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Environmental Law in Madagascar: The Nagoya Protocol on Genetic Resource Use, Access and Benefit Sharing

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ENVIRONMENTAL LAW IN MADAGASCAR:
The Nagoya Protocol on Genetic Resource Use, Access, and Benefit Sharing

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SIT Study Abroad Tanzania/Zanzibar: Coastal Ecology and Natural Resource Management

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ABSTRACT

The rapid expansion of the biosciences has led many to turn to nature in search of genetic resources of commercial value. Bioprospecting, or the search for plants and animals from which commercially valuable compounds can be obtained, is often a transnational activity. Four-fifths of the world’s biodiversity is found in developing countries, and those searching to exploit the biodiversity of these nations overwhelmingly tend to come from developed, wealthy countries. This asymmetry, when coupled with the lack of institutional legislative frameworks and regulation, creates a plethora of user/host conflicts. This paper seeks to examine the current state of affairs regarding environmental law in Madagascar as it relates to management of bioprospecting and genetic resource use conflicts. Firstly, it will examine international and domestic environmental law – with an emphasis on the recently ratified Convention on Biodiversity and the Nagoya Protocol. Secondly, non-governmental contractual agreements between local and foreign entities will be
examined, with an emphasis on the International Cooperative Biodiversity Group as a case study. The study will conclude with suggestions, warnings, and potential future research opportunities.

INTRODUCTION

Madagascar is a highly diverse island nation located off the coast of Africa in the Indian Ocean. Madagascar broke off from the mainland Africa 165 million years ago, and from India 70 million years ago. Since then, it has followed a relatively isolated evolutionary path resulting in one of the most unique ecosystems on earth. Madagascar is host to 12,000 species of vascular plants (96% endemic). Over 90% of all its wildlife is found nowhere else on earth, and 5% of all of earth’s biodiversity is found on Madagascar (Madagascar – Country Profile).

Harnessing Madagascar’s biodiversity has been an invaluable tool in ensuring the prosperity and livelihood of its people. Madagascar’s rich ecosystems provide food, medicine, construction tools, and energy. An estimated 18 million people depend on biodiversity in Madagascar for their subsistence needs, and at least 70% of the population depends on agriculture (Madagascar – Country Profile).

Just as Madagascar’s biodiversity has sustained life for its people, it has also attracted considerable foreign interest, particularly from those wishing to utilise and exploit Madagascar’s biodiversity – namely, bioprospectors.

Bioprospecting has played a critical role in how humans interact and use the nature that surrounds us for centuries. It is how we discover what is edible, what is medicinal, what can be grown and what should be avoided. Yet the rapid recent
growth of the biosciences and the commercialisation of nature has morphed bioprospecting into its current form. Elsa Tsioumani defines it as, “the search for plants and animals from which commercially valuable compounds can be obtained. (Tsioumani, 2015)" It occurs across several sectors such as agriculture, cosmetics, energy, and medicine, and in ecosystems ranging from forests to marine. When done carefully and properly, bioprospecting has the potential to produce results beneficial to humankind.

In the food and agriculture sector, plants and food sources shown to be drought resistant, flood resistant, and pest resistant have contributed considerably to the genetically modified food industry. In turn, these discoveries have paved the way for increased food security – and sovereignty – in countries that are the most affected by climate change, poverty, and hunger (Duraisamy, 2011).

The cosmetics industry constantly has to respond to the vast market demand on beauty and personal hygiene products. Consumers – and thus suppliers – are constantly searching for anti-aging, anti-acne, anti-dandruff, and skin whitening formulas, in addition to the basic colouring products of lipstick and eye shadow. Bioprospecting enables them to keep up with that demand through discovery of useful compounds found in nature. For example, many skin-whitening products find their active molecules in liquorice extracts, mulberry, and aloe (Duraisamy, 2011).

It is the pharmaceutical industry that invests the greatest amount of resources in bioprospecting. Plants are humans’ original source of healthcare, and the World Health Organisation (WHO) estimates that even with the development of occidental medicine, “approximately 80% of the global population rely
predominantly on traditional [plant-based] medicines as their primary source of health care.” This is true in Madagascar, and approximately one million tonnes of medicinal plants are exported each year at a value of $3.59 million (Madagascar – Country Profile).

Outcomes of bioprospecting have the potential to save lives, cure diseases, and pave the way for new scientific discoveries and insights. Yet in the absence of a national regulatory framework, bioprospecting in Madagascar has resulted in conflicts over resources. Implementation of this framework is of paramount importance for the continued development of Madagascar. This paper will discuss various case studies of conflicts that have arisen as a result of bioprospecting in Madagascar, followed by the international, domestic, and non-governmental attempts to control and manage the sustainable use and mutual benefit of Madagascar's genetic resources.

**METHODS**

This study was conducted from the 5th to the 28th of November 2015. Informational sources include a collection of both primary and secondary sources. Primary information was gathered through a series of interviews conducted at the offices of those being interviewed. Interviews took place primarily in English, though some were conducted in French or Malagasy with the assistance of a translator. Prior informed consent was granted for utilisation of information obtained during the interview.
Secondary sources come from a range of available academic literature regarding environmental law, bioprospecting in Madagascar, and various international treaties and conventions.

No raw data was collected from field surveys or otherwise.

**GENETIC RESOURCE USE CONFLICTS IN MADAGASCAR**

With nature providing the obvious source of potential compounds, the next question then becomes *how* to go about searching for these compounds. With hosts ranging from plants and marine organisms to microbes and fungi, scientists must figure out a way to effectively and efficiently narrow down the hundreds of thousands of potential species to be evaluated.

The five primary selection and screening techniques are random, taxonomically guided, eco-rational, ethnobotanical, and zoopharmacognosy (Table 1). Random collection is most often used to gather large amounts of data and establish population baselines, surveys, and botanical diversity counts. They are rarely effective as a primary means of compound discovery, as they tend to be far too broad (Miller, J.S., 2005).

Taxonomically guided screening uses families or genera of presumed chemical interest to direct research. Eco-rational and zoopharmacognosy methods involve observing animal or ecological species interactions for behaviour or characteristics. An example of this comes from observation of the sea sponge. Cancer research institutes have long been searching for compounds that break down or stop cell growth. Rapid, uncontrollable cell replication causes the growth of
tumours, and scientists have long been searching for a compound that, when targeted, can stop or slow the replication of cells and break down existing ones. It was through an observation of the defence mechanisms of the sea sponge that its potential was revealed (Richmond, Lecture 15/10/2015).

**Table 1. Methods of selection of plant species for pharmaceutical evaluation.**

<table>
<thead>
<tr>
<th>Method</th>
<th>Aim</th>
<th>References</th>
</tr>
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<tbody>
<tr>
<td>Random</td>
<td>A random selection of species</td>
<td>Spjut 1985; Miller and Gereau 2000</td>
</tr>
<tr>
<td>Taxonomically Guided</td>
<td>Families or genera of presumed chemical interest</td>
<td>Miller and Gereau 2000</td>
</tr>
<tr>
<td>Eco-Rational</td>
<td>Species with observed ecological interactions of interest</td>
<td>Caporale 1995</td>
</tr>
<tr>
<td>Ethnobotanical</td>
<td>Species with history of indigenous use</td>
<td>Balick 1990; Cox 1990; Farnsworth 1994; Lewis and Elvin-Lewis 1995</td>
</tr>
<tr>
<td>Zoopharmacognosy</td>
<td>Species observed to be used by other animal species</td>
<td>Wright 1983; Nishida 1983; Rodríguez et al. 1985</td>
</tr>
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The sea sponge is an immobile marine invertebrate usually found in coral reefs with high sunlight. Due to its immobility, the sea sponge has had to develop defence mechanisms that protect it against coral that often grows over the sponge, thus blocking its access to light and starving it. To protect against this, when the sea sponge senses coral intruding on its territory, it releases chemicals that break down the corals calcium carbonate skeleton, and prevent it from continued growth (Richmond Lecture, 15/10/2014).

It was through observation of this defence mechanism that scientists began to investigate further the anti-cancer potentials of sea sponges. A Caribbean sponge has been discovered to generate compounds used in AZT (zidovudine, *Retrovir*), which is used to fight the AIDS virus (Sandhu, H.S., 2006).

While these techniques of bioprospecting provide the fewest social conflicts with local populations, they can often lead to overexploitation of endemic flora,
fauna, and fungi. This happened in Madagascar, Cameroon, and several other African nations with the case of the African Cherry, or *Prunus africana*. The *P. africana* is a secondary forest canopy tree species whose overexploitation has resulted in severe Afromontane deforestation. Extracts from the bark began to be used to treat prostatic hyperplasia, and the trade was worth approximately $220 million in the 1990s. The high demand for the bark on European markets led to the annual collection of 3300 tonnes of bark annually (Bodeker, G., 2014).

Improper collection techniques and a high demand ultimately resulted in the once common species being included in Appendix II of the Convention on International Trade in Endangered Species (CITES) of Wild Flora and Fauna at the Ninth CITES Conference of the Parties in 1995. As Bodeker notes, “Overexploitation of *P. africana* has occurred in the absence of legally binding treaties, the historic neglect of customary ownership issues, the disregard for the rights of traditional knowledge holders, and the complicity of governments in allowing unsustainable trade, attributed by some commentators to endemic corruption within the concerned governments.” (Bodeker, G., 2014).

Finally, ethnobotanical bioprospecting involves using local or traditional knowledge about plant uses to guide surveys and testing. Yet it is another grey area that has led to several conflicts between users and providers of genetic resources (Miller, J.S., 2005).

There are currently 2,300 plants used for medicinal purposes in Madagascar, and traditional healers, as the possessors of that knowledge, have never constituted a threat to the conservation of biodiversity (Madagascar – Country Profile). Despite
pre and post colonial-era stigmatisations and the legal oppression of traditional healers, including its official prohibition until 2007, Malagasy healers have often been very open about sharing their knowledge of plants (Ratsimbason, Interview 11/11/15).

Yet the improper use of traditional knowledge (TK) has resulted in cases of biopiracy, in which TK is exploited for commercial gain with no compensation to the indigenous people themselves (Shiva, 1997). Perhaps one of the most famous and oldest cases of biopiracy is that of the *Catharanthus roseus*, or the rosy periwinkle, which dates to the 1960s. The plant, while native to Madagascar, has been widely introduced to other tropical countries around the world. Researchers obtained TK from communities in Jamaica regarding its efficacy as a cure for diabetes. Yet the introduction into other countries created a transnational situation in which different countries are reported as having different beliefs about the uses of the plant (Quansah, N., pers. comm. 3/12/2015). The transnational nature of the plant meant that researchers could obtain knowledge in one country, and cultivate the plant in another one. This further complicates claims of who, or which community, deserves compensation and for what (Shiva, 1997).

Research by the Western pharmaceutical company, Eli Lilly, revealed alternate uses from the traditional ones. Importantly, the Hodgkin’s Lymphoma chemotherapy drugs vinblastine and vincristine (for childhood leukaemia) were derived from the rosy periwinkle. Development of these drugs has resulted in $100 million net profit annually for Eli Lilly, though no benefits (monetary or otherwise) have been given to source communities. This conflict of benefit sharing is at the
heart of modern legal discourse surrounding the use of genetic resources.

(Quansah, N., pers. comm. 3/12/2015).

The Malagasy government has also come in conflict with the non-profit sector. The NGO *l’Homme et l’Environnement* recently partnered with the UNEP World Conservation Monitoring Centre and *Chanel Parfums Beauté*. They developed the book “*Inventaire des Plantes Médicinales de Vohimana* Madagascar,” which outlines the plants of Vohimana and their traditional medicinal uses. The *Office National pour l’Environnement* (ONE) was unhappy with this publication for two reasons. Firstly, the process was carried out without the consent of the Malagasy government. Secondly, the publication of this traditional knowledge places it in the public domain with *l’Homme et l’Environnement* as the technical owners of this information, making it much more difficult to protect (Raharimalala, V., Interview, 26/11/2015).

The improper use of traditional knowledge raises further the issue of prior informed consent (PIC). PIC is defined as “*assent to permit an occurrence that is based on a complete disclosure of facts needed to make the decision intelligently, such as knowledge of the risks entailed or alternatives*” (West’s Encyclopaedia of American Law, 2008). PIC does not only apply to the use of TK, but also grants organisations wishing to bioprospect access to the communities’ resources.

In the absence of a national regulatory framework outlining the requirements for PIC, the onus lies on companies to obtain PIC. Yet what this often means is that with nothing to check companies, PIC is either not obtained, obtained
through dishonest or obscure means, or it is obtained, but not from a figure with the authority to give consent (Shiva, 1997).

Finally, international patenting laws were created primarily by and for industrialised countries. General rules are that a product to be patented must be new, novel, and it cannot be in its naturally occurring form. In the pharmaceutical sector, this generally means that you can use a plant for medicine and patent it, but only the isolated active molecule responsible for the medicinal purposes is patented (no longer in its naturally occurring form) (World Trade Organisation, 2006).

The process of isolating an active molecule is a lengthy, difficult, and costly process that involves equipment most research organisations in Madagascar do not have access to. So, instead, Malagasy pharmaceutical companies and research centres like IMRA, CNARP, and SOTRAMEX often settle for isolating the compound as an essential oil, putting it in pill form, and patenting the whole pill. The active molecule is in the pill – they just do not have a precise chemical formula for it.

What this means is that under international patent law, the Malagasy company has a patent on the pill as a whole. So, if a foreign company were to take that exact pill and manage to isolate the active molecule within it (or take it out of its naturally occurring form by isolating or synthesising it) and then develop a drug that makes millions, it is a perfectly legal loophole that cheats and excludes Madagascar out of their profits (Ratsimbason Interview, 11/11/2015).

With so many conflicts arising out of the use of genetic resources, legislation must be comprehensive and broad to ensure adequate access, use, and benefit sharing for both user and provider countries.
Convention on Biodiversity (CBD) and the Bonn Guidelines

Discussions regarding genetic resources have been on the international agenda since the 1990s. In 1992 the United Nations Conference on the Environment and Development led to a record 157 signatories to the Convention on Biological Diversity (CBD) and its ratification in December 1993. The CBD paved the way for Multilateral Environmental Agreements (MEAs), and the legal backbone of international environmental governance (McGraw, D., 2002).

Article 1 of the CBD outlines its three main goals; conservation of biodiversity, sustainable use of resources, and equitable sharing of benefits derived from the use of genetic resources. It is the final goal that makes the CBD so revolutionary, and reflects the bargaining power held by developing countries as the collective owners of four-fifths of the world’s biodiversity (McGraw, D., 2002). These biologically rich countries, like Madagascar, felt they were not receiving adequate compensation from high yielding pharmaceuticals and cosmetics whose core elements come from their territories. They argued that this asymmetrical economic benefit system reduced the incentive to conserve. Thus, the ability to include the equitable sharing of benefits as an objective of the CBD was an important step in recalibrating the incentives for biodiversity conservation.

Articles 15, 16, 19, and 18(j) cover access and benefit sharing (ABS) provisions in the CBD. Article 15 of the CBD addresses the terms and conditions for access to genetic resources by outlining the basic principles it should uphold.
Importantly, it recognises the sovereignty of States over their natural resources. This places the government as custodian, and in the position to grant or deny access subject to the prior informed consent (PIC) of the contracting party providing such resources. Terms of access shall be “based on mutually agreed upon terms (MAT) in order to ensure the sharing of benefits arising from the commercial or other utilization of these genetic resources with the Contracting Party providing such resources (CBD, 2001)”

Furthermore, the CBD includes compliance and enforcement provisions. Article 18.3 was responsible for the establishment of a Clearing House Mechanism (CHM), which was implemented after Conference of the Parties to the Convention (COP) 10 Decision X/15. The Clearing Houses’ main goals include promoting information sharing to facilitate the implementation of the Nagoya Protocol and National Biodiversity Strategies and Action Plans, a network of CHMs, and the establishment of a national focal point for the CHM (CBD Website).

Madagascar was signatory to this convention on 8 June 1992, and ratified the convention on 4 March 1996, under the Presidency of Albert Zafy. Like many other countries, this treaty provided Madagascar with the legal backing to demand compensation for, and regulate the use of, its genetic resources. Many in the country greeted the CBD with open arms (Ramiandrarivo, L., Interview, 17/11/2015).

Although the CBD entered into force at the end of 1993, and despite it being a legally binding document, few countries had developed domestic legislation in an attempt to comply with CBD principles, and even fewer were enforcing that legislation. Furthermore, those countries who did have the legal capacity to
translate CBD provisions into ABS law tended to be industrialised countries with advanced biotechnology and pharmaceutical industries – those with both a heightened interest in access to resources and little desire to engage in benefit sharing. It seemed that the victory developing countries had achieved in ensuring Access and Benefit Sharing (ABS) provisions in the CBD was purely nominal (Morgera, E., 2012).

Madagascar, continuing down its own path as a fledgling democracy with a weak central government, was not in a position to draft, approve, or enforce ABS legislation. Madagascar continued to face issues regarding access and use of genetic resources, as previously indicated with the cases of the *Prunus Africana* and the *Rosy Periwinkle*.

It was not until 1999 that attempts to operationalize the ABS provisions of the CBD began. Work began on drafting the Bonn Guidelines on Access to Genetic Resources and the Fair and Equitable Sharing of Benefits Arising Out of Their Utilisation.

The first draft of the Bonn Guidelines was presented in October 2001, and eventually adopted with some changes during COP 6, in April 2002. Though the guidelines are *not* legally binding, their unanimous adoption by some 180 countries gives them clear and indisputable authority. As stated in the introduction to the Bonn Guidelines, written by Executive Secretary Hamdallah Zedan:

> The Guidelines identify the steps in the access and benefit-sharing process, with an emphasis on the obligation for users to seek the prior informed consent of providers. They also identify the basic requirements for mutually agreed terms and define the main roles and responsibilities of users and providers and stress the importance of the involvement of all stakeholders.
They also cover other elements such as incentives, accountability, means for verification and dispute settlement. Finally, they enumerate suggested elements for inclusion in material transfer agreements and provide an indicative list of both monetary and non-monetary benefits.

The suggested elements for inclusion in material transfer agreements and list of monetary and non-monetary benefits have been included as Appendices A and B respectively.

The Bonn Guidelines operated under the assumption that all countries are both users and providers of genetic resources. As such, countries were expected to adopt “both source-country measures, including provisions clarifying each country’s sovereign rights over genetic resources, and the identification of access procedures and requirements; and user-country measures, by which each country addresses the responsibility of users under its jurisdiction who are utilising genetic resources from other countries. (Morgera, E., 2012)”

Similar to the CBD, little progress was made by Parties to actualise ABS legislation following the adoption of the Bonn Guidelines. It was, after all, a non-binding document. Nevertheless, four months later, in August 2002, the World Summit on Sustainable Development triggered the negotiations that led to the development of the Nagoya Protocol.

**Nagoya Protocol**

The Nagoya Protocol on Access to Genetic Resources and the Fair and Equitable Sharing of Benefits Arising Out of Their Utilisation to the Convention on Biological Diversity is the culmination of almost two decades of discussion and negotiation regarding ABS. It entered into force on 12 October 2014 after being
ratified by 54 countries – including Madagascar. It provides a much more thorough, and legally binding alternative to the Bonn Guidelines. Madagascar is currently in the process of implementation.

It is hoped that the Nagoya Protocol will leverage the interests of all stakeholders in a way that results in mutually beneficial arrangements. Benefit sharing agreements will incentivise provider countries to make their genetic resources accessible. On the other hand, enhancing researchers’ access based on reliable decisions at low transaction costs will encourage scientific breakthroughs and the innovation of useful goods and services whilst promoting country development (Morgera, E., 2012).

This section assesses what Madagascar’s obligations as Party to the Protocol are, the trans-sectorial legal implications of the Nagoya Protocol, and the implementation process and challenges Madagascar faces going forward.

**Madagascar’s Obligations as Party to the Protocol**

Though many criticised the document as inadequate (COP 10, pg. 98 – 102) – including Madagascar and the African Group – major steps were taken in setting precedents for access, institutional obligations, and benefit-sharing mechanisms.

First, the Nagoya protocol outlined and defined several key terms and concepts that had otherwise been left amorphous. Article 2.c states “utilisation of genetic resources” to mean, “to conduct research and development on the genetic and/or biochemical composition of genetic resources, including through the application of biotechnology.” It defines in Article 2.d biotechnology as “any technological application that uses biological systems, living organisms, or derivates
thereof, to make or modify products or processes for specific use.” Finally, it defines “derivates” in Article 2.e as “a naturally occurring biochemical compound resulting from the genetic expression or metabolism of biological or genetic resources, even if it does not contain functional units of heredity.”

Definition of these terms is of paramount importance, as it sets the precedent and scope for what may or may not be under the jurisdiction of the Protocol.

Secondly, in Articles 6, 7, and 12, issues regarding access to genetic resources and the traditional or indigenous knowledge associated with said resources are addressed. Madagascar is responsible under Article 6 to take steps to establish:

1. Legal certainty, clarity, transparency, and timeliness;
2. Fair and non-arbitrary access rules and procedures;
3. Information on how to apply for PIC;
4. Clear and transparent written decision by a competent national authority, in a cost effective manner and within a reasonable period of time; and
5. Issuance of a permit or its equivalent at the time of access as evidence of PIC and the establishment of mutually agreed upon terms (MAT).

Similar to the Bonn Guidelines, the Protocol operates off the assumption that all countries are both user and provider countries. As such, administrative procedures for obtaining prior informed consent and establishing rules of access are the same for both foreign and domestic entities seeking access rights.

Madagascar’s government must provide the necessary institutional arrangements to ensure the accessibility of its genetic resources, and to develop domestic regulations regarding the parameters of benefit sharing, as stated in Article 15 (Compliance with Domestic Legislation or Regulatory Requirements on Access and Benefit Sharing), and Article 16 (Compliance with Domestic Legislation or Regulatory Requirements on Access and Benefit Sharing for Traditional
Knowledge Associated with Genetic Resources). Furthermore, precise terms and arrangements for the process and activation of ABS are to be arranged among relevant parties in the development of MAT.

Benefits shared may be monetary (in the form of access fees, milestone payments, royalty payments, or research funding), or non-monetary (in the form of information sharing, product development participation, technology transfers, or institutional capacity building projects). Benefits are encouraged to promote the first two goals of the CBD, conservation and sustainable use. See Appendix A for the full list of suggested monetary and non-monetary benefits under the Nagoya Protocol.

On a more broad level, Article 21 stresses the importance of awareness raising projects to be done. These include the establishment of local or indigenous committees (21.b), dissemination of information through a national clearing-house (21.d), and the education and training of users, providers, and relevant stakeholders during the negotiation and implementation process (21.g). In Madagascar, the National Educational Policy Related to the Environment enforces this through close collaboration between the Ministry of Education and Scientific Research and the Ministry in charge of Environment and Forests (Madagascar – Country Profile).

With regards to compliance and enforcement mechanisms of ABS laws and benefit-sharing arrangements, the Protocol’s system is highly complex, with implications that will be discussed later. The three cornerstones are

1. Article 15 (compliance with domestic legislation or regulatory requirements on ABS);
2. Article 18 (compliance with MAT); and
3. Article 17 (monitoring the utilisation of genetic resources).
The system is based on “a mix of international and domestic measures, including: basic obligations on users to respect national access laws, supportive monitoring measures, including through designated ‘checkpoints,’ the issuing of internationally recognised certificates of compliance as evidence of legal acquisition in provider countries, and the future establishment of an international mechanism to address the compliance of Parties with their Protocol obligations in a cooperative and non-adversarial manner (Duriasamy, A., 2011).

Trans-sectorial and International Legal Implications of the Nagoya Protocol

The Nagoya Protocol deals with resources that span across several different ecosystems. Furthermore, companies, organisations, and individuals use the resources to achieve a wide range of goals. The Nagoya protocol is now on par with internationally legally binding documents from various other organisations including the World Health Organisation (WHO), the World Trade Organisation (WTO), and the Food and Agriculture Organisation (FAO). It is important to note how the Nagoya Protocol fits into, and challenges, existing cross-sectorial legal frameworks (McGraw, D., 2002).

With regards to environmental protection, the Nagoya Protocol has the potential to reshape how we approach conservation and protection. The Protocol strikes a balance between the economic and non-economic values of biodiversity. As Beck et al. notes, articles 9 and 10 of the Protocol “tightly [link] access and benefit sharing with the first and second objectives of the CBD – conservation and sustainable use.” Even the benefits outlined in the appendix are geared towards rewarding those who successfully conserve biodiversity. Several of the concepts regarding the crossroads of development and the environment are reflected in the UN Sustainable Development Goals, which replaced the Millennium Development Goals in 2015.

The Nagoya Protocol adds another dimension to how parties approach international human rights law. A heavy historical influence of colonialism has resulted in the marginalisation of indigenous people. Despite the presence of international human rights law aimed towards preventing such marginalisation, the
treatment of indigenous people falls under the jurisdiction of regional and national law. So, the societal marginalisation many indigenous people face is more often than not reflected in discriminatory legal practices (Savaresi, A., 2013).

The Nagoya Protocols’ ABS provisions are ground breaking in that it is the first time “that such obligations are triggered by the use of traditional knowledge for research and development purposes in an international legally binding instrument. (Tsioumani, E., 2015)” Traditional knowledge, and by extension the possessors of that knowledge, is protected under international law.

Furthermore, the Nagoya Protocol aims towards legal empowerment of Indigenous and Local Communities (ILCs) through the creation of a compliance committee. The committee is consists of 15 regional representatives. “In addition, two ILC representatives nominated directly by ILCs, and with at least one from a developing country, shall serve as observers and participate in the deliberations of the committee, albeit not in decision-making. (Tsioumani, E., 2015)” Despite falling short of awarding ILCs full voting rights, their presence in the committee is an indispensable legal outlet for them to voice concerns and share opinions regarding cases that directly affect them (Savaresi, A., 2013).

Further implications for human rights identified by Savaresi include issues of information accessibility (which is enhanced with the ABS Clearing-House), and the participatory decision making process and justice accessibility of the compliance committee (Savaresi, A., 2013).

During negotiations, developed countries and the WHO were highly concerned about their ability to access pathogens in the case of emergencies or
pandemics. They worried that stricter legislation would make their ability to respond and create vaccines in a timely manner would be hindered. Developing countries worried that emergencies would be used as a pretext for expedited access, and they would not receive adequate benefits – particularly affordable vaccine access. Negotiations on these issues brought up in Nagoya played a large role in the creation of the 2011 WHO Pandemic Influenza Preparedness Framework for the Sharing of Influenza Viruses and Access to Vaccines and other Benefits (Glowka, L., 2013).

Finally, the CBD and Nagoya Protocol had several implications for the World Trade Organisation, World Intellectual Property Organisation, and Trade Related Aspects of Intellectual Property Rights (TRIPS) agreement. TRIPS, ratified in 1995, set a minimum global standard for the protection and enforcement of intellectual property rights and patents. It makes no reference to traditional knowledge because unlike the CBD, it does not consider customary ownership a form of intellectual property because, “without patent protection, ownership does not exist.” Furthermore, TRIPS requires each country to set their own patent systems. These systems are unenforceable outside their patent domain – a sui generis system (WTO Report, 2006).

As of now, there are still unresolved issues. For example, a coalition of governments charged that pharmaceutical companies must state where they source their genetic material in order to receive a patent. This amendment has not been made, especially because several members of TRIPS feel that increased regulatory measures in TRIPS will result in a decreased autonomy for countries to implement
their own standards. As such, it has been difficult to reconcile conflict areas between the CBD and TRIPS (WTO Report, 2006).

**Implementation: Process and Challenges**

While it is one thing to ratify a treaty and agree upon its principles, it is another thing entirely to put those principles into practice. As Tsioumani puts it;

“Implementation is thus expected to entail a dynamic web of legal relationships: administrative decisions on access are set out in domestic permits, linking to contractual benefit-sharing agreements between private parties and backed by the establishment of benefit-sharing arrangements to be supported by an enabling framework of national laws in provider and user countries.”

Interviews with Liva Ramiandrarivo and Naritiana Rakotoniaina, the National Focal Points for Madagascar, outlined some of the foreseeable implementation challenges. These include financing, capacity building, political/governmental blocks, and institutional arrangements.

One of the major problems Madagascar faces stems from a lack of – and limited access to – funding. The 2009 political crisis resulted in the withdrawal of several investors, who worried that the unstable political climate made the risk of investment too high. Though Madagascar’s government has stabilised, it has never regained its investor base (Ramiandrarivo Interview, 17/11/2015).

Now, Madagascar has drafted its National Biodiversity Strategy Action Plan (NBSAP), yet without a source of funding, it is difficult to implement. Ramiandrarivo’s work with the ministry has seen similar issues. He and his team have established 123 new protected areas in Madagascar. While the government is willing to provide funding for the Ministry of Forestry, they are incapable due to
budgetary constraints to provide funds for the management of those areas. Now, Madagascar is in the process of preparing its proposal to submit at the buyer conference in 2016 (Ramiandrarivo Interview, 17/11/2015).

The lack of funding has resulted in challenges in capacity building. One example is the Ministry of Forestry’s inability to determine the economic value of biodiversity in Madagascar. As Ramiandrarivo pointed out, “it is important for us to know the economic value of our biodiversity because it enables us to better defend our position in negotiations against those who wish to degrade it. (Ramiandrarivo Interview, 17/11/2015)”

In recent negotiations between the Ministry of Forestry and the mining sector, and with petitions going to the government for sub-marine petrol exploration, the ministry found it difficult to defend their position and advance their cause. Both the mining and petrol sectors had monetary gains they could point to as beneficial to the Malagasy economy. But without knowing the economic value of biodiversity in Madagascar, conservation and aims to push implementation of the CBD remained far too abstract for concrete action (Ramiandrarivo Interview, 17/11/2015).

Naritiana Rakotoniaina faced similar challenges with the Malagasy government in trying to implement the Nagoya Protocol. In 2011, SAGE submitted a political letter outlining the national approach to implementation, yet due to political instability, it was a low priority. Furthermore, it would have taken over two years to elaborate the legal framework and create an official ABS law by the time the law made it through the bureaucratic steps. So, efforts are now being focused on
transitory measures based on existing research authorisation processes (Rakotoniaina Interview, 24/11/15). The Ministry responsible for the environment is also working with the GIZ-led multi-donor ABS Capacity Development Initiative to further their goals (Robinson, D., 2014).

Furthermore, internal discussions regarding the institutional arrangement necessary for the implementation of an ABS law have been fraught. Bioprospecting’s nature as a cross-sectorial issue requires the coordination of various government offices, ranging from the ministry of fisheries, to agriculture, to marine. Madagascar has yet to nominate a competent national authority because the question remains who or what ministry will host the authority (Rakotoniaina Interview, 24/11/15).

Should there be the creation of a new bureau designated specifically for issues regarding access, benefit sharing, and research rights? Or should it be a committee comprised of representatives from affected ministries? Both set ups have their pros and cons that need to be examined. The creation of an entirely new bureau comes with issues of its potential functionality and fairness dealing with a very sensitive topic. Furthermore, the creation of a new bureau would require funds the Malagasy government does not have the ability to provide. Yet the creation of a committee raises issues of its ability to make timely decisions, as existing ministries are hesitant to give up their autonomy in general resource management. Either way, the absence of a strong central government makes both options difficult to manage (Rakotoniaina Interview, 24/11/15).

Finally, since Madagascar already has several bioprospecting ventures under way, existing projects must be taken into account. It is not possible to retroactively
apply laws, and so the draft legislation must attempt to tackle value chain
management in order to effectively ensure benefit sharing without retroactive
application of new legislation (Rakotoniaina Interview, 24/11/15).

**NON-GOVERNMENTAL CONTRACTUAL AGREEMENTS**

Due to the absence of a national framework, trends among corporations seeking
to utilise domestic resources in Madagascar often depend on contractual
agreements. One such example of this, and widely considered a success story, is that
of the International Cooperative Biodiversity Groups (ICBG) Madagascar.

**International Cooperative Biodiversity Groups - Madagascar**

The ICBG is a consortium of American government research institutions,
pharmaceutical companies, and international conservation organisations founded in
1992. It was founded to “integrate improvement of human health through drug
discovery, creation of incentives for conservation of biodiversity, and promotion of
scientific research and sustainable economic activity that focuses on environment,
health, equity, and democracy. (Rosenthal, 1998)”

The ICBG was conceived as a way to combine the diverse interests of various
parties under the shared mission of environmental conservation. The belief was that
the promotion of scientific capacity building and economic incentives would lead to
a market based conservation mechanism designed to protect the biological
resources from which commercial products are derived (ICBG).

Yet despite its commercial motivations, and the fact that the U.S. never
ratified the CBD or Nagoya protocol, the ICBG’s mission ensures that it closely
adopts the access and benefit sharing provisions of both the CBD and Nagoya protocol. As Mr Michel Ratsimbason, Director of the Centre National d’Application des Recherches Pharmaceutiques, states, “even though the U.S. never ratified the CBD, it is clear that they uphold the spirit of the Nagoya protocol.” (Ratsimbason Interview, 11/11/15)

Dr David Kingston, of Virginia Polytechnic Institute, heads ICBG’s Madagascar chapter. The chapter was founded in 1998 and went through three successive five-year funding cycles, from 1998 – 2003, 2003 – 2008, and 2008 – 2013. Funding comes from the U.S. National Institute of Health (NIH), National Science Foundation, and U.S. Department of Agriculture (USDOA) (Rosenthal, J. 1998). These three institutions are partnered with the following members of the Madagascar consortium:

- Virginia Polytechnic Institute and State University in Blacksburg, Virginia – The university that Dr David Kingston is based, and the site most research on extracts and ex situ conservation are done at;
- Centre National d’Application des Recherches Pharmaceutiques (CNARP) – CNARP is a public Malagasy research institution partially funded by the state. Their goal is to reinforce and valorise the traditional medicine system of Madagascar, and does both research and synthesis of pharmaceutical products (Ratsimbason Interview, 11/11/2015);
- Centre National de Recherches sur l’Environnement (CNRE);
- Centre National des Recherches Océanographiques (CNRO);
• Missouri Botanical Gardens (MBG) – MBG is an American Botanical society with a presence in Madagascar. Their objectives are mostly botanical research, species identification, and the establishment of a national plant database, though they have recently gotten more involved with community based conservation efforts (Birkinshaw Interview, 23/11/2015);
• Conservation International (CI);
• Eisai Pharmaceutical Research Institution; and
• Dow Agrosciences (DAS).

Managing to get such diverse organisations to agree and cooperate was no easy feat, and was accomplished through an “all-party Research Agreement.” Since the funding agencies (NIH, USDOA, and NSF) are not parties to the research, “they are prohibited by U.S. Federal law from stipulating specific contractual terms.” (Rosenthal) Rather, they encourage parties to develop agreements that abide by the general framework of principles:

1. Active participation of host country individuals and organisations from the planning stage onward,
2. Multi-disciplinary research on diseases of both local and international significance,
3. Local training and infrastructure development in both drug discovery and biodiversity management,
4. Biodiversity inventory and monitoring, and
5. Equitable intellectual property and benefit-sharing arrangements. (Rosenthal)

The contract, written by a lawyer from Conservation International (Robinson, 51, 2014), is confidential, as most private sector commercial agreements are. The ICBG rejected Madagascar’s offer of support in drafting the contract, opting
instead to use CI’s lawyer (Rakotoniaina Interview, 24/11/15). This is important to note, as it makes the transparency that could potentially be achieved through governmental contracts and the ABS clearing-house mechanism non-existent. The implications of this lack of transparency could result in abuse of contracts, and limited compliance enforcing capabilities.

According to Rakotoniaina, the contract was signed in the U.S., and Madagascar’s government was simply notified it was signed, and they never received a copy of the document (Rakotoniaina Interview, 24/11/15).

Furthermore, the confidential nature of the document makes it difficult for the general public – including directly and indirectly affected indigenous and local community members – to know what lies within their rights, and what parties to the agreement are obligated to do. This makes it difficult to protect against potential human rights abuses.

Nevertheless, discussions with members of the ICBG provide insights as to agreements within the Research Agreement. Agreements cover a range of topics, such as access regarding use and type of genetic resources, intellectual property rights and confidentiality, use of traditional knowledge, prior informed consent, and compensation and royalties.

Access and Use

The types of genetic resources accessible include plants (whose use and documentation is monitored by Michel Ratsimbason at CNARP and MBG), marine life (monitored by CNRO), and microbial extracts (monitored by Rado Rasolomampianina at CNER). Extracts include both biochemical compounds and
DNA. Resources are to be used for scientific and potential commercial purposes. Finally, sectorial use is limited to the agriculture industry for pesticides, herbicides, and crop protections through DAS, and pharmaceutical use through Eisai and previously, Bristol-Myers Squibb (Robinson, D., 2014).

As MBG botanist Chris Birkinshaw emphasised, no live organic matter was removed from Madagascar despite requests and petitions to the Malagasy government (Birkinshaw Interview, 23/11/2015).

No ethnobotanical knowledge was used during the surveying and collection of plants. Whilst in the field with local guides, even if local knowledge regarding plant uses was volunteered, MBG researchers were instructed to not record it. All field journals were made public, verifying that no record was taken of traditional knowledge received (Birkinshaw Interview, 23/11/2015).

Prior informed consent (PIC) was “given at the national level by the Government through the Ministry in charge of Scientific research (who signed the contract), at the regional level by the “Chef de région,” and at the local level by local authorities (mainly mayors) and by the local communities (pers. corr. Christian Camara, 27/11/2015).” With the local communities, representatives of the ICBG project would explain the project and implications to the committee of villagers. They would explain the benefit sharing that would result from consent, and the community members would make a decision (Birkinshaw Interview, 23/11/2015).

Though “there was no real legal obligation in Madagascar for the project to [obtain PIC], the consortium agreed from the start that ICBG would comply with
international standards. The CBD was used as reference (pers. corr. Camara, 27/11/2015).”

Yet as Chris Birkinshaw noted, throughout the process it was unclear whether or not villagers entirely understood the implications of the ICBG program, or whether they simply agreed in order to receive the benefits. As he put it, “telling a group of villagers that they would receive thousands of dollars to build schools, bridges, and wells in exchange for a tea spoon of soil from their forest seems preposterous.” (Birkinshaw Interview, 23/11/2015)

This dilemma outlines the importance of Article 21 of the Nagoya Protocol. Article 21 seeks to raise awareness about ABS and the Nagoya Protocol, with the hope that with this knowledge communities will be better informed to make educated decisions regarding their resources.

Though authorities and community members granted consent, it was granted in the absence of participation from a competent national authority accountable to the Nagoya Protocol standards. Thus, it is impossible to determine whether the consent granted complied with protocol that determines what constitutes prior informed consent, even if it fully complies with the terms outlined in the all party Research Agreement.

Although “PIC was given every time the project intervention site was changed, (pers. corr. Camara, 27/11/2015)” changing environmental, economic, and social landscapes have the potential to make the context consent was given irrelevant – yet another slippery slope.
Subsequent to obtaining PIC, access was granted and use was limited to members of the ICBG consortium. Restrictions were placed on third party transfers in order to maximise potential benefit to consortium members Dow and Eisai. What remains unclear, however, is “if third party transfers might occurs at a later date in the future, and what terms the contract has relating to this. (Robinson, D. 49, 2014)”

For Naritiana Rakotoniaina, the ambiguity surrounding third party use provides a problem for the Malagasy governments’ enforcement of the Nagoya Protocol. Now that the project has concluded, there is no way for the Malagasy government to monitor samples that have been sent out of the country for ex-situ conservation or research (Rakotoniaina Interview, 24/11/2015).

The ICBG counters that working through CNARP checks this threat. CNARP would collect, identify, and dry out the plants, and send them to U.S. research institutions with a code system. The code system prevented the U.S. researchers from knowing exactly what species the plant was and where it was obtained. Without this information, access to biomass becomes much more difficult (Birkinshaw Interview, 23/11/2015).

**Benefit Sharing**

Perhaps the most obvious and immediate benefit received from the ICBG came from the Compensation Fund. The fund was paid for by Eisai and Dow, and was a way to provide compensation for the collection and use of genetic resources regardless of what came out of the research. This is especially important, since the development process often takes 5 – 15 years (Birkinshaw Interview, 23/11/2015).
50% of the fund went directly to local communities, and manifested itself in development and conservation projects. Schools, bridges, wells, and the like were built. Conservation projects included community forests and agricultural ventures. In the first phase of the project, Zahamena was the only community working with the ICBG and had access to all 50% of the compensation fund. Yet as the project grew and worked with more communities, the fund was divided among communities they worked with (Birkinshaw Interview, 23/11/2015).

The other 50% of the compensation fund was directed to the national government and Malagasy research institutions working with ICBG (CNARP, CNRE, and CNRO). For Mr Ratsimbason and his team at CNARP, the compensation fund was an invaluable tool in setting up CNARP’s malaria lab. Malaria runs rampant among the Malagasy population, and CNARP has managed to dedicate significant amounts of time and energy to researching malaria. This would not have been possible without the assistance of equipment purchased through the compensation fund. Mr Ratsimbason believes that without the ICBG, combatting malaria would not be at the level it is today in Madagascar. Furthermore, the ICBG paid for several of CNARP’s researchers to be sent for training at Virginia Polytechnic Institute, with all expenses paid (Ratsimbason Interview, 11/11/2015).

Another example of the benefits the compensation fund has provided Madagascar is with CNRE. CNRE was able to obtain very expensive soil analysis equipment through the compensation fund, and possession of that equipment has since enabled them to win a lucrative contract with a mining company (Birkinshaw Interview, 23/11/2015).
Yet officials in the Malagasy government are unhappy with the compensation fund, believing it to be insufficient in comparison to the potential profits and scale of use of resources. Had a national framework been in place, negotiations to set a number the Malagasy government agreed with would have been much more productive (Rakotoniaina Interview, 24/11/2015).

Apart from the initial compensation fund, the ICBG set up milestone payments (to be paid at key development intervals), and royalties (percentage shares of profits received once a drug is developed and reaches the market) (Birkinshaw Interview, 23/11/2015).

As of now, no drugs have been developed, so milestone and royalty payments are inactive. This is verified by MBG, who says that they would know if a plant contained compounds of interest because the orders of biomass would go significantly up to supply the increase in research activity, and MBG and CNARP would notice (Birkinshaw Interview, 23/11/2015).

Another check to ensure Madagascar is not being cheated is also a part of the non-monetary benefits scheme – information sharing. Each year, Dr David Kingston is required to publish the findings and research of the ICBG’s efforts. This serves two purposes; firstly, publication renders the information public and thus not patentable, since the information is no longer new or novel. This in turn protects Madagascar against biopiracy cases, and is further protected with the coding system discussed previously (Birkinshaw Interview, 23/11/2015).

Secondly, the information sharing system provides Madagascar the option to pursue research of interest in Madagascar even though it may not be in the U.S.
Access to and permission to use that information saves considerable time and effort on Madagascar’s end (Birkinshaw Interview, 23/11/2015).

While not without its flaws, the general consensus has been that ICBG Madagascar has been one of the more successful ICBG projects in the world. It is important to take into account the potential success of non-governmental contractual agreements when developing a national framework for implementation of the Nagoya protocol, in order to ensure flexibility among partnerships, and that international standards are upheld.

**CONCLUSION**

As Madagascar continues its laudable work at developing ABS frameworks, there remain several factors to be taken into account. The first factor is the several legal grey areas that exist. For example, are genetic resources found on private property government property? Who is responsible for the ultimate authorisation – landowner or government?

Secondly, Madagascar must continue to look forward in light of the recent Sustainable Development Goals and the 2020 Aichi Biodiversity Targets and attempt to work ABS provisions in with the broader goal of environmental conservation.

Work must continue to tackle the hurdles blocking a successful implementation of Nagoya. Suggested research should include continued surveys of implementation stages, research on the feasibility of various institutional arrangements, methods for capacity building, and enhancing cross-sectorial communication and coordination. The Nagoya Protocol has the potential to be
incredibly beneficial for all parties involved. Yet for it to work, Madagascar must do all it can to promote its effective implementation in the coming years.

APPENDIX

APPENDIX A: Suggested Elements for Material Transfer Agreements

Material transfer agreements may contain wording on the following elements:

A. Introductory provisions
   1. Preambular reference to the Convention on Biological Diversity
   2. Legal status of the provider and user of genetic resources
   3. Mandate and/or general objectives of provider and, where appropriate, user of genetic resources

B. Access and benefit-sharing provisions
   1. Description of genetic resources covered by the material transfer agreements, including accompanying information
   2. Permitted uses, bearing in mind the potential uses, of the genetic resources, their products or derivatives under the material transfer agreement (e.g. research, breeding, commercialization)
   3. Statement that any change of use would require new prior informed consent and material transfer agreement
   4. Whether intellectual property rights may be sought and if so under what conditions
   5. Terms of benefit-sharing arrangements, including commitment to share monetary and non-monetary benefits
   6. No warranties guaranteed by provider on identity and/or quality of the provided material
   7. Whether the genetic resources and/or accompanying information may be transferred to third parties and if so conditions that should apply
   8. Definitions
   9. Duty to minimize environmental impacts of collecting activities

C. Legal provisions
   1. Obligation to comply with the material transfer agreement
   2. Duration of agreement
   3. Notice to terminate the agreement
   4. Fact that the obligations in certain clauses survive the termination of the agreement
   5. Independent enforceability of individual clauses in the agreement
   6. Events limiting the liability of either party (such as act of God, fire, flood, etc.)
   7. Dispute settlement arrangements
   8. Assignment or transfer of rights
   9. Assignment, transfer or exclusion of the right to claim any property rights, including intellectual property rights, over the genetic resources received through the material transfer agreement
   10. Choice of law
   11. Confidentiality clause
   12. Guarantee
APPENDIX B: Monetary and Non-Monetary Benefits

1. Monetary benefits may include, but not be limited to:
   a. Access fees/fee per sample collected or otherwise acquired;
   b. Up-front payments;
   c. Milestone payments;
   d. Payment of royalties;
   e. License fees in case of commercialization;
   f. Special fees to be paid to trust funds supporting conservation and sustainable use of biodiversity;
   g. Salaries and preferential terms where mutually agreed;
   h. Research funding;
   i. Joint ventures;
   j. Joint ownership of relevant intellectual property rights.

2. Non-monetary benefits may include, but not be limited to:
   a. Sharing of research and development results;
   b. Collaboration, cooperation and contribution in scientific research and development programmes, particularly biotechnological research activities, where possible in the provider country;
   c. Participation in product development;
   d. Cooperation and contribution in education and training;
   e. Admission to ex situ facilities of genetic resources and to databases;
   f. Transfer to the provider of the genetic resources of knowledge and technology under fair and most favourable terms, including on concessional and preferential terms where agreed, in particular, knowledge and technology that make use of genetic resources, including biotechnology, or that are relevant to the conservation and sustainable utilization of biological diversity;
   g. Strengthening capacities for technology transfer to user developing country Parties and to Parties that are countries with economies in transition and technology development in the country of origin that provides genetic resources. Also to facilitate abilities of indigenous and local communities to conserve and sustainably use their genetic resources;
   h. Institutional capacity-building;
   i. Human and material resources to strengthen the capacities for the administration and enforcement of access regulations.
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ISP REVIEW SHEET

1. Your topic - suitability, development, accessibility

*My topic was very interesting, and accessible. However with the limited time period it was hard to set up as many interviews as I’d have liked. It involved a lot of waiting for people to reply to me. Taxiing around the city was efficient but expensive.*

2. Location of field study - where you conducted your field study, who helped set it up (who was helpful and who was not; include names, addresses, and phone numbers if possible), strengths and weaknesses of the site

*I conducted my study in Antananarivo, mostly in the offices of people I was interviewing. Joel, the pharmacology student assisting me was very useful in helping me get around. My advisor, Voahangy, provided a wonderful starting point for people I could interview.*

3. Nuts and bolts - where to get water & food, costs, where to stay, medical resources, other problems

*I stayed with Patricia’s parents in Ivandry. Very useful, they provided me with delicious food and beverages.*

4. Other noteworthy comments

List your secondary sources and contacts, where they were found, and which were most helpful here:-