to await patents being granted. Since patenting is usually tied to commercialization and since both are usually regarded as very lengthy processes by industry, this reveals a rather strong commercial influence on research. Alternatively, if the patent process does not take very long this could indicate that commercialization is also not so long away. At least, one cannot argue for both alternatives at the same time.

Also the NCI patents imply some limitations on AIMS ability to pursue further work on the biological material.

A benefit sharing agreement has been established between AIMS in the case of commercialization of the pharmaceuticals derived from the sponges. So far, it has not triggered monetary benefits for AIMS.

As mentioned earlier, industry often prefers to gain access via universities. In addition it was pointed out that the larger companies tend to access material through buying up of smaller firms with much more focused research aims (such as a focus on one assay – discovery platform). This would seem to add to the confusion about who is responsible for fulfilling ABS obligations. If this is a general situation, buying up of the bioprospecting company could become a major way in which to circumvent ABS regulation. Therefore, ABS contracts need to regulate this as one potential scenario.

This harks back to the intermediary role played by academia in biodiscovery agreements (section 5.1) and how key actors in academia view their ability to secure benefit sharing of revenues from utilization of biological material. According to Eskitis, a major challenge with ABS is to identify them or the contracting company that constitute the biodiscovery entity. In their view, the pharmaceutical corporations are not so keen on being recognized as such an entity in ABS contracts. In accordance with Queensland legislation, Eskitis has benefit sharing obligations to the state, but this does not seem to be the case for the pharmaceutical companies commissioning the academic institutions: The universities hence enter into ABS contracts for pure scientific activities, while industry – which takes the material further into the commercial activity – is not the counterpart to the signing of ABS contracts. Again this probably raises general question of legal personality and difficult third-party questions in ABS contracts.

Thus, the intermediary role seems to be confusing the different roles as well as traceability and control in the ABS game, and according to interviewees the industry tends to hide behind this confusion to avoid benefit sharing obligations. This seems to be in contrast to the expressed wish of the pharmaceutical industry in Australia and elsewhere to 'do the right thing' and their support of and even demand for ABS in normative terms. At the same time, there seems to be ambivalence among some of the scientists concerning whether the commercialized part of biodiscovery (at the stage of derivatives and patenting) should involve benefit sharing. That ambivalence resembles the user side of the ABS debate at the international level. It raises complex questions regarding third parties to the original ABS contracts. Typically, what is later transferred to the company might not be identical or even close to the original material collected in the wild or received from the provider. If the contractual relationship with the provider country originally concerns another object than that which is sold or leased to the company, it adds to the obstacles to the obligations to target the activity where benefits are created, so a fair and equitable part may be shared. Complexity on the user side on genetic resources is often descriptive of the situation in ABS. This has the potential to create problems.

Above we discussed the difficulty of distinguishing between biodiscovery for scientific and for commercial use. While the Commonwealth biodiscovery legislation has been viewed as pioneering in separating the two and introducing a simplified procedure for non-commercial use, the Eskitis Institute scientists explain that they would prefer ABS legislation that goes straight to include the commercial bit up front. Their biodiscovery activities all point towards commercialization.

Queensland government officials on ABS also maintain that one solution to the problem of changed intent is to work more closely with the universities on the permits that are issued, as this is where gains are generated. In that way, they could get notification if the scientific activity changes into commercial activity. For this to happen, strong partnerships between the government and universities would be required, and also one could perceive ABS contracts as a long-term collaboration rather than a one-time access incident.

As mentioned above, Queensland officials also believe the most effective way to keep track of the material and the activities is through disclosure of origin in patent applications. As discussed in the previous section, this avenue does not seem to be a likely choice by the present Australian government.

Although Queensland's expectations in relation to getting a share of any commercial benefits arising from biodiscovery have not been met, the State appreciates that its universities are benefiting from collaborations with the private sector on biodiscovery in terms of technology, collections and research. In that respect, a little bit trickles back to the State, but as pointed out by the government officials, benefit sharing from biodiscovery is far from being sufficient to cover conservation needs or, for that matter, costs involved prior to biodiscovery generating profits. The view from academia is that there is often (both public and private)

funding for infrastructure, but seldom for operating and salaries, which is another reason why it is necessary to turn to large pharmaceutical companies for collaboration on biodiscovery. Also from the sponge case at AIMS, there have been non-monetary benefits in terms of PhDs, infrastructure and capacity building for research.

Finally, on the question of compliance with biodiscovery legislation and benefit sharing arrangements, our impression is that there is a lack of resources – and maybe also to some extent lack of political will – to enforce biodiscovery legislation both at the Commonwealth and State level. The penalty for accessing biological resources in Commonwealth areas is 50 penalty units[48] (equivalent to 5,500 AUD), and it has been argued that this size of a fine of this size lacks deterrent value and undermines the effectiveness of the regulations given the potentially large profits to be made (Hawke, 2009).

In summing up this section we have observed that for biodiscovery aimed at researching the medicinal properties of biological resources, it is often difficult to pinpoint the distinction between the scientific and the commercial intent. The Commonwealth legislation makes a distinction between biodiscovery for scientific and commercial or potentially commercial purposes, including an inbuilt clause for change of intent in the former. The Queensland and Northern Territory legislations aim directly at activities with commercial intent. The large number of non-commercial permits compared to commercial permits hardly gives an accurate picture of the situation.

In addition, the typical course of a biodiscovery process involves many stages and actors. Hence, the sharp division between providers and users as contractors of benefit sharing – envisaged in the CBD/Nagoya Protocol as well as in Australian legislation – is also difficult to trace. This applies in particular to the close involvement of academic institutions and other intermediaries in biodiscovery stages all the way to the patenting and commercialization of the developed products – it is difficult to identify the 'the biodiscovery entity' and industry may hide behind this confusion. The statutory declaration in Commonwealth legislation is, however, a legal instrument that could be used to make the bioprospector responsible to provide information if genetic material is transferred to third parties. Still, a contractual obligation is vulnerable to transfer among parties because what is being transferred is not necessarily identical to the original material. In these situations, it becomes blurred whether a benefit sharing obligation applies. The legislation does not clarify the required level of connection between the initial biological resources and the end product for which benefit sharing obligations are triggered. This cluster of reasons makes it difficult to implement and comply with commercial, monetary benefit sharing arrangements and may be an additional reason that there are so few examples of commercial benefit sharing from biodiscovery in Australia.

[48] EPBCR 8A.06(1),

Lastly, inadequate enforcement of the ABS legislation and its permits might also have contributed to the limited materialization of commercial benefit sharing.

5.3 Ratification and implementation of the Nagoya Protocol – is Australia ready?

Australia has signed but not ratified the Nagoya Protocol (NP) and, like many other States, Australia is conducting internal consultations on the matter. As mentioned in the introduction, these include topics such as disclosure of source in patent applications, penalties for non-compliance and requirement for users of genetic resources to comply with ABS legislation in provider countries. According to ABS government officials, draft legislation enabling ratification is in the pipeline. Still, if and when Australia will ratify is hard to predict and will depend on a number of factors further discussed below.

One factor pointing to a further delay of the process is the recent shift from a labour to a conservative led government. The new Government will need time to assess whether it shares the former government's support for the NP. The NP could be viewed as having trade implications and earlier conservative governments have been quite sceptical to regulate trade in international environmental agreements. Pointing in the reverse direction is the fact that the current Commonwealth ABS legislation described above was put in place by a conservative government, and that the NP could be seen as providing a simplified and more functional system – a level playing field for all actors involved. A key argument of the competent authority *vis-à-vis* the Government is that staying outside the NP could negatively affect cooperation with foreign ABS actors including industry. Australia does keep a close watch of the ratification process of the EU and quick ratification by the EU and Member States might speed up the Australian process.

When the draft legislation has been approved by the Government, it will go into the queue of legislation to be considered by Parliament.

The ABS stakeholders we interviewed are generally in support of the NP and of its Australian ratification and see it is an opportunity for creating new momentum to biodiscovery. Also, it is a general opinion that except for the NP required measures for States to support compliance in countries providing genetic resources to them (user measures), the Commonwealth broadly has the legal measures in place to comply with the Protocol. (See the more detailed examination of this question below.)

Industry and research institutions in Australia conducting biodiscovery increasingly see it in their own interest to be conducting their activities in a responsible and legally correct manner. Thus, they welcome the opportunity provided by the NP to obtain international certificates of compliance. The Eskitis Institute also sees the NP as an opportunity for them to act as a trusted institution in issuing such certificates.

The Australian ABS legislation only applies to wild biological resources while the NP makes no distinction between wild and domesticated

genetic material except for material covered by the Multilateral System of the FAO International Treaty on Plant Genetic Resources for Food and Agriculture (ITPGRFA). Australia's Department of Agriculture, Fisheries and Forestry is competent authority for the ITPGRFA and is generally responsible for legislation and policies on genetic resources for food and agriculture. The Department is still unclear on the implications of the NP on genetic resources for food and agriculture and the interaction between the NP and the ITPGRFA. The Department is also still considering its position on possible development of more specialized ABS agreements for specific types of uses of genetic resources (sectoral approach) envisaged in NP Art 4.2 and currently discussed under the FAO and WHO.

Consistency

In the following it is assessed to which extent Australia on the basis of its current Commonwealth legislation assessed against the most important provisions of the NP is prepared for ratification and implementation.

Scope and access

The NP in accordance with Article 3 applies to genetic resources within the scope of Article 15 of the Convention. Commonwealth legislation extends the scope to the broader notion of 'biological resources'. This is not in conflict with the NP.

Commonwealth legislation is broader than the NP in terms of the scope of biological (rather than genetic) resources for which access requires prior informed consent (PIC). NP Article 6.1 stipulates as the main rule that access to genetic resources shall be subject to prior informed consent (PIC) for their utilization without further specification. Commonwealth legislation is narrower, however, in restricting this utilization to wild biological resources and to the purposes of research and development into its genetic and biochemical makeup. Also according to Commonwealth legislation, PIC is restricted to resources for which Australia is the country of origin (native biological resources). Article 6.1 of the NP lays down that the Party providing the resources shall be the country of origin or a country that has acquired the resources in accordance with the CBD.

The above-mentioned limitations of the scope of the NP as regards PIC are allowed under the NP since the PIC provisions of NP Article 6.1 applies 'unless otherwise determined by the Party'.

Fair and equitable benefit sharing

NP Article 5 requires that benefits arising from the utilization of shall be shared in a fair and equitable way with the Party providing the resources. Commonwealth legislation requires as a condition for PIC that a benefit sharing agreement be concluded, but only for commercial purposes. On scientific purposes the collector shall give a written report on the results of any research on the biological resources to the access provider(s) and offer a taxonomic duplicate of each sample to an Australian institution that is a repository of taxonomic specimens.

Access to resources on indigenous land and to traditional knowledge

NP Articles 5 and 7 require Parties to take domestic measures to enable benefits from genetic resources and traditional knowledge that are held by indigenous peoples and local communities. According to Australia's legislation prior informed consent is required from the indigenous land owner where access to biological resources is applied on indigenous peoples' land. Moreover, the competent national authority as a safeguard shall control that the conditions for PIC and mutually agreed terms meet certain criteria. Also, there are clear minimum requirements for benefit sharing agreements in cases where traditional knowledge has been used.

As discussed above, it has been argued that Australian legislation is not adequate in ensuring equitable benefits to indigenous land and knowledge holders and that it does not create concrete obligation for an access applicant to directly provide a portion of the benefits from the use of traditional knowledge to the knowledge holders. Also it may be argued that a gap exists in the Commonwealth legislation by only requiring PIC for the use of indigenous knowledge when it is used for commercial purposes.

The restriction of the Commonwealth legislation in geographical scope combined with fact that the Northern Territory Biological Resources Act is the only piece of legislation at the State/Territory level to address access on indigenous controlled land and traditional knowledge implies a gap in vis-à-vis the NP provisions in this field.

Certificates of compliance

Article 17.3 of the Nagoya Protocol creates an international recognized certificate of compliance that the genetic resources have been accessed in accordance with PIC and MAT. This is very much in line with the requirements of Commonwealth legislation. Along with Mexico, Australian officials helped refine the concept of internet-based international recognition of national permits as evidence of lawful use. In 2005, Australia began placing information about ABS permits on the net, providing verification of compliance with PIC and MAT of Australian law. This formed the basis for the certificates of legal provenance to be recorded under the CBD ABS Clearing House, as accepted as a key part of the Nagoya Protocol.

Derivatives

The question of whether the NP should cover only genetic resources or also the 'derivatives' of such was a controversial issue throughout the Protocol negotiations. An agreement was reached through focusing on the intent of the utilization rather than on defining the nature of the material to be utilized. Utilization is in NP Article 2 defined as 'to conduct research and development on the genetic and or biochemical composition of genetic resources including through the application of biotechnology'. This made it clear that sharing of benefits from the utilization of genetic resources includes the outcome of research and development.

This approach is very much in line with Australian legislation which defines access as taking biological resources for the purpose of research and development. The contractual mechanism seeks to include a 'reach through' obligation, where the idea is that also subsequent users are bound by the same contractual obligations. The access contract needs to clarify the relationship down the development line.

Simplified procedures

During the Protocol negotiations developed countries argued hard that the establishment of norms for the utilization of genetic resources should not create obstacles for pure non-commercial research. Article 8A of the NP lays down that Parties shall create favourable conditions for research including through simplified measures on access for non-commercial research purposes 'taking into account the need to address a change of intent for such research'.

Again, this is very much in line with the Australian simplified and free access permits for non-commercial research, while containing a universal condition that should the research lead to commercial outcomes, then a detailed benefit sharing contract must be entered into.

User measures

Through Articles 15 and 16 the NP establishes a framework to ensure compliance with the legislation of provider countries to promote the sharing of benefits from utilizing genetic resources or associated traditional knowledge. Parties shall take appropriate domestic measures to that effect. Also Australia is bound by CBD Art 15.7 which obliges countries to take appropriate administrative, policy and legislative measures to encourage fair and equitable benefit sharing.

While a comprehensive legal framework has been established for Australia as a provider of biological resources, Australia has not enacted legislation as a user of other countries' genetic resources to support compliance with the legislation of these countries. Thus, as a user country, further measures will be required to comply with the NP. We were informed that as a starting point an accreditation system is planned to be set up to track genetic resources including those accessed in other countries. This would then be administered by a trusted institution.

As described above, one user measure that has received particular attention under the CBD both during and before the NP negotiations is a requirement to disclose evidence of prior informed consent and mutually agreed terms in patent applications for inventions making use of genetic resources. In spite of a strong push from developing countries, it was finally not included as a requirement in the NP. Still, a number of countries have introduced it as a domestic requirement and this possibility is also discussed in Australia.

As described above most of our interviewees see great opportunities in linking the ABS and IPR systems through a disclosure requirement, but doubt whether there will be political will for such a move.

6 Conclusion / Summary

Abstaining from economic development of pristine areas for the sake of conserving biodiversity, setting up the infrastructure (i.a. universities) for collecting, storing, searching for active compounds and preparing biological material for the final assessments for medicinal use, these are all costly activities and they are to a large extent borne by the public sector. Patenting active compounds and developing these into the medicines that finally reach the counter, these are also time-consuming and costly activities, primarily borne by private companies. In the end, the pharmaceutical sector is dominated by very large multinational companies and generates large revenues.[49] The question is whether and how those revenues could also be applied in carrying some of the high costs associated with the first part of the process, i.e. conservation and the initial research and development costs initiated by the public sector, in the cases that lead to commercial products. This would also be a long-term investment in bioprospecting/biodiscovery.

Normatively speaking, all actors seem to agree that benefit sharing should be the case. According to most of our interviewees, the biotechnology and pharmaceutical companies actively support ABS frameworks, arguing their wish to be in compliance with the international ABS regime of the CBD. Doing the right thing in this context improves companies' image and make them more competitive, is what we hear. We have also seen that the Australian ABS legislations both at the Commonwealth level, but also in Queensland and the Northern Territories, go a long way in establishing frameworks for this to take place. Nevertheless, under Commonwealth legislation there is still only one biodiscovery case involving commercial benefit sharing, an indication that the high expectations for ABS in Australia may not have been met. Based on our interviews, we discussed three major lines of factors that could account for this situation.

Firstly we studied whether the interest and demand for biodiscovery for commercial purposes have declined. We found that on the side of the public authorities, the enthusiasm prevailing when ABS legislation was enacted in Queensland and at Commonwealth level has clearly dropped and with it much financial support. On the other hand, we learned that the pharmaceutical industry again has more confidence in natural than synthetic products. Thus, the demand for biodiscovery persists as demonstrated by research collaborations between industry and academic institutions such as the Eskitis Institute under Griffith University and the Australian Institute of Marine Science (AIMS). Collaborations have had high returns for the institutions in a number of fields, but so far not in the form of commercial benefit sharing. Also, we saw a demand for making use of traditional knowledge for pharmaceutical production and thereby a

[49] The global pharmaceutical industry had revenues estimated US$995.5 billion in 2011. The ten largest companies account for over one-third of this market which is 40% of total revenues of the top 50 pharmaceutical companies. Five are based in the United States and the other five in Europe. (*Bioscience at a Crossroads*, a policy brief on the pharmaceutical industry prepared for the CBD Secretariat by Sarah A. Laird, 2013. www.cbd.int/abs/policy-brief/default.shtml/.)

potential for benefit sharing agreements with indigenous groups. However, the willingness of these groups to capitalize on this opportunity and share their knowledge varies.

We further examined the adequacy and perceived effectiveness of the Australian ABS legislation. The Commonwealth legislation is quite advanced and pioneering in giving national effect to the third objective of the CBD with mandatory permits for all biodiscovery and mandatory benefit sharing agreements for biodiscovery with a commercial intent. The legislation also provides safeguards for prior informed consent and benefit sharing arrangements with indigenous holders of biological resources and associated traditional knowledge. ASB practitioners were generally happy with the legislation, but also noted that the ABS jurisdiction is shared with the States and Territories, and among those only Queensland the Northern Territory has enacted legislation, leaving large parts of Australia uncovered by ABS legislation.

Our study identified a weakness in following the material and the capacity to use the vast resources needed for checking whether material under an agreement has actually led to commercialization. One main lesson is probably that there is generally a need for improving the dynamic element in ABS contracts, building in a clearer trigger point for when the obligations to share are actualized and reverse the burden of tracking and follow-up to the user rather than leaving it to the provider. If a rich country like Australia lacks sufficient resources to follow the future development based on its material, this speaks volumes for poor provider countries. It might also be the case that Australia does have in place an enforceable ABS legislation, but chooses a lenient approach rather than strict enforcement. It could be argued that Australia's developed country legal system is acting as an effective deterrent along with the fact that its biodiscovery scientific community is sufficiently small. It is therefore likely that deviant behaviour would become known. Moreover ex-situ collections providing genetic resources have strong administrative systems in place so that the identity of the source of bioactive compounds is not disclosed until formal contracts are in place.

Many of those we interviewed believed that linking the ABS and IPR legislation through disclosure of the source of biological resources in patent applications would be an appropriate legal measure to track compliance with legislation and benefit sharing arrangements. Even disclosure may not, however, be a sufficient measure, although it receives large attention in the CBD, WIPO and TRIPS Council (Tvedt 2006).

Finally, we looked at the possibility of biodiscovery activities bypassing existing legislation as a reason for the apparent lack of commercial benefit-sharing. We found that it is difficult to determine when biodiscovery passes from being purely scientific to commercial and that this complicates the preparation and implementation of benefit sharing arrangements. In addition, the typical course of a biodiscovery process leading to commercialization involves many stages and actors from academia, the private sector and others; hence it is likely to confuse who are actually the providers and the users and thereby partners of benefit sharing arrangements. The statutory declaration in Commonwealth

legislation is, however, a legal instrument that could bind the user to Australian criminal law, but holds a more limited prospect for following and tracking genetic material as it is transferred to third parties.

Another related issue which is left unsolved in the NP is the required link between the original genetic resource or traditional knowledge and the end product for the benefit sharing obligation to trigger benefit sharing. If contracts do not specify this issue in more detail, the likelihood of benefit sharing actually taking place is dubious. Lastly, enforcement of the ABS legislation by the authorities is not vigorous, and the incentives for the user to come back and renegotiate a new agreement at the stage of a successful hit are low.

A common trigger point is when the user decides to seek patent protection. An interesting topic that surfaced was the relationship between scientific activities leading to publishing of results and commercial activities involving patents. Most of the time, the story from companies is that commercial results from biodiscovery are still such a long way away, there are simply no grounds for expecting benefit sharing anytime soon. At the same time, we were told that scientists usually waited for the patents to be granted before they considered publishing results from collaboration between universities and bioprospecting companies. This makes sense because publishing must be postponed in order not to block the patent criterion of novelty (the search for prior art). Patenting, however, is a strong indication of commercial interest – at least a potential one. As both the commercialization and the IPR process are claimed to be very long and costly, there can hardly be a smooth relationship with sharing pure scientific results. Alternatively, this could indicate that more commercial activities and results with a potential for benefit sharing are taking place – at a quicker pace than we are led to believe.

There does not seem to be much domestic political attention to ABS at present and observers doubt that there will be changes made in the system in the near future, including filling the legal gap in most of Australia's States/Territories. However, one aspect makes it very relevant to revisit the whole ABS system, namely the decision that has to be taken on whether Australia should ratify the Nagoya Protocol.

From the perspective of the Commonwealth legislation, Australia has already come a long way in implementing rules that are in accordance with those of on the provider side of ABS according to the Protocol. However, as a country not only providing biological resources, but also using such from other countries, Australia will have to enact legislation to support compliance with the access legislation of provider countries. It is also generally recognized that legislation is not adequate to implement the NP in terms of ensuring equitable benefits to indigenous land and knowledge holders for biodiscovery on their land and associated traditional knowledge mainly because only the Commonwealth and the Northern Territory have enacted legislation to that effect.

The National Consistent Approach from 2002 intended regulatory consistency across Australia, and the NP clearly actualizes the need to

now apply this approach. Not only does that seem necessary in terms of complying with the Protocol, it would avoid confusion for both providers and users of biological resources especially in cases where biodiscovery crosses jurisdictional boundaries. It could also close the legal gaps where a biodiscoverer who finds the regulation too strict can biodiscover in a territory which is not covered by ABS and thus avoid any requirements. These gaps can therefore become drivers in a race to the bottom for those actors with a mindset of following the law, but no further than the minimum required by the law.

Australia played an important role in the negotiations leading to the NP, and its legislation inspired some of the Protocol's provisions. On that basis and being a mega-biodiversity country with extensive ABS experience and wide support by the biodiscovery stakeholders to the NP, it would seem obvious and in the interest of the country to become a party to the NP.

The outside world would also benefit from Australia being a party because Australia has learned many ABS lessons to be shared with other parties of which many will not have come nearly as far in their ABS experience. Among others, there are lessons about drawing up an effective regulatory system, but also about legal challenges for federal nations with mixed jurisdictions between the federal and state level. These lessons concern partnerships between public academic institutions and the private sector with great benefits for both parties, as well as difficulties in distinguishing scientific from commercial biodiscovery and defining roles.

The Australian government earlier has been involved in ABS capacity building activities in countries in the region, but stopped this activity because of lack of resources. It could be very useful for international NP implementation if Australia could resume this activity.

Acknowledgement

This report is based on an interview study tour to Australia by Steinar Andresen, Christian Prip and Kristin Rosendal, November 2013. We are very grateful to our interviewees, who were very knowledgeable and shared their insights candidly with us.

References

Andersen, Regine and Tone Winge. 2012. *The Access and Benefit Sharing Agreement on Teff Genetic Resources: Facts and Lessons*. FNI Report 6/2012. Lysaker.

Biber-Klem, Susette, 2014. In Oberthür, Sebastian and G. Kristin Rosendal (eds). 2014. *Global Governance of Genetic Resources. Access and Benefit Sharing after the Nagoya Protocol*. Routledge: London, New York.

Burton, Geoff. 2013. The JUSCANZ group in Nagoya negotiations; the unlikely lot. In Morgera et al., (eds) 2013.

Ernst & Young. 2010, Beyond Borders. *Global Biotechnology Report*. (Ernst & Young).

Fowler, C. 2001. Protecting farmer innovation: The convention on biological diversity and the question of origin. *Jurimetrics*, *41*(4), 477-488.

Grajal, A. 1999. Biodiversity and the nation state: Regulating access to genetic resources limits biodiversity research in developing countries. *Conservation Biology*, *13*(1), 6-10.

Gleckman, H. 1995. 'Transnational Corporations' Strategic Responses to "Sustainable Development" ', in H.O. Bergesen and G. Parmann (eds), *Green Globe Yearbook of International Co-operation on Environment and Development 1995*, The Fridtjof Nansen Institute and Oxford University Press, Oxford, pp. 93-106.

Hawke Allan 2009. :he Australian Environment Act – Report of the Independent Review of the Environment Protection.

Koester, V. 1997. 'The Biodiversity Convention Negotiation Process and Some Comments on the Outcome', *Environmental Policy and Law*, vol. 27, no. 3, pp. 175-92.

Laird, Sarah, Monagle, ,Catherine, Johnston, Sam. 2008. Queensland Biodiscovery Collaboration. The Griffith University AstraZeneca Partnership for Natural Product Discovery. An Access and benefit Sharing Case Study. *Report by the United Nations University – Institute of Advanced Studies (UNU-IAS).*

Medaglia, Jorge Cabrera , Morten Walløe Tvedt, Frederic Perron-Welch, Ane Jørem and Freedom-Kai Phillips. 2013. *The Interface between the Nagoya Protocol on ABS and the ITPGRFA at the International Level: Potential Issues for Consideration in Supporting Mutually Supportive Implementation at the National Level*. FNI Report, 1/2013.

Mittermeier G. and Mittermeier, (eds.) 1997. *Megadiversity: Earth's biologically wealthiest nations*. Cemex, Mexico.

Morgera, Elisa, Matthias Buck, Elsa Tsioumani (eds). 2012. *The 2010 Nagoya Protocol on Access and Benefit Sharing in Perspective. Implications for international law and implementation challenges*. Brill.

Oberthür, Sebastian and G. Kristin Rosendal (Eds). 2014. *Global Governance of Genetic Resources. Access and Benefit Sharing after the Nagoya Protocol*. Routledge: London, New York.

Pavoni, Riccardo. 2013. 'The Nagoya Protocol and WTO Law', in Morgera, Elisa, Buck, Matthias and Tsioumani, Elsa (eds.) *The 2010 Nagoya Protocol on Access and Benefit Sharing in Perspective.* Leiden: Martinus Nijhoff, 185-213.

Rosendal, G.K. 2000. *The Convention on Biological Diversity and Developing Countries*, Kluwer Academic Publishers: Dordrecht.

Rosendal, G. Kristin, Ingrid Olesen and Morten Walløe Tvedt. 2012. *Access to, Equity and Protection of Genetic Resources in Ghana: The Case of Tilapia* (O. niloticus). FNI Report 15/2012. Lysaker.

Rosendal, G. Kristin. 2010. *Access to and Benefit Sharing of Genetic Resources in Cameroon: Legal and Institutional Developments and Challenges*. FNI Report 8/2010. Lysaker, FNI, 2010, 29 p.

Rosendal, G. Kristin. 2010. *Analytical Framework for Analysing Experiences from Case Studies of ABS in Africa*. FNI Report 7/2010. Lysaker.

Schei, P.J. 1997. 'Konvensjonen om biologisk mangfold' in W.M. Lafferty, O.S. Langhelle, P. Mugaas and M. Holmboe Ruge (eds) *Rio + 5*: *Norges oppfølging av FN-konferansen om miljø og utvikling* (Oslo: Tano Aschehoug).

Simpson, Bradley S, Claudie, David J , Smith, Nicholas M , McKinnon, Ross A , Semple, . Susan J. Learning from Both Sides: Experiences and Opportunities in the Investigation of Australian Aboriginal Medicinal Plants. *J Pharm Pharm Sci*, 16 (2): 259-271, 2013

Siswandi, Achmad Gusman. Should Australia sign the Nagoya Protocol? A submission to the department of sustainability, environment, water, population and communities. Australian National University College of Law, PhD Fellow, Canberra.

Svensson, U. 1993. 'The Convention on Biodiversity – A New Approach', in S. Sjøstedt and H. Aniansson (eds), *International Environmental Negotiations*; *Process, Issues and Context*, FRN Utrikespolitiska Institutet, Stockholm.

Tvedt, Morten Walløe. 2013. Tvedt, Morten Walløe, 'Disentangling Rights to Genetic Resources Illustrated by Aquaculture and Forest Sector'. *Law Environment and Development Journal*, Vol 9, No 3, 2013, pp. 3-20.

Tvedt, Morten Walløe. 2014. In Oberthür and Rosendal (eds.).

UNDP. 1999 and 2000. *Human Development Report*, United Nations Development Programme, New York, Chapter 2.

The Fridtjof Nansen Institute is a non-profit, independent research institute focusing on international environmental, energy, and resource management. The institute has a multi-disciplinary approach, with main emphasis on political science and international law. It collaborates extensively with other research institutions in Norway and abroad.

FRIDTJOF NANSENS INSTITUTT
FRIDTJOF NANSEN INSTITUTE

Fridtjof Nansens vei 17, P.O. Box 326, NO-1326 Lysaker, Norway
Phone: (47) 67 11 19 00 – Fax: (47) 67 11 19 10 – E-mail: post@fni.no
Website: www.fni.no