A Critical Analysis of the Protection that South Africa's

Bioprospecting Legislation affords Indigenous Communities,

in the context of the country's International Obligations and

with particular regard to Implementation Challenges

By

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Declaration

I, Renelle Lindy Moodley, hereby declare that this that all sources have been accurately reported and a not previously in its entirety or in part been submit academic qualification.	acknowledged, and that this document has
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My greatest thanks to God, for His wisdom, knowledge and unfailing love.

Dedication

To my beautiful daughters, Tiara and Tayley.

May you be inspired to reach for your dreams and always aspire to be the very best you can be.

Abstract

Indigenous communities have developed a wealth of knowledge, which plays a crucial role in providing leads for the use of genetic resources and bioprospecting. However, such knowledge is under increasing threat due to the misappropriation of the biological resources and associated traditional knowledge of indigenous communities, through both bioprospecting, as well as the inappropriate exercise of intellectual property rights.

The internationally agreed Convention on Biological Diversity (CBD) attempts to provide a bulwark against biopiracy and although it assists indigenous communities to regain some control, the CBD has proven inadequate in the protection of the traditional knowledge of indigenous communities. The subsequent Nagoya Protocol on Access to Genetic Resources and the Fair and Equitable Sharing of Benefits Arising from their Utilization to the Convention on Biological Diversity (Nagoya Protocol) attempts to address some of these limitations but unfortunately has its own shortcomings, as it was largely concluded on the basis of a compromise between developed and developing countries.

This dissertation will undertake a critical analysis of the provisions of the CBD and Nagoya Protocol, with a view to establishing the level of protection these instruments afford indigenous communities. It will be shown that notwithstanding the drawbacks of both the CBD and Nagoya Protocol, they nevertheless represent major achievements in the journey to protect the genetic resources and associated traditional knowledge of indigenous communities

It is in this context that this dissertation will analyse South Africa's Access and Benefit Sharing (ABS) regime in relation to the protection it affords indigenous communities and in the light of the implementation challenges that such legislation presents. A particular focus will be on whether South Africa's ABS legislation complies with the country's international obligations relating to the protection of indigenous communities and whether South Africa's approach to the protection of the genetic resources and associated traditional knowledge of indigenous communities, in the context of bioprospecting, is adequate or whether there exists potential for its enhancement.

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LIST OF ACRONYMS

ABS Access and Benefit Sharing

ASEAN Association of South East Asian Nations

BABS South Africa's Regulations on Bioprospecting, Access and Benefit Sharing

BCP Biocultural Community Protocol

BSA Benefit Sharing Agreement

CBD Convention on Biological Diversity

COP Conference of the Parties

COP/MOP Conference of the Parties Serving as the Meeting of the Parties

DEA Department of Environmental Affairs

EU European Union

GRULAC Group of Latin American and Caribbean Countries

IBR Indigenous Biological Resources

LMMC Like-Minded Megadiverse Countries

MTA Material Transfer Agreement

NEMBA National Environmental Management: Biodiversity Act

PAIA Promotion of Access to Information Act

PAJA Promotion of Administrative Justice Act

PIC Prior Informed Consent

TK Traditional Knowledge

UNEP United Nations Environment Programme

Chapter One: Introduction

1.1 The Importance of Traditional Knowledge

Indigenous communities¹ throughout the world have developed economic, social and cultural systems that are supported by the sustainable use of natural resources.² Most indigenous communities depend on their continued relationships with local ecosystems for their physical and cultural survival, and as a result, they have gained exceptional insights on how best to preserve and sustainably use the world's biological diversity.³ Over centuries of close dependence on these resources, indigenous communities have developed intimate knowledge of the use and functioning of biological and natural resources.

Traditional uses, production and innovations provide a wealth of resources and knowledge not only for indigenous communities, but for the food, agriculture and health needs of the world as a whole.⁴ In this regard, the World Health Organization estimates that 80 percent of the world's population depends on traditional medicine for primary health care.⁵ In addition, the knowledge of indigenous communities is vital for sustainable development, as the multiplicity of interrelated

¹ The legal meaning of the word 'indigenous' is open to various interpretations. The widely accepted definition of what constitutes 'indigenousness' is one that was proposed by Erica-Irene Daes, then Chairperson-Rapporteur of the United Nations Working Group on Indigenous Peoples. It highlights the following elements:

i) A priority in time;

ii) The voluntary perpetuation of cultural distinctiveness;

iii) An experience of subjugation, marginalization and dispossession; and

iv) Self-identification.

The term 'indigenous' therefore only has meaning in relation to another dominant group and the word is also used to mean 'local'. Chennells, R, 'Ethics and Practice in Ethnobiology: The Experience of the San Peoples of Southern Africa' in McManis, R (Ed) *Biodiversity and the Law*, Earthscan, London, 2007, 413 at 414-415.

Although the Convention on Biological Diversity and The Nagoya Protocol on Access to Genetic Resources and the Fair and Equitable Sharing of Benefits Arising from their Utilization to the Convention on Biological Diversity make use of the term 'indigenous and local communities', South Africa's legislation on access and benefit-sharing relating to genetic resources (ABS) makes use of the term 'indigenous communities' only. In this dissertation, the term 'indigenous communities' is used with reference to both international, as well as national law.

² Amiott, J, 'Investigating the Convention on Biological Diversity's Protections for Traditional Knowledge' in 11 *Mo. Envtl. L.& Pol'y* Rev.3, 2003,1 at 2. Available at http://wp.cedha.net/wp-content/uploads/2011/05/investigating-the-convention-on-biological-diversitys-protection.pdf. Accessed on 15 September 2012.

⁴ Swiderska, K, 'Banishing the Biopirates: A New Approach to Protecting Traditional Knowledge' in *Gatekeeper Series 129*, International Institute for Environment and Development, 2006, 1 at 3. Available at http://pubs.iied-org/pdfs/14537IIED.pdf. Accessed on 15 September 2012.
⁵ *Ibid*.

knowledge, innovations and practices provide potential uses of biological resources, which, in turn, can result in tremendous economic potential.⁶

Traditional knowledge⁷ plays a crucial role in providing leads for the use of genetic resources⁸ and bioprospecting,⁹ as the originators and custodians of such knowledge are the indigenous communities, who, through years of consistent usage, trial and error and keen observation, have developed a wealth of a knowledge base.¹⁰ Much of this knowledge involves innovations and practices relating to animals, plants, insects, or ecosystems, which can provide interesting leads, as well as the initial screening for isolating particular properties of genetic resources found in nature.¹¹ Consequently, traditional knowledge has guided a number of companies in the development of new products and has formed a crucial foundation for research and development, particularly in the areas of botanical medicines, pharmaceutical and cosmetic products. Despite the importance of traditional knowledge, such knowledge is rapidly disappearing and is under increasing threat from both intellectual property regimes and economic globalization processes, which, in turn, undermines the livelihoods of indigenous communities.

1.2 Biopiracy¹²

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⁶ Jonas, H, Bavikatte, K, & Shrumm, H, 'Community Protocols and Access and Benefit Sharing' in *Asian Biotechnology and Development Review*, Vol. 12, No.3, 2010, 49 at 50.

⁷ Traditional Knowledge has been defined as the knowledge, innovations and practices of indigenous and local communities, which have been developed from experience gained over the centuries and adapted to the local culture and environment and which is transmitted orally from generation to generation and tends to be collectively owned. CBD Website: About Article 8(j), CBD: Traditional Knowledge and the CBD. Available at http://www.cbd.int/traditional/intro.shtml. Accessed on 6th February 2013.

⁸ Genetic resources are defined as genetic material of plant, animal, microbial or other origin containing functioning units of heredity, of actual or potential value. Article 2, Convention on Biological Diversity, 1992. Available at http://www.cbd.int/convention/text/.

⁹ Bioprospecting has been defined as the exploration of biological material for commercially valuable genetic and biochemical properties. Wynberg, R & Laird, S, 'Bioprospecting, Access and Benefit Sharing: Revisiting the 'Grand Bargain' in Wynberg, R et al (Eds.), Indigenous Peoples, Consent and Benefit Sharing: Lessons from the San Hoodia Case, Springer Science + Business Media B.V. 2009, 69 at 70.

¹⁰ Jospeh, RK, 'International Regime on Access and Benefit-sharing: Where are we now?' in *Asian Biotechnology and Development Review*, Vol. 12 No.3, 2010, 77 at 79.

¹¹ Greiber, T, Moreno, SP, Âhrén, M, Carrasco, J N, Kamau, EC, Medaglia, JC, Oliva, MJ and Perron-Welch, F in cooperation with Ali, N and Williams, C, 'An Explanatory Guide to the Nagoya Protocol on Access and Benefitsharing' in *IUCN Environmental Policy and Law Paper*, No. 83, 2012, 1 at 10. Available at https://cmsdata.iucn.org/downloads/an explanatory guide to the nagoya protocol.pdf. Accessed on 12th October 2013

¹² 'Biopiracy' is a term used to describe the misappropriation and/or misuse of genetic resources and/or associated traditional knowledge. Dutfield, G, 'Protecting the Rights of Indigenous Peoples: Can Prior Informed Consent Help?' in Wynberg, R et al (Eds.), *Indigenous Peoples, Consent and Benefit Sharing: Lessons from the San Hoodia Case*, Springer Science + Business Media B.V. 2009, 55 at 56.

In the last several decades, indigenous communities have had to contend with the misappropriation of their biological resources and associated traditional knowledge through bioprospecting and the inappropriate exercise of intellectual property rights. ¹³ In the well-known *Neem* case, the United States Patent and Trade Mark Office (USPTO), as well as the European Patent Office (EPO) granted patents to a United States company, W R Grace, in respect of products that were made from pirated extracts of the *Neem* tree, that has been bred through a traditional Indian plant breeding system and whose chemical properties have long been recognised by Indians. ¹⁴ It was on this basis that India successfully petitioned the USPTO and EPO in order to secure nullification of the patents. ¹⁵ Similarly in the *Tumeric* case, India successfully secured nullification of a patent granted in the United States by USPTO to two Indian nationals, in respect of the use of the turmeric plant for the healing of wounds. ¹⁶ This was possible as the patent granted was based on pirated traditional knowledge, which was already well known in Indian traditional medicine. ¹⁷

The internationally agreed Convention on Biological Diversity (CBD)¹⁸ attempts to provide a bulwark against biopiracy and assists indigenous communities to regain some control. The CBD is, however, not without its limitations and the subsequent Nagoya Protocol on Access to Genetic Resources and the Fair and Equitable Sharing of Benefits Arising from their Utilization to the Convention on Biological Diversity (Nagoya Protocol)¹⁹ attempts to address some of these limitations. The Nagoya Protocol has its own shortcomings, as it was largely concluded on the basis of compromise between user²⁰ and provider²¹ countries.²² The CBD and the Nagoya Protocol nevertheless remain a critical means of safeguarding genetic resources as well as the traditional knowledge of indigenous communities against biopiracy.

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¹³ Zainol, ZA, Amin, L, Akpoviriand F, Ramli R, 'Biopiracy and State's Sovereignty over their biological resources' in *African Journal of Biotechnology* Vol. 10(58), 2011, 12395 at 12395.

¹⁴ *Ibid* at 12404. US Patent No. 5,124,349 and European Patent No. 436257.

¹⁵ *Ibid*.

¹⁶ *Ibid*. US Patent No. 5,401,504.

¹⁷ Ihid

¹⁸ Convention on Biological Diversity, 1992. Available at http://www.cbd.int/convention/text/.

¹⁹ The Nagoya Protocol on Access to Genetic Resources and the Fair and Equitable Sharing of Benefits Arising from their Utilization to the Convention on Biological Diversity, 2010. Available at http://www.cbd.int/abs/text/.

²⁰ Parties to the CBD which provide genetic resources (predominantly countries with high levels of biodiversity).

²¹ Parties to the CBD in whose jurisdictions are located commercial users of genetic resources.

²² Zainol, ZA *et al* (n. 13) at 12407.

1.3 **Objectives of Dissertation**

This dissertation will undertake a critical analysis of the provisions of the CBD and Nagoya Protocol, with a view to establishing the level of protection these instruments afford indigenous communities. This dissertation will show that notwithstanding the drawbacks of both the CBD and Nagova Protocol, they both represent major achievements in the journey to protect the genetic resources and associated traditional knowledge of indigenous communities. However, traditional knowledge nevertheless remains under increasing threat, particularly from the misappropriation by bioprospectors, who tend to undermine traditional livelihoods based on natural resource management.²³

This is especially so for South Africa, which is considered one of the most mega-diverse countries in the world.²⁴ South Africa boasts an exceptionally rich biodiversity and is home to a treasure of largely undiscovered genetically valuable resources. South Africa further hosts a multitude of cultural systems of knowledge, with varying geographical regions, languages and ethnic groups. Having regard to its eleven official languages and numerous cultural traditions and indigenous communities, there is no doubt that South Africa is regarded as one of the world's most culturally diverse countries.²⁵ South Africa is also one of the strongest economies and driving economic forces in the African continent. ²⁶ Hence, with an emphasis on economic interests and development, the country's biodiversity provides a strong means of economic growth. However, the lack of legislation to govern access and benefit-sharing regarding genetic resources (ABS) has historically led to unrestricted access to South Africa's bioresources, which

²³ Swiderska, K (n. 4) at 4.

²⁴ Megadiverse countries are a group of Countries that contain the majority of the Earth's species and are considered extremely biologically diverse. This group of countries represents less than ten percent of the global surface but supports more than 70 percent of the biological diversity of the Earth. See Cancun Declaration of Like-Minded Megadiversity Countries. Available at http://www.cbd.int/doc/meetings/cop/cop-06/information/cop-06-inf-33- en.pdf. The Like-minded Megadiverse Countries comprise 17 developing countries, including South Africa: Bolivia, Brazil, China, Colombia, Costa Rica, Democratic Republic of Congo, Ecuador, India, Indonesia, Kenya, Madagascar, Malaysia, Mexico, Peru, Philippines, Venezuela and South Africa. The Group was formally constituted through the Cancun Declaration of 18 February 2002 as a 'consultation and co-operation mechanism' to promote common interests and priorities relating to the conservation and sustainable use of biodiversity. See www.megadiverse.org and http://www.cbd.int/doc/meetings/cop/cop-06/information/cop-06-inf-33-en.pdf. Accessed on 7th November 2013.

²⁵ Rutert, B, Dilger, H, Matsabisa, GM, 'Bioprospecting in South Africa: Opportunities and Challenges in the Global Knowledge Economy-a Field in the Becoming,' in CAS Working Paper Vol.1. 1 at 7. Available at http://edocs.fuberlin.de/docs/servlets/MCRFileNodeServlet/FUDOCS derivate 000000001753/cas wp no 1 11.pd <u>f?hosts</u>. Accessed on 17/06/13. ²⁶ *Ibid* at 6.

in turn has resulted in bioresources being reaped in destructively excessive quantities and exported for research, development and commercial gain, with no benefit to the traditional knowledge-holding indigenous communities.²⁷

Against this backdrop, this dissertation will analyse the steps taken by South Africa to protect the genetic resources and associated traditional knowledge of indigenous communities. In this regard, the strengths and weaknesses of provisions in the National Environmental Management: Biodiversity Act 10 of 2004 ²⁸ and the 2008 Bioprospecting Access and Benefit-sharing Regulations²⁹ which relate to indigenous communities will be assessed. A particular focus will be on whether South Africa's Access and Benefit Sharing (ABS) legislation complies with the country's international obligations relating to the protection of indigenous communities and whether South Africa's approach to the protection of the genetic resources and associated traditional knowledge of indigenous communities, in the context of bioprospecting, is adequate or whether there exists potential for its enhancement. It will be shown that although South Africa's ABS legislation predominantly complies with the country's international obligations, the implementation of such legislation is fraught with complexity and remains enormously challenging.

A critical analysis of the implementation challenges facing both indigenous communities, as well as those wishing to enter into bioprospecting agreements with such communities, in the context of South Africa's ABS legislation, will be undertaken. It will be shown that, ultimately, it is vital for indigenous communities to be empowered in the management and protection of their biological resources and associated traditional knowledge. Current international and national policies, based on dominant paradigms of access and benefit-sharing and intellectual property rights, unfortunately fail to adequately protect the genetic resources and traditional knowledge of indigenous communities, as they reflect western norms and laws. A new approach to the protection of the genetic resources and traditional knowledge of indigenous communities, in the context of bioprospecting, is therefore crucial.

²⁷ Crouch, NR, Douwes, E, Wolfson, MM, Smith, GF & Edwards, TJ, 'South Africa's Bioprospecting, Access and Benefit-sharing legislation: Current Realities Future Complications and a Proposed Alternative' in *South African Journal of Science* 104, 2008, 355 at 355.

²⁸ Act 10 of 2004.

²⁹ GN R 138 in Government Gazette 30739 of 8 February 2008.

There has been significant argument for the recognition of indigenous community rights and control over their natural resources and traditional knowledge.³⁰ The Nagoya Protocol provides formal international recognition of Community Protocols and customary laws, in relation to the traditional knowledge of indigenous communities and in so doing, the Nagoya Protocol is a significant achievement for the protection of traditional knowledge of indigenous communities. This dissertation will argue that the emergence of biocultural rights and, in particular, Biocultural Community Protocols, ³¹ provides South Africa with an effective tool to enable indigenous communities to become mobilized and empowered. It will be shown that Biocultural Community Protocols, being community-led, can assist indigenous communities to proactively address the implementation challenges of South Africa's ABS legislation and to engage with ABS, in accordance with their values and on their own terms.

This dissertation will propose that although South African law makes no provision for Biocultural Community Protocols, such Protocols remain an effective, alternate practical measure and legal tool to improve the current South African situation, with the aim of curbing biopiracy and achieving enhanced protection of the biological resources and associated traditional knowledge of indigenous communities. It will be shown that Community Protocols provide a valuable framework, with which indigenous communities can assess whether the proposed ABS will enhance or encumber their communal aspirations, pertaining to their natural resources, knowledge, innovations and practices. However, as to whether such Protocols will deliver the protection and benefits for which they were designed, this will ultimately depend on the manner in which indigenous communities engage with the framework provided in the Nagoya Protocol, on a local level.³²

1.4 Structure of Dissertation

Chapter Two will address the international response to biopiracy and the protection of the genetic resources and associated traditional knowledge of indigenous communities. This will

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³⁰ Bavikatte, K & Robinson, DF, 'Towards a Peoples History of the Law: Biocultural Jurisprudence and the Nagoya Protocol on Access and the Benefit Sharing' in *Law Environment and Development Journal* Vol. 7(1), 2011, 35 at 40. Available at http://www.lead-journal.org/content/11035.pdf.

³¹ Biocultural Community Protocols constitute Charters of rules and responsibilities, in which indigenous communities set out their customary rights to natural resources, in accordance with customary, national and international law.

³² Jonas, H *et al* (n. 6) at 49.

Protocol, as well as a critical analysis of the provisions of the Nagoya Protocol. Chapter Three will look at South Africa's approach to the protection of the genetic resources and associated traditional knowledge of indigenous communities, in the context of bioprospecting. This will involve a critical analysis of South Africa's ABS legislation, with particular regards to the level of protection these laws afford indigenous communities, with a view to establishing whether such legislation would suffice, once the Nagoya Protocol comes into operation. The protection and this will involve addressing the complexities pertaining to capacity development, vesting of ownership of genetic resources, identifying the stakeholders, obtaining prior informed consent and negotiating benefit-sharing agreements. In addition, the difficulties relating to transboundary genetic resources and traditional knowledge, as well as the hurdles facing NGOs and Civil Society Organizations in the facilitative role that they play in bioprospecting matters affecting indigenous communities will be addressed.

Chapter Five will take an in-depth look at the use of Biocultural Community Protocols as an implementation tool in bioprospecting matters involving indigenous communities and this will entail a discussion on the emergence of biocultural rights of indigenous communities, the recognition of such rights as well as Community Protocols in the Nagoya Protocol and the development of Biocultural Community Protocols, including an analysis of the potential challenges involved in the development of such Protocols. Chapter Six will then conclude this dissertation with the proposal that South Africa's Access and Benefit Sharing legislation be amended to provide for the recognition of Biocultural Community Protocols as an effective tool in addressing the implementation challenges inherent to South Africa's ABS legislation, thereby enhancing the protection of the genetic resources and associated traditional knowledge of indigenous communities in South Africa.

³³ Article 33 of the Nagoya Protocol states that the Nagoya Protocol will come into force on the ninetieth day after it has been ratified by fifty Parties to the CBD. As at 12th November 2013, The Nagoya Protocol has twenty six (26) ratifications. See http://www.cbd.int/abs/nagoya-protocol/signatories/default.shtml. Accessed on 12th November 2013.

Chapter Two: The International Response to Biopiracy and the Protection of the Genetic Resources and Associated Traditional Knowledge of Indigenous Communities

2.1 Introduction

International law has historically permitted free access to genetic resources due to the world view that such resources constituted the common heritage of humankind.³⁴ This view changed due to the increased emphasis on intellectual property rights and private ownership of products of genetic resources.³⁵ This, in turn, paved the way for the introduction of the CBD, a new legal framework which entrenched the sovereign rights of States over their genetic resources. However, notwithstanding the CBD's explicit access and benefit sharing provisions, biopiracy, persisted.

The demand for an international regime on Access and Benefit Sharing emerged as a result of the increasing number of cases of biopiracy which came to light in the late 1990s. In addition, many criticisms were voiced against the Access and Benefit Sharing provisions in the CBD, including criticisms concerning the lack of protection that such provisions afforded indigenous traditional knowledge. 36 Essentially the general feeling among indigenous communities was that the ABS provisions failed to benefit such communities and that after almost two decades subsequent to the CBD coming into force, indigenous communities were still waiting for the protection of their genetic resources and associated traditional knowledge. 37 A well-known example of the misappropriation of the genetic resources and associated traditional knowledge of indigenous communities relates to Eli Lilly's extraction of the rosy periwinkle plant and associated traditional knowledge from Madagascar. ³⁸ The commercialization of the resultant drug generated US \$ 100 million in profits, with no returns to the local indigenous community.³⁹

It was in this context that the biodiversity rich countries demanded an international regime which would allow access to the genetic resources and associated traditional knowledge of indigenous communities, subject to prior informed consent (PIC) and mutually agreed terms (MAT), having

³⁴ Jospeh, RK (no. 10) at 78. ³⁵ *Ibid*.

³⁶ Koutouki, K & von Bieberstein, KR, 'The Nagoya Protocol: Sustainable Access and Benefit-Sharing for Indigenous and Local Communities' in Vermont Journal of Environmental Law, Vol. 13, 2012, 513 at 515. ³⁷ Ibid.

³⁸ Ibid.

³⁹ *Ibid*.

been established.⁴⁰ The result was the Nagoya Protocol, which was adopted at the tenth CBD Conference of the Parties (COP 10) in Nagoya, Japan in October 2010 and which opened for signature on 2 February 2011. According to Article 33 of the Nagoya Protocol, it will come into force ninety days after its fiftieth ratification.

2.2 Chapter Overview

This Chapter will consider the international response to biopiracy and the protection of the genetic resources and associated traditional knowledge of indigenous communities, in the context of bioprospecting. The relevant provisions of the CBD will be analyzed and its limitations reviewed, with particular regards to the protection it affords to indigenous communities. The Bonn Guidelines, which were developed by the Ad-Hoc Open-ended Working Group on ABS in order to provide guidance to users and providers in developing ABS mechanisms and frameworks, will be considered with a view to evaluating their success.

This Chapter will then provide a critical overview of the events that led to the negotiation of the Nagoya Protocol, with particular regards to the role that indigenous communities played during such negotiations. An assessment of the provisions of the Nagoya Protocol will then be undertaken in order to establish the level of protection it affords indigenous communities in the context of their genetic resources and associated traditional knowledge.

2.3 The Convention on Biological Diversity

2.3.1 State Sovereignty

The CBD was essentially adopted as a framework to meet the objectives pertaining to conservation of biological diversity, the sustainable use thereof and the fair and equitable sharing of benefits arising from the utilization of genetic resources. ⁴¹ The CBD entrenches the sovereign right of States over their genetic resources. ⁴² Article 15, which is the main ABS article in the CBD begins by establishing the absolute rights of States over their genetic resources. It states

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⁴⁰ Although there were other reasons for which an international regime was supported, for the purposes of this dissertation, the focus will be on those issues concerning indigenous communities.

⁴¹ Article 1, CBD.

Article 3, CBD. Genetic resources are defined (when read with the definition of 'genetic material') as material of plant, animal, microbial or other origin containing functioning units of heredity, of actual or potential value. Article 2, Convention on Biological Diversity, 1992.

'Recognizing the sovereign rights of States over their natural resources, the authority to determine access to genetic resources rests with the national governments and is subject to national legislation'. Article 15 therefore eliminates any doubts and irrefutably establishes the absolute rights of States over their genetic resources, for the first time in international law.⁴³ Such sovereign rights over genetic resources were previously not recognized in international law.

2.3.2 Access and Benefit Sharing

Under the CBD, access to genetic resources is only possible with the Prior Informed Consent (PIC) of the Contracting Party providing the genetic resources (unless the Party determines otherwise)⁴⁴ and Contracting Parties with jurisdiction over the users of such genetic resources have an obligation to take appropriate measures with the aim of sharing benefits arising from the commercialization of products that are based on the genetic resources. 45 Where access is granted, it needs to occur on the basis of mutually agreed terms (MAT) between the Party providing the genetic resources and the potential user. 46 Accordingly, PIC and MAT are the primary means to authorizing access to genetic resources and establishing the fair and equitable sharing of benefits from their use. Of significance is the fact that Article 15 makes no mention of any rights of indigenous communities over genetic resources and hence the rights of indigenous communities within the CBD were in fact enervated.⁴⁷

Traditional Knowledge associated with Genetic Resources 2.3.3

The CBD does, however, encourage Contracting Parties to provide a means for the protection of traditional knowledge associated with genetic resources. Article 8(j) of the CBD provides that as far as possible and as appropriate, each Party shall

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

⁴³ Bavikatte, K & Robinson, DF (n. 30) at 41.⁴⁴ Article 15.5, CBD.

⁴⁵ Article 15.7, CBD.

⁴⁶ Article 15.4, CBD.

⁴⁷ Bavikatte, K & Robinson, DF (n. 30) at 41.

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

The innocuous and limited nature of Article 8 (j) of the CBD reveals that, from a rights perspective, Article 8(j) is weak. It is an outcome of politically fraught negotiations as is evident from the number of qualifications it contains. Article 8 (j) begins with the words '...shall as far as possible and appropriate, subject to national legislation...' and continues with the words '... with the approval and involvement of the holders of such knowledge, innovations and practices and encourage the equitable sharing of benefits...'. The wording of Article 8(j) is designed to weaken State obligations and the Article makes no provision for the mandatory nature of 'prior informed consent' and 'benefit sharing' in the context of the utilization of traditional knowledge, innovations and practices of indigenous peoples.

Many provider countries welcomed the CBD as the 'panacea against rampant biopiracy' that had persisted long before it. ⁵⁰ However, since the coming into force of the CBD in 1993, user countries have done little to meet their obligations under the CBD and the ABS regimes of provider States therefore remained the lone tool in preventing biopiracy. ⁵¹

2.4 The Bonn Guidelines on Access to Genetic Resources and Fair and Equitable sharing of the Benefits Arising out of their Utilization

2.4.1 The Development of the Bonn Guidelines

The Conference of the Parties to the Convention on Biological Diversity (COP) at its Fifth Ordinary Meeting (COP5)⁵² of 2000 established the Ad Hoc Open-ended Working Group on Access and Benefit-Sharing (WG-ABS) with the mandate to develop guidelines to provide input for Parties when developing and drafting legislative, administrative or policy measures, in accordance with Article 8(j) and to work jointly with the Working Group on Article 8(j) and

⁴⁸ Ibid.

⁴⁹ *Ibid*.

⁵⁰ Kamau, EC, Fedder, B & Winter, G, 'The Nagoya Protocol on Access to Genetic Resources and Benefit Sharing: What is new and what are the implications for Provider and User Countries and the Scientific Community?' in *Law, Environment and Development Journal*, Vol. 6/3, 2010, 246 at 248.

⁵¹ *Ibid* at 249.

⁵² Fifth Ordinary Meeting of the Conference of the Parties to the Convention on Biological Diversity, Nairobi, Kenya, 15 – 26 May 2000. Meeting Report available at http://www.cbd.int/meetings/final-reports.aspx?grp=cop&menu=cops.

related provisions. The WG-ABS developed the Bonn Guidelines⁵³ which were adopted by COP 6⁵⁴ in 2002. The Bonn Guidelines on Access to Genetic Resources and Fair and Equitable Sharing of the Benefits Arising out of their Utilization provide guidance to users and providers in developing ABS mechanisms and frameworks, based on prior informed consent (PIC) and mutually agreed terms (MAT).⁵⁵

2.4.2 Guidance concerning Indigenous Communities

The Bonn Guidelines encourage competent national authorities of Parties to respect the established legal rights of indigenous communities, whose genetic resources or traditional knowledge associated with such genetic resources, are being accessed. ⁵⁶ The Guidelines recommend that under these circumstances, the PIC of indigenous communities and the approval and involvement of the traditional knowledge holders be obtained, in accordance with their traditional practices and subject to national access policies and domestic laws. ⁵⁷ The Bonn Guidelines accordingly distinguish between access to the genetic resources of indigenous communities, and access to the traditional knowledge associated with such genetic resources and, in both instances, the Guidelines encourage users to obtain PIC from the relevant indigenous community. The Guidelines therefore encourage far greater protection for indigenous communities in ABS matters than that which is required by the CBD.

The Bonn Guidelines aim to assist Parties and stakeholders in the development of MATs to ensure the fair and equitable sharing of benefits and provide certain elements which could be considered as guiding parameters in contractual agreements. ⁵⁸ Such elements include the regulation of the use of resources in order to take into account the ethical concerns of indigenous communities and making provision to ensure the continued customary use of genetic resources and associated traditional knowledge. ⁵⁹ In the implementation of MATs, the Bonn Guidelines

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⁵³ Bonn Guidelines on Access to Genetic Resources and Fair and Equitable Sharing of the Benefits Arising out of their Utilization, in Report of the Sixth Meeting of the Conference of the Parties to the CBD, UN DOC UNEP/CBD/COP/6/20(2002). Available at http://www.cbd.int/meetings/final-reports.aspx?grp=cop&menu=cops.

⁵⁴ Sixth Ordinary Meeting of the Conference of the Parties to the Convention on Biological Diversity, The Hague, Netherlands, 7 – 19 April 2002. Meeting Report available at http://www.cbd.int/meetings/final-reports.aspx?grp=cop&menu=cops.

⁵⁵ Bonn Guidelines, Part IV.

⁵⁶ *Ibid* at para 31.

⁵⁷ Ibid.

⁵⁸ *Ibid* at para 41.

⁵⁹ *Ibid* at para 43.

encourage users to respect the customs, traditions, values and customary practices of indigenous communities.⁶⁰ The Bonn Guidelines further encourage Parties with users of genetic resources under their jurisdiction to take appropriate legal, administrative or policy measures to ensure compliance with PIC requirements of the Party providing the resources.⁶¹ One such measure proposed by the Guidelines encourages the disclosure of the country of origin of the genetic resources, as well as the associated traditional knowledge of indigenous communities, in applications for intellectual property rights.⁶²

2.4.3 Drawbacks of the Bonn Guidelines

Notwithstanding the advances made by the Bonn Guidelines, in encouraging the enhancement of the protection afforded to indigenous communities in ABS matters, they were criticized for placing too much emphasis on measures for provider countries, as opposed to measures for user countries. This was problematic as, although access to the genetic resources and finalization of a benefit-sharing agreement takes place in the country providing the genetic resources, the actual utilization of the genetic resources and the resultant benefits therefrom often takes place in another country. Hence, user country measures, which could ensure compliance with the ABS legislation of provider countries and monitor the utilization of, as well as the benefit-sharing in respect of, genetic resources and associated traditional knowledge, were critical and unfortunately received insufficient emphasis in the Bonn Guidelines.

The Bonn Guidelines played a significant role in the development of provider country ABS measures, but they did not achieve similar success, as far as the obligations of users were concerned, as their implementation was completely voluntary. As a result of the voluntary nature of the Bonn Guidelines, not many countries established national systems of ABS, which, in turn, has resulted in many users of genetic resources and associated traditional knowledge not feeling obliged to follow the principles of PIC and Benefit-Sharing. Hence, many bio-diverse

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⁶⁰ *Ibid* at para 16(b)(ii).

⁶¹ *Ibid* at para 16(d).

⁶² *Ibid* at para 16(d) (ii).

⁶³ Koutouki, K & von Bieberstein, KR (n. 36) at 523.

⁶⁴ Ihid.

⁶⁵ Kamau, EC, Fedder, B & Winter, G (n. 50) at 249.

⁶⁶ Bavikatte, B & Robinson, D.F (n. 30) at 38.

provider countries, as well as indigenous communities, sought to develop binding international obligations based on principles set out in the Bonn Guidelines.⁶⁷

2.5 The Road to the Nagoya Protocol on Access to Genetic Resources and the Fair and Equitable Sharing of Benefits Arising from their Utilization to the Convention on Biological Diversity

2.5.1 The Mandate to negotiate an International ABS Regime

At the World Summit for Sustainable Development in Johannesburg in August 2002, the Group of Like-Minded Megadiverse Countries (of which South Africa is a member)⁶⁸ argued that the lack of clear international rules on access to genetic resources may result in them restricting access thereto by researchers, business and private investment.⁶⁹ An agreement was then reached towards the close of the Summit to negotiate an international ABS regime within the framework of the CBD and Bonn Guidelines.⁷⁰

At COP 7⁷¹ in 2004, the WG-ABS was given a new mandate to elaborate and negotiate, together with the Working Group on Article 8(j), an international regime on access to genetic resources and benefit-sharing in order to effectively implement Article 15 and Article 8(j) of the CBD.⁷² Of significance is that Decision VII/19, which was taken at COP 7, directed the WG-ABS to ensure the participation of indigenous communities.⁷³ This constituted a major advancement for

⁶ *Ibid* at 39.

⁶⁸ The Like-minded Megadiverse Countries comprise 17 developing countries: Bolivia, Brazil, China, Colombia, Costa Rica, Democratic Republic of Congo, Ecuador, India, Indonesia, Kenya, Madagascar, Malaysia, Mexico, Peru, Philippines, Venezuela and South Africa. The Group was formally constituted through the Cancun Declaration of 18 February 2002 as a 'consultation and co-operation mechanism' to promote common interests and priorities relating to the conservation and sustainable use of biodiversity. The development of an international regime to promote and safeguard the fair and equitable sharing of benefits arising out of the utilization of genetic resources was adopted by the group in its action plan as one of the five areas of priority and action. See www.megadiverse.org and http://www.cbd.int/doc/meetings/cop/cop-06/information/cop-06-inf-33-en.pdf.

⁶⁹ Kamau, EC and Winter, G (Eds), Genetic Resources, Traditional Knowledge and the Law: Solutions for Access and Benefit – Sharing, London, Earthscan, 2009 at 28.

⁷⁰ Plan of Implementation of the World Summit on Sustainable Development, Johannesburg, 2002, Paragraph 42(O).

⁷¹ Seventh Ordinary Meeting of the Conference of the Parties to the Convention on Biological Diversity, Kuala Lumpur, Malaysia, 9 – 20 February 2004. Available at http://www.cbd.int/meetings/final-reports.aspx?grp=cop&menu=cops.

Decision VII/19, COP 7, 2004. Available at http://www.cbd.int/meetings/final-reports.aspx?grp=cop&menu=cops.

Part D1 of Decision VII/19, COP 7.

indigenous communities, as it presented an opportunity for them to influence the negotiation of an international regime on access and benefit-sharing relating to genetic resources.

2.5.2 The Significance of Decision IX/12

Decision IX/12.⁷⁴ which emerged from the ninth CBD COP held in Bonn, in May 2008, set out certain significant points of convergence amongst the Parties, which included a framework and elements for an international regime on ABS. The elements were divided along a 'bricks' and 'bullets' formula, in terms of which the 'bricks' were those elements of an 'international regime' agreed upon by the Parties but which required further elaboration. On the other hand, 'bullets' referred to those possible elements, which required further consideration as there was no consensus between the Parties as to whether they should be included in the international regime.⁷⁵ In addition, an agreement was reached to begin text based negotiations through an invitation to Parties, other governments, international organizations, indigenous peoples and local communities, as well as other relevant stakeholders, to submit views and proposals, including operational text, with supporting rationale, regarding an international ABS regime.⁷⁶

Decision IX/12 further established three Groups of Technical and Legal Experts to advise the Working Group on ABS on issues pertaining to:

- (i) Compliance;
- Concepts, terms, working definitions and sectoral approaches; and (ii)
- Traditional knowledge associated with genetic resources.⁷⁷ (iii)

It was agreed that the pace and intensity of negotiations be escalated by scheduling three meetings of the Working Group on ABS prior to COP 10, in order to ensure completion of the negotiations towards an international ABS regime in time for the deadline of the tenth COP, which was scheduled for October 2010.⁷⁸ The setting of a concrete deadline for the finalization of the negotiation process was of strategic importance as it provided the WG-ABS with a final

⁷⁴ Decision IX/12, COP 9, 2008. Available at http://www.cbd.int/meetings/final-reports.aspx?grp=cop&menu=cops.

Annex 1 of Decision IX/12, COP 9.

Para 9 of Decision IX/12, COP 9.

⁷⁷ Para 11 of Decision IX/12, COP 9.

⁷⁸ Para 5 of Decision IX/12, COP 9.

goal towards which it could work and in addition, it increased the pressure on Parties to move forward in the negotiations.⁷⁹

2.5.3 The Group of Technical and Legal Experts (GTLE) on Traditional Knowledge associated with Genetic Resources

A group of technical and legal experts on traditional knowledge associated with genetic resources was established to further examine the issue of traditional knowledge associated with genetic resources in order to assist the Working Group on ABS. ⁸⁰ The expert group was to be composed of thirty experts nominated by Parties and fifteen observers, which were to include seven observers from indigenous and local communities, nominated by such communities. ⁸¹ In addition, Parties were encouraged to nominate experts from indigenous and local communities, where possible. ⁸²

At the meeting of the Group of Technical and Legal Experts (GTLE) on Traditional Knowledge associated with Genetic Resources, set up at the ninth COP in Bonn by the Working Group on ABS, another crucial opportunity for indigenous communities to further influence the negotiations of the WG on ABS presented itself.⁸³ The final decision on electing experts for the GTLE meeting rested with the Secretariat of the CBD and in narrowing down the final list of nominations, the Secretariat of the CBD chose nominees well-versed with community concerns, rather than individuals who were technically versed or represented State interest. ⁸⁴ Such nominated experts had a good grounding on community issues and were accordingly sympathetic to community concerns. ⁸⁵ In addition, a large number of the chosen experts were from indigenous communities themselves, thereby ensuring that the balance of power shifted towards community interests. ⁸⁶

⁷⁹ Greiber, T *et al* (n. 11) at 20.

⁸⁰ Section C of Annex II to Decision IX/12.

⁸¹ *Ibid*.

⁸² *Ibid*.

⁸³ CBD Secretariat, Report of the Meeting of the Group of Technical and Legal Experts on Traditional Knowledge Associated with Genetic Resources in the context of the International regime on Access and Benefit-Sharing, Ad Hoc Open-Ended Working Group on ABS, Eighth Meeting, Montreal, 9-15 Nov. 2009. UNEP/CBD/WG-ABS/8/2 regarding 15 July 2009 meeting in Hyderabad. Available at http://www.cbd.int/doc/meetings/abs/abswg-09/.../abswg-09-02-en.pdf.

⁸⁴ Bavikatte, K & Robinson, DF (30) at 43.

⁸⁵ *Ibid*.

⁸⁶ *Ibid*.

2.5.4 The Report of the meeting of the GTLE on Traditional Knowledge Associated with Genetic Resources

The Report of the meeting of the GTLE on Traditional Knowledge Associated with Genetic Resources, which took place in Hyderabad in June 2009, was used to inform the negotiations of the Nagoya Protocol. The GTLE expansively interpreted Article 8(j) of the CBD and in so doing; certain critical victories were achieved for indigenous communities through the GTLE process.⁸⁷ Such victories included the following:

- 1. The experts agreed that there is an intrinsic link between genetic resources and traditional knowledge and that the international regime should therefore embrace traditional knowledge;⁸⁸
- 2. It was concluded that there is a clear basis in international law for PIC of indigenous and local communities when traditional knowledge associated with genetic resources is accessed and that this should be included in the international regime;⁸⁹
- 3. It was agreed that the granting of access will usually be guided by the indigenous and local communities' customary laws and community level procedures and that consequently when indigenous and local communities have customary laws and community level procedures pertaining to traditional knowledge in place, such laws and procedures should be relevant in the international regime;⁹⁰
- 4. It was suggested that where associated traditional knowledge is shared between indigenous and local communities spread across national boundaries or in situations where indigenous and local communities with differing values and customary norms and laws apply, countries should encourage and support the development of community

⁸⁷ Ihid

⁸⁸ Report of the Meeting of the Group of Technical and Legal Experts on Traditional Knowledge Associated with Genetic Resources in the context of the International Regime on Access and Benefit-Sharing, UNEP/CBD/WG-ABS/8/2, 15 July 2009, para 20 at p 8. Available at https://www.cbd.int/doc/?meeting=ABSGTLE-03. Accessed on 15th September 2013.

⁸⁹ *Ibid* at para 71 at p 15.

⁹⁰ *Ibid* at para 34 at p 11.

protocols, which will provide potential users of such associated traditional knowledge with clear and transparent rules for acquiring PIC;⁹¹

The experts highlighted the value of an internationally recognized certificate and agreed 5. that such certificate would be useful as evidence of PIC from indigenous and local communities, in relation to traditional knowledge associated with genetic resources. 92

The Report of the GTLE therefore provided practical guidance as to how the intricate issues surrounding traditional knowledge and an international ABS regime might be addressed.

The Meetings of the Working Group on ABS 2.5.5

2.5.5.1 The Eighth Meeting of the Working Group on ABS

The eighth meeting of the WG-ABS, which was held in Montreal in 2009, constituted an important step forward in the negotiation process as it resulted in the adoption of the 'Montreal Annex,' which included the first-ever complete draft of the international regime. 93 The Annex incorporated operational text on all elements and the meeting report further included a second Annex, which contained points for open discussion relating to the international regime for the next WG-ABS meeting. 94 The Montreal Annex was nevertheless still heavily bracketed, reflecting a lack of agreement between the Parties and as there was less than a year left until the CBD COP 10, the pressure on the negotiating partners increased substantially. 95 It was accordingly decided to convene two informal intersessional meetings in order to accelerate the negotiation process before the next WG-ABS meeting. These comprised the meeting of the ABS Friends of the Co-Chairs in Montreal in January 2010 and the ABS Co-Chairs Informal Interregional Consultation (CIIC) in Cali, Colombia, in March 2010. 96

The Ninth Meeting of the Working Group on ABS 2.5.5.2

⁹¹ *Ibid* at para 86 at p 17.92 *Ibid* at para 98 at p 19.

⁹³ Greiber, T *et al* (n. 11) at 21.

⁹⁴ Ibid.

⁹⁵ Ihid.

⁹⁶ *Ibid* at 22.

At the first part of the ninth meeting of the Working Group on ABS held in Cali during March 2010, the Co-Chairs provided the Parties with a Co-Chair's text, which was minimalist in nature and which was adopted as the future basis for negotiations. ⁹⁷ A decision was taken at the ninth Meeting of the Working Group on ABS in Cali to the effect that the international agreement would take the form of a Protocol under the CBD. ⁹⁸ This was critical from a procedural perspective, as according to Article 28(3) of the CBD, any proposed Protocol to the Convention must be communicated to the Parties by the Secretariat at least six months before a meeting of the Conference of the Parties. Considering only seven months remained until the CBD COP 10, this decision was crucial and marked the next critical step on the road to Nagoya. The Co-Chairs took a further strategic decision to establish an Interregional Negotiating Group (ING), ⁹⁹ which worked in a roundtable format and consisted of a small number of negotiators and observers. Of significance for indigenous communities is that the ING included two representatives for indigenous communities.

2.5.5.3 The Co-Chairs Text

A major advance for indigenous communities was that the Co-Chairs' text included prior informed consent and benefit-sharing provisions for indigenous communities (relating to the use of their traditional knowledge) and further required Parties to ensure that such consent and benefit-sharing is in accordance with the indigenous communities' customary laws and Community Protocols. ¹⁰⁰ The customs and value systems of indigenous communities were therefore being recognized.

The text was however notably silent on compliance provisions and it made no mention of the rights of communities over genetic resources. ¹⁰¹ The omission pertaining to compliance was in favor of the European Union's position that the World Intellectual Property Organization's Intergovernmental Committee on Intellectual Property and Genetic Resources, Traditional

⁹⁷ CBD Secretariat, Report of the First Part of the Ninth Meeting of the Ad HOC Open-Ended Working Group on Access and Benefit-Sharing. Ninth Meeting, Cali, Colombia, March 2010. UNEP/CBD/WG-ABS/9/3. Available at www.cbd.int/doc/?meeting=ABSWG-09.

⁹⁸ Greiber, T *et al* (n. 11) at 22.

⁹⁹ The Inter-regional Negotiating Group was established by the ABS Working Group to produce a draft Protocol and of significance is that this Group included two representatives from indigenous and local communities. Lewis, M, 'The Nagoya Protocol and its Potential Implications for South Africa' in *SAJELP* 17, 2010, 69 at 79.

¹⁰¹ Bavikatte, K & Robinson, D.F (n 30) at 44.

Knowledge and Folklore (WIPO IGC) should deal with all compliance provisions relating to traditional knowledge. The WIPO IGC has been taking an in depth look into the intellectual property aspects of ABS and its mandate includes, *inter alia*, discussing appropriate national and international patent measures, including disclosure of origin and evidence of PIC, as compliance provisions in ABS matters. It is for this reason that the European Union contended that the WIPO IGC should deal with all compliance provisions relating to traditional knowledge. However, the WIPO IGC is yet to forge consensus on the issue.

The second omission pertaining to the rights of communities over genetic resources was as a result of no Party supporting the rights of communities to genetic resources. The indigenous communities clearly had the odds heavily stacked up against them, the most insurmountable thereof being the fact that although indigenous communities could participate in the negotiations, they ultimately required the unequivocal support of a Party for any text that they wanted introduced in the Protocol. Sessentially, the Party States are the primary subjects of the CBD and the CBD attributes sovereignty over natural resources to national governments. It has been argued that this marginalizes the indigenous communities' rights to natural resources within their territories and severs the all-important connection between community and biodiversity. It has further been argued that although the CBD recognizes the need to protect traditional knowledge associated with genetic resources, due to the generally tense nature of the relationship between State and indigenous communities, it is unlikely that States would give indigenous communities unfettered access to the international arena in order to assert their rights.

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¹⁰² The World Intellectual Property Organization (WIPO) is a specialized agency of the United Nations established by the WIPO Convention in 1967, and is dedicated to the protection of intellectual property worldwide. The WIPO IGC is a forum which was established by the WIPO General Assembly in 2000, in order to facilitate discussions among member States and it is currently undertaking text-based negotiations with the aim of establishing an international legal instrument that will ensure the effective protection of traditional knowledge, traditional cultural expression/ folklore and genetic resources. *Ibid* at 41. WIPO Convention of 1967 available at http://www.wipo.int/treaties/en/text.jsp?file_id=283854.

To International Centre for Trade and Sustainable Development, 'Access, Benefit Sharing and Intellectual Property Rights', COP-8 Biodiversity and Trade Briefings No. 2, March 2006 at 3. Available at http://ictsd.org/i/ip/25948/?view=document. Accessed on 20th September 2013.

¹⁰⁵ Bavikatte, K & Robinson, D.F (n. 30) at 44.

¹⁰⁶ Ihid.

¹⁰⁷ Koutouki, K & von Bieberstein, KR (n. 36) at 520.

¹⁰⁸ *Ibid* at 519.

There were fierce negotiations surrounding the Co-Chairs' text. Nevertheless, by the end of the Cali meeting, further progress had been made on the negotiation of an international ABS regime.

The Negotiations leading to the Compromise Text 2.5.5.4

As the text-based negotiations were not finalized by the end of the Cali meeting, it was decided to resume the meeting in Montreal in July. 109 Negotiations continued in the ING format at the resumed meeting and after numerous day and night sessions involving discussions and negotiations, a further advanced draft Protocol, with a common understanding on important issues relating to compliance, access, and benefit-sharing, resulted. 110 However, further additional consultations were required for the development of a draft Protocol capable of being presented at COP 10. Accordingly, the WG-ABS reconvened the ING in September in Montreal and in October in Nagoya; and two days prior to the opening of COP 10, the WG-ABS adopted a draft Protocol, which although not finalized, was ready to be presented to COP 10, for consideration.¹¹¹

Negotiations continued throughout the full two weeks of CBD COP 10 in Nagoya and in order to facilitate such negotiations, an Open-ended Informal Consultative Group on ABS (ICG) was established in the first plenary session of COP 10, which was tasked to finalize the Protocol text. 112 It soon became clear that the ICG would fail to agree on a final text and a compromise text was tabled by the Japanese COP Presidency, as a basis for Ministerial informal consultations. 113 The text that was eventually adopted as the Protocol did not contain all that had been negotiated by the ABS- Working Group and the final text was in fact a compromise text. 114

2.5.5.5 The adoption of the Nagova Protocol

The Nagoya Protocol on Access to Genetic Resources and the Fair and Equitable Sharing of Benefits Arising from their Utilization to the Convention on Biological Diversity (Nagoya

¹⁰⁹ Greiber, T *et al* (n. 11) at 22.

¹¹⁰ *Ibid*.

¹¹¹ *Ibid*.

¹¹² *Ibid*.

¹¹⁴ Lewis, M, 'The Nagoya Protocol and its Potential Implications for South Africa' in SAJELP (2010) 17 69 at 78.

Protocol)¹¹⁵ was adopted in the early hours of 30 October 2010, marking the conclusion of a long and arduous negotiation process, following the mandate established at the 7th meeting of the Conference of the Parties to the CBD held in Kuala Lumpur in 2004. 116 It was a text finally drafted by a small unelected group that was eventually presented for adoption by the Japanese Presidency in the closing hours of the deadline given for the adoption of the Nagoya Protocol. 117 Accordingly, the Nagoya Protocol emerged as a partially negotiated text. Nevertheless, the Nagoya Protocol remains a significant achievement for indigenous communities as it represents a high-water mark in international jurisprudence. 118 It must be noted, however, that according to Article 33(1) of the Nagoya Protocol, the Protocol will only enter into force on the ninetieth day after the date of deposit of the fiftieth instrument of ratification, acceptance, approval, or accession by States that are Parties to the CBD.

2.6 A Critical Analysis of the Nagoya Protocol

Access to Genetic Resources and Associated Traditional Knowledge of Indigenous **Communities**

The Nagoya Protocol deals with the rights of indigenous communities in relation to both genetic resources ¹¹⁹ and traditional knowledge associated with such resources. ¹²⁰ Article 6.2, which relates to the access to genetic resources over which indigenous communities have rights, states:

In accordance with domestic law, each Party shall take measures, as appropriate, with the aim of ensuring that the prior informed consent or approval and involvement of indigenous and local communities is obtained for access to genetic resources where they have the established right to grant access to such resources.

¹¹⁵ Nagova Protocol on Access to Genetic Resources and the Fair and Equitable Sharing of Benefit Arising from their Utilization to the Convention on Biological Diversity, Nagoya, 29 October 2010. Available at http://www.cbd.int/cop 10/doc/.

Nijar, GS, 'The Nagoya Protocol on Access and Benefit Sharing of Genetic Resources: Analysis and Implementation Options for Developing Countries' in Research Papers 36, South Centre, 2011 at 1. Available at http://www.southcentre.org/index.php?option=com_docman&task=doc_download&gid=2001&Itemid=182&lang=e n. Accessed on 29^{th} September 2012. 117 *Ibid*.

¹¹⁸ Jonas, H *et al* (n. 6) at 49.

¹¹⁹ Article 6, Nagoya Protocol.

¹²⁰ Article 7, Nagoya Protocol.

Article 7, which pertains to access to the traditional knowledge of indigenous communities that is associated with genetic resources states:

In accordance with domestic law, each Party shall take measures, as appropriate, with the aim of ensuring that traditional knowledge associated with genetic resources that is held by indigenous and local communities is accessed with the prior informed consent or approval and involvement of these indigenous and local communities, and that mutually agreed terms have been established.

Accordingly, access in both these instances may be secured by either 'prior and informed consent or approval and involvement of indigenous and local communities'. The fact that the Nagoya Protocol makes reference to the rights of indigenous communities in relation to both genetic resources and traditional knowledge associated with such resources, in respect of which PIC or the approval and involvement of indigenous communities are required, is undoubtedly an enhancement of the rights of the indigenous communities. In this regard, the CBD only deals with access to the traditional knowledge of indigenous and local communities, with the approval and involvement of the holders of such knowledge. Hence the CBD makes no reference to the rights of indigenous communities in relation to access to genetic resources, nor does it make provision for the stricter prior informed consent requirement.

2.6.1.1 The meaning of the terms 'prior informed consent' and 'approval and involvement'

With regards to the difference between the terms 'PIC' and 'approval and involvement', Nijar argues that the Parties to the CBD have consistently considered the latter expression as meaning PIC. An example he furnishes is that of the General Principle of PIC adopted at COP5, which stipulated that 'access to traditional knowledge, innovations and practices of indigenous local communities should be subject to prior informed consent or prior informed approval from the holders of such knowledge, innovations and practices'. Furthermore, the Bonn Guidelines, which were developed by the Parties in 2002 to assist Parties and governments to develop

¹²¹ Article 6 and 7, Nagoya Protocol.

¹²² Article 8(j), CBD.

¹²³ Nijar, GS (n.116) at 25.

¹²⁴ CBD Secretariat, Access and Benefit Sharing, Decision Adopted by the Conference of the Parties to the CBD at its Fifth Ordinary Meeting, Nairobi, Kenya, 15 – 26 May 2000, Decision V/16, Annex at 73. Available at http://www.cbd.int/meetings/final-reports.aspx?grp=cop&menu=cops.

legislative, administrative or policy measures on ABS, suggest that Parties developing a system of PIC in accordance with Article 15.5 of the CBD should abide by the principle that the 'consent of relevant stakeholders such as indigenous and local communities ... should also be obtained'. Accordingly, Nijar argues that there is no appreciable difference between the expressions of PIC and 'approval and involvement', as in both instances Parties are required to take measures with the aim of ensuring that the genetic resource and/or the traditional knowledge of indigenous communities are accessed with their PIC. 126

Although there may be traces of differences between the terms 'approval' and 'consent' in the English language, these differences are insignificant and it can be concluded that the terms 'approval' and 'consent' essentially have the same meaning, particularly when viewed in the context of the Nagoya Protocol. 127 In the circumstances, making use of the words 'or approval and involvement' in addition to the term PIC could therefore appear to be redundant. However, Greiber et al highlight that the term 'consent' may almost be referred to as a term of art, as it has acquired a particular status under international law, in terms of which certain elements automatically attach to the concept. 128 The term 'approval', on the other hand, is seldom used in international legal instruments, and can therefore not be referred to as a term of art, with specific elements automatically attaching to it. 129 Greiber et al proceed to argue that, having regard to international law, PIC has acquired a particular status and there may accordingly be a material difference between references to 'PIC' and to 'approval and involvement'. 130 Similarly, certain domestic jurisdictions may have a formal definition of PIC and such States may prefer to make use of the flexibility offered by the use of the term 'approval and involvement' in their ABS legislation, so as to deliberately avoid the incorporation of certain elements of the defined concept of PIC into their ABS legislation. 131

Hence, although indigenous communities are entitled to determine access to genetic resources and traditional knowledge associated with genetic resources, held by them, Parties have the

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¹²⁵ Bonn Guidelines (n.53) at para 26(d).

¹²⁶ Nijar, GS (n. 116) at 25.

¹²⁷ Greiber, T *et al* (n. 11) at 110.

¹²⁸ *Ibid*.

¹²⁹ *Ibid*.

¹³⁰ *Ibid*.

¹³¹ *Ibid*.

flexibility to decide on whether to ensure that access is determined based either on 'PIC' or on 'approval and involvement'. ¹³² This distinction is relevant where PIC has acquired a distinct meaning, either as a term of art under international law or through definitions in national legislation. ¹³³ Notwithstanding the above distinction, the PIC provisions in the Nagoya Protocol is stronger than Article 8(j) of the CBD, which only promotes the wider application of access to traditional knowledge, with the approval and involvement of indigenous communities.

2.6.1.2 The use of the term 'in accordance with domestic law'

Both Articles 6.2 and 7 of the Nagoya Protocol, which pertain to indigenous communities in relation to access to genetic resources and associated traditional knowledge, respectively, are qualified by the words 'in accordance with domestic law'. Article 8(j) of the CBD is qualified by the words 'subject to national law' and during the negotiations in the lead up to the adoption of the Nagoya Protocol some Parties were steadfast in their belief that such a qualification should be retained. Countries such as New Zealand and Canada had reservations about this term, arguing that it undermined treaties they had with their indigenous peoples, which were not 'subject to national law'. It was the African Group that proposed the replacement of this term with a more temperate 'in accordance with national law'. This way forward was readily accepted by countries such as New Zealand and Canada. The effect was the elimination of the term 'subject to national law' and the replacement thereof by 'in accordance with domestic law'.

Views concerning the meaning of this wording are divided. On the one hand, it has been argued that the phrase 'in accordance with domestic law' implies that the State has a facilitative role to play in PIC, as well as approval and involvement processes, when indigenous communities are in need of such support. On the other hand, there has been argument to the effect that the cumulative effect of the references to 'as appropriate' and 'in accordance with domestic law'

¹³² *Ibid*.

¹³³ *Ibid*.

¹³⁴ Article 6.2 & 6.3 and Article 7, Nagoya Protocol.

¹³⁵ Bavikatte, K and Robinson, DF (n. 30) at 45.

¹³⁶ Ihid

¹³⁷ Article 6.2 and 6.3 and Article 7, Nagoya Protocol.

¹³⁸ Bavikatte, K and Robinson, DF (n. 30) at 45.

¹³⁹ Greiber, T *et al* (n. 11) at112.

renders the PIC or approval and involvement requirement at the sole discretion of a Party. However, Greiber *et al* point out that these arguments do not appear to find support in the actual wording of the provisions of Articles 6.2 and 7. Based on the structure of these Articles, it would appear that the term 'in accordance with domestic law' refers only to the manner in which Parties shall take measures. Half Accordingly, the Nagoya Protocol requires Parties to take measures in accordance with national law and the reference to 'in accordance with domestic law' does not qualify States' material obligation to take measures with the aim of ensuring that PIC or 'approval and involvement' requirements are complied with, before traditional knowledge associated with genetic resources held by indigenous communities is being accessed. Hence, Parties are free to determine, on their own, which measures they shall take and they are entitled to take measures that are in accordance with what their national law permits or requires. Ultimately, the qualification of 'in accordance with domestic law' is a provision which provides flexibility for countries to deal with issues pertaining to traditional knowledge, particularly in the light of the diverse ways in which traditional knowledge is approached, in the various countries.

2.6.1.3 The meaning of 'as appropriate'

Both Articles 6.2 and 7 of the Nagoya Protocol, which pertains to indigenous communities in relation to access to genetic resources and associated traditional knowledge, respectively, further make reference to measures being taken by Parties 'as appropriate'. The use of the term 'as appropriate' implies that Parties are free to choose appropriate measures; which could comprise legislative, administrative, or policy measures or any other measures the Party deems appropriate in order to ensure implementation of its obligations under Articles 6.2 and 7. Accordingly, the focus is on the aim and not on the type of measures to be taken. Having regard to varying national ABS legislation, as well as local circumstances, it is anticipated that there will be a diversity of measures taken from country to country. Hence, the term 'as appropriate' provides

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¹⁴⁰ *Ibid*.

¹⁴¹ *Ibid*.

¹⁴² Nijar, GS (n.116) at 26.

¹⁴³ Greiber, T et al (n. 11) at 87.

¹⁴⁴ *Ibid*.

flexibility to Parties when deciding on the type of measures to take, in their implementation of Articles 6.2 and 7.

2.6.1.4 The mandatory nature of Articles 6.2 and 7

Articles 6.2 and 7 of the Nagoya Protocol make use of the word 'shall', which makes the obligations being imposed on parties mandatory in nature. Hence, Parties are obliged to, in accordance with national law, take appropriate measures with the aim of ensuring that prior informed consent or approval and involvement of indigenous and local communities is obtained with regards to the use of their genetic resources and traditional knowledge associated with such genetic resources.

Article 6.2 ends with the words 'where they have the established right to grant access to such resources'. Therefore, the obligation to obtain PIC or approval and involvement of indigenous communities under Article 6.2, only becomes necessary if the indigenous communities have an established right to grant access to such resources. Hence, if the indigenous communities do not have such an established right, a Party is under no obligation to take measures with the aim of ensuring that the PIC or approval and involvement of indigenous communities are obtained.

The reasoning behind the use of the phrase 'where they have the established right' is not very clear. Having regard to the negotiation of the Nagoya Protocol, one view that emerged is that the phrase 'where they have the established right' originated from an attempt by indigenous communities to have their rights acknowledged in the Nagoya Protocol, in the same manner as they are recognized in international law. He words 'established right' are unqualified and it therefore depends on the interpretation thereof as to whether such rights are to be established by way of national law or international law. According to Bavikatte and Robinson the unqualified nature of 'established right' is known as 'strategic ambiguity' in the negotiation process, as it has the effect of leaving this term open to jurisprudential growth and interpretation.

¹⁴⁵ *Ibid* at 100.

¹⁴⁶ Ihid.

¹⁴⁷ Bavikatte, K and Robinson, DF (n. 30) at 47.

¹⁴⁸ *Ibid*.

2.6.1.5 Final analysis of the provisions of Articles 6.2 and 7

The use of the terms 'in accordance with domestic law' and 'as appropriate', together with the qualification of 'with the aim of ensuring', offers Parties flexibility with regards to the measures that they can take in their implementation of Articles 6.2 and 7 of the Nagoya Protocol. As States are only encouraged to take measures 'as appropriate', it appears that States are under no general obligation to take such measures. It would appear that States need only take measures when they have identified a need for such measures. ¹⁴⁹ Furthermore, the references to both 'as appropriate' and 'in accordance with domestic law' under Articles 6.2 and 7 clarifies that States are free to determine the type of measures that would be best suited to satisfy the identified need. ¹⁵⁰ Of significance is that the measures taken must merely 'aim' to ensure that the genetic resources of indigenous communities and traditional knowledge associated with such genetic resources are accessed with the PIC or approval and involvement of indigenous communities.

It must be highlighted, however, as stressed by Greiber *et al*, that the above qualifications do not offer States the option not to take measures when there is clearly an identified need for such measures to be taken.¹⁵¹ Both Article 6.2, as well as Article 7, proclaim that States 'shall' take measures and the obligation to do so is therefore mandatory in nature. States are only granted flexibility with regards to the type of measures they may take.¹⁵²

Notwithstanding the caveats discussed above, the provisions of Article 6.2 and 7 of the Nagoya Protocol embody a significant achievement by indigenous communities as they have the effect of extending the scope of Article 8(j) of the CBD, by recognizing that there is an inseparable link between genetic resources and traditional knowledge. This link is further highlighted in the preamble to the Nagoya Protocol, which notes the 'interrelationship between genetic resources and traditional knowledge and their inseparable nature for indigenous and local communities'. It must be noted, however, that not all Parties to the CBD will automatically become Parties to the Nagoya Protocol and accordingly, the scope of the CBD is only extended for those countries

¹⁴⁹ Greiber, T *et al* (n. 11) at 112.

¹⁵⁰ *Ibid*.

¹⁵¹ *Ibid*.

¹⁵² *Ibid*.

¹⁵³ Preamble, Nagoya Protocol.

which are Parties to both the CBD, as well as the Nagoya Protocol. It has no impact on the obligations imposed by the CBD on States which are Parties to the CBD only.

2.6.2 Benefit Sharing based on Mutually Agreed Terms

Under article 5.2 of the Nagoya Protocol, Parties are required to take appropriate legislative, administrative or policy measures with 'the aim of ensuring' that benefits arising from the utilization of genetic resources held by indigenous and local communities are shared in a fair and equitable manner with the communities concerned (in accordance with domestic legislation regarding the established rights of these communities over such genetic resources), based on mutually agreed terms (MAT). 154 It is interesting to note that the language of Article 5.1 of the Nagoya Protocol, which relates to benefit-sharing in respect of Parties, is much stronger and is unqualified. It states that benefits arising from the utilization of genetic resources 'shall be' shared in a fair and equitable manner with the Party providing such resource. 155 The benefitsharing provisions of Article 5.2, which pertains to indigenous communities, are, however, watered down by the words 'as appropriate', 'with the aim of ensuring', and 'in accordance with domestic legislation regarding the established rights' of indigenous and local communities.

Nevertheless the obligation under Article 5.2, with regard to the fair and equitable sharing of benefits arising from the utilization of genetic resources held by indigenous communities, is significant, as parties are now obliged to take appropriate measures, with the aim of ensuring that the benefits arising from the utilization of genetic resources held by indigenous communities are shared on mutually agreed terms. This is undoubtedly a monumental improvement on Article 8(j) of the CBD, which only 'encourages' the equitable sharing of benefits that arise from the use of traditional knowledge.

The wording of Article 5.5 of the Nagoya Protocol which deals with the sharing of benefits arising from the utilization of traditional knowledge is somewhat stronger than the provisions of Article 5.2, in that it requires Parties to take measures 'in order that' benefits are shared in a fair and equitable way with the indigenous communities holding such knowledge. As discussed above, under Article 5.2 of the Nagoya Protocol, Parties are required to take measures with 'the

Article 5.2, Nagoya Protocol.Article 5.1, Nagoya Protocol.

aim of ensuring' that benefits arising from the utilization of genetic resources held by indigenous communities are shared in a fair and equitable manner with the communities concerned. As with Article 5.2, the provisions of Article 5.5 are nevertheless qualified to the extent that Parties are only required to take legislative, administrative or policy measures 'as appropriate'. Accordingly, Parties have the flexibility to decide the type of measures to take in their implementation of the provisions of Article 5.5.

2.6.3 Reference to the United Nations Declaration on the Rights of Indigenous Peoples (UNDRIP). 156

A significant hurdle for indigenous communities to overcome during the negotiation of the Nagoya Protocol was the retention of the reference to the United Nations Declaration on the Rights of Indigenous Peoples(UNDRIP). Although the UNDRIP is non-binding, it was adopted by 144 States and is widely supported by indigenous communities. ¹⁵⁷ It supports the rights of indigenous communities over their biodiversity-related traditional knowledge and states that 'indigenous peoples have the right to maintain, control, protect and develop their... traditional knowledge and ... the manifestations of their sciences, technologies and cultures, including genetic resources, seeds and medicines..... ¹⁵⁸ Reference to the importance of the provisions of UNDRIP was therefore critical to indigenous communities in interpreting the provisions of the CBD, for the purposes of the Protocol. ¹⁵⁹ Canada was the only CBD party that refused to accept reference to the UNDRIP being made in the preamble of the Nagoya Protocol. ¹⁶⁰ As a result of media releases, press conferences and lobbying that the Canadian indigenous peoples organizations undertook in both Canada and Japan during the negotiation process, Canada finally relented and accepted the following reference to the UNDRIP being made in the preamble to the Nagoya Protocol: 'Noting the United Nations Declaration on the Rights of Indigenous

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¹⁵⁶ United Nations Declaration on the Rights of Indigenous Peoples, UN General Assembly Resolution 61/295, 13 September 2007. Available at http://www.un.org/esa/socdev/unpfii/en/drip.html.

¹⁵⁷ Swiderska, K *et al*, 'Community Protocols and free, prior informed consent – overview and lessons learnt' in Swiderska, K *et al* (Eds), *Overview: Biodiversity and Culture: Exploring Community Protocols, Rights and Consent*, International Institute of Environment and Development, 2012. 25 at 29. Available at http://pubs.iied.org/pdfs/G03395.pdf. Accessed on 15th August 2013.

¹⁵⁸ Article 31.1, UNDRIP.

¹⁵⁹ Bavikatte, K and Robinson, DF (n. 30) at 43.

¹⁶⁰ *Ibid* at 47.

Peoples...'.¹⁶¹ However, the preamble to the Nagoya Protocol is not legally binding in nature and at best can be used as an interpretive tool.¹⁶² Furthermore, the wording used in the reference to the UNDRIP is unfortunately extremely weak as it merely notes the UNDRIP's existence. It makes no endeavor to encourage Parties to consider the provisions of UNDRIP in their implementation of the Nagoya Protocol. Of significance, for indigenous communities, however, is that the reference to UNDRIP in the Nagoya Protocol marks the first time that UNDRIP has been referred to in an international treaty.¹⁶³

2.6.4 Derivatives of Genetic Resources

The CBD only makes reference to genetic resources and does not recognize the derivatives of genetic resources. The CBD defines genetic resources as genetic material, being material of plant, animal, microbial or other origin, containing functional units of heredity, which has actual or potential value. ¹⁶⁴ Derivatives are defined under the Nagoya Protocol as the naturally occurring biochemical compounds resulting from the genetic metabolism of genetic resources, even if they do not contain functional units of heredity. ¹⁶⁵ Bioprospecting usually entails the commercial use not only of genetic resources, but also of the biochemical compounds found within organisms, as well as the derivatives from the genetic material. ¹⁶⁶ Once identified, the biochemical compounds of genetic resources can be chemically synthesized and there would be no need to access the genetic resources again. ¹⁶⁷ It is these extracts, which include secondary metabolites such as gums, resins and latex, which are considered the true marketable products of genetic resources. ¹⁶⁸

As industry makes use of derivatives to create new products that are commercially valuable, developing countries wanted derivatives of genetic resources included in the scope of protection

¹⁶¹ *Ibid* and preamble to Nagoya Protocol.

¹⁶² See Vienna Convention on the Law of Treaties, 22 May 1969, Article 31(1)-(2). Available at http://www.worldtradelaw.net/misc/viennaconvention.pdf.

¹⁶³ Koutouki, K & von Bieberstein, KR (n. 36) at 525.

Article 2, CBD.

Article 2, CBD.

Article 2, Nagoya Protocol.

¹⁶⁶ Wynberg, R & Laird, S, 'Bioprospecting, Access and Benefit Sharing: Revisiting the 'Grand Bargain' in Wynberg, R *et al* (Eds.), *Indigenous Peoples, Consent and Benefit Sharing: Lessons from the San Hoodia Case*, Springer Science + Business Media B.V. 2009, 69 at 81.

¹⁶⁷ Jospeh, RK (n. 10) at 81.

¹⁶⁸ *Ibid*.

offered by the Nagoya Protocol. ¹⁶⁹ Developing countries pressed hard on this issue, as the derivatives of genetic resources are used in a major portion of the marketable products that results from genetic resources. The developed countries did not want derivatives included within the scope of the Protocol and this issue was contested at length during the negotiation of the Protocol. While the Protocol's scope provision ¹⁷⁰ does not include derivatives of genetic resources, the definition of 'derivative' was retained under Article 2 of the Nagoya Protocol, on the insistence of the Africa Group and the Group of Latin American and Caribbean Countries (GRULAC). ¹⁷¹ Furthermore, although the term 'derivative' has not been used anywhere else in the Nagoya Protocol, it has been suggested that the definition of 'utilization of genetic resources'. ¹⁷² under the Nagoya Protocol may be interpreted to include derivatives. ¹⁷³ In this regard, the 'utilization of genetic resources' is defined to include the conducting of 'research and development on the genetic and/or biochemical composition of genetic resources'. ¹⁷⁴

Nevertheless the Nagoya Protocol remains unclear on this issue and it is possible to make the interpretation that the Protocol does not require user countries to assist in the prevention of biopiracy when derivatives of genetic resources are involved. Excluding derivatives from the CBD and Nagoya Protocol undoubtedly has far-reaching consequences for provider countries and it significantly limits benefit-sharing opportunities for indigenous communities.

2.6.5 Compliance Measures

Article 16 of the Nagoya Protocol pertains to compliance measures relating to traditional knowledge. Parties are obliged to take 'appropriate, effective and proportionate legislative, administrative and policy measures' to ensure that traditional knowledge associated with genetic resources utilized within their jurisdiction, is accessed in accordance with prior informed consent or approval and involvement of indigenous communities, and that mutually agreed terms have been established, as required by the domestic ABS law or regulatory requirements of the other

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¹⁶⁹ *Ibid* at 80.

¹⁷⁰ Article 3, Nagoya Protocol.

Jospeh, RK (n. 10) at 91.

¹⁷² Article 2(c), Nagoya Protocol.

¹⁷³ International Centre for Trade and Sustainable Development, 'CBD Clinches ABS Protocol in Nagoya' in *Bridges Trade BioRes*10:20, 8 November 2010, 3 at 4. Available at http://ictsd.org/i/news/biores/94075/. Accessed on 12th October 2012.

¹⁷⁴ Article 2, Nagoya Protocol.

¹⁷⁵ Lewis, M (n. 114) at 93.

Party, where such indigenous communities are located.¹⁷⁶ These measures are regarded as 'user-country' or simply 'user' measures.¹⁷⁷ There is a further obligation on Parties to take appropriate, effective and proportionate measures to address situations of non-compliance with the user measures established under Article 16.1 as set out above.¹⁷⁸ The obligations under these provisions of the Nagoya Protocol are novel, as they establish, for the first time, mandatory compliance measures in respect of traditional knowledge associated with genetic resources. The effectiveness of such compliance measures will, however, depend on the provider country providing protection for traditional knowledge in its domestic ABS legislation. The Nagoya Protocol fails to set out criteria for what constitutes 'appropriate, effective and proportionate' measures that a Party should impose, for failure to comply with the provider country's ABS requirements. Ideally a clear and objective criteria for what constitutes appropriate, effective, and proportionate measures needs to be established through a decision of the Conference of the Parties to the CBD, acting as the Meeting of the Parties to the Nagoya Protocol (COP-MOP).¹⁷⁹

Article 16.3 imposes a weak obligation on Parties to co-operate in cases of alleged violation of domestic ABS laws. Such obligation is qualified by the words 'as far as possible' and 'as appropriate' and there are no criteria set out as to what 'appropriate' would constitute. In a case of alleged violation, a country may be called upon to co-operate and any unreasonable refusal to do so may be the subject of non-compliance with the Protocol. Although vague in nature, Article 16.1 of the Nagoya Protocol requires Parties with jurisdiction over users of genetic resources to take effective measures to assist provider countries in complying with their ABS legislation. Of significance is that with regards to traditional knowledge, the measures taken need only be 'as appropriate', whereas this qualification does not apply to access to genetic resources themselves.

Hence the obligations placed on user countries differ and are watered down somewhat when it comes to the use of traditional knowledge associated with genetic resources. This is of concern,

¹⁷⁶ Article 16.1, Nagoya Protocol.

¹⁷⁷ Nijar, GS (n. 116) at 6.

¹⁷⁸ Article 16.2 Nagoya Protocol.

¹⁷⁹ Nijar, GS (n. 116) at 6.

¹⁸⁰ Article 16.3, Nagoya Protocol.

¹⁸¹ Article 16.1, Nagoya Protocol.

¹⁸² Article 15.1, Nagoya Protocol.

particularly as provider countries that have established ABS-specific legislation that offers protection to indigenous communities usually have difficulty in ensuring protection of the genetic resources and associated traditional knowledge of such indigenous communities, when research and development in respect thereof takes place in a foreign jurisdiction.¹⁸³

2.6.6 Monitoring Measures

As a means to ensure compliance, the Nagoya Protocol requires Parties to designate a minimum of one 'checkpoint', which will collect or receive relevant information relating to PIC, the source of the genetic resources and the establishment of MAT and/or utilization of genetic resources. Parties must, as appropriate and depending on the particular characteristics of a designated checkpoint, require the users of genetic resources to furnish the aforesaid information at the checkpoint and to take appropriate measures to address situations of non-compliance. 185

The Nagoya Protocol further provides for the creation of an internationally recognized Certificate of Compliance, which will serve as evidence that the genetic resource which it covers has been accessed in accordance with PIC and that MATs have been established, as required by the ABS legislation of provider countries. Article 17(2) of the Nagoya Protocol stipulates that a permit or its equivalent, issued in order to allow access to the genetic resources, which is then made available to the ABS Clearing House, 187 shall constitute an internationally recognized Certificate of Compliance. Accordingly, the creation of checkpoints and internationally recognized Certificates of Compliance is intended to assist with the monitoring of the utilization of genetic resources by user countries.

There is however a significant omission of reference to associated traditional knowledge in the monitoring provisions of the Nagoya Protocol. ¹⁸⁹ There is accordingly no obligation imposed on Parties to monitor the use of the associated traditional knowledge, despite the fact that such

¹⁸³ Lewis, M (n. 114) at 87.

¹⁸⁴ Article 17.1. (a)(i), Nagoya Protocol.

¹⁸⁵ Article 17.1 (a)(ii), Nagoya Protocol.

¹⁸⁶ Article 17(3), Nagoya Protocol.

¹⁸⁷ Article 14 of the Nagoya Protocol establishes the ABS Clearing House to serve as a means for sharing ABS-related information. In particular, the ABS Clearing House is to provide access to information, made available by each Party that is relevant to the implementation of the Nagoya Protocol.

¹⁸⁸ Article 17(2), Nagoya Protocol.

Article 17, Nagoya Protocol.

knowledge might have been accessed without PIC and MAT of the provider country. In addition, there is no obligation on Parties to report the use of the associated traditional knowledge that has been accessed without PIC and MAT to the ABS Clearing House or the provider country. ¹⁹⁰ Furthermore, an internationally recognized Certificate of Compliance, which may be shown to the checkpoint as evidence of lawful access, relates only to the genetic resource and not the associated traditional knowledge. ¹⁹¹ Although Article 17.4 sets out the minimum information proposed for the internationally recognized Certificate of Compliance and further makes specific reference to genetic resources, it makes no reference to associated traditional knowledge. ¹⁹² Similarly, Article 17.1(a) (i), which sets out the minimum information for checkpoints to collect or receive, makes no reference to associated traditional knowledge. Hence, monitoring mechanisms making specific mention of the utilization of traditional knowledge are lacking in the Nagoya Protocol.

Having regard to the fact that monitoring measures are in place to support compliance measures, there is no reason why traditional knowledge should be excluded from the monitoring measures of the Nagoya Protocol. As Nijar correctly points out, this exclusion sends the incorrect signal and may well encourage the misappropriation of traditional knowledge. Having regard to the distinction that the Nagoya Protocol draws between the utilization of traditional knowledge associated with genetic resources and the utilization of genetic resources, this omission has the potential to have far reaching consequences. He is therefore critical that the COP-MOP encourage the development of monitoring measures for the use of traditional knowledge.

2.6.7 Designated Checkpoints

Under the Nagoya Protocol, Contracting Parties are required to take measures, as appropriate, to monitor and enhance transparency regarding the utilization of genetic resources. ¹⁹⁵ As stated above, such monitoring measures must include one or more designated checkpoints. ¹⁹⁶ The monitoring provisions in Article 17 were left vague with regards to the appropriate checkpoints

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¹⁹⁰ Nijar, GS (n. 116) at 27.

¹⁹¹ Article 17.3, Nagoya Protocol.

¹⁹² Article 17.4 (f), Nagoya Protocol.

¹⁹³ Nijar, GS (n. 116) at 27.

¹⁹⁴ Kamau, EC, Fedder, B and Winter, G (n. 50) at 253.

¹⁹⁵ Article 17.1, Nagoya Protocol.

¹⁹⁶ Article 17.1(a), Nagoya Protocol.

for collection of information. Although the Like-Minded Megadiverse Countries (LMMC) argued for the mandatory inclusion of patent offices as designated check-points in the Nagoya Protocol, these were not included in the adopted Protocol. 197 Had they been included, this could have had the effect of mandating Parties to provide disclosure of origin requirements in national patent laws, which could assist in the mitigation of patent-related biopiracy.

Developing countries argued for the disclosure mechanism to be incorporated within the intellectual property system, as the registration of patents constitutes the point at which genetic resources are commercialized and benefits are generated. 198 It was argued that the mandatory disclosure in patent applications would have the following benefits:

- (a) Patent applicants would be obliged to comply with national ABS law;
- (b) Patent offices would be encouraged to be more vigilant when examining patent applications pertaining to genetic resources and associated traditional knowledge;
- (c) It would serve as an essential tool for user countries in monitoring applications based on genetic resources and associated traditional knowledge and in so doing, would assist provider countries in tracking suspicious patents applications. 199

South Africa's experience in the *Pelargonium* case is an example of what could have been avoided if the mandatory disclosure in patent applications were in place. In the *Pelargonium* case, a plant used as a herbal remedy known as *Umckaloabo* was part of a patenting dispute between the indigenous community from Alice in the Eastern Cape and the company Schwabe Pharmaceuticals from Germany. The community of Alice, together with certain NGOs, challenged the validity of patents registered with the European Patents Office, in favor of Schwabe Pharmaceuticals, on the basis that Schwabe Pharmaceuticals had registered patents based on an extraction method used to produce *Umckaloabo*, which had in fact been used by the community of Alice for centuries. 200 Schwabe Pharmaceuticals failed to obtain the PIC of or to enter into BSAs with the community of Alice. One of the patents was ultimately revoked by the European Patents Office on the basis that the extractive method used by Schwabe Pharmaceuticals to produce *Umckaloabo* lacked an inventive step, as the community of Alice

¹⁹⁷ Bavikatte, K and Robinson, DF (n. 30) at 48.

¹⁹⁸ Jospeh, RK (n.10) at 82.

²⁰⁰ Rutert, B et al (n. 25) at 18.

had used the same extraction method to produce *Umckaloabo* for centuries. The European Patents Office allows patents to be granted even if they rely on resources which were obtained in breach of a provider country's ABS legislation and more stringent checkpoint provisions in the Nagoya Protocol, as advocated by the LMMCs, may have required a change in this regard.

Proposals concerning the mandatory disclosure in patent applications were strongly resisted by Japan, Australia, New Zealand, the European Union and Switzerland, which argued that such requirements would conflict with international intellectual property law. ²⁰¹ The developing countries proposed a compromise to the effect that if intellectual property offices were not specifically identified as checkpoints in the Nagoya Protocol, then alternate effective checkpoints should be identified. ²⁰² However, even this suggested compromise was refused by countries such as Canada, Japan and Australia and the Protocol fails to identify any specific checkpoints. ²⁰³ Accordingly, the Contracting Parties have flexibility in designating checkpoints and the decision is theirs as to whether to specify their patent office as a checkpoint. ²⁰⁴ The end result is that the adopted version of the Nagoya Protocol gives Parties substantial discretion with regards to the type of checkpoints to be designated, the type of information to be disclosed at such checkpoints and the measures to be taken in the event of non-compliance. Article 17 of the Nagoya Protocol simply requires that the appointed checkpoints be 'effective' and the measures to address non-compliance be 'appropriate, effective and proportionate'. ²⁰⁶

Of further significance is that there is no obligation on the Contracting Parties to inform the Clearing House/Secretariat of their designated checkpoints, whereas provider countries are obligated to notify the Secretariat of their designated focal points, as well as their national competent authority.²⁰⁷ The compliance provisions in the Nagoya Protocol are therefore weak as no effective checkpoints have been identified and there is no mandatory requirement for users to disclose all relevant information relating to PIC, the source of the genetic resource, the establishment of MAT and/or the utilization of genetic resources, at checkpoints due to the

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²⁰¹ International Institute for Sustainable Development (IISD) Reporting Services 'ABS-4 Highlights: Wednesday, 1 February 2006' in *Earth Negotiations Bulletin* 9:342, 2 February 2006, 1 at 2. Available at http://www.iisd.ca/biodiv/abs-wg4/. Accessed on 18/03/13.

Jospeh, RK (n. 10) at 90.

²⁰³ *Ibid* at 91.

²⁰⁴ *Ibid*.

Article 17(1)(iv), Nagoya Protocol.

²⁰⁶ Article 17(1)(ii), Nagoya Protocol.

²⁰⁷ Articles 13 & 14, Nagoya Protocol.

qualifier of 'as appropriate and depending on the particular characteristics of a designated checkpoint'. ²⁰⁸ Furthermore, the Protocol requires no specific sanctions to remedy the non-disclosure of designated checkpoints by user countries. Hence, it would appear that the Nagoya Protocol falls short in dealing with concerns relating to bio-piracy and intellectual property.

2.6.8 Customary Laws and Community Protocols

A major achievement for indigenous communities is the recognition of customary laws and Community Protocols in the Nagoya Protocol.²⁰⁹ A more detailed discussion on Community Protocols is undertaken in Chapter Five of this dissertation. Article 12.1 of the Nagoya Protocol states that

In implementing their obligations under this Protocol, Parties shall in accordance with domestic law take into consideration indigenous and local communities' customary laws, Community Protocols and procedures, as applicable, with respect to traditional knowledge associated with genetic resources.

Indigenous communities succeeded in retaining reference to customary laws and Community Protocols in the Nagoya Protocol, notwithstanding strenuous opposition by France.²¹⁰ France argued that the inclusion of such references would affect France's interests with its overseas territories and it would result in the creation of a new precedent of references to customary law in an international treaty.²¹¹

A term 'community level procedures' was therefore proposed by France as an alternative to 'customary laws and Community Protocols' but this was opposed by the African Indigenous Peoples Organization on the basis that 'community level procedures' re-affirmed State Control and lacked true community processes. Agreement was eventually reached whereby France agreed to the retention of the term 'customary laws and Community Protocols' in exchange for the removal of reference to 'indigenous and local community laws. The African Indigenous Peoples Organization was of the view that the words 'customary laws' would in any event cover

²⁰⁸ Articles 17.1 (a)(i) & 17.1(a)(ii), Nagoya Protocol.

²⁰⁹ Article 12, Nagoya Protocol.

²¹⁰ Bavikatte, K and Robinson, DF (n. 30) at 45-46.

²¹¹ *Ibid* at 46.

²¹² *Ibid*.

²¹³ *Ibid*.

'indigenous and local community laws' and France was appeased by the phrase 'in accordance with domestic law'. 214

Although France agreed to the use of the term 'Parties shall' in Article 12, such Article still includes several caveats, such as the phrases 'in accordance with domestic law', 'take into consideration' and 'as applicable'. Having regard to the discussion under Part 2.6.1 above, the use of such caveats means that Parties have the discretion to decide the extent to which they will take into consideration 'customary laws and Community Protocols', in the implementation of their obligations under the Nagoya Protocol. The use of the terms 'in accordance with domestic law' and 'as applicable', offers Parties flexibility with regards to their consideration of 'customary laws and Community Protocols'.

As with the provisions of Articles 6.2 and 7 of the Nagoya Protocol, the above qualifications do not offer States the option not to take into consideration 'customary laws and Community Protocols' when there is clearly an identified need to do so. Article 12 proclaims that States 'shall' take into consideration 'customary laws and Community Protocols' in the implementation of their obligations under the Nagoya Protocol and the obligation to do so is therefore mandatory in nature. States are only granted flexibility with regards to the extent they wish to take such governance mechanisms into account. ²¹⁵ The provisions of Article 12 therefore constitute a significant achievement for community rights and communal control over natural resources. ²¹⁶ They represent a milestone on the path of indigenous communities towards self-determination and highlight the emergence of biocultural rights (these being rights of indigenous communities over all aspects of their ways of life that are relevant to conservation and sustainable use of biodiversity). ²¹⁷

However, notwithstanding the significant achievement Article 12 represents for indigenous communities, the provisions of Article 12 are relatively weak. In this regard, Parties have the discretion as to the extent they will take into consideration indigenous communities' customary laws, Community Protocols and procedures, with regards to traditional knowledge associated

²¹⁴ *Ibid*.

²¹⁵ Greiber, T *et al* (n. 11) at 140.

²¹⁶ *Ibid*.

²¹⁷ Jonas, H et al (n. 6) at 1.

with genetic resources, in the implementation of their obligations under the Nagoya Protocol. Furthermore, Parties are to endeavor to support, as appropriate, the development by indigenous communities of Community Protocols, pertaining to access to traditional knowledge associated with genetic resources and the fair and equitable sharing of benefits arising out of the utilization of such knowledge; minimum requirements for MATs to secure the fair and equitable sharing of benefits arising from the utilization of traditional knowledge associated with genetic resources and model contractual clauses for benefit-sharing arising from the utilization of traditional knowledge associated with genetic resources. In addition, in their implementation of the Nagoya Protocol, Parties are required, as far as possible, not to restrict the customary use and exchange of genetic resources and associated traditional knowledge within and amongst indigenous communities. The use of the phrases 'in accordance with domestic law', 'endeavor to support', 'as appropriate' and 'as far as possible', renders the provisions of Article 12 of the Nagoya Protocol subject to the discretion of the Party, with no objective criteria being established for the assessment as to whether such discretion has been appropriately exercised. 221

The provisions of Article 12 of the Nagoya Protocol can be strengthened at COP-MOP level by way of a COP-MOP resolution, urging Parties to take into account customary laws and Community Protocols, in the implementation of their obligations under the Nagoya Protocol. However, it may be argued that there is no justification for the strengthening of Article 12, as to do so would invariably detract from the sovereignty of Parties, bearing in mind that it is the States and not indigenous communities that are Parties to the Nagoya Protocol.

Notwithstanding the apparent weakness of the provisions of Article 12 of the Nagoya Protocol, such provisions are significant in the light of biocultural jurisprudence. In the international environmental context, biocultural rights have been advanced as a means to prevent biopiracy and to enhance State protection of indigenous communities, knowledge and resources.²²²

²¹⁸ Article 12.1, Nagoya Protocol.

²¹⁹ Article 12.3, Nagoya Protocol.

²²⁰ Article 12.4 Nagoya Protocol ²²¹ Nijar, GS (n. 116) at 28.

²²² Bavikatte, K and Robinson, DF (n. 30) at 50.

2.6.9 Transboundary Co-operation

Two transboundary instances are referred to in the Nagoya Protocol and these relate to (i) where the same genetic resources are found 'in situ'²²³ within the territory of more than one Party²²⁴ and (ii) where the same traditional knowledge associated with genetic resources is shared by one or more indigenous community in several Parties. 225 In both these instances, Parties are to 'endeavor to cooperate, as appropriate, with the involvement of indigenous ... communities concerned'. 226 Parties are therefore encouraged to cooperate on the sharing of benefits, with the participation of the relevant indigenous communities. As genetic resources may be found in geographical areas that straddle many countries in a particular region, the cooperation of such countries becomes essential. For example, diverse genetic resources can be found in the Mesoamerican region, which comprises more than fifteen countries; however access to such genetic resources is generally not regulated. 227 This unfortunately opens the door to bioprospectors substituting one country with another, simply because it has fewer ABS constraints.²²⁸

Regional ABS laws should ideally provide for a participatory, collective benefit-sharing mechanism, which would provide a solution in instances where the genetic resource is prevalent to a particular region.²²⁹ This would safeguard against users targeting the weakest link with a view to obtaining access on less cumbersome terms and, in doing so, prejudicing certain indigenous communities.²³⁰ The proposed ASEAN Draft ABS Framework Agreement requires members to be informed of any access application approval or denial and it further provides for member countries to discuss benefit-sharing where resources exist in more than one member country. 231 The ASEAN Draft ABS Framework Agreement is a good example of how regional ABS co-operation can be achieved.

²²³ 'In situ' refers to genetic resources that exist within its own ecosystems and natural habitats. Article 2, CBD.

²²⁴ Article 11.1, Nagoya Protocol.

²²⁵ Article 11.2, Nagoya Protocol.

²²⁶ Article 11, Nagoya Protocol.

²²⁷ Jospeh, RK (n.10) at 88.

²²⁸ *Ibid*.

²²⁹ Nijar, GS (n. 116) at 32.

²³⁰ Nijar, GS, 'Incorporating Traditional Knowledge in an international Regime on Access to Genetic Resources and Benefit-Sharing: Problems and Prospects' in The European Journal of International Law, Vol. 21, No. 2, 2010, 457 at 469. ²³¹ *Ibid*.

2.6.10 Global Multilateral Benefit Sharing Mechanism

Of further significance is the prospective 'global multilateral benefit sharing mechanism', which, if established, would address the fair and equitable sharing of benefits derived from the utilization of genetic resources and traditional knowledge associated with such genetic resources, that occur in transboundary situations or for which it is not possible to grant or obtain PIC. 232 Throughout negotiations of the Nagoya Protocol, the African Group insisted that an international ABS regime that failed to provide for such situations would in effect sanction and perpetuate historical injustices and biopiracy. 233 The African Group was concerned about the limits to the geographical and temporal scope of the Nagoya Protocol and in particular, those genetic resources found in areas beyond national jurisdiction or accessed before the Protocol enters into effect. 234 Developing countries were particularly concerned about the status of and potential benefits realized from the use of genetic resources found in gene banks and botanical gardens of developed countries. The exclusion of gene bank collections from the scope of the Protocol would undoubtedly prejudice indigenous communities, by limiting their benefit-sharing potential.

In terms of Article 10, the Protocol requires future work for Parties to consider the need for and modalities of a global multilateral benefit-sharing mechanism. It is important to note that Article 10 pre-empts the work of Parties by specifying the purpose of the mechanism, and stating where benefits derived from the utilization of genetic resources and associated traditional knowledge are to be directed. In this regard, benefits shared through the global multilateral benefit-sharing mechanism are to be directed towards the conservation of biological diversity and sustainable use of its components, globally. At the second meeting of the Intergovernmental Committee for

²³² Article 10, Nagoya Protocol.

²³³ Mafuratidze, R, 'Critical Review of the Nagoya Protocol on Access and Benefit-Sharing: Analysis of its Provisions against the African Model Law and Possibilities for its implementation at National Level' in RAEIN-Africa at 14. Available at http://www.ctdt.co.zw/attachments/079_NAGOYA%20PROTOCOL.pdf. Accessed on 28th August 2013.

²³⁴ International Institute for Sustainable Development(IISD), Reporting Services, 'Summary of the Second Meeting of the Intergovernmental Committee for the Nagoya Protocol on Access and Benefit-Sharing to the Convention on Biological Diversity: 2-6 July 2012' in *Earth Negotiations Bulletin*, ICNP2 Final, Vol. 9 no. 579, 9 July 2012, 1 at 14. Available at http://www.iisd.ca/download/pdf/enb09579e.pdf. Accessed on 20th September 2013.

the Nagova Protocol²³⁶ (ICNP2) held in New Delhi in July 2012, preliminary discussions relating to the global multilateral benefit-sharing mechanism revealed that there is no common understanding among the Parties of which situations such mechanism would cover, whether such mechanism would work parallel to or as an alternative to co-operative efforts in relation to transboundary genetic resources referred to in Article 11, who will benefit from the mechanism and precisely how the benefits are to contribute to biodiversity conservation and sustainable use.²³⁷

It is important to note that Article 10 merely asks Parties to consider the need for the establishment of a global multilateral benefit-sharing mechanism; it does not call for the establishment of such mechanism. Hence, certain Parties have emphasized that prior to trying to decipher the meaning of Article 10, Parties should first determine whether there is in fact a need for such a mechanism. ²³⁸ A list of questions to facilitate a systematic exchange of views on the various ways that Article 10 may be operationalized has been prepared by the ICNP2 for distribution among Parties; but it remains to be seen whether this will result in a constructive exchange on the usefulness, interpretation and implementation of a global multilateral benefitsharing mechanism.²³⁹

2.6.11 Compliance Mechanism²⁴⁰

Article 30 of the Nagoya Protocol provides that the COP-MOP shall, at its first meeting, consider and approve cooperative procedures and institutional mechanisms, in order to promote compliance with the provisions of the Protocol and to address cases of non-compliance. Such procedures and mechanisms are to include provisions to offer advice or assistance, where appropriate. 241 The Nagoya Protocol, in other words, envisages the establishment of a

²³⁶ The Open-ended Ad Hoc Intergovernmental Committee (ICNP) for the Nagoya Protocol on ABS was established at the tenth meeting of COP as an interim governing body for the Nagoya Protocol, until the first meeting of the Parties to the Protocol, at which time the ICNP shall cease to exist. Decision X-1, COP 10, Available at http://www.cbd.int/abs/icnp/.

International Institute for Sustainable Development (IISD) (n. 234) at 14.

²³⁸ *Ibid*.

²⁴⁰ Note that the compliance discussion under Part 2.6.5 of this Chapter addresses the means of ensuring user compliance with provider country ABS legislation whereas the compliance discussion under this part of the Chapter addresses Parties non-compliance with the provisions of the Nagoya Protocol. ²⁴¹ Article 30, Nagoya Protocol.

compliance mechanism, and the ICNP has been tasked with negotiating a draft text on this mechanism in anticipation of the Protocol's entry into force. At the second meeting of the ICNP, held in New Delhi in July 2012, negotiations towards the compliance mechanism involved certain contentious issues relating to indigenous communities and their traditional knowledge.²⁴² The Parties were divided on the issue as to whether indigenous communities should be allowed to participate in the compliance procedures and mechanisms and, in this regard, some Parties feared that indigenous communities would use the compliance committee to 'bypass' national institutions, while others expressed concern that submissions by indigenous communities will 'flood' the system. ²⁴³ Parties proposed a variety of options to ensure that indigenous communities would in fact be involved in the compliance mechanism. Such options ranged from a community trigger of the procedure, to enabling indigenous community representatives to participate in the compliance committee, either as members or observers.²⁴⁴ In addition, further options involved the possibility of communities submitting information on cases (that have already been opened) directly to the compliance committee, as well as the possibility of the said committee consulting directly with the relevant communities on compliance issues which affect such communities.²⁴⁵

The African Group proposed the creation of an ombudsman, to provide assistance to developing countries and indigenous communities, in identifying instances of non-compliance and making submissions to the compliance committee. ²⁴⁶ Hence the ombudsman would act as an intermediary, addressing implementation challenges between the Party concerned and its relevant indigenous community, with limited international facilitation but without unnecessary interference in domestic affairs. ²⁴⁷ The creation of an ombudsman could be an alternative means to select well-founded community submissions for transmission to the compliance committee, having regard to a proposal being made to the effect that the indigenous communities'

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²⁴² CBD, Report on the Open-ended Ad Hoc Intergovernmental Committee for the Nagoya Protocol on Access to Genetic Resources and the Fair and Equitable Sharing of Benefits Arising from their Utilization, Second Meeting, New Dehli, 2-6 July 2012, UNEP/CBD/ICNP/REC/2/7. Available at https://www.cbd.int/doc/meetings/abs/icnp-02/official/icnp-02-cop-11-06-en.pdf. Accessed on 16th September 2013.

²⁴³ International Institute for Sustainable Development (IISD), (n. 234) at 14.

²⁴⁴ Ibid.

²⁴⁵ *Ibid*.

²⁴⁶ CBD, Recommendations Adopted by the Intergovernmental Committee for the Nagoya Protocol at its Second Meeting, New Dehli, 2-6 July 2012, UNEP/CBD/ICNP/2/1/Rev.1. F (bis).Ombudsman.Available at https://www.cbd.int/recommendation/icnp/?id=13091. Accessed on 16th September 2013.

⁴⁷ International Institute for Sustainable Development (IISD), (n. 234) at 15.

submissions to the compliance committee are only to be permitted once certain screening criteria have been met.²⁴⁸

The role of indigenous communities in the development of the compliance mechanism, as envisaged under Article 30 of the Nagoya Protocol, evokes divergent views between developed and developing countries. The ICNP is accordingly likely to submit a heavily bracketed document to COP-MOP1, which would in effect reflect a lack of agreement on most issues.²⁴⁹ Although the ICNP delegates have laid the groundwork by outlining the main issues of proposing options, COP-MOP1 is where the 'real' negotiations on the contention and compliance mechanism is expected to take place. 250 The difficulty facing Parties will be to find the correct balance between ensuring Parties are satisfied with an international source of guidance and support on implementation, while simultaneously respecting the roles and expertise of indigenous communities.²⁵¹ No easy feat, considering the diverging approaches to the issue.

2.6.12 Publicly Available Traditional Knowledge

During the negotiation of the Nagoya Protocol, the issue of publicly available traditional knowledge resulted in intense and prolonged negotiations with developing countries, led by China and India, arguing that such knowledge was not freely accessible and that the PIC and MAT requirements should therefore apply. ²⁵² They further argued that where traditional knowledge was diffused throughout the country, or there was no identifiable holder of the said knowledge, PIC had to be obtained and MAT established with the relevant Party. 253 Developed countries opposed this argument, with some of them arguing that the State had no role in the

²⁴⁸ *Ibid*.

At the Eleventh Meeting of the Conference of the Parties to the Convention on Biological Diversity, Hyderabad, India, 8-19 October 2012, Decision XI/1 was taken and annexed to this Decision is the current draft text, which is indeed heavily bracketed. See Annex IV Cooperative Procedures and Institutional Mechanisms to Promote Compliance with the Provisions of the Nagoya Protocol and address cases of non-compliance. Available at http://www.cbd.int/doc/decisions/cop-11/full/cop-11-dec-en.pdf.

International Institute for Sustainable Development (IISD), (n. 234) at 15. Note however that at COP11 Parties decided to reconvene the ICNP for a third meeting in order to address outstanding issues relating to, inter alia, the compliance mechanism. Decision XI/1. Available at http://www.cbd.int/doc/decisions/cop-11/full/cop-11-dec-<u>en.pdf</u>.

Ibid.

²⁵² Nijar, GS, 'The Nagoya Protocol on Access and Benefit Sharing of Genetic Resources: An Analysis', in Ceblaw (Centre of Excellence for Biodiversity Law) Brief, 2011 at 28. Availabl http://biogov.uclouvain.be/multistakeholder/presentations/Gurdial-Nijar-NagoyaProtocolAnalysis-CEBLAW- Available at Brief.pdf. Accessed on 16th September 2013. ²⁵³ *Ibid*.

matter, while others argued that this issue fell outside the scope of the CBD, which dealt only with indigenous and local communities. The developing countries countered that this in effect would mean that the traditional knowledge could be accessed for free. The developed countries further relied on the 'public domain' concept²⁵⁵ to argue against the necessity for PIC and MAT. This argument was strenuously rejected by the developing countries, on the basis that such concept could not be relied upon to reverse the obligations imposed on Parties by the provisions in the CBD, relating to access and benefit sharing of traditional knowledge. The developing countries proposed provisions for the Nagoya Protocol, which would deal with two scenarios: the one where the traditional knowledge was not obtained directly from indigenous and local communities, and the other, where the owners of the genetic resource were not identifiable, as the traditional knowledge was passed down from generations ago. These proposed provisions comprised the following:

Article 9.5

Parties shall take appropriate legislative, administrative or policy measures so that users of traditional knowledge associated with genetic resources, whether oral or documented or in other forms, obtained from a source other than directly from indigenous and local communities, to enter into fair and equitable benefit sharing arrangements with the rightful holders of such knowledge as may be determined by the provider Party.

Article 9.5 bis

Where traditional knowledge is held by a Party on behalf of indigenous and local communities and the original holders within these communities cannot be identified, such Parties may take legislative, administrative or policy measures, as appropriate, so that users of such traditional knowledge enter into fair and equitable benefit-sharing arrangements with that Party for the benefit of the local and indigenous communities.²⁵⁸

China, Nepal and India explained at great length that traditional knowledge was held at three levels in their countries: the indigenous and local communities, the individual (such as traditional

²⁵⁴ *Ibid*.

²⁵⁵ The 'public domain' concept shows the existence of prior art to defeat claims of innovation in patent applications. Nijar, GS, *Ibid*.

²⁵⁶ *Ibid*.

²⁵⁷ *Ibid*.

²⁵⁸ *Ibid* at 29.

healers), as well as at national level, in circumstances where such knowledge was not held by indigenous and local communities or the individual or where such knowledge was common to a number of communities. There was therefore a diversity of circumstances under which traditional knowledge was held or owned by indigenous and local communities, as well as at national level. Notwithstanding the above explanations and arguments, the developed countries remained steadfast in their stance in the matter and in the end, all references to the publicly available traditional knowledge were simply eliminated in their entirety from the Nagoya Protocol. ²⁵⁹ This was a major blow for the advancement of the concerns of indigenous communities and all that remains of the issue is recognition in the preamble of the Protocol of 'the diversity of circumstances in which traditional knowledge associated with genetic resources is held or owned by indigenous and local communities'. ²⁶⁰

Although developing countries can still look to the COP-MOP for legal clarity and the establishment of rules governing publicly available traditional knowledge, Nijar highlights that it is unlikely that the developed countries will easily agree to interpretations that run counter to what they have secured in their favor in the first place. The complete omission of reference to publicly available traditional knowledge in the Nagoya Protocol constitutes a critical loss for indigenous communities and any potential beneficial outcome with regards to this issue is likely to involve considerable time and energy. This unfortunately does not bode well for indigenous communities, as it translates to further misappropriation of traditional knowledge, with no benefits accruing to the relevant indigenous communities.

2.7 Concluding Remarks

As discussed under Part 2.5 above, the Nagoya Protocol constitutes a partially negotiated instrument, in respect of which transparency; legal certainty and balance appear to have been sacrificed. ²⁶² The critical demands of provider countries appear to have been substantially watered down in the process of finalizing the Nagoya Protocol. The very general nature of the provisions of the Protocol does, however, offer the necessary flexibility to enable Parties to exercise a variety of options available to them at the crucial implementation stage.

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²⁵⁹ *Ibid*.

²⁶⁰ Preamble, Nagoya Protocol.

²⁶¹ Nijar, GS (n. 252) at 29.

²⁶² Jospeh, RK (n. 10) at 92.

Notwithstanding its drawbacks, the Nagoya Protocol ultimately advances the rights of the indigenous communities holding genetic resources and associated traditional knowledge and encourages stronger involvement by such communities in bioprospecting matters.

<u>Chapter Three: South Africa's approach to the Protection of the Genetic Resources and Associated Traditional Knowledge of Indigenous Communities in the context of Bioprospecting</u>

3.1 Introduction

South Africa is one of the world's most biodiverse countries. It holds the Cape Floristic Region, which is one of the most significant concentrations of plant diversity in the world. With more than thirty thousand species of higher plants and ten percent of the world's known plant species, South Africa is undoubtedly a country abundant in temperate floras. The immense floristic and geological diversity of South Africa supports the rich and diverse invertebrate and vertebrate faunas. South Africa's rich bioresources provide potential for the development of new commercial products and has attracted significant interest from bioprospectors.

However, South Africa's historical lack of bioprospecting legislation resulted in unconstrained access to South Arica's bioresources, which, in turn, resulted in resources being harvested in excessively destructive quantities and being exported for research and development abroad, culminating in off-shore financial benefit. ²⁶⁶ As a result, South Africa, and more especially its indigenous communities, whose traditional knowledge often establishes the leads for commercial companies in bioprospecting matters, have failed to benefit from the commercialization of its genetic resources and associated traditional knowledge. For example, records that date back several years reveal that the genus *Freesia*, which is near-endemic in South Africa, earned the Dutch flower industry almost 300 million rand annually, from the sale of *freesias* alone. ²⁶⁷ Furthermore, revenue of approximately six billion US dollars per annum has been generated from the sales of *Pelargonium* cultivars, derived from South African species, with no associated benefits to South Africa. ²⁶⁸ Due to its significantly rich and unique biodiversity, there are high

²⁶³ Crouch, NR et al (n.27) at 355.

²⁶⁴ Rutert, B et al (n. 25) at 5.

²⁶⁵ Crouch, NR et al (n. 27) at 355.

²⁶⁶ *Ibid*.

²⁶⁷ *Ibid*.

²⁶⁸ *Ibid*.

levels of interest in bioprospecting in South Africa. ²⁶⁹ There is great potential for the development of new medicines, crops, cosmetics and other useful products as a result of South Africa's unusually high genetic diversity. More significantly, South Africa's technological and scientific research capacity, together with its developed infrastructure and institutional capacity, makes it a leader in Africa for bioprospecting development. ²⁷⁰ South Africa is regarded as one of the strongest economies and a driving economic force of the African continent and, with its focus on economic interests and development, the country's rich biodiversity undoubtedly provides a strong means of economic growth. ²⁷¹ In accordance with its obligations as a ratifying Party to the CBD, South Africa has developed a specific regulatory framework addressing ABS, which is established in the National Environmental Management: Biodiversity Act (hereinafter referred to as the 'Biodiversity Act' or 'NEMBA') ²⁷² and the Regulations passed under that Act, known as the Bioprospecting Access and Benefit-Sharing(BABS) Regulations. ²⁷³ Chapter Six of the Biodiversity Act and the BABS Regulations aim to regulate ABS in South Africa and to give effect to the provisions of the CBD.

3.2 Chapter Overview

In this Chapter, the development of South Africa's ABS legislation will be reviewed and a critical analysis of the country's current ABS legislation will be undertaken, with particular regards to the protection South African law affords indigenous communities in respect of their genetic resources and associated traditional knowledge. South Africa's current ABS legislation will be considered in the context of the provisions of the CBD and Nagoya Protocol, with a view to establishing whether such legislation will comply with the country's international obligations regarding the protection of indigenous communities, once the Nagoya Protocol comes into force.

3.3 South Africa's old Access and Benefit Sharing Regime

3.3.1 Lack of bioprospecting legislation

²⁶⁹ Wynberg, R & Taylor, M, 'Finding a Path through the ABS Maze-Challenges of Regulating Access and Benefit-Sharing in South Africa, in Kamau, EC & Winter, G (Eds.), *Genetic Resources, Traditional Knowledge and the Law: Solutions for Access and Benefit Sharing*, Earthscan, London, 2009 at 201.

²⁷¹ Rutert, B et al (n. 25) at 6.

²⁷² Act 10 of 2004.

²⁷³ GN R 138 in Government Gazette 30739 of 8 February 2008.

Historically, as a result of the lack of bioprospecting legislation in South Africa, the commercial development of South Africa's biological resources took place in a 'legislative vacuum'. This resulted in unconstrained access to and commercialization of the genetic resources and associated traditional knowledge of indigenous communities in South Africa, with no benefit accruing to such communities. This situation offered no protection at all to indigenous communities. For example, in the well-known San *Hoodia* case, in which the traditional knowledge about the appetite-suppressing properties of *Hoodia* was used without the consent of the San people, who were the traditional knowledge holders, and which case is discussed in more detail under Chapter Four below, the absence of ABS legislation in South Africa at the time weakened the bargaining position of the indigenous community when negotiating a benefit-sharing agreement (BSA). It was predominantly due to the negative publicity that the BSA was eventually negotiated. Indeed, were it not for the considerable negative media attention, things could have turned out very differently for the *San* people.

3.3.2 South Africa's bioprospecting legislation

The first national policy to prioritize the need for legislative and administrative mechanisms to control access to genetic resources and ensure fair benefit-sharing in South Africa was the 1997 White Paper on the Conservation and Sustainable use of South Africa's Biological Diversity. Several years later in 2004, the Biodiversity Act was promulgated in South Africa, which marked the beginning of a new era for bioprospecting in South Africa. The Biodiversity Act is a framework statute that broadly covers all aspects of biodiversity conservation and use. It contributes to the implementation of the National Environmental Management Act 107 of 1998 (NEMA) and advances the applicable provisions 276 and principles, as set out in NEMA.

Chapter 6 of the Biodiversity Act, which is entitled 'Bioprospecting, Access and Benefit-Sharing', establishes the framework for the regulation of ABS in South Africa. It aims to regulate bioprospecting involving indigenous biological resources (IBRs); regulate the export of

²⁷⁴ *Ibid* at 203.

²⁷⁵ Department of Environmental Affairs and Tourism 'White Paper on the Conservation and Sustainable Use of South Africa's Biological Diversity (1997). Available at www.polity.org.za/polity/govdocs/white papers/diversity.html.

²⁷⁶ Sec. 6(1), NEMBA.

²⁷⁷ Sec. 7, NEMBA.

indigenous biological resources for the purpose of bioprospecting or any other kind of research; and provide for the fair and equitable sharing of benefits by stakeholders from bioprospecting involving indigenous biological resources. 278 Essentially, the Biodiversity Act and BABS Regulations, which were passed under that Act in 2008, comprise the primary legislative means for regulating ABS in South Africa and seek to give effect to the CBD, to which South Africa has been a contracting party since 1995. ²⁷⁹ The Nagoya Protocol, which is yet to come into force, was ratified by South Africa on 10th January 2013.²⁸⁰ It is important to note that not all Parties to the CBD will automatically be Parties to the Nagoya Protocol and in fact the Nagoya Protocol will only be binding on those Parties that, in addition to being a Party to the CBD, have further signed and ratified the Nagova Protocol.

3.3.3 Bioprospecting permits for initial research phase of bioprospecting

Initially the Biodiversity Act required permits to be issued even for the initial research into the potential uses of a biological resource, prior to its commercial value being determined. Accordingly all applicants seeking access to genetic resources in South Africa were required to obtain PIC from the relevant stakeholders and to enter into Benefit-Sharing Agreements (BSAs) with such stakeholders. ²⁸¹ In addition to obtaining PIC and entering into BSAs with stakeholders, the applicant requiring a bioprospecting permit was also required to enter into a Material Transfer Agreement (MTA) with the bioresource provider²⁸² and both the BSA and MTA required approval by the Minister of Environmental Affairs, before the actual bioprospecting permit was issued.²⁸³ BSAs are required to set out the manner and extent to which indigenous biological resources are to be utilized, as well as the manner and extent to which stakeholders will share in the benefits that may arise from bioprospecting. ²⁸⁴ The definition of 'stakeholders' includes an indigenous community which will be providing the indigenous biological resources and/or the traditional knowledge pertaining to such resources.²⁸⁵ Ultimately, the Minister (the

²⁷⁸ Sec. 80, NEMBA.

²⁷⁹ South Africa ratified the CBD on 2nd November 1995. See CBD website: http://www.cbd.int/convention/parties/list/. Accessed on 13th May 2013.

280 CBD website: http://www.cbd.int/abs/nagoya-Protocol/signatories/default.shtml. Accessed on 13th May 2013.

²⁸¹ Sec. 82(2) (b)(ii), NEMBA (now amended).

²⁸² Sec. 82(2)(b)(i),NEMBA (now amended).

²⁸³ Sec. 82(2)(c), NEMBA(now amended).

²⁸⁴ Sec.83(1)(d) and Sec. 83(1) (e), NEMBA.

²⁸⁵ Sec. 82(1)(b), NEMBA.

issuing authority for bioprospecting permits) may only issue a bioprospecting permit after he/she has ensured that the interests of all stakeholders, including indigenous communities, are protected by way of BSAs and MTAs, that PIC has been obtained from the stakeholders and that there has been full disclosure of the proposed bioprospecting to the relevant stakeholders.²⁸⁶

3.3.4 The Problem with South Africa's initial bioprospecting legislation

Hence, previously under South African law even the initial exploratory phase, when the commercial value of biological resources was yet to be determined, required compliance with the stringent requirements set out above, failing which, the research was regarded as illegal and the person undertaking such research guilty of an offence. 287 The problem with this approach is that in the initial research phase of bioprospecting it is impossible to determine the value of benefits, if any, which may result. Nor is it possible to establish, with certainty, the manner and extent to which the bioresources that may be harvested during bioprospecting may eventually be used for commercial gain. The cumbersome nature of South Africa's previous ABS legislative regime resulted in a BSA process fraught with difficulty. 288 In addition to BSAs being difficult to negotiate, it was also a costly exercise and was unnecessarily onerous on applicants undertaking only exploratory research into the potential uses of bioresources, prior to the determination of their commercial value. 289 More significantly, as a result of the Biodiversity Act's aforesaid approach, the Department of Environmental Affairs was flooded with a large volume of permit applications, which it lacked the capacity to process. ²⁹⁰ The Biodiversity Act was therefore subsequently amended to only require bioprospecting permits once the commercial value of the biological resources has been determined. 291 This resulted in an enhancement of the ABS legislation in South Africa. However, the BABS Regulations, with particular regards to Regulation 4(1), ²⁹² are yet to be amended to be brought in line with the Biodiversity Act.

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²⁸⁶ Reg. 8(1)(a)-(d), Chapter 2, BABS.

²⁸⁷ Reg. 20(a)(i), BABS.

²⁸⁸ Crouch *et al* (n. 27) at 359.

²⁸⁹ *Ibid*.

²⁹⁰ Lewis, M (n. 114) at 82.

²⁹¹ Sections 29, 38 and 39 of the National Environmental Laws Amendment Act 14 of 2009.

²⁹² Regulation 4(1) of BABS states that the discovery phase and/or commercialisation phase of a bioprospecting project may only be carried out with a bioprospecting permit issued by the Minister, as the issuing authority.

The Biodiversity Act now distinguishes between the discovery and commercialization phases of bioprospecting, with the discovery phase being defined as that phase of bioprospecting when 'the nature and extent of actual or potential commercial or industrial exploitation in relation to the project is not sufficiently clear or known to begin the process of commercialization'. ²⁹³ The commercialization phase, on the other hand, is defined as the phase in bioprospecting when the nature and extent of actual or potential exploitation 'is sufficiently established to begin the process of commercialization'. ²⁹⁴ Since 1 April 2011, only activities that fall within the commercialization phase of bioprospecting will require a bioprospecting permit, ²⁹⁵ whereas those engaging in the discovery phase of bioprospecting need only notify the Minister of their activities and sign a commitment to subsequently comply with the requirements of the commercialization phase of bioprospecting, when entering this phase. The simplified approach now adopted by South Africa will encourage bioprospecting and the potential for economic growth among indigenous communities.

3.4 A Critical Analysis of South Africa's current Access and Benefit-sharing legislation, in relation to the protection it affords indigenous communities and in the light of the country's international obligations

3.4.1 The definition of 'bioprospecting'

Section 1 of the Biodiversity Act defines 'bioprospecting' as to include 'research on or development or application of, indigenous biological resources for commercial or industrial exploitation'. A distinction is therefore drawn between research that is for commercial purpose and research that is not. 97

²⁹³ Sec. 1, NEMBA.

²⁹⁴ *Ibid*.

²⁹⁵ Sec. 81(1)(a)NEMBA.

²⁹⁶ According to Section 1 of NEMBA, this includes:

⁽a) the systematic search, collection or gathering of such resources or making extractions from such resources for purposes of such research, development or application;

⁽b) the utilization for purposes of such research or development of any information regarding any traditional uses of indigenous biological resources by indigenous communities; or

⁽c) research on, or the application, development or modification of, any such traditional uses, for commercial or industrial exploitation.

²⁹⁷ Under South Africa's bioprospecting legislation, non-commercial research does not require bioprospecting permits and the consent of indigenous communities is consequently not required for such research, nor are they entitled to any benefits therefrom.

3.4.2 Genetic Resources and Derivatives

In contrast to reference to the 'utilization of genetic resources' as set out in both the CBD and the Nagoya Protocol, the Biodiversity Act refers to 'bioprospecting involving indigenous biological resources'. 298 The term 'indigenous biological resources' is defined in the Biodiversity Act to include any derivative of an animal, plant or other organism belonging to an indigenous species.²⁹⁹ Hence the provisions of the Biodiversity Act and the BABS Regulations apply to both the genetic resources, as well as their derivatives. Although the Nagoya Protocol defines the term 'derivative', 300 it does not make express reference to the term in any of its provisions. The CBD defines 'genetic resources' as 'genetic material of actual or potential value' and 'genetic material' is defined as 'any material of plant, animal, microbial or other origin containing functional units of heredity'. 301 As discussed under Chapter Two of this dissertation, the metabolism of genetic material results in derivatives such as gums, resins and latex, and it is usually these secondary metabolites that industry uses to create new products that are commercially valuable. It would appear that the CBD definition of genetic resources was based on traditional bioprospecting activities, involving the screening of biological material for new genes or chemicals which could be incorporated into new drugs. 302 However, this approach fails to recognize that there has been a significant increase in the use of natural products, which would include both genetic resources as well as the derivatives thereof, in industries such as cosmetics, herbal medicines and foods, together with an increase in patenting in these sectors, over the past few decades.³⁰³

South Africa's ABS legislation, which includes provision for derivatives, recognizes and reflects these trends. The Biodiversity Act defines 'indigenous biological resource' (IBR) to include any living or dead organism of an indigenous species, any derivative or genetic material of such organism, or any products obtained, which, through the use of biotechnology, have been altered

²⁹⁸ Lewis, M (n. 114) at 92.

²⁹⁹ Sec.1 and Sec. 80(2)(a), NEMBA.

Article 2, Nagoya Protocol defines a derivative 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'.

³⁰¹ Article 2. Use of Terms, CBD.

³⁰² South Africa's Bioprospecting, Access and Benefit-Sharing Regulatory Framework, Published by Department of Environmental Affairs at p 3. Available at www.environment.gov.za. Accessed on 25 July 2013.

³⁰³ *Ibid*.

with genetic material or chemical compounds found in indigenous species.³⁰⁴ This definition accordingly includes all indigenous species in South Africa, as well as the use of their genes or biochemical compounds. The Biodiversity Act and BABS Regulations accordingly go further than the CBD and Nagoya Protocol and in so doing, expands the protection afforded to indigenous communities.

3.4.3 Bioprospecting Permit Applications

With regards to bioprospecting permit applications, the Minister of Environmental Affairs is the issuing authority for both bioprospecting permits, as well as integrated export and bioprospecting permits. 305 Under the BABS Regulations, bioprospecting and integrated export and bioprospecting permits may only be issued once the Minister is satisfied that the relevant stakeholders have been identified and there has been disclosure of information to the relevant stakeholders. 306 In addition, the Minister must further be satisfied that the applicant has obtained the PIC of the stakeholders involved and has entered into the required MTAs and BSAs with the parties providing or granting access to the IBR. 307 In particular, the Minister is required to satisfy himself/herself that the applicant has obtained the PIC of and entered into BSAs with affected indigenous communities. 308 In order to ensure that these requirements are met, the Minister may require the applicant to show what steps have been taken to identify the stakeholders involved; take further steps to adequately identify stakeholders; provide evidence that the relevant information pertaining to the bioprospecting has been disclosed to the identified stakeholders; and provide evidence that the PIC of the identified stakeholders has been obtained. 309 These BABS provisions presume that bioprospectors will always inform the Minister of the existence of indigenous communities as stakeholders in the application and the question arises as to how indigenous communities are to assert their rights in circumstances where bioprospectors have failed to inform the Minister of the existence of such a community. This potential problem is

³⁰⁴ Sec. 1 and Sec. 80(2)(a), NEMBA.

³⁰⁵ Reg. 6, BABS.

³⁰⁶ Sec. 82 (2)(a), NEMBA and Reg. 8(1)(a) – (b), BABS.

³⁰⁷ Sec. 82(2)(a) & (b), NEMBA and Reg. 8(1)(c)-(d), BABS.

³⁰⁸ Sec. 82(3) (a) and (b) and Reg. 8(1)(d), BABS.

³⁰⁹ Reg. 8(2), BABS.

exacerbated by the lack of a mandatory requirement for bioprospectors to furnish public notice of a bioprospecting application.³¹⁰

A detailed bioprospecting permit application process and requirements are set out in South Africa's Biodiversity Act and BABS Regulations. South Africa provides certainty, clarity and transparency with regards to its ABS legislation and regulatory requirements, and accordingly complies with its international obligations. In this regard, Article 6(3)(a) of the Nagoya Protocol provides that Parties shall take the necessary legislative, administrative or policy measures, as appropriate, to provide for legal certainty, clarity and transparency of their domestic ABS legislation and regulatory requirements.

However, from a practical implementation perspective it is uncertain as to whether issuing authorities will have the capacity to ensure compliance with South Africa's bioprospecting legislation. The South African government has acknowledged that a major implementation challenge of its ABS legislation is the lack of human capacity. 311 Indigenous communities themselves lack capacity and skills in relation to bioprospecting matters and they would ordinarily look to government authorities to provide technical assistance and guidance. Should government lack the capacity to do so, this would invariably negatively prejudice indigenous communities, in the protection of their rights in bioprospecting matters. The challenges in implementing South Africa's ABS legislation, with particular regards to the lack of capacity at government level, is discussed in more detail under Chapter Four of this dissertation.

3.4.4 Benefit-Sharing Agreements

The Biodiversity Act, together with the linked Regulations, describes the content and form of the BSAs and MTAs. 312 The Biodiversity Act provides that the BSA must be in the prescribed format and must specify the following:

(a) The type of the IBRs to which the bioprospecting application relates;

³¹⁰ The African Centre for Biosafety, 'Critical Overview of South Africa's bioprospecting laws' in Biosafety, Biopiracy and Biopolitics Series, Pressprint, 2009. at http://www.acbio.org.za/images/stories/dmdocuments/ACB Bioprospecting Laws.pdf. Accessed on 2nd May 2013. Department of Environmental Affairs and Tourism, Republic of South Africa, 'South Africa's Fourth National Report to the Convention on Biological Diversity' March 2009 http://www.cbd.int/doc/world/za/za-nr-04-en.pdf. Accessed on 12th October 2012. at p.

³¹² Sec. 83 NEMBA and Reg. 17, BABS with Annex. 8 (BSAs) and Sec. 84(1) NEMBA and Reg. 16, BABS read with Annex. 7 (MTAs).

- (b) The area or source from which the IBRs are to be collected or obtained;
- (c) The quantity of IBRs to be collected or obtained;
- (d) Any traditional uses of the IBRs by an indigenous community; and
- (e) The present potential uses of the IBRs. 313

The relevant BSA must also set out the names of the parties involved, the manner in which and the extent to which the IBRs are to be utilized or exploited by the bioprospecting, and the manner and extent to which the stakeholder will share in the benefits arising from bioprospecting, and in addition, the relevant BSA must make provision for the regular review of the BSA by the respective parties, as the bioprospecting progresses.³¹⁴ The BABS Regulations go further and requires that the Minister must be satisfied that the BSA is fair and equitable to all parties concerned, before approving the BSA.³¹⁵ Any BSA or related amendment must be submitted to the Minister for approval and does not take effect unless approved by the Minister.³¹⁶

The Minister has the discretionary power not to approve the BSA unless it makes provision for the enhancement of scientific knowledge and technical capacity of persons, organs of state or indigenous communities to conserve, use and develop IBRs or any other activity that promotes the conservation, sustainable use and development of the relevant IBRs. Annexure 8 of the BABS Regulations sets out the prescribed format of BSAs and this form stipulates that where an indigenous community's representative signs the BSA on behalf of an indigenous community, a Resolution adopted by the said indigenous community must be attached. Such Resolution must confirm that the representative of the indigenous community has been duly authorized to enter into the BSA on behalf of the indigenous community, that the said community has full knowledge of the bioprospecting project and that it accordingly consents to entering into the BSA.

Both the Biodiversity Act and its related Regulations require that all BSAs must be approved by the Minister,³¹⁹ once the Minister is satisfied that the BSA is fair and equitable to all parties. In

³¹³ Sec. 83 (1) (a) and (b), NEMBA.

³¹⁴ Sec. 83(1) (c) to (f), NEMBA.

³¹⁵ Reg. 17(3) (a), BABS.

³¹⁶ Sec. 83(2) (a) & (b), NEMBA.

³¹⁷ Reg. 17(4), BABS.

³¹⁸ Annexure 8, BABS.

³¹⁹ Sec. 82(2)(3) and 82(3)(c), NEMBA and Reg. 11(1)(a), BABS.

coming to this decision, the Minister is authorized to consult any person competent to give technical advice on the agreement and the Minister may further invite public comment thereon, provided that confidential information is not made public. This in effect means that the Minister has the discretion but is not obliged to invite public comment on the BSA being considered for approval. This limitation in South Africa's ABS legislation has the potential to preclude meaningful public comment altogether.

In this regard, on 2 July 2010, the Department of Environmental Affairs published non-confidential information in the *Government Gazette* relating to a draft BSA involving Parcevale (Pty) Ltd, Schwabe Extracta GMBH and CO.KG. and the Imingcangathelo Development Trust.³²¹ The information published was limited to the names of the parties and the following:

- (a) The Imingcangathelo Development Trust intends to cultivate the IBR *Pelargonium* sidoides and *Pelargonium reniforme*, to which the bioprospecting permit application relates;
- (b) The BSA provides for monetary, non-monetary and in-kind benefits to the Imingcangathelo Development Trust;
- (c) The BSA between the respective parties is based on access to the resource and not the use of traditional knowledge.³²²

Accordingly, apart from clarifying that the BSA relates to access to the IBR and not the use of traditional knowledge, the information published is general in nature. As highlighted by the African Centre for Biosafety, it would appear that a watered down version of the BSA has been published and that no information indicating the use of the IBR by indigenous communities or the potential uses of the IBR has been published. Similarly, a draft BSA relating to the bioprospecting permit granted to the Edakeni Community in Kwazulu-Natal and Edakeni Muthi Futhi Trust, for the cultivation, processing and marketing of herbal products containing forty IBRs, which was published for public comment, contained so little detail due to the restriction on the publication of confidential information, that public participation has been largely

³²⁰ Reg. 17(3), BABS.

³²¹ Schwabe Extracta GMBH & Co. KG. Parceval (Pty)Ltd and the Imingcangathelo Development Trust, GN 677 in *Government Gazette* 33348 of 2 July 2010.

The African Centre for Biosafety (n. 310) at 15.

precluded. ³²⁴ This limitation in South Africa's bioprospecting legislation has negative implications for indigenous communities, as due to limited resources, knowledge and capacity, indigenous communities rely largely on NGOs and community-based organizations to assist them in protecting their interests. The discretion afforded to the Minister to invite public comment on BSAs, as well as the restriction on the publication of confidential information, will undoubtedly make the task of NGOs and community-based organizations harder to fulfill and in fact has the potential to render such organizations ineffective in the vital bridging role they play between indigenous communities and bioprospectors. This particular issue and more importantly, the critical role that NGOs and supporting organizations can play during the negotiation of an acceptable benefit-sharing agreement, in relation to indigenous communities, is discussed in greater detail under Chapter Four of this dissertation.

3.4.5 Traditional Use of Genetic Resources

Of significance is that indigenous biological resources may be harvested and sold for traditional use without a bioprospecting permit. This is by virtue of section 86 of the Biodiversity Act, which enables the Minister to make certain exemptions from the bioprospecting provisions of the Act, by way of notice in the *Government Gazette*. In terms of this provision, the Minister published a list of exempted activities in 2008 which includes 'the collection, use, propagation, cultivation or trade of indigenous biological resources for domestic use or subsistence purposes'. As the majority of South Africans rely on traditional medicine as part of their healthcare, it is significant that 'domestic use' is defined to mean the use 'for direct consumption or traditional practices'. Accordingly, the aforesaid exemption allows for indigenous biological resources to be harvested and sold for traditional use without a bioprospecting permit. This is critical from the perspective of indigenous communities, as it recognizes that the majority of indigenous communities rely on traditional medicine as a form of healthcare. In so doing, the traditional cultural practices of indigenous communities are being protected. This approach aligns with Article 12.4 of the Nagoya Protocol, which encourages Parties, in the implementation of the Protocol, not to restrict the customary use and exchange of

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³²⁴ Endakeni Community in Kwazulu-Natal and Edakeni Muthi Futhi Trust, GN133 in Government Gazette 34093, 10 March 2011

³²⁵ GN R149 in Government Gazette 30739 of 8 February 2008.

³²⁶ Lewis, M (n. 114) at 83.

³²⁷ GN R149 in Government Gazette 30739 of 8 February 2008.

genetic resources and associated traditional knowledge, within and among indigenous communities. More importantly, it aligns with Article 10(c) of the CBD which urges Parties to protect and encourage 'customary use of biological resources in accordance with traditional cultural practices'. This Article does, however, go on to state that such traditional cultural practices are to be compatible with conservation or sustainable use requirements. Having regard to an estimated 20,000 tons of plant material being consumed as traditional medicine every year, the traditional use of indigenous biological resources undoubtedly contributes significantly to the rapidly declining medicine plant populations. Although Article 24 of UNDRIP recognizes that indigenous people have the right to their traditional medicines and to maintain their health practices, it further highlights the need for conservation of vital medicinal plants for indigenous people. Accordingly, a balance needs to be struck between the protection of the rights of indigenous communities relating to traditional cultural practices, and conservation and sustainable use requirements.

3.4.6 Bioprospecting Trust Fund

South Africa's bioprospecting legislation makes provision for the establishment of a Bioprospecting Trust Fund, into which all funds arising from BSAs and MTAs and which are due to stakeholders, must be paid. BSA is to be regarded as a trust instrument and the Trust Fund is to be managed in accordance with Treasury Regulations issued in terms of the Public Finance Management Act No. 1 of 1999 and administered by the Director-General (DG) of Treasury, who is responsible for the safekeeping and proper use of all money received. All payments due to or for the benefit of stakeholders are to be paid from this Trust Fund. DG importance to indigenous communities is that the DG is obliged to advise parties to the BSA of any money received in respect of such BSA and the amount due to each stakeholder in terms of the BSA. In addition, the DG must distribute all monies received in accordance with the relevant BSA. More importantly, holders of bioprospecting permits must notify the DG when money due to stakeholders, as specified in the BSA, will be transferred or paid into the Trust

³²⁸ Article 10 (c), CBD.

³²⁹ Lewis, M (n. 114) at 83.

³³⁰ Sec. 85, NEMBA and Reg. 19(1), BABS.

³³¹ Sec. 85(3), NEMBA and Reg. 19, BABS.

³³² Sec. 85(1), NEMBA and Reg. 19(4)(c)-(5) BABS.

³³³ Reg.19(4) (b) (i) & (ii), BABS.

³³⁴ Reg. 19 (4) (c), BABS.

Fund and, in addition, the holders of bioprospecting permits must notify those stakeholders entitled to a monetary benefit in terms of the BSA that the funds were so transferred or paid.³³⁵ These provisions accordingly provide transparency regarding payments being made into the Trust Fund and in so doing, assist with building trust. This is particularly important to indigenous communities in light of the historic misappropriation of their genetic resources and traditional knowledge.

Surplus funds in the Trust Fund may be used for a variety of purposes, including, *inter alia*, to build capacity among indigenous communities with regards to their rights in terms of the Biodiversity Act and to enable them to negotiate benefit-sharing agreements that are fair and equitable. 336 Although this recognition of the necessity for capacity building among indigenous communities is commendable, it is unlikely that there will ever be significant surplus funds in the Trust Fund, due to its current structure, which, at present, comprises no more than a conduit for money due to stakeholders.³³⁷ Hence it is unlikely that indigenous communities will receive benefits from the Trust Fund beyond those to which they are entitled in terms of specific BSAs. Wynberg and Taylor argue that the Biodiversity Act could have ensured that some of the benefits of bioprospecting be distributed to the wider community, by requiring that bioprospecting agreements contribute financially or in-kind to the conservation of the area being accessed; requiring that there be some form of transfer of skills to South African research institutions; or requiring that research results be shared with South African institutions. 338 The Act could also have required that all BSAs incorporate a benefit that advances a national interest or provides that a portion of the financial benefit is to be retained in the Bioprospecting Trust Fund, with the Fund being obliged to distribute the surplus money in accordance with public interest. 339 Such surplus funds could be used specifically to educate indigenous communities on issues pertaining to bioprospecting, thereby building their capacity and knowledge, and in so doing, enhancing their negotiation skills. These measures would benefit indigenous communities in asserting and protecting their rights in bioprospecting matters.

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³³⁵ Reg. 18(1) (a) & (b), BABS.

³³⁶ Reg. 19(6) (c), BABS.

³³⁷ Wynberg, R and Taylor, M (n. 269) at 217.

³³⁸ *Ibid*.

³³⁹ *Ibid*.

Compliance and Monitoring

Notwithstanding South Africa's stringent ABS legislation, it has not proved successful in eliminating biopiracy, particularly with regards to traditional knowledge. The compliance and monitoring provisions of the Nagoya Protocol, as discussed in Chapter Two above, will (once the Protocol enters into force) place obligations on user countries, which will have the effect of harnessing the assistance of user countries in the enforcement of South Africa's ABS legislation, thereby improving the plight of the indigenous communities of South Africa. This is of critical importance especially now that South Africa's ABS legislation only requires bioprospecting permits at the commercialization phase, at which stage the relevant genetic resources may have already been exported to its foreign destination.³⁴⁰

3.4.7.1 Monitoring in User Countries

As the compliance and monitoring provisions created in the Nagoya Protocol are reliant on the existence of provider countries' ABS legislation, South Africa, which already has its own established ABS legislation, is in a position to benefit from the obligations that the Nagova Protocol places on user countries. In this regard, Article 16.1 requires that Parties are to take measures to provide that genetic resources and associated traditional knowledge utilized within their jurisdictions has been accessed with the PIC of indigenous communities and that MATs have been established as required by the domestic access and benefit-sharing legislation or regulatory requirements of the other Party, where such indigenous communities are located. The indigenous communities of South Africa will therefore benefit from the monitoring obligations placed on user countries by the Nagoya Protocol and more particularly from the potential benefit of the establishment of checkpoints to monitor the use of genetic resources. Ultimately, however, the effectiveness of monitoring in user countries will depend largely on the type of checkpoints user countries appoint.³⁴¹

3.4.7.2 Patents Amendment Act No. 20 of 2005

³⁴⁰ Lewis, M (n. 114) at 89. ³⁴¹ *Ibid* at 91.

In its efforts to secure returns from intellectual property rights and to minimize the misappropriation of genetic resources and associated traditional knowledge, South Africa introduced the Patents Amendment Act of 2005. 342 In terms of the provisions of the Patents Amendment Act, applicants for patents are required to furnish a statement to the Registrar of Patents stipulating whether the proposed invention in respect of which protection is being requested, is based on or derived from an indigenous biological resource, genetic resource or traditional knowledge or traditional use. 343 If so, the applicant must provide proof that the relevant authority to make use of the indigenous resource, genetic resource, traditional knowledge or the traditional use was in fact granted.³⁴⁴ Should the applicant lodge a false statement or a representation that is material and which the applicant knew or ought reasonably to have known to be false, that would constitute grounds for the revocation of the patent.³⁴⁵ In addition, if the applicant is found to be aware that the information furnished was false, such applicant may be found guilty of a criminal offence. South African legislation therefore establishes a patent law system that effectively incorporates the county's national ABS requirements, thereby offering enhanced protection to indigenous communities in bioprospecting matters.

3.4.8 South Africa's role as a User Country

South Africa's ABS legislation regulates bioprospecting, export and benefit-sharing in relation to South Africa's indigenous biological resources only. As highlighted by Lewis, the provisions of the Biodiversity Act and its related Regulations relate only to resources that are indigenous to South Africa and fail to acknowledge that all parties to the Nagoya Protocol are required to adopt user measures as well. Hence, South Africa's ABS legislation focuses exclusively on South Africa's role as a provider country and fails to take into consideration its obligations as a user country. Accordingly, South Africa, having ratified the Nagoya Protocol on 10th January 2013, and must now recognize its role as a user country as well and establish legislation to monitor the use of genetic resources within South Africa from other Parties. Such legislation must ensure that

³⁴² Patents Amendment Act, 20 of 2005.

³⁴³ Sec. 30(3A), Patents Act.

³⁴⁴ Sec. 30(3B), Patents Act.

³⁴⁵ Sec. 61(1)(g), Patents Act.

³⁴⁶ Sec. 80(1), NEMBA.

³⁴⁷ Lewis, M (n. 114) at 89.

³⁴⁸ CBD website: http://www.cbd.int/abs/nagoya-Protocol/signatories/default.shtml. Accessed on 13th May 2013.

foreign genetic resources and traditional knowledge utilized in South Africa have been accessed in accordance with the ABS requirements of the provider countries and in addition, provide measures to address non-compliance with both provider country requirements and established MATs. An example to draw from would be the Norwegian law, which provides that genetic material imported for use in Norway, from a State that requires consent for the collection or export of such material, may only take place in accordance with the required consent.³⁴⁹ The Norwegian law further states that the person in control of such genetic material is obliged to comply with the conditions under which the consent was granted and in addition thereto, it entitles Norway to enforce such conditions, by bringing legal action on behalf of the person that set them.³⁵⁰ It is suggested that the development of similar legislation in South Africa could take place by way of amendments to the Biodiversity Act and its related Regulations, as Sec. 2 (b) of the Biodiversity Act stipulates that an objective of the Biodiversity Act is to 'give effect to ratified international agreements relating to biodiversity which are binding on the Republic'.³⁵¹

South Africa's Patent Act could be used to create a checkpoint to monitor compliance, as required by Article 17 of the Nagoya Protocol. In this regard, an amendment to the Patents Act, so as to extend its existing provisions to cover inventions based on or derived from foreign genetic resources would be necessary. In addition thereto, the Patents Act can be further enhanced to allow for internationally recognized certificates of compliance, as provided for in the Nagoya Protocol, to be presented as proof that an applicant has the relevant authority to make use of the indigenous biological resource or traditional knowledge related thereto. Such measures are necessary to protect the rights of indigenous communities beyond the jurisdiction of South Africa.

3.4.9 Customary Law and Community Protocols

South Africa's ABS legislation presents some critical challenges, with particular regards to the implementation thereof, in the context of indigenous communities. The identification of the relevant authorities within indigenous communities and the negotiation of BSAs, together with

³⁴⁹ Sec. 60, Nature Diversity Act No. 100 of 2009.

³⁵⁰ *Ibid*.

³⁵¹ Lewis, M (n. 114) at 89.

³⁵² *Ibid* at 89-90.

the linked PIC requirement, are some of the complex and cumbersome implementation challenges facing South Africa. These challenges will be discussed in greater detail under Chapter Four of this dissertation. In the light of the implementation challenges and complexities facing indigenous communities, in the context of bioprospecting, it is therefore critical for indigenous communities to become organized and empowered in order to assert and secure their rights. As discussed under Chapter Two, Article 12.1 of the Nagoya Protocol encourages Parties to take into consideration the customary laws, Community Protocols and procedures of indigenous communities, in the implementation of their obligations under the Protocol. Although the provisions of Article 12 are weak in that the Article contains various caveats, which in fact give Parties significant discretion regarding the extent to which they will recognize the customary laws and Community Protocols of indigenous communities, Article 12 of the Nagoya Protocol nevertheless remains a major milestone in the advancement of the rights of indigenous communities in bioprospecting-related matters.

It will be argued under Chapter Five of this dissertation that the development of Community Protocols, setting out procedures regarding applications for access to genetic resources and traditional knowledge and identifying the relevant authorities within indigenous communities entitled make decisions on PIC and negotiate BSAs, invariably provides the basis of building functional interfaces between indigenous communities, bioprospectors and government. Such Protocols can facilitate the empowerment of indigenous communities, as well as provide clarity to bioprospectors, in ABS matters. In so doing, Community Protocols can be a vital tool in overcoming the challenges facing South Africa in the implementation of its ABS legislation, particularly in the context of indigenous communities. South Africa's ABS legislation unfortunately fails to acknowledge the role that Community Protocols can play in diminishing the implementation challenges that its ABS legislation presents. Although South Africa's ABS legislation makes no provision for Community Protocols, it's Bioprospecting Guidelines for Providers, Users and Regulators³⁵³ have recognized that such Protocols can assist in ensuring that the indigenous community resolution, as required under Annexure 8 of the BABS

³⁵³ Department of Environmental Affairs, 'South Africa's Bioprospecting, Access and Benefit-Sharing Regulatory Framework: Guidelines for Providers, Users and Regulators' July 2012 at 21. Available at https://www.environment.gov.za/sites/default/files/legislations/bioprospecting regulatory framework guideline.pdf Accessed on 16th June 2013. These Guidelines have been developed with a view to promoting and facilitating practical implementation of the ABS legislation in South Africa.

Regulations, is not an impromptu decision but is instead a decision based on good community process. ³⁵⁴ More significantly, South Africa's Bioprospecting Guidelines recognize that Community Protocols will provide government with a clear way of verifying the integrity of the community resolution obtained and in addition, will provide potential bioprospectors with well-defined steps to follow, when engaging with indigenous communities. ³⁵⁵ Accordingly, Community Protocols have been identified as a crucial implementation tool that can assist indigenous communities in the protection of their rights, in relation to bioprospecting matters. It is a pity then that this approach is not entrenched in South African ABS legislation. There is clearly a need for South Africa to recognize Community Protocols in the implementation of its national ABS legislation and it is accordingly proposed that South Africa's ABS legislation be amended to reflect this position, as is recommended by the Nagoya Protocol.

3.5 Concluding Remarks

South Africa's ABS legislation predominantly aligns itself with the provisions of the CBD and Nagoya Protocol, in that it enshrines the principles of PIC, MAT and BSAs and acknowledges the collective rights of indigenous communities to benefit from the use of genetic resources and associated traditional knowledge. In addition, South African legislation has a patent law system that effectively incorporates the national ABS requirements, thereby offering a vital protection in the compliance therewith. However, as discussed above, the Biodiversity Act and its related Regulations exclusively reflect the provider obligations of the Nagoya Protocol and fail to recognize South Africa's role as a user of genetic resources. South Africa must therefore prioritize the development of its ABS laws to incorporate the user measures and obligations that the Nagoya Protocol requires. More importantly, South Africa must amend its ABS legislation to recognize the role of Community Protocols in the implementation of the provisions of its ABS legislation, so as to enhance the protection afforded to indigenous communities, in bioprospecting-related matters.

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³⁵⁴ *Ibid* at p 21.

³⁵⁵ *Ibid*.

<u>Chapter Four: Challenges in Implementing South Africa's Access and Benefit Sharing</u> <u>Legislation, in the context of Indigenous Communities</u>

4.1 Introduction

Although the South African ABS legislation complies with many of the requirements of the Nagoya Protocol, in that it, *inter alia*, establishes a permitting process and provides potential bioprospectors with clarity as to the process for obtaining access to indigenous biological resources within South Africa, South Africa's ABS legislation presents some critical challenges, with particular regards to the implementation thereof, in the context of indigenous communities.

4.2 Chapter Overview

This Chapter will highlight the major challenges facing South Africa in the implementation of its ABS legislation, insofar as indigenous communities are concerned. The lack of capacity, on the part of both government and indigenous communities, to deal with ABS matters and the need for the development thereof will be discussed. In addition, the challenges presented by the vesting of ownership of genetic resources in landowners and not the State will be explored and suggestions proposed to meet such challenges. The difficulties surrounding the identification of stakeholders will be highlighted and the complexities involved in obtaining PIC from, and negotiating BSAs with, indigenous communities will be analyzed. Furthermore, the challenges that transboundary genetic resources and traditional knowledge present will be discussed and suggestions made to overcome such challenges. The critical role of NGOs and supporting organizations in assisting indigenous communities to assert their rights in bioprospecting matters, together with the legislative challenges that such organizations are faced with in doing so, will be assessed with a view to providing solutions to the difficulties involved. It will be shown that, ultimately, the building of capacity on all fronts will be required in order to provide effective protection to indigenous communities, in the context of bioprospecting.

4.3 Capacity Development

Major challenges in implementing South Africa's ABS legislation include insufficient capacity, political will and a lack of awareness regarding the rights, roles and responsibilities of the various interest groups and constituencies.³⁵⁶

4.3.1 Lack of Capacity at National Level

Capacity building is critical, particularly within the national Department of Environmental Affairs, where capacity is required to be developed to ensure greater leadership and strategic direction, to provide essential information and to provide technical assistance to provincial government departments, researchers and communities. The complexity of issues surrounding ABS, the expertise required to deal with such issues is difficult to attain. Wynberg and Taylor thus suggest that it will be necessary to consider the employment of individuals with the necessary scientific, and commercial expertise; or, alternatively, to consider obtaining independent technical advice in order to ensure that decisions are being made on an informative basis. Although an expert ABS task team has recently been established to advise the national department with regards to the implementation of ABS Regulations, the confinement of such task team to government representatives fails to recognize and reflect the diversity of stakeholders involved in bioprospecting, with particular regards to indigenous communities. The surface of the stakeholders involved in bioprospecting, with particular regards to indigenous communities.

4.3.2 The need for Capacity Building at Provincial Level

The provincial departments of environmental affairs are also in dire need of capacity building in order that they may be educated on the implications of ABS legislation and on their roles and responsibilities, including with respect to indigenous communities affected by the ABS regulations. Wynberg and Taylor suggest that such capacity development could include the compilation of a package of materials aimed specifically towards the interests and rights of the various user groups, which can be translated and simplified where necessary. ³⁶⁰ Due to the permitting requirements and processes embodied in the Biodiversity Act, information

³⁵⁶ Wynberg, R & Taylor, M (n. 269) at 220.

³⁵⁷ *Ibid*.

³⁵⁸ *Ibid*.

³⁵⁹ *Ibid*.

³⁶⁰ *Ibid* at 221.

management remains a critical part of implementation. In this regard, Wynberg and Taylor recommend a single electronic database for permit applications, which would include information about the permit application, its status, as well as the existing permits which have already been granted.³⁶¹

4.3.3 Lack of Human Capacity

The South African government has acknowledged that a major implementation challenge of its ABS legislation is the lack of human capacity. ³⁶² It has been confirmed that notwithstanding a Human Capital Development Strategy being developed to address the shortage of skills, the reality is that there remains an inadequate number of skilled individuals to undertake the work and expertise required. ³⁶³ It has further been recognized that the lack of capacity negatively impacts on enforcement and monitoring and that additional resources, capacity and innovation are accordingly required to effectively counter these implementation challenges. ³⁶⁴ It is hoped that with the amendments to the Biodiversity Act, the number of bioprospecting permits required to be processed would have reduced substantially, thereby lessening the burden on the Department of Environmental Affairs and limiting the lack of human capacity as an implementation challenge in South Africa's ABS legislation.

4.3.4 South Africa's Bioprospecting, Access and Benefit-Sharing Regulatory Framework: Guidelines for Providers, Users and Regulators

Having regard to the above, the Department of Environmental Affairs has been concerned with capacity building and raising awareness of South Africa's ABS regulatory requirements, and it has now been recognized that additional implementation tools are required to encourage stakeholders in ensuring the fair and equitable negotiation and conclusion of BSAs and MTAs. In this regard, the Department has developed South Africa's Bioprospecting, Access and Benefit-Sharing Regulatory Framework: Guidelines for Providers, Users and Regulators (South Africa's

³⁶¹ *Ibid*.

³⁶² Department of Environmental Affairs and Tourism, Republic of South Africa, 'South Africa's Fourth National Report to the Convention on Biological Diversity' March 2009 at x. Available at http://www.cbd.int/doc/world/za/za-nr-04-en.pdf. Accessed on 12/10/12.

³⁶³ *Ibid*.

³⁶⁴ *Ibid* at xii.

³⁶⁵ Department of Environmental Affairs, 'South Africa's Bioprospecting, Access and Benefit-Sharing Regulatory Framework: Guidelines for Providers, Users and Regulators' July 2012 (n. 353) at vi.

Bioprospecting Guidelines), with a view to promoting and facilitating practical implementation of the ABS legislation. 366 These Guidelines outline a practical approach for compliance with the said legislation, for providers, users and regulators, and they endeavor to assist the various stakeholders in understanding the legal requirements and their rights in terms of South Africa's ABS legislation. South Africa's Bioprospecting Guidelines aim to enhance awareness of the principles and concepts pertaining to ABS and to provide direction in negotiating, concluding and evaluating BSAs and MTAs. Such Guidelines have been heralded as a tool to assist indigenous communities in enabling access to their genetic resources and associated traditional knowledge. 367 Although the Guidelines are simple, user-friendly and offer practical guidance to indigenous communities, they should ideally be translated into the various indigenous languages, so as to provide a more effective tool for indigenous communities in bioprospecting matters. In addition, the Guidelines need to be made more accessible to indigenous communities and one of the ways in which this can be achieved is by making simple, user-friendly and translated Guidelines available, in pamphlet form, at the various rural Community Centers and Local Government offices. Having regard to the lack of capacity and skill on the part of indigenous communities, government needs to adopt a more pro-active approach in their efforts to build the capacity and skill of indigenous communities to a level that empowers them with understanding their rights in the context of bioprospecting. This would inevitably enable indigenous communities to negotiate more favorable BSAs.

4.4 **Vesting of Ownership of Genetic Resources**

Central to the challenge of implementation is that the Biodiversity Act does not vest ownership of indigenous biological resources in the State, and this has the effect that the State has no right to benefit in bioprospecting, unless the collection of such resources takes place on State land. Similar to ABS legislation in other provider countries, South Africa's ABS legislation relies on the property rights relating to the physical aspect of the resource to define its legal status.³⁶⁸ Hence the landowner in South Africa owns both the biological and genetic resources on or under

³⁶⁶ *Ibid*.

³⁶⁷ Statement by the Department of Environmental Affairs on Bioprospecting Permits and Guidelines, 27 July 2012. http://www.polity.org.za/article/sa-statement-by-the-department-of-environmental-affairs-on-bioprospecting-permits-and-guidelines-27072012-2012-07-27. Accessed on 26th October 2012. 368 Crouch, N.R *et al.*, (n. 27) at 357.

his/her property. ³⁶⁹ Accordingly, indigenous communities that own the land which they occupy invariably own the genetic resources on the land. As discussed under Chapter Two of this dissertation, Articles 5.2 and 6.2 of the Nagoya Protocol, which relate to access to genetic resources of indigenous communities and the fair and equitable sharing of benefits derived therefrom, apply only when indigenous communities have established rights in respect of such genetic resources, under national law. Having regard to South Africa's approach that landowners own the genetic resources on or under their property, indigenous communities that are landowners accordingly have established rights to genetic resources under national law. Chapter Three of this dissertation highlights that both PIC and BSAs are provided for under South Africa's ABS legislation, with particular regards to indigenous communities. South Africa accordingly complies with the recommendations of the Nagoya Protocol, that Parties take appropriate measures to ensure that PIC is obtained from indigenous communities for access to their genetic resources and that there is fair and equitable sharing of benefits derived therefrom, where indigenous communities have established rights in respect of such resources. Although there may be certain benefits in recognizing the rights of indigenous communities over genetic resources, communal ownership of genetic resources is not without its complications.

4.4.1 Common Law of Land Ownership

When drafting South Africa's ABS legislation, legislators were reluctant to vest ownership of genetic resources in the State due to concern that this may result in an infringement of constitutionally protected property rights. ³⁷⁰ Under South African common law, everything beneath ³⁷¹ and above ³⁷² the land is deemed to be owned by the registered landowner. Hence, legislators feared that to vest ownership of genetic resources in the State may amount to a deprivation of landowner's rights to the use and disposal of such resources. ³⁷³ The South African Constitution ³⁷⁴ provides that no landowner may be deprived of property unless in terms of a law

³⁶⁹ *Ibid*.

³⁷⁰ Wynberg, R & Taylor, M (n. 269) at 210.

³⁷¹ Struben v. Cape Town District Waterworks Co. 1892 (9) SC 68; London and SA Exploration Co. v. Rouliot 1891 (8) SC 74 90; Union Government (Minister of Railways and Harbors) v. Marais 1920 AD 246.

³⁷² Louw v. Watermeyer Trustee of Mostert 1857 (4) EDC 381; Barnett v. Rudman 1934 AD 203; Secretary for Lands v. Jerome 1922 AD 103.

³⁷³ Wynberg, R & Taylor, M (n. 269) at 210.

³⁷⁴ Constitution of the Republic of South Africa, 1996.

of general application and, in addition thereto, no law may permit the arbitrary deprivation of property.³⁷⁵

Wynberg and Taylor argue that the common law concept of land ownership was developed long before any understanding regarding genetic resources and that therefore a strong case can be made that such common law concept of land ownership is outdated and erroneous, particularly in the context of genetic resources.³⁷⁶ They go on to argue that even if the common law concept of ownership over the biological resources on one's land includes the genetic components of such resources, the common law can be changed by legislation, provided that this legislation does not contradict the Constitution.³⁷⁷ Wynberg and Taylor propose that legislation vesting ownership of genetic resources in the State will not contradict the provisions of the Constitution, due to the following:

- Genetic resources are intangible and information-based in nature and are common to those resources where they are found. They are therefore not unique to the resources on a particular land owner's property;
- b) It is reasonable to distinguish between physical organisms and the genetic material contained in those organisms and this distinction provides sufficient basis in law to restrict landowners' property rights to genetic material, while permitting the enjoyment of their property rights over the physical organisms located on their land;
- c) Although the above distinction may result in the deprivation of landowners' right to use the resources, dispose of the resources and refuse access to such resources, the deprivation will be justified if contained in legislation applicable to everyone.³⁷⁸

4.4.2 Potential to Marginalize Indigenous Communities

Hence, with regards to genetic resources, there may be a justifiable basis for the distinction between the rights over the physical property and the genetic information that the resources contain. This is particularly relevant in respect of communal land ownership and related traditional cultural based concepts of control. Not all cases of ownership will be straight-forward

³⁷⁵ Sec. 25(1), Constitution.

³⁷⁶ Wynberg, R & Taylor, M (n. 269) at 210-211.

³⁷⁷ *Ibid* at 211.

³⁷⁸ *Ibid*.

and it would be essential that users and providers share a common understanding of the precise nature of the rights being granted in terms of the ABS agreement, so as to avoid user uncertainty. When South African bioresources are exported for bioprospecting purposes, users will need to determine and legally acknowledge the differences between the owners of the land on which the genetic resource is located, the owner of the biological resource and the owner of the genetic resource. The current South African ABS legislation relating to the vesting of ownership in genetic resources has the potential to marginalize communal land-owners, as users will be more inclined to seek out resource owners whose ownership status is more clear-cut. This is particularly so in the light of the fact that land ownership in South Africa is characterized by a broad division between western and customary notions of land ownership. 379

4.4.3 Customary Land Tenure

While most state land and white commercial agricultural land is held under freehold, land comprising 13% of the country is held under customary tenure.³⁸⁰ Customary tenure comprises various forms and is governed by various statutes in South Africa.³⁸¹ As a result of the past racially discriminatory laws, African people and invariably indigenous communities were dispossessed of their land and given insecure tenure over the land to which they were entitled. With the advent of democracy in South Africa, the South African Constitution seeks to reverse

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³⁸⁰ Wynberg, R, 'South African legislative Case Study' in Lewis-Lettington, RJ & Mwanyiki, S (Eds.), *Case Studies on Access and Benefit-Sharing*, International Plant Genetic Resource Institute, Rome, Italy, 2006. 129 at 130.

³⁸¹ The Black Land Act 27 of 1913 and the Native Trust and Land Act 21 of 1923 (now known as the Development Trust and Land Act No. 18 of 1936) were the key statutes that determined where indigenous communities could live in South Africa. The Black Land Act contained a schedule setting out the areas in which only African people could purchase, hire or occupy land. The Development Trust and Land Act was enacted to make provision for the establishment of the South African Native Trust (the Trust) and the release of more land for occupation by Africans. The Act stipulated all land which was reserved or set aside for occupation by 'natives' only and the Act further stipulated that land within the scheduled 'native areas' and 'released areas' vested in the Trust (Section 6). The land was for the exclusive use and benefit of 'natives' (Section 18(1)) and the Trustee (being the Governor-General at the time) had the power to grant, sell, lease or otherwise dispose of land to 'natives' on such conditions as he/she deemed fit (Section 18 (2)). The Governor-General had the power to make regulations dictating the conditions on which 'natives' may purchase, hire or occupy land held by the Trust (Section 48(1)(g)) and the conditions under which African people could lawfully purchase, hire or occupy land held by the Trust were dealt with comprehensively under the Bantu Areas Land Regulations (Proclamation R188 GG 2486, 11 July 1969, made in terms of Section 25(1) of the Black Administration Act 38 of 1927, read together with Section 21 (1) and Section 48(1) of the Development Trust and Land Act) and Township Regulations (Proclamation R293 GG 373, 16 November 1962, made in terms of Section 6(2) and 25(1) of the Black Administration Act 38 of 1927, read together with Section 21 of the Development Trust and Land Act). The Bantu Areas Land Regulations recognized quitrent tenure (Chapter 4) as well as tenure pertaining to the occupation of land under permission to occupy (Chapter 5). Although defined to mean a 'title deed relating to land', quitrent tenure did not confer full ownership on the holder and was subject to strict conditions and restrictions prescribed in the Regulations.

this and accordingly entitles communities whose tenure of land is legally insecure as a result of past racially discriminatory laws and practices, to tenure which is now legally secure. 382 The Communal Land Rights Act No. 11 of 2004 was enacted in order to provide legally secure tenure and to compensate communities whose land tenure was legally insecure due to the racist policies of apartheid. 383 The Communal Land Rights Act was however declared unconstitutional and there remains uncertainty regarding the land rights of indigenous communities. 384

While statutes³⁸⁵ are in place in South Africa in respect of both land held under freehold and customary tenure by indigenous communities, in communal areas, customary law also has application.³⁸⁶ Hence the land system applicable in communal areas is not well-understood by western society and is best implemented by the communities living in the area. 387 Of significance is that in communal areas, customary laws form an essential component of the practice of natural resource use. This will naturally make it more difficult for potential users in bioprospecting matters to establish the resource owners that are required to furnish the necessary PIC and this could result in bioprospectors being more inclined to seek out resource owners whose ownership is well-defined. This has negative connotations not only for indigenous communities, but for South Africa as a whole. The amending of the Biodiversity Act to vest ownership of genetic resources in the State has the potential to remedy this situation.

However, if ownership of all genetic resources in South Africa were to vest in the State, the ultimate decision on whether to allow access to such resources would also vest in the State. While having the benefit of simplifying access procedures, this could also have the effect of overlooking the interests of indigenous communities when genetic resources are being harvested from communal land. It is therefore suggested that any amendment to the Biodiversity Act, vesting ownership of genetic resources in the State, must still provide for the PIC of the relevant

³⁸² Section 25(6), Constitution of South Africa, 1996.

³⁸³ Constitutional Court judgement in Tongoane and Others v Minister for Agriculture and Land Affairs and Others 2010 (6) SA 214 (CC) at Paragraph 80.

³⁸⁴ Ibid and Du Plessis, WJ, 'African Indigenous Land Rights in a Private Ownership Paradigm' in PER (14) 7, 2011, 45 at 46.

Under the Apartheid government, various laws were issued in order to segregate the various groups of colour in South Arica. These comprised the so-called 'Land Acts'. There were approximately seventeen thousand statutory measures to control the division of land, with fourteen different land control systems in place in South Africa, by the time South Africa attained democracy. Du Plessis WJ (n. 384) at 45.

³⁸⁶ Constitutional Court judgement in Tongoane and Others v Minister for Agriculture and Land Affairs and Others 2010 (6) SA 214 (CC) at Paragraph 85. Wynberg, R (n. 380) at 130.

indigenous community, as well as the distribution of benefits to such indigenous community in circumstances where the genetic resources are being harvested from communal land. An example can be found in the ABS legislation of Costa Rica, where although the State is the owner of the genetic resources, the basic requirement for access obliges bioprospectors to obtain the PIC of the representatives of indigenous communities, for bioprospecting activities that fall within territories that are communally owned, and to ensure the equitable distribution of benefits derived therefrom.³⁸⁸

4.5 **Identifying the Stakeholders**

One of the primary goals of the Biodiversity White Paper³⁸⁹ was to ensure that national interests were served by the use and development of South Africa's genetic resources. However, this was largely unrealized as the approach of the Biodiversity Act is to ensure that benefits arising out of bioprospecting go to stakeholders.

4.5.1 Definition of Stakeholders

Stakeholders are defined as

- a person, including any organ of state or community, providing or giving access to the (a) indigenous biological resources to which the application relates; and
- an indigenous community -(b)
- i) whose traditional uses of the indigenous biological resources to which the application relates have initiated or will contribute to or form part of the proposed bioprospecting; or
- whose knowledge of or discoveries about the indigenous biological resources to which ii) the application relates are to be used for the proposed bioprospecting.³⁹⁰

No definition of 'indigenous community' is provided for in the Biodiversity Act, however a definition is furnished in the Regulations. Regulation 1 defines 'indigenous community' as

³⁸⁸ Aquilar, G, 'Access to Genetic Resources and the Protection of Traditional Knowledge in the Territories of Indigenous Peoples' in Environmental Science Policy 4 241, 2001, 47 at 48.

³⁸⁹ Department of Environmental Affairs and Tourism 'White Paper on the Conservation and Sustainable Use of South Africa's Biological Diversity (1997) (n. 275). ³⁹⁰ Sec. 82(1)(a) &(b), NEMBA.

any community of people living or having rights or interests in a distinct geographical area within the Republic of South Africa with a leadership structure and –

- whose traditional uses of the indigenous biological resources to which an application for a) a permit relates, have initiated or will contribute to or form part of the proposed bioprospecting; or
- b) whose knowledge of or discoveries about the indigenous biological resources to which an application for a permit relates are to be used for the proposed bioprospecting.

The Regulations fail to substantiate what constitutes the required 'leadership structure' of the indigenous community, which would have assisted in the unambiguous identification of the appropriate indigenous community with traditional knowledge, that qualifies to enter into BSAs. 391 This may be as a result of the public consultation process held prior to the drafting of the Regulations, where it became apparent that applicants may have great difficulty in identifying the relevant indigenous communities, in certain cases.³⁹²

4.5.2 Complexities involved in Identifying Traditional Knowledge Holders

In order to negotiate a BSA involving traditional knowledge, applicants will need to first establish whether the traditional knowledge holders are identifiable, organized, coherent and able to enter into negotiations. Regulation 8 (2)(a) of the BABS Regulations simply requires applicants to show what steps have been taken to identify indigenous communities. It provides no guidance as to the steps to be taken. There are numerous complexities that arise when endeavoring to identify traditional knowledge holders. Questions arise as to whether the knowledge vests in a small sector of the indigenous community, for example, among the traditional healers or a particular family within the community, and whether the community as a whole should benefit or whether just the small sector within the community should benefit from any ABS relationship. 393

³⁹¹ Crouch, et al (n. 27) at 360.

³⁹² Wynberg, R and Taylor, M (n. 269) at 217.

³⁹³ Wynberg, R, Chennells, R & Schroeder, D, 'Conclusions and Recommendations: Towards Best Practice for Community Consent and Benefit Sharing' in Wynberg, R (Ed) in *Indigenous Peoples, Consent and Benefit-Sharing*: Lessons from the San Hoodia Case, Springer Scientific Business Media B.V. 2009 at 341.

Further difficulties arise when the traditional knowledge is held by various indigenous communities and the question arises as to whether the applicant for a bioprospecting permit is obliged to obtain PIC from all of these communities. This is common in South Africa, where traditional knowledge is often shared by different ethnic groups. ³⁹⁴ In the San *Hoodia* case, which is discussed in more detail under Part 4.7 below, there was evidence that the *Hoodia* species was not only used by the San but also by a range of other indigenous communities, including the Nama, Damara and Topnaar, as a medicinal remedy and as a food and water substitute. ³⁹⁵ Negotiating a BSA with various communities will require several costly meetings with large community groups at differing geographical locations, which may be a distance away from each other. The BSA must be accompanied by Resolutions from the various indigenous communities to the effect that they have identified the representative/s authorized to enter into a BSA on their behalf, that they have full knowledge of the proposed project, and that they provide their recorded consent. ³⁹⁶

Problems also arise where the traditional knowledge straddles political boundaries.³⁹⁷ A situation may arise where some communities are prepared to grant PIC, while others are not; and some communities may remain unaware of the ABS application, notwithstanding the best efforts of applicants.³⁹⁸ There is also the possibility that additional stakeholders may emerge subsequent to a BSA being finalized and a bioprospecting permit being issued. Ideally, harmonized ABS legislation with adjacent countries, will resolve these potential problems. The issue of transboundary genetic resources and traditional knowledge will be discussed in more detail under Part 4.8 below.

Further complexities arise if a community is continually changing and is not formally organized. The definition of 'community' in the South African context is complex and evolving and has been the subject of a number of legal cases which have emphasized the importance of looking at customary and living law and practices that define community membership, including shared rules that determine access to, use of, or benefits from a resource or property right held in

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³⁹⁴ Crouch *et al* (n. 27) at 362.

³⁹⁵ Wynberg, R, 'Rhetoric, Realism and Benefit-Sharing: Use of Traditional Knowledge of Hoodia species in the Development of an Appetite Suppressant' in *Journal of World Intellectual Property*, 7(6), 2004, 851 at 852.

³⁹⁶ Annexure 8, 4.4, BABS.

Wynberg, R, Chennells, R & Schroeder, D, (n. 393) at 341.

³⁹⁸ Crouch *et al* (n. 27) at 363.

common by the group. ³⁹⁹ The definition in the BABS Regulations must be understood broadly in line with this developing jurisprudence. The determination of a representative under such circumstances will be fraught with difficulties. As South African ABS legislation provides no guidance as to what constitutes a 'leadership structure' among indigenous communities, it can be presumed that the responsibility for determining whether an indigenous community has an acceptable 'leadership structure' should default to the Minister to make a decision in this regard. ⁴⁰⁰

4.5.3 Impact on South Africa's economy

The difficulty in identifying traditional knowledge holders may have contributed significantly to the reported reduction in bioprospecting activities in several large South African pharmaceutical companies. Holder This is due to companies not wanting to take the risk of legal conflicts over IPR ownership and negative publicity linked to perceived biopiracy. For example, in the *Hoodia* case, which is discussed in more detail under Part 4.7 below and which occurred prior to any ABS legislation being implemented in South Africa, it was indeed the negative publicity which led to a BSA being finalized so speedily. A British newspaper, 'The Observer', published a leading story about the case, which heightened interest in the involvement of traditional knowledge and indigenous communities in ABS matters; and pressurized the Council for Scientific and Industrial Research (CSIR) to enter into high-level negotiations with the San and to finalize a BSA with them. Holder the significant in the second significant significant in the second significant significant significant significant significant signifi

Companies often adopt a hands-off approach to the use of traditional knowledge; undoubtedly due, in part, to the problems of identifying the true holders or owners of traditional knowledge. An emerging economy, such as South Africa, cannot afford to restrict its bioprospecting potential and Wynberg *et al* thus suggest that principles should be developed in collaboration

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³⁹⁹ High Court and Constitutional Court judgements in Tongoane and Others v Minister for Agriculture and Land Affairs and Others. 2010 (8) BCLR 838 (GNP) and 2010 (6) SA 214 (CC); 2010(8) BCLR 741 (CC). The High Court recognised 'the layered nature' of communal rights in customary systems, including those existing at family, clan, village and group levels. A definition of community must incorporate smaller or independent communities living within the boundaries of larger communities that may have been given substance and form partly through apartheid legislation. Paragraphs 29 and 31.

⁴⁰⁰ Crouch *et al* (n. 27) at 363.

⁴⁰¹ *Ibid*.

⁴⁰² Wynberg, R & Chennells, R, 'Green Diamonds of the South: An Overview of the San-Hoodia Case in Wynberg, R *et al.* (Eds), *Indigenous Peoples, Consent and Benefit-Sharing: Lessons from the San Hoodia Case*, Springer Science & Business Media B.V. 2009, 89 at 101.

with indigenous communities, to provide guidance on the process of identifying the correct stakeholder. 403 Traditional knowledge holders should be identified by processes that are incremental and socially astute, and clear roles and responsibilities should be developed for indigenous communities. Government needs to establish simple and clear information channels with a view to guiding bioprospectors on how to go about identifying the correct stakeholders. An attempt in this regard is made in South Africa's Bioprospecting Guidelines, which sets out practical measures that can be adopted in identifying traditional knowledge holders. The proposed measures include publication of a notice in the media, calling for any person or group with traditional knowledge about the resource to come forward; approaching the local municipality for direction to the relevant traditional knowledge holders; and, in circumstances where the traditional knowledge is held widely by various indigenous communities and it is difficult to identify the traditional knowledge holders, it is recommended that the Department of Environmental Affairs is approached for assistance and advice. 404 Although these are practical suggestions, ideally, the creation of a directory of indigenous communities and their appointed representatives would simplify the process for bioprospecting applicants, thereby encouraging bioprospecting and in so doing, enhancing South Africa's emerging economy.

4.6 Obtaining Prior Informed Consent

The negotiation of BSAs with their linked PIC requirement has proven to be one of the most complex and cumbersome aspects for an applicant of a bioprospecting permit, particularly in so far as indigenous communities are involved. Although the South African ABS Regulations require that PIC be obtained from every stakeholder, they fail to elaborate on the preferred means of engaging with indigenous communities, in order to obtain such PIC. The Regulations merely stipulate that the applicant must show that it has obtained PIC of affected indigenous communities and that BSAs have been entered into with such communities.

4.6.1 What constitutes Prior Informed Consent?

⁴⁰³ Wynberg, R Chennells, R & Schroeder, D, (n. 393) at 342.

⁴⁰⁴Department of Environmental Affairs, 'South Africa's Bioprospecting, Access and Benefit-Sharing Regulatory Framework: Guidelines for Providers, Users and Regulators' July 2012 (n. 353) at 34.

⁴⁰⁵Crouch *et al* (n. 27) at 362.

⁴⁰⁶Regulation 8(1)(d), BABS.

Obtaining PIC in diverse and extremely different cultural settings of indigenous communities can be immensely challenging. According to a working definition devised by Posey and Dutfield, PIC is consent to an activity that is given after there has been full disclosure regarding:-

- a) the reasons for the activity;
- b) specific procedures that would be involved in the activity;
- c) potential risks involved in the activity; and
- d) full implications that are realistically foreseeable. 408

4.6.2 The Peruvian Medicinal Plant Sources of New Pharmaceuticals Project

An interesting foreign example of the difficulties that can be encountered in obtaining PIC is a project entitled 'Peruvian Medicinal Plant Sources of New Pharmaceuticals'. In this project, which ran from 1994 to 2000, and which was funded by four US government agencies under a programme known as the International Co-operative Biodiversity Group (ICBG), 409 it soon became apparent that PIC would prove a major challenge.

4.6.2.1 Background

One of the awardees of the ICBG was the Washington University, whose consortium included the Universidad Peruana Cayetano Heredia, the Museo de Historia Natural, Universidad Nacional Mayorde San Marcos, G.D. Searle & Co. (a pharmaceutical firm) and the Aguaruna people. The Aguaruna are a large Amazonian population of over 45 000 people, who live in more than 180 communities, most of which are affiliated to at least 13 organizations which are

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⁴⁰⁷Dutfield, G, 'Protecting the Rights of Indigenous Peoples: Can Prior Informed Consent Help?' in Wynberg, R *et. al* (Eds.) *Indigenous Peoples, Consent and Benefit-Sharing: Lessons from the San Hoodia Case*, Springer Scientific Business Media B.V. 2009, 53 at 53.

⁴⁰⁸*Ibid* at 60. Darrell Posey is an esteemed ethnoecologist and campaigner for indigenous peoples' rights.

⁴⁰⁹ This was an innovative programme established by the Fogarty International Centre of the National Institutes of Health, together with the United States Agency for International Development (USAID) with the aim of discovering and developing pharmaceutical and other useful agents from natural products, while promoting sustained economic growth in developing countries and conserving the biological resources from which such products are derived. Berlin B & Berlin, EA, 'Community Autonomy and the Maya ICBG Project in Chiapas, Mexico: How a Bioprospecting Project that should have Succeeded Failed' in *Human Organization*, Vol. 63, No. 4, 2004, 472 at 474.

⁴¹⁰ Lewis, WH & Ramani, V, 'Ethics and Practice in Ethnobiology: Analysis of the International Cooperative Biodiversity Group Project in Peru' in McManis, CR (Ed) *Biodiversity and the Law*, Earthscan, London, 2007, 394 at 401.

run by the Aguaruna, either jointly with neighboring ethnic groups or alone.⁴¹¹ The project was ethnobotanical in nature in that it involved the use of traditional knowledge of the Aguaruna people, relating to their use of plants for traditional medicine.⁴¹²

4.6.2.2 Difficulties in Identifying the correct Representative Body

The project leader identified the Organizacion Central de Communidades Aguarunas del Alto Maranon (OCCAAM) as representative of the Aguaruna people and therefore as the potential partner organization. 413 Accordingly, it was understood that consent by this organization could have been taken to mean the consent of the entire Aguaruna people. Subsequent to the grant of the award, the project leader was advised to approach a larger, more organized and easier to communicate with organization, the Consejo Aguaruna Huambisa (CAH). 414 This was done and a Letter of Intent was entered into with ICBG and CAH regarding annual payments for plant collections and royalties. 415 The Washington University then negotiated a formal agreement with Searle, in terms of which the University would receive payments from Searle and thereafter pass a share thereof to CAH. 416 CAH objected on the grounds that they were not informed in an appropriate and timely manner of this separate agreement between Washington University and Searle, and that it was made without their direct involvement. 417 Once the matter became public, both Washington University and Searle were condemned as biopirates, for failing to be transparent, keeping the Aguaruna out of substantial negotiations and for offering them too small a share of the proceeds. 418 A major issue raised was that the CAH did not sufficiently represent the entire Aguaruna population. 419

CAH subsequently withdrew from the project, leaving the Consortium without any Aguaruna representation. The Washington University decided to approach OCCAAM, which was happy to enter into a written agreement with the ICBG. OCCAAM and the two other Aguaruna

⁴¹¹ Dutfield, G (n. 407) at 60.

⁴¹² Lewis, WH & Ramani, V (n. 410) at 401 -402.

⁴¹³ Dutfield, G (n. 407) at 61.

⁴¹⁴ Rosenthal, J, 'Politics, Culture and Governance in the Development of Prior Informed Consent and negotiated Agreements with Indigenous Communities' in McManis, CR (Ed) *Biodiversity and the Law*, Earthscan, London, 2007, 373 at 377.

⁴¹⁵ *Ibid*.

⁴¹⁶ Dutfield, G (n. 407) at 61.

⁴¹⁷ Rosenthal, J (n. 414) at 377.

⁴¹⁸ Dutfield, G (n. 407) at 62.

⁴¹⁹ *Ibid*.

organizations were affiliated with a national indigenous peoples confederation, 'Confederation de Nacionalidades Amazonicas de Peru' (CONAP), which became involved in the matter. 420 CONAP organized a meeting of community and organization leaders, which included representatives of OCCAAM and several other Aguaruna organizations, representatives of the ICBG Consortium, including Searle as well as other interested individuals. This resulted in the formation of a Consortium made up of CONAP and several Aguaruna organizations, which reached agreement that three representatives could go to Searle's headquarters to negotiate a contract. A contract was agreed which included a know-how license agreement, in terms of which license fees were to be paid as long as Searle used plant extracts, together with the collective medicinal know-how of the Aguaruna people. 421 However, it has been argued that it was presumptuous of CONAP and its associates to agree to license the collective know-how of all the Aguaruna people, particularly since they represented fewer than half the Aguaruna. 422 Of further significance is that acceptance by CONAP and its affiliates did not automatically mean acceptance by all Aguaruna Committees and in many instances, individual communities challenged CONAP and its Affiliates' authority to consent to the project on their behalf. Such communities further refused access to ICBG researchers to work in their communal territory, notwithstanding their association with one of CONAP's affiliates. 423

4.6.2.3 The Complexities involved when putting PIC into practice

Although this project was novel in that it gave a group of indigenous people control and full ownership of their traditional knowledge, all its efforts in putting the PIC requirement into practice resulted in unsatisfactory levels of representation and sharp divisions among the Aguaruna. The project highlighted the fragmented nature of most indigenous communities and the difficulty of identifying the correct representative body, as well as obtaining PIC. 424 More importantly, this project highlights that notwithstanding the best intentions and most prudently made plans by users, misperception, confusion, inappropriate marginalization, resentment and even internal conflict can result from endeavoring to put the PIC concept into practice, where

⁴²⁰ *Ibid*.

⁴²¹ *Ibid*.

⁴²² *Ibid*.

⁴²³ *Ibid*.

⁴²⁴ Lewis, WH & Ramani, V (n. 410) at 409.

indigenous communities are involved. 425 This is particularly so when there is confusion and uncertainty regarding indigenous governance structures and representation.

4.6.2.4 Similarities with a local BSA involving the *buchu* plant

Locally, we have seen similar issues emerge when a BSA was signed between Cape Kingdom Nutraceuticals (CKN), the South African San Council (SASC) and the National Khoi-San Council (NKC) on 19th August 2013, enabling CKN to use the *buchu* plant for commercial purposes. The BSA acknowledges that, as the primary traditional knowledge holders of the medicinal benefits of the *buchu* plant, the San and Khoi communities are legally entitled to share in the benefits that result from the commercial development of such plant. In terms of the BSA, which was drawn up in accordance with the Biodiversity Act, CKN agreed to share three percent of the profits with the San and Khoi communities. However, allegations subsequently emerged from the Khoi organization 'People of the South' to the effect that the NKC lacked the necessary mandate from the Khoi people to make the deal. In response, Roger Chennells, a lawyer who assisted the NKC with legal advice during the negotiation of the BSA, highlighted that government, by approving the BSA, acknowledged the NKC as the legitimate spokesman for the fractured Khoi community, and that it is in fact due to this recognition that the NKS is placed in a position to benefit from the commercialization of the *buchu* plant.

Having regard to the lack of clarity that the BABS Regulations provide in their definition of 'indigenous communities', coupled with the generally fragmented nature of indigenous communities, it is most likely that the complexities involved in identifying indigenous governance structures and representation will persist. Successfully satisfying the PIC requirement, particularly in the context of uncertainty and confusion regarding indigenous representation, is undoubtedly challenging and a community-specific process. It is a process that

⁴²⁵ Ibid.

⁴²⁶ Press Release dated 19th August 2013 entitled 'Cape Kingdom Nutraceuticals signs Agreement with the San and Khoi, Health24, Available at http://www.health24.com/Natural/News/Cape-Kingdom-Nutraceuticals-signs-benefit-sharing-agreement-with-the-San-and-Khoi-20130819. Accessed on 30th October 2013.

⁴²⁸ Cape Times news article dated 4th September 2013 entitled 'National Khoi-San Council comes under fire for negotiating buchu deal'. Available at http://www.pharmacychoice.com/News/article.cfm?Article_ID=1097307. Accessed on 30th October 2013.

⁴²⁹ *Ibid*.

⁴³⁰ *Ibid*.

progresses over time and is focused on relationship building and establishing trust. The flexibility involved in obtaining PIC from indigenous communities may prove difficult to maintain in the context of the relatively rigid, legal ABS framework of South Africa.

4.6.3 The Maya International Cooperative Biodiversity Group Project

The Maya International Cooperative Biodiversity Group (Maya ICBG) project was a five year research project which was funded by the ICBG programme and which focused on drug discovery, medical ethnobiology, biodiversity inventory and sustainable development among the Maya people in the central highlands of Chiapas, Mexico. This project began in 1998 and reveals the importance of obtaining PIC built on trust and adequate representation by the relevant indigenous community.

4.6.3.1 Background

The Maya ICBG project recognized the indigenous highlanders as major stakeholders as the anticipated collection of plants from the rich and biodiverse region of the central highlands of Chiapas, Mexico, was to take place on their lands. ⁴³¹ Notwithstanding the indigenous communities being identified as crucial stakeholders, the initial consortium in the Maya ICBG project did not include Maya representation, as the Maya ICBG did not view including the Maya people as a partner as a pre-condition but rather viewed it as a goal of the project. ⁴³²

Although the researchers aimed to provide comprehensive information to the Maya people, they elected to only discuss certain consent issues such as patenting at a later stage, if and when necessary, so as to avoid having to deal with such complex matters at the beginning of the project. In some respects a similar approach is taken by South Africa as PIC, BSAs and MATs are now only required at the commercialization phase of bioprospecting. The problems with taking this approach, as enunciated in this project, are therefore relevant in the South African context.

433 *Ibid* at 320.

⁴³¹ Feinholz-Klip, D, Barrios, LG & Lucas, JC, 'The Limitations of Good Intent: Problems of Representation and Informed Consent in the Maya ICBG Project in Chiapas, Mexico' in Wynberg R *et al* (Eds.), *Indigenous Peoples, Consent and Benefit Sharing: Lessons from the San Hoodia Case*, Springer Science + Business Media B.V. 2009, 315 at 317.

⁴³² *Ibid*.

The Maya ICBG encountered opposition due to their approach to PIC and the representation of the indigenous community. A major problem was that while the Maya ICBG intended for benefits to flow to the Maya people, the actual process as to how this would take place was decided by the research community. In this regard, the immediate, medium and long-term benefits for the indigenous community were set out in the Benefit-Sharing and Protection of Intellectual Property Agreement prior to the Maya communities being approached regarding the project. Accordingly, the major decisions had already been taken without consultation and negotiation with the Maya communities.

4.6.3.2 The concept of 'community'

In accordance with the requirements of the CBD, the Maya ICBG worked on the basis that 'community' referred to a specific, geographically situated socio-political unit, which had to give PIC for the project. However, due to the shifting nature of 'community' in Chiapas, difficulties were inevitable. The concept of 'community' in Chiapas is uncertain and for some it is regarded as an administrative convenience that may not necessarily bear any relationship to local residential patterns or social organization. It has been argued that the Chiapas ethnic identity is initially determined by a person's membership to a 'municipality' and thereafter by such person's identification with a specific 'community'. Notwithstanding Chiapas communities being located within specified municipality boundaries, as recognized by Mexican law, due to the Maya traditions of village autonomy, municipal government authorities usually have no power in respect of bioprospecting related matters.

The lack of an established, credible and broadly representative governance system of the Maya people was the key to the demise of the Maya ICBG project. The Maya ICBG project attracted negative publicity and was viewed as biopiracy; essentially due to questions being raised regarding the validity of the community agreements entered into with the indigenous

⁴³⁴ Berlin B & Berlin, EA, 'Community Autonomy and the Maya ICBG Project in Chiapas, Mexico: How a Bioprospecting Project that should have Succeeded Failed' in *Human Organization*, Vol. 63, No. 4, 2004, 472 at 478

⁴³⁵ Feinholz-Klip, D *et al* (n. 431) at 321.

⁴³⁶ *Ibid* at 319.

⁴³⁷ *Ibid* at 318.

⁴³⁸ *Ibid*.

⁴³⁹ Rosenthal, J (n. 414) at 381.

⁴⁴⁰ Berlin B & Berlin, EA (n. 434) at 481.

communities and whether such communities were adequately and correctly represented.⁴⁴¹ Other areas of concern that emerged pertained to the quality and completeness of the information furnished to communities; particularly in the light of the Maya ICBG withholding information regarding patents and certain risks of bioprospecting.⁴⁴²

4.6.3.3 Efforts to obtain PIC

During their negotiation with communities regarding PIC, researchers invited community members to watch presentations about the project, in the form of a theatrical performance, which involved a narrator who described, in native languages, a series of mimed skits performed by project members. Such skits included an introduction of the project's overall goals, as well as each component of the project's activities, its aims, objectives and potential benefits. Haddition, community leaders were taken on a tour of the herbarium, laboratory facilities, as well as the experimental gardens and they were also provided with written summaries of the projects goals, activities and proposed benefit-sharing program, in various native languages. Notwithstanding the above endeavors in negotiating PIC, the project failed due to a lack of trust and adequate representation. The establishment of a comprehensive, 'credible and broadly representative governance system of indigenous communities' In Chiapas, to which PIC requests could be directed and the recognition that a project of this nature was required to be built on the gradual establishment of trust and collaboration among stakeholders, was essential and unfortunately, lacking.

Like many other indigenous communities, the Maya people and their cultural traditions suffered at the hands of colonialism and these inevitably affected conditions for trust. Issues of trust and representation will undoubtedly always complicate benefit-sharing, with particular regards to indigenous communities and accordingly, a PIC process that progresses over time and is focused on relationship-building is essential. The Maya ICBG Project reveals that even the most sincere and elaborately planned efforts to obtain PIC can lead to unforeseen complications and can

⁴⁴¹ Feinholz-Klip, D et al (n. 431) at 323.

⁴⁴² *Ibid*.

⁴⁴³ Berlin B & Berlin, EA (n. 434) at 477.

⁴⁴⁴ *Ibid*.

⁴⁴⁵ *Ibid*.

⁴⁴⁶ Rosenthal, J (n. 414) at 386.

⁴⁴⁷ Feinholz-Klip, D *et al* (n. 431) at 326, as well as Berlin B & Berlin, EA (n. 434) at 479.

ultimately, fail. As a result of the negative publicity and allegations of biopiracy, the local researchers decided to halt bioprospecting until such time as the indigenous communities had established a formal authorized representative body to represent and protect their interests; and administrative as well as legal mechanisms and procedures were in place for obtaining PIC. Hence, it was recognized that an organization that was representative of the indigenous communities and which would assume the responsibility of facilitating information and discussion in the PIC process, was a major failing of the project.

4.6.3.4 The progressive nature of obtaining PIC

It is essential to recognize that obtaining PIC is not a quick, one-off process but rather a progressive one, which depends largely on collaboration with local intermediaries and support organizations. Although PIC remains essential, a certain level of flexibility is required when dealing with indigenous communities, as circumstances vary from community to community. Both users and indigenous communities must ideally approach the challenging PIC process with versatility, in order to adapt to varying circumstances and be dedicated to building relationships over a period of time. Ultimately, parties desiring access to traditional knowledge and genetic resources of indigenous communities must make sustained efforts to build long-term relationships with the relevant indigenous communities and in so doing, will minimize the potential for exclusion and misunderstandings.

4.7 Negotiating Benefit-Sharing Agreements

The negotiation of benefit-sharing agreements with representatives of indigenous communities provides practical challenges that cannot always be resolved by way of legislation.

4.7.1 Differing decision-making processes

During such negotiations bioprospectors are most likely to be represented by a small group of highly educated professionals, who focus on expediency and quick decision-making whereas decisions from indigenous communities are more likely to take long periods of time, as decision-

⁴⁴⁸ *Ibid* at 324.

Wynberg, R, Chennells, R & Schroeder, D, (n. 393) at 340.

⁴⁵⁰ *Ibid*.

⁴⁵¹ *Ibid*.

making among indigenous communities will involve consultation with large groups of the community, with a view to reaching consensus on issues. 452 The decision-making of bioprospectors does not involve the wider consultation of stakeholders and decisions are made by a small number of individuals who are knowledgeable of the legalities involved and the consequences of their decisions. Decision-making by indigenous communities, on the other hand, is often undertaken by a large number of members of the community, who usually have limited knowledge of the legalities and implications of their decision. 453 This distinct difference in the decision-making processes of bioprospectors and indigenous communities, strains the negotiation process, with one party looking for quick decisions to satisfy shareholders, while the other requires lengthy periods of time to facilitate consultation with the community, particularly with regards to the implications of their decisions. The difference between the respective parties' approach to decision-making procedures and time frames often proves to be detrimental to indigenous communities, in that their decision-making abilities become compromised due to the bioprospectors' requirements of quick and speedy resolutions and decisions.

4.7.2 The San – Hoodia case

The San – *Hoodia* case encompasses one of the most famous benefit-sharing agreements and this case, among other things, reveal the challenges involved in negotiating and developing a benefit-sharing agreement between bioprospectors and indigenous communities.

4.7.2.1 Background

The San community made use of *Hoodia* and related species as food, and more especially as a liquid substitute and appetite suppressant.⁴⁵⁵ The Council for Scientific and Industrial Research (CSIR), a South African research institution, identified the potential of the *Hoodia* species as a non-toxic appetite suppressant and a patent application was filed by CSIR in South Africa in 1995, for the use of the active components of the *Hoodia* plant which were responsible for

⁴⁵² *Ibid* at 345.

⁴⁵³ Wynberg, R, Schroeder, D, Williams S and Vermeylen, S, 'Sharing Benefits Fairly: Decision-Making and Governance' in Wynberg, R *et al* (Eds) *Indigenous Peoples, Consent and Benefit-Sharing: Lessons from the San Hoodia Case*, Springer Science + Business Media BV. 2009, 231at 231.

⁴⁵⁴ *Ibid* at 232.

⁴⁵⁵ Wynberg, R & Chennells, R (n. 402) at 94.

suppressing appetites. ⁴⁵⁶ CSIR subsequently signed a licensing agreement for the further development and commercialization of the product with Phytopharm in 1998 and this licensing agreement gave Phytopharm an exclusive worldwide license to manufacture and market *Hoodia*-related products. ⁴⁵⁷ After developing and advancing the drug through a programme called 'P57', Phytopharm entered into a license and royalty agreement with US-based pharmaceutical giant, Pfizer, to ensure further development and commercialization. ⁴⁵⁸ Pfizer discontinued clinical development of the drug in July 2003 and returned the licensing rights to Phytopharm, which entered into an exclusive global license with Unilever, involving *Hoodia gordonii* extracts and the incorporation thereof into existing food brands as a weight loss product. ⁴⁵⁹

4.7.2.2 Failure to consult the San

All the agreements for the development and commercialization of the *Hoodia* drug proceeded without any acknowledgement to the San Community. In fact, a newspaper quoted the Head of Phytopharm as saying that, to the best of his knowledge, the San community was extinct. As a result of the work of South African based NGO, Biowatch South Africa, as well as uncompromising investigative journalism on the part of the foreign media, the prejudicial and exploitative nature of the CSIR-Phytopharm agreement was exposed. This heightened interest in the involvement of traditional knowledge and indigenous communities in ABS matters and resulted in pressurizing CSIR to enter into high-level negotiations with the San. The bargaining and political leverage of the San was considerably strengthened, as they were now part of a high-profile case which was being followed throughout the world, due to CSIR's initial failure to consult the San.

4.7.2.3 Leadership Structure of the San

Although South African San were fortunate in having a leadership structure at the time, which had developed over six years of participation in meetings with the Working Group of Indigenous

⁴⁵⁶ South African Patent No. 983170.

Wynberg, R and Chennells, R, (n. 402) at 95.

⁴⁵⁸ Ibid

⁴⁵⁹ *Ibid* at 96

⁴⁶⁰ Chennells, R, 'Ethics and Practice in Ethnobiology: The Experience of the San Peoples of Sothern Africa' in McManis, R (Ed) *Biodiversity and the Law*, Earthscan, London, 2007, 413 at 421.

⁴⁶² Wynberg, R and Chennells, R, (n. 402) at 101.

Minorities in Southern Africa (WIMSA), the *Hoodia* controversy hastened the registration of a legally constituted South African San Council. 463 In addition to WIMSA and the South African San Council, the Cape Town-based South African San Institute (SASI), a San service NGO, which helps San-based organizations to access funding and expertise, played significant roles in the San-*Hoodia* case. Initially a Memorandum of Understanding was entered into between CSIR and the San, in which CSIR acknowledged that their lead for *Hoodia* arose from the traditional knowledge of the San and that the San were accordingly entitled to share in the benefits arising from the use of such knowledge. 464 Subsequent to the finalization of the Memorandum of Understanding, negotiations pertaining to a benefit-sharing agreement began in earnest.

4.7.2.4 Capacity of the San to negotiate a BSA

During the negotiations, a fair amount of effort was ploughed into capacity building of the San negotiating team, in order to ensure effective decision-making. In this regard, the entire negotiating team of the San attended all meetings with CSIR and, prior to all meetings, the San negotiating team held preparatory meetings, with a view to discussing the aims and objectives of the impending meeting and to share the responsibilities connected therewith. In addition, a number of educational meetings and two major workshops were held among the San community to assist with building knowledge and awareness of the matter, as well as its implications. Concerted efforts were being made to slow down the negotiation process, in order to enhance the flow of information, thereby increasing awareness. However, the San negotiating team was faced with constraints in this regard, as CSIR was paying for the negotiating process due to WIMSA having limited technical capacity and funding. CSIR funded a number of workshops and meetings between the representatives of the San, the CSIR and, in certain instances, government departments and NGOs, with a view to discussing and resolving concerns and positions.

4.7.2.5 Transboundary traditional knowledge concerning *Hoodia*

⁴⁶³ Wynberg, R, Schroeder, D, Williams S and Vermeylen, (n. 453) at 239.

⁴⁶⁴ *Ibid* at 240.

⁴⁶⁵ *Ibid* at 241.

⁴⁶⁶ *Ibid*.

⁴⁶⁷ *Ibid* at 242.

⁴⁶⁸ Wynberg, R & Chennells, R (n. 402) at 103.

With regards to identification of the true holders of the traditional knowledge pertaining to *Hoodia*, as the plant and traditional knowledge about its use was found in Namibia, South Africa and Botswana, the matter was potentially complex and fraught with difficulty. Fortunately however, at an annual general meeting in 2001, a decision was taken by WIMSA, to the effect that heritage was indivisible and that benefits arising from shared heritage should be shared equally among the San people. Accordingly, during the negotiation process, the San agreed that to endeavor to link benefit-sharing to specific communities utilizing *Hoodia* would prove divisive and it was therefore decided that there would be equal division of the financial benefit arising from a benefit-sharing agreement among the countries represented by WIMSA. This approach assisted in resolving the difficulty of identifying precisely which San community was entitled to share in the benefits arising from the commercialization of the *Hoodia* plant.

4.7.2.6 Benefit-sharing Agreement

Less than two years after negotiations commenced, a mutually accepted benefit-sharing agreement was signed on 24th March 2003. 471 In addition to the benefit-sharing agreement pertaining to agreed royalties 472 and the establishment of the San-*Hoodia* Trust, 473 it also committed parties to the conservation of biodiversity and utilization of the best-practice procedures for the collection of plants. 474 The benefit-sharing agreement further required CSIR to grant the San access to existing study bursaries and the agreement also covered intellectual property issues, over and above setting out details regarding benefit-sharing and administrative matters. 475 In this regard, Provision 4 of the benefit-sharing agreement stipulates that any intellectual property, including a patent, trademark or plant-breeders' right, developed or created by CSIR as a result of any use of traditional knowledge, shall be vested in CSIR. 476 Furthermore,

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⁴⁶⁹ *Ibid* at 106.

⁴⁷⁰ *Ibid*.

⁴⁷¹ Chennells, R (n. 460) at 421.

⁴⁷² It was agreed that the San would receive 6% of all royalties received by CSIR from Phytopharm from the successful exploitation of *Hoodia* products and the San would also receive 8% of certain milestone income received by CSIR from Phytopharm during the product development period, once performance targets were reached. Wynberg, R & Chennells, R (n. 402) at 107.

⁴⁷³ The monies received by the San from the benefit-sharing agreement were to be paid into a Trust, which was set up jointly by CSIR and the South African San Council, with the view to enhance the standard of living and general well-being of the San population. *Ibid*.

⁴⁷⁴ Wynberg, R & Chennells, R (n 402) at 108.

⁴⁷⁵ *Ibid*.

⁴⁷⁶ *Ibid* at 109

the South African San Council will have no right to claim co-ownership of the patents or products derived from the patents.⁴⁷⁷ The benefit-sharing agreement reached between CSIR and the San was based on established international benefit-sharing models for the pharmaceutical industry and was made public by an announcement by Ben Ngubane, then South Africa's Minister of Arts, Culture, Science and Technology, who referred to the agreement as restoring the dignity of indigenous societies and adding value to the biodiversity and indigenous knowledge systems of Southern Africa.⁴⁷⁸

4.7.2.7 Western Society vs. Traditional Indigenous decision-making

The negotiation process between CSIR and the San highlights the difference between the models of democratic decision-making and traditional indigenous decision-making. In Western Society, communal decision-making is facilitated through long established groups that have legal standing, with agreed operating mechanisms in place and duly appointed, educated representatives, who make decisions without having to consult with those they represent. On the other hand, communal decision-making among traditional indigenous communities usually involves all the members of the community, which makes decision-making time-consuming and not conducive to the negotiating processes of bioprospectors. Ideally a balance needs to be struck between the processes of indigenous communities, which require capacity-building and awareness raising and thus time; and the economic expectations of bioprospectors, who require speedy decision-making, immediacy and certainty.

In the San-Hoodia case, the San needed a legally representative group to negotiate with CSIR. The existing groups were unfortunately still in their infancy and lacked the time and resources required to ensure speedy decision-making by duly authorized professional representatives, as opposed to unpaid community leaders, who required capacity building. The establishment of a duly authorized representative body of the San was a race against time and the decision-making abilities of the San appear to have been compromised by the need for urgent resolution. In this

⁴⁷⁷ *Ibid*.

⁴⁷⁸ Address by the Minister of Arts, Culture, Science and Technology at the signing of a benefit-sharing agreement between the CSIR and San, 24 March 2003, Molopo Lodge, South Africa. Available at http://www.polity.org.za/article/ngubane-signing-of-agreement-between-csir-amp-san-24032003-2003-03-24. Accessed on 26th October 2012.

⁴⁷⁹ Wynberg, R, Schroeder, D, Williams S and Vermeylen, (n. 453) at 247.

⁴⁸⁰ *Ibid* at 248.

regard, CSIR and its commercial partners were anxious to avoid negative publicity and the San, being largely dependent on the resources of CSIR, were also under pressure to finalize an agreement as speedily as possible. In addition to the tensions revolving around the time-frames involved, the San negotiating team lacked adequate financial resources to fund meetings, obtain additional advice and enhance their negotiating skills. On request by the San, CSIR invested in facilitating San representation and decision-making capacity; primarily as CSIR needed to conclude an agreement with the San and negotiation was critical to reaching such agreement. This scenario undoubtedly placed undue pressure on the San to make hasty decisions.

The San-*Hoodia* case has revealed that the difference over decision-making processes and speeds can leave indigenous communities in a weaker position. The decision-making abilities of the San were prejudiced by the need for urgent resolution by CSIR and its commercial partners. Unfortunately, bioprospectors are not likely to indulge indigenous communities by allowing years for community consultation processes and they are more likely to halt bioprospecting rather than risk more time and money required for continued indecision. However, on the contrary, to insist on speedy decision-making processes from indigenous communities is both unacceptable and unfeasible, from a practical perspective.

4.7.2.8 Impact of the lack of ABS legislation

Undoubtedly, the lack of ABS legislation in South Africa at the time that negotiations were taking place between the CSIR and San presented a major challenge, as the negotiations were then taking place without any legal requirement for benefit-sharing agreements with owners/holders of traditional knowledge and/or genetic resources. The absence of legislation created uncertainties as to the parties to the benefit-sharing agreement, as well as how PIC in respect of the traditional knowledge and or genetic resources was to be obtained.⁴⁸⁴

The Biodiversity Act, 485 which subsequently came into operation, now obliges the South African government to ensure that negotiations between indigenous communities and bioprospectors

⁴⁸¹ *Ibid*.

⁴⁸² *Ibid*.

⁴⁸³ Wynberg, R, Chennells, R and Schroeder, D (n. 393) at 345.

⁴⁸⁴ Ibid

⁴⁸⁵ The National Environmental Management: Biodiversity Act 10 of 2004.

occur on an equal footing when benefit-sharing agreements are being negotiated. In effect, capacity-building and education of indigenous communities, when negotiating an ABS agreement, becomes the responsibility of national government and the Biodiversity Act locates support for consultations firmly with government. Although this may present a partial solution to the problem, the implementation of such provisions requires government to have the capacity and knowledge to monitor and ensure that benefit-sharing agreements are in fact negotiated on an equal footing. Furthermore, this approach will only be successful if government officials are honest, impartial and free of any influence by powerful resource extractive corporations.

The South African Biodiversity Act is commendable in that it aims to ensure that indigenous communities are not disadvantaged during benefit-sharing negotiations, but it is unlikely that government has the capacity to follow through with this statutory provision. In fact, the practical implementation of this requirement remains hampered by capacity, resource and knowledge constraints. 488 Government needs to adopt a more pro-active approach in its endeavor to build the capacity and skills of indigenous communities, so as to enable them to negotiate on a more equal footing with their bioprospector counter-parts. Considering the lack of capacity and skill on the part of government, as discussed under Part 4.3 above, this will inevitably take time and it is unlikely that government's intervention in empowering indigenous communities, no matter how pro-active, is likely to yield immediate results. In the interim, NGOs can play a critical role in bridging the gap between bioprospectors and indigenous communities during the negotiation of BSAs. The bridging role that NGOs can play is discussed in more detail under Part 4.9 below. Ultimately, the ideal is for indigenous communities to attain a level of capacity and skill where they are in a position to negotiate BSAs without outside intervention and it is argued under Chapter Five that the establishment of Biocultural Community Protocols will greatly assist in empowering indigenous communities to achieve this goal.

Having ABS legislation in place has nevertheless enhanced the bargaining power of indigenous communities when negotiating BSAs. As discussed under Chapter Three, the Biodiversity Act, together with the BABS Regulations, now describe, in detail, the content and form of BSAs. In addition, Annexure 8 of the BABS Regulations stipulates the requirements involved where an

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⁴⁸⁶ Section 82(4)(b)NEMBA.

⁴⁸⁷ Wynberg, R, Chennells R and Schroeder, D (n. 393) at 345.

⁴⁸⁸ Wynberg, R, Schroeder, D, Williams S and Vermeylen, (n. 453) at 231.

indigenous community's representative signs the BSA on behalf of the indigenous community. Of particular significance is that the Biodiversity Act and the related BABS Regulations requires the Minister, prior to issuing a bioprospecting permit, to satisfy himself/herself that the applicant has obtained PIC and entered into a BSA with the indigenous community involved. In order to ensure that these requirements are met, the Minister may require the applicant to show what steps have been taken to identify the stakeholders involved; take further steps to adequately identify stakeholders; provide evidence that the relevant information pertaining to the bioprospecting has been disclosed to the identified stakeholders and provide evidence that the PIC of the identified stakeholders has been obtained. Accordingly, now that the Biodiversity Act and BABS Regulations are in place in South Africa, there is far more clarity regarding the identification of stakeholders, the PIC requirement and the content of BSAs. This undoubtedly enhances the bargaining power of indigenous communities when negotiating BSAs, post the San-Hoodia case.

4.8 Transboundary Genetic Resources and Traditional Knowledge

A further lesson to be learned from the San-Hoodia case is that often genetic resources are found across political boundaries, with knowledge of such resource being shared among the various indigenous communities that straddle the boundaries. More importantly, the laws and policies relating to ABS and traditional knowledge vary between the different countries. In the San-Hoodia case, the traditional knowledge relating to the use of Hoodia was shared among the San people in Botswana, Namibia and South Africa. Accordingly, the plant and traditional knowledge about its use extend across Botswana, Namibia and South Africa, which invariably presents complexities and challenges, with particular regards to the distribution of benefits to the various impoverished and indigenous communities across three countries. The differing ABS policies between the countries further exacerbated the challenges.

4.8.1 South Africa's Role

In the San-Hoodia case, while South Africa had significantly advanced the development of commercial partnerships with multinational companies; Botswana and Namibia, by comparison, had not yet developed any commercial partnerships.⁴⁹¹ In addition, while South Africa has now

⁴⁸⁹ Sec. 82(3)(a) & (b), NEMBA and Regulation 8(1)(d), BABS.

⁴⁹⁰ Reg. 8(2), BABS.

⁴⁹¹ Wynberg, R & Chennells, R (n. 402) at 116.

adopted ABS legislation which recognizes the San as an indigenous community with rights to benefit from the use of *Hoodia*, the policies of both Namibia and Botswana remain ambivalent. 492 Namibia and Botswana both do not have ABS legislation in place and they both regard the benefits derived from *Hoodia* as belonging to the State and not the indigenous communities. 493

4.8.2 ABS legislation and policy in Namibia

Although Namibia adopted a progressive and proactive ABS policy since as early as 1997, there is no national ABS legislation in place as yet. 494 Namibia took the decision to delay establishing ABS legislation until the adoption of the Nagoya Protocol. 495 An Awareness Raising Workshop recently held by the NGO, Natural Justice, and attended by the Namibian Minister of Environment and Tourism, Namibian Members of Parliament, Traditional Authority representatives and representatives of indigenous and local communities, aimed to inform key decision makers in Namibia about the importance of the sustainable utilization of genetic resources in order to preserve Namibia's biodiversity and enhance the livelihoods of the people of Namibia. 496

Notwithstanding the lack of ABS-specific legislation in Namibia, Namibia has regulated ABS in the country through bilateral agreements, existing legislation 497 that facilitates ABS and the

⁴⁹² *Ibid*.

⁴⁹³ *Ibid.* Although this is a 2009 source, it does not appear that there have been any more recent developments regarding the establishment of ABS legislation in Namibia and Botswana.

⁴⁹⁴ Wynberg, R, 'Policies for Sharing Benefits from *Hoodia*' in R, Wynberg et al (Eds.), *Indigenous Peoples*, Consent and Benefit Sharing: Lessons from the San-Hoodia Case, Springer Science and Business Media B.V 2009, 127 at 134.

⁴⁹⁵ Union for Ethical Biotrade, 'Access and Benefit Sharing: Evolving laws and regulations around the World' 1 at 3. Available at http://ethicalbiotrade.org/dl/benefit-sharing/UEBT%20ABS%202013.pdf. Accessed on 12th November 2013.

⁴⁹⁶ Natural Justice website, 'Natural Justice advises Namibian Government on draft ABS Legislation,' 24th February 2012, Available at http://natural-justice.blogspot.com/2012/02/natural-justice-advises-namibian.html. Accessed on 12th November 2013.
⁴⁹⁷ Such legislation includes:

⁽i) Nature Conservation Ordinance No. 4 of 1975, which is the primary legislation governing nature conservation in Namibia and puts in place a permitting system for protected species such as *Hoodia*, by requiring prior authorization for harvesting and trade. Such legislation also establishes a permit requirement for the picking, transport, sale, donation, export and removal of protected plants and more importantly, it requires the written permission of landowners before any indigenous plant is picked.

⁽ii) Environmental Management Act No. 7 of 2007, which establishes benefit-sharing as a requirement and sets up an advisory council, which includes access to genetic resources.

active engagement of government, research institutions and NGOs via an Interim Bioprospecting Committee (IBPC). 498 Such Committee was established in 2007, to regulate and facilitate all bioprospecting activities. 499 Namibia has now developed draft ABS legislation, which has undergone regional consultations as part of the review process and aims to create a new dedicated unit on genetic resources and traditional knowledge within the Namibian Ministry of Trade and Environment, which will replace the IBPC. 500 This draft legislation on 'Access and Benefit Sharing for Sustainable Utilization of Cultural and Natural Assets' is under review and close to finalization.⁵⁰¹

4.8.3 Botswana's ABS legislation and policy

Similarly, Botswana does not have specific legislation that regulates bioprospecting activities, ABS and traditional knowledge, although there is a proposed National Environmental Management Act, which will most likely include provisions to regulate such activities. 502 Of significance is that, although there is recognition of the importance of traditional knowledge, the requirements for PIC from indigenous communities are not articulated in any law or policy in Botswana. 503 Most natural resource statutes in Botswana do not specifically deal with ABS and such laws are instead designed to meet the objectives of conservation and sustainable use. 504 There are, however, various pieces of sectoral policy and legislation, which are, to an extent, relevant to ABS. 505

⁽iii) Environmental Investment Fund of Namibia Act No. 13 of 2001, which establishes a fund to support environmental and natural resource management in Namibia. Wynberg, R (n. 495) at 131.

⁴⁹⁸ *Ibid* at 134.

⁴⁹⁹ Union for Ethical Biotrade (n. 495) at 3.

 $^{^{500}}$ Ibid .

⁵⁰¹ *Ibid*.

⁵⁰² UNU-IAS Institute of Advanced Studies, 'Access to Genetic Resources in Africa: Analyzing ABS Policy Countries' Four African UNEP, 2008, 1 at http://www.ias.unu.edu/resource_centre/ABS%20in%20Africa.pdf.Accessed on 15th October 2013. Wynberg, R (n. 494) at 134.

⁵⁰⁴ *Ibid* .

⁵⁰⁵ These include:

⁽i) Wildlife Conservation and National Parks Act No. 28 of 1992, which governs the use of resources in national parks, protected areas and game reserves. This Act also governs the procedures to access biological resources;

⁽ii) The Agricultural (Conservation) Resources Act of 2006, which provides for the establishment of regulations to control access to biological resources and sets in place permitting processes for the harvesting, export and trade of Hoodia. This Act contains no specific provision for PIC and BSAs;

⁽iii) Forest Act No. 38 of 2004, which protects and regulates the use of forest resources;

There is therefore a somewhat decentralized ABS institutional framework within Botswana, which is largely guided by various legislation administered by varying government departments. The key elements of prior informed consent, negotiating BSAs and MATs, and a clear bioprospecting application process for ABS are unfortunately lacking in the current institutional framework of Botswana's legislation. The Wildlife and National Parks Act No. 28 of 1992 and the Agricultural Resources Act of 2006, provide, to a reasonable extent, structures, processes and procedures for application to access resources, albeit not specifically genetic resources. These two Acts provide a solid foundation on which to develop ABS legislation in Botswana. As it stands, however, because Botswana's natural resource legislation was not tailored to deal with ABS, it does not contain the necessary elements to meet the CBD's objectives for access to and equitable sharing of benefits from genetic resources.

4.8.4 Complexities involved with Transboundary genetic resources and traditional knowledge

Accordingly, the three countries involved in the San-Hoodia case are at varying points of legislating for ABS and have adopted different approaches to bioprospecting and ABS. The San-Hoodia case raises critical questions of how benefits can be equitably shared by indigenous communities across various regions and what policies can best be implemented at regional level. Although some mechanisms have been put in place by the three countries to collaborate regarding Hoodia poaching and trade, as well as the trade and transport of illegally harvested material, the more pertinent issues relating to benefit-sharing and the rights of indigenous people remain disconnected and incoherent between the countries. Furthermore, notwithstanding the San-Hoodia Trust implementing benefit-sharing across regional boundaries, based on the

⁽iv) Tribal Land Act No. 32 of 2002, which recognizes that a community collectively owns the land as well as the resources on it. The decision making power in respect of such resources is, however, given to tribal land boards. This has relevance for PIC and the negotiation of BSAs;

⁽v) Community-Based Natural Resource Management Policy of 2006, which includes provisions on traditional knowledge protection and benefit-sharing and aims to protect the intellectual property rights of communities;

⁽vi) National Biodiversity Strategy and Action Plan of 2004, which recommends the development of a strategy on ABS, traditional knowledge and property rights. Wynberg, R (n. 495) at 132.

⁵⁰⁶ UNU-IAS Institute of Advanced Studies (n. 502) at 17.

⁵⁰⁷ *Ibid*.

⁵⁰⁸ *Ibid* at 24.

⁵⁰⁹ Wynberg, R, Chennells, R and, Schroeder, D (n. 393) at 346.

acceptance by the San of the collective and shared nature of *Hoodia* knowledge, there remains a necessity for benefit-sharing strategies to be developed at regional levels, particularly where genetic resources are shared across regional political boundaries.

4.8.5 Can the Global Multilateral Benefit-Sharing Mechanism provide a solution?

As discussed under Chapter Two above, Article 10 of the Nagoya Protocol makes provision for the establishment of a global multilateral benefit-sharing mechanism, to deal with certain transboundary situations. The second meeting of the Intergovernmental Committee for the Nagoya Protocol has, however, revealed that there is no common understanding among the CBD Parties on the modalities of such a mechanism; nor is there agreement on whether in fact such mechanism is necessary. Considering that Article 10 already dictates that all benefits shared through the global multilateral benefit-sharing mechanism (if such mechanism is established) are to be directed towards the global conservation of biological diversity and sustainable use of its components, it would appear that the provisions of the Nagoya Protocol relating to such mechanism differs substantially from the general trend of the provisions of the Nagova Protocol, which provide flexibility regarding how benefit-sharing occurs and where benefits are directed. It is thus submitted that the use of a global multilateral benefit-sharing mechanism to address benefit-sharing in respect of transboundary resources/knowledge would constitute an unacceptable intrusion on the sovereignty of Parties to the Protocol. It is for this reason, coupled with the fact that there is likely to be no common understanding among Parties pertaining to the establishment and modalities of such a mechanism for a long while yet, that it is argued that the global multilateral benefit-sharing mechanism will not effectively facilitate benefit-sharing in transboundary cases. It is suggested that this issue would instead be best addressed at regional level among Parties.

4.8.6 Common Regional ABS Policies

Common regional policies should ideally govern the sharing of benefits arising from the use of transboundary genetic resources and traditional knowledge relating thereto. However, from a practical perspective, the San-*Hoodia* case has shown that the complexity and diversity of legal and institutional mechanisms across countries, as well as the cross-cutting nature of traditional knowledge, conservation, intellectual property and benefit-sharing, makes it difficult for

governments to adequately streamline policies. ⁵¹⁰ From a South African perspective, although the Nagoya Protocol calls for cooperation in respect of transboundary genetic resources and traditional knowledge, South Africa's ABS legislation does not provide for such cooperation with neighboring countries. It must be noted, however, that the Nagoya Protocol is not yet in force and therefore does not yet impose any legal obligations on South Africa. Nevertheless, it would appear that the South African government is now working on this issue and aims to conclude bilateral agreements with regards to certain species including *Hoodia* by 2014. ⁵¹¹

In cases where the holders of traditional knowledge reside in various countries and genetic resources straddle political borders, it is essential that governments effectively co-operate and communicate with one another. There should be development of common policy approaches toward benefit-sharing and the establishment of joint strategies to enhance the promotion and protection of indigenous communities and their traditional knowledge. Such policies should be as specific as possible regarding PIC procedures and the nature and disbursement of expected benefits. Furthermore, such policies must ideally recognize and work in a meaningful manner together with indigenous and customary approaches.

4.9 NGOs and Civil Society Organizations

All three case studies discussed under Part 4.7 above have highlighted the importance of building relations between the various role players and the importance of having established community based institutions, which can represent indigenous communities during ABS negotiations. They demonstrate the critical role that NGOs and supporting organizations can play during the negotiation of an acceptable benefit-sharing agreement. Capacity building, among not only indigenous communities, but also among supporting NGOs and organizations, as well as government bodies, is vital to fair benefit-sharing. Indigenous communities, in particular, no doubt require knowledge and organizational skills to engage in meaningful PIC processes and to negotiate and facilitate equitable benefit-sharing agreements. The long-term goal should be to build capacity among indigenous communities themselves, as this is critical to ensure that such communities eventually become equal partners in negotiations and decision-making in

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⁵¹⁰ Wynberg, R (n. 494) at 137.

⁵¹¹ Lewis, M (n. 114) at 84.

⁵¹² Wynberg, R, Chennells, R and Schroeder, D (n. 393) at 347.

⁵¹³ *Ibid*.

bioprospecting matters.⁵¹⁴ However, the reality is that very few indigenous communities are in effect equipped to adequately protect their own interests in bioprospecting negotiations and hence NGOs and supporting organizations have stepped in to provide support.

4.9.1 Provisions of the Biodiversity Act

The Biodiversity Act affords indigenous communities protection in bioprospecting matters. Such protection includes the disclosure of all material information pertaining to the bioprospecting, obtaining the indigenous communities' PIC and negotiating requirements relating to MTAs and BSAs. However, NGOs as well as interested and affected parties do not appear to have been afforded any recognition under the Act. As discussed above, it is necessary to ensure that a balance is reached between respecting the culture and practices of the indigenous communities and fulfilling the Western-based expectations of bioprospectors. In order to assist in maintaining such balance, NGOs and local support organizations can play a vital bridging role. 515

Although the Biodiversity Act does make provision for consultation and public participation, such processes are limited by Section 99 of the Biodiversity Act, which provides that the consultative and public participation provisions are only obligatory where the relevant section giving rise to the statutory power being exercised specifically states that such power must be exercised in accordance with Section 100 of the Biodiversity Act. ⁵¹⁶ Section 100 of the Biodiversity Act stipulates that the Minister may give notice of the proposed exercise of power in the Government Gazette and in either a national or local newspaper. ⁵¹⁷ Such notice must contain sufficient information to enable members of the public to make meaningful representations or objections and it must invite members of the public to make written representations and objections to the proposed exercise of power, within 30 days of the publication of the notice. ⁵¹⁸

As highlighted by the African Centre for Biosafety, various sections in the Biodiversity Act require the Minister to follow the consultative process in accordance with Sections 99 and 100

⁵¹⁴ *Ibid* at 342.

⁵¹⁵ *Ibid* at 345.

⁵¹⁶ The African Centre for Biosafety (n. 310) at 20.

⁵¹⁷ Sec.100(1), NEMBA.

⁵¹⁸ Sec. 100(2), NEMBA.

and these requirements can be found in sections pertaining to the listing of threatened national ecosystems or species, identification of threatening processes, restriction of activities involving threatened or protected species, and invasive species.⁵¹⁹ However, there are no such requirements under the bioprospecting and access and benefit-sharing provisions of the Biodiversity Act.⁵²⁰ There is therefore no obligation on the issuing authority to follow the consultative and public participation process set out in Section 100 of the Biodiversity Act and the BABS Regulations unfortunately do not remedy this position.⁵²¹ Accordingly, no provision is made for public comment on bioprospecting permitting applications and appeals, while the Minister may, at his or her sole discretion, call for public comment on BSAs, provided that no confidential information is being made public.⁵²²

4.9.2 Promotion of Administrative Justice Act No. 3 of 2000

When dealing with the issuing of permits, the issuing authority is required to consider, *inter alia*, the national environmental management principles, any applicable international agreements binding on the Republic and the Promotion of Administrative Justice Act No. 3 of 2000 (PAJA).⁵²³ The national environmental principles⁵²⁴ provide for the promotion of participation of all interested and affected parties in environmental governance⁵²⁵ and further require that the interests, needs and values of all interested and affected parties must be taken into account. This includes the recognition of all forms of knowledge, including traditional knowledge.⁵²⁶ In addition, any decisions must be consistent with the provisions of the Promotion of Administrative Justice Act (PAJA).⁵²⁷ These provisions of NEMBA are accordingly significant, particularly in the context of bioprospecting permitting matters.

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⁵¹⁹ The African Centre for Biosafety (n. 310) at 20. Also see Sec. 63, read with Sec. 52(1), Sec. 53(1), Sec. 56(1) and Sec. 57(1) and Sec. 79 read with Sec. 66(1), Sec. 67(1), Sec. 68, Sec. 70(1) and Sec. 72, NEMBA.

⁵²⁰ The African Centre for Biosafety (n. 310) at 21.

⁵²¹ *Ibid*.

⁵²² Reg. 17(3) (c), BABS.

⁵²³ Sec. 88(3), NEMBA. Promotion of Administrative Justice Act No. 3 of 2000.

These principles apply to the actions of all organs of state that may affect the environment and guide the administration of any law concerned with the protection and management of the environment.

⁵²⁵ Sec. 2 (4) (f), NEMA.

⁵²⁶ Sec. 2 (4) (g), NEMA.

⁵²⁷ Promotion of Administrative Justice Act No. 3 of 2000.

Any administrative action, which materially and adversely affects the rights or legitimate expectations of any person, must be procedurally fair.⁵²⁸ In these circumstances, PAJA provides for adequate notice, a reasonable opportunity to make representations, a clear statement of the administrative action, adequate notice of any right of review or internal appeal, and adequate notice of the right to request reasons.⁵²⁹ Section 4 of PAJA stipulates that, where the administrative action materially and adversely affects the rights of the public, the administrator must decide whether to hold a public enquiry, follow a notice and comment procedure or follow both procedures. In circumstances where the administrator is empowered to follow a procedure that is fair yet different, the administrator may decide whether to follow that particular procedure or another procedure that complies with the provisions of Section 3 of PAJA.⁵³⁰

Having regard to the above, the African Centre for Biosafety has pointed out that PAJA provides a means for NGOs, community-based organizations and other interested and affected parties to assert their right to be heard in the bioprospecting permitting process. Under the provisions of PAJA, if an NGO, community-based organization or other interested and affected party can show that a bioprospecting permitting decision materially or adversely affects their rights or legitimate expectations, the issuing authority would be required to follow a procedure that complies with the provisions of Section 3 of PAJA. Similarly, where it can be shown that a bioprospecting permitting decision materially or adversely affects the rights of the public, the requirements of Section 4 of PAJA will have to be complied with. 532

4.9.3 Public Comment on Benefit-Sharing Agreements

The Biodiversity Act requires that bioprospectors must disclose all material information relating to the bioprospecting to the stakeholders. ⁵³³ However, the Biodiversity Act does not require the disclosure of information pertaining to bioprospecting to interested and affected parties who are not stakeholders. There is often controversy surrounding bioprospecting activities and benefit-sharing agreements due to such agreements not being equitable, with indigenous communities and traditional knowledge holders being unfairly exploited. Due to the limited resources,

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⁵²⁸ Sec. 3, PAJA.

⁵²⁹ The African Centre for Biosafety (n. 310) at 21.

⁵³⁰ *Ibid*.

⁵³¹ *Ibid*.

⁵³² *Ibid*.

⁵³³ Sec. 82(2)(a) & 82(3)(a), NEMBA.

knowledge and capacity of indigenous communities, they rely largely on NGOs and community-based organizations to assist them in protecting their interests. However, the lack of consultation and participation provisions applicable to the bioprospecting permitting process makes the task of NGOs and community-based organizations harder to fulfill and has the potential to render such organizations ineffective in playing a bridging role between indigenous communities and bioprospectors.

Even though the BABS Regulations provides that the Minister may invite public comment on BSAs; this provision is qualified to the effect that no confidential information may be furnished by the Minister. ⁵³⁴ The definition of 'confidential information' is very broadly defined as 'information which, if disclosed, may be detrimental to the commercial or financial interests of a party to a benefit-sharing agreement' and this includes:

- (i) information about the research being carried out, including details of the species to be collected and the areas in which specified species are to be collected;
- (ii) financial, commercial, scientific or technical information, including trade secrets;
- (iii) indigenous knowledge, if the disclosure of such knowledge may be detrimental to the relevant indigenous community.⁵³⁵

There is therefore a lack of publicly available information regarding bioprospecting permit applications and this invariably impacts on the quality of the contributions that NGOs and community-based organizations can make to the process. 536

4.9.4 The Promotion of Access to Information Act No. 2 of 2000

As highlighted by the African Centre for Biosafety, the Promotion of Access to Information Act, Act No. 2 of 2000 (PAIA) offers some assistance in remedying the situation.⁵³⁷ PAIA takes precedence over the BABS Regulations and if information in a BSA is withheld from the public on the basis of confidentiality, such information may still be requested under the provisions of PAIA.⁵³⁸ The test for confidentiality set out in PAIA would therefore have to be considered

⁵³⁴ Reg. 17(3)(c), BABS.

⁵³⁵ Reg.1, BABS.

⁵³⁶ The African Centre for Biosafety (n. 310) at 22.

⁵³⁷ *Ibid*.

⁵³⁸ *Ibid*.

rather than the test set out in the BABS Regulations.⁵³⁹ The Minister should ideally use PAIA as a guideline as to what information to publish if he/she intends publishing a benefit-sharing agreement for comment. However, as we have seen with the two draft BSAs relating to Parcevale (Pty) Ltd, Schwabe Extracta GMBH and CO.KG. and the Imingcangathelo Development Trust and Endakeni Community in Kwazulu-Natal and Edakeni Muthi Futhi Trust, both of which were published for public comment, this has not been the case.

4.9.5 The Pelargonium case

The African Centre for Biosafety (ACB)⁵⁴⁰ is a South African NGO that has been working with the Alice community in the Eastern Cape with a view to assisting such community in asserting its rights pertaining to traditional knowledge relating to the use of extracts from *Pelargonium* for medicinal purposes.⁵⁴¹ A German company, Schwabe Pharmaceuticals marketed a commercial product known as *Umckaloaba*, which is based on the extracts of *Pelargonium*, and such company had several European Patents over the product registered in the European Patents Office (EPO).⁵⁴²

ACB, on behalf of the Alice community, argued that Schwabe Pharmaceuticals, in contravention of the CBD, had failed to obtain PIC or enter into BSAs with either the South African government or the Alice community for use of extracts from *Pelargonium* for medicinal purposes. One of the patents was ultimately revoked by the EPO, not because it breached the CBD, but on the basis that the extractive method used by Schwabe Pharmaceuticals to produce *Umckaloaba* lacked an inventive step, as the indigenous community had used the same

⁵³⁹ Under the provisions of PAIA, the following information can be withheld:

⁽i) trade secrets:

⁽ii) financial, commercial, scientific or technical information, other than trade secrets, if the disclosure of that information would be likely to cause harm to the commercial or financial interests of a party to the agreement or any other third party;

⁽iii) information that, if disclosed, could reasonably be expected to put a party to the agreement at a disadvantage in contractual or other negotiations; and/or

⁽iv) information about research, the disclosure of which would be likely to expose a party to the agreement or a person carrying out the research or the subject matter of the research to serious disadvantage or to prejudice a party to the agreement in commercial competition. See Sec. 36(1) and 43(1), PAIA.

⁵⁴⁰ The African Centre for Biosafety is a non-profit organization, based in South Africa and provides authoritative information, research and policy analysis on, *inter alia*, genetic engineering, biosafety, biopiracy.

⁵⁴¹ The African Centre for Biosafety (n. 310) at 22.

⁵⁴² *Ibid*.

⁵⁴³ Lewis, M (n. 114) at 75.

extraction method to produce *Umckaloaba* for centuries.⁵⁴⁴ Although the *Pelargonium* case constitutes a major advance for indigenous communities, in their quest to preserve their rights over their traditional knowledge, it must be highlighted that such breakthrough came only after the relevant patents were challenged by the NGO involved. Miriam Mayet of the African Centre for Biosafety was quoted as saying, 'Nevertheless we regret that such action comes only after such patents have been challenged by us'.⁵⁴⁵

During its work with the Alice community, the ACB made several PAIA requests for information relating to bioprospecting permit applications made in respect of *Pelargonium Sidiodes* and *Pelargonium Reniform*. However, not only did it take months for them to receive a response, but the response received contained minimal information and the Department of Environmental Affairs relied heavily on the definition of 'confidential information' to justify the marginal response furnished. The definition of 'confidential information' is accordingly too wide and fails to balance the interests of the bioprospecting permit applicants and interested and affected parties. It has been argued that the withholding of entire permit applications based on the fact that they contain some confidential information constitutes an unnecessary restriction on the public's right to access to information. ⁵⁴⁶ Of relevance is that the Constitutional Court has indicated that, apart from information that could reasonably be withheld for the protection of certain prescribed interests, government authorities are obliged to make public information in their possession. ⁵⁴⁷

4.9.6 Lack of public participation and consultation provisions

The Biodiversity Act and the BABS Regulations leave NGOs and civil society organizations in a difficult position relating to public participation, predominantly as neither the Biodiversity Act nor the BABS Regulations impose a mandatory requirement for applicants to give public notice of bioprospecting permit applications. Although the Biodiversity Act and the BABS Regulations require the disclosure of all material information regarding bioprospecting to the identified stakeholders, there is no similar provision regarding the disclosure of information to interested and affected parties who are not stakeholders. Furthermore the wide definition of confidential

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⁵⁴⁴ Rutert, B et al (n. 25) at 18.

⁵⁴⁵ *Ihid*.

⁵⁴⁶ The African Centre for Biosafety (n. 310) at 25.

⁵⁴⁷ Biowatch Trust v Registrar Genetic Resources and Others. 2009 (10) BCLR 1014 (CC), at 1032.

information has resulted in requests for information under PAIA being refused. The powers exercised by issuing authorities are not subject to the general public participation and consultation provisions and, accordingly, South Africa's ABS legislation fails to promote the participation of NGOs and civil society organizations or to ensure that the interests of such organizations are adequately protected. Such participation would, in turn, enhance the protection of the interests of indigenous communities in relation to bioprospecting matters.

It is essential that a balance is struck between protecting confidential information and providing sufficient information to enable NGOs and civil society groups to submit meaningful representations or objections, on behalf of indigenous communities, who are usually unskilled and lack resources and capacity. While the provisions of the BABS Regulations give bioprospectors a wide discretion on what constitutes 'confidential information', the Minister must ensure that this is reasonable and does not preclude effective public involvement, particularly considering the need for the involvement by NGOs and community organizations in the protection of the genetic resources and traditional knowledge of indigenous communities.

4.10 Concluding Remarks

Capacity development of indigenous communities is required not only to ensure adequate PIC processes and ABS negotiating procedures, but is also necessary in the context of such communities establishing efficient administrative systems, management structures and financial procedures. Accordingly, strong efforts are required to build the capacity of indigenous communities to engage in the PIC process, efficiently negotiate with bioprospectors and effectively receive and distribute the funds arising from benefit-sharing. Furthermore, stable, robust and representative institutions, as well as sufficient time and financial support, are essential elements in capacity building. There should ideally be a focus on developing the capacity of bioprospectors to support indigenous communities and the capacity of government to ensure compliance and implementation of the ABS legislation, and more importantly, the capacity of NGOs and other supporting organizations of indigenous communities, considering that such organizations play a critical role in bridging the gap between bioprospectors and indigenous communities.

⁵⁴⁹ *Ibid*.

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⁵⁴⁸ Wynberg, R, Chennells, R and Schroeder, D (n. 393) at 343.

<u>Chapter Five: Biocultural Community Protocols as an Implementation Tool in Bioprospecting</u>

5.1 Introduction

One of the means adopted by indigenous communities in order to address the implementation challenges of ABS legislation has been the development of a range of legal and quasi-legal instruments, including research guidelines and *sui generis* contracts, based on customary law in order to regulate access to and use of traditional knowledge. These instruments have collectively and individually come to be known as 'Community Protocols'. Although progressive ABS laws which enforce benefit-sharing and recognize the rights of indigenous communities are essential, they remain inadequate to ensure fairness among indigenous communities. As discussed under Chapter Four, there are numerous implementation challenges and complexities facing indigenous communities in the context of bioprospecting. It is therefore critical for indigenous communities to become organized and empowered in order to assert and secure their own rights. Accordingly, there is an urgent need for the establishment of new forms of protection for indigenous communities, in order to prevent the misappropriation of traditional knowledge, over and above the current ABS laws.

5.2 Chapter Overview

This Chapter will look at the emergence of the biocultural rights of indigenous communities and the recognition thereof in the Nagoya Protocol. More particularly, Biocultural Community Protocols will be explored as a response to the implementation challenges facing indigenous communities, in the protection of their genetic resources and associated traditional knowledge. The development of Biocultural Community Protocols will be discussed and the well-known Biocultural Community Protocol of the Bushbuckridge will be evaluated, as a case study, to give a practical perspective of the benefits that such Protocols can offer. The potential challenges facing indigenous communities in establishing Biocultural Community Protocols will also be highlighted and it will be suggested that such challenges can be overcome by providing guidance to indigenous communities and by the adoption of a participatory approach. It will be shown that

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⁵⁵⁰ Tobin, B, 'Setting Protection of TK to Rights-Placing Human Rights and Customary law at the Heart of TK Governance', in Kamau, EC & Winter, G (Eds), *Genetic Resources, Traditional Knowledge and the Law: Solutions for Access and Benefit-Sharing*. Earthscan, London, 2009 at 113.

notwithstanding the potential drawbacks of establishing Biocultural Community Protocols, such Protocols have the ability to become a crucial implementation tool in assisting indigenous communities in the protection of their rights, in relation to bioprospecting matters.

5.3 The Emergence of Biocultural Rights of Indigenous Communities

In the last two decades, there has been an emergence of third generation rights called 'group rights' or 'collective rights', which differ from first generation civil and political rights, as well as the second generation social and economic rights. ⁵⁵¹ Biocultural rights have emerged from the third generation 'group rights', but they differ from such group rights, due to the commitment that biocultural rights have to conservation and the sustainable use of biodiversity. ⁵⁵² Indigenous communities advocated biocultural rights in international environmental negotiations as a means to avoid biopiracy, and they have based their assertion on the fact that the way of life of indigenous communities enhances conservation and sustainable use of biological diversity. ⁵⁵³ Furthermore, this 'way of life' is critical in securing rights to culture, knowledge and practices. ⁵⁵⁴ Essentially, biocultural rights protect this way of life of indigenous communities and ecosystems. ⁵⁵⁵ Biocultural rights comprise the rights of indigenous communities over the various aspects of their way of life that pertain to conservation and the sustainable use of biodiversity. ⁵⁵⁶ Such aspects relate, *inter alia*, to their knowledge, innovations, practices, customary laws and natural resources. ⁵⁵⁷

5.4 Recognition of Biocultural Rights and Community Protocols in the Nagoya Protocol

The Nagoya Protocol contains certain crucial biocultural rights which enshrine the self-determination of indigenous communities. These include provisions in Articles 6 and 7 of the Nagoya Protocol, respectively, which pertain to access to the genetic resources and traditional knowledge of indigenous communities. Both these Articles encourage the prior informed consent or approval and involvement of indigenous communities before there is access to their genetic resources and associated traditional knowledge. Article 6.2 is particularly significant as it

⁵⁵¹ Bavikatte, K & Robinson, DF (n.30) at 49.

⁵⁵² *Ibid* at 50.

⁵⁵³ *Ibid*.

⁵⁵⁴ *Ibid*.

⁵⁵⁵ *Ibid*.

⁵⁵⁶ *Ibid* at 51

⁵⁵⁷ *Ibid*.

encourages Parties to uphold the rights of indigenous communities over their genetic resources; something which was not recognized in the CBD. Article 5 of the Nagoya Protocol highlights another biocultural right of indigenous communities in that it encourages Parties to ensure that indigenous communities benefit from the utilization of their traditional knowledge and genetic resources by third parties. As discussed under Chapter Two, the caveats contained in Articles 5, 6 and 7 of the Nagoya Protocol offer Parties flexibility and discretion with regards to the implementation of these provisions. Parties are, however, only granted flexibility with regards to the type of measures that they may take in the implementation of these provisions of the Nagoya Protocol. They do not have the option not to take measures when there is clearly a need for measures to be taken.

An important biocultural right contained in the Nagoya Protocol is the right of self-governance of indigenous communities, by reference being made to their customary laws and Community Protocols. Under Article 12 of the Nagoya Protocol, Parties are encouraged to consider the customary laws and Community Protocols of indigenous communities in their implementation of the provisions of the Nagoya Protocol. The Nagoya Protocol accordingly recognizes the governance systems of indigenous communities and in so doing, recognizes indigenous communities' rights of self-determination. 559

The use of the terms 'in accordance with domestic law' and 'as applicable' under Article 12 of the Nagoya Protocol offers Parties flexibility with regards to their consideration of customary laws and Community Protocols and implies that States are under no general obligation to take into consideration customary laws and Community Protocols. As with the provisions of Articles 5, 6 and 7 of the Nagoya Protocol, the above qualifications do not, however, offer States the option not to take into consideration the customary laws and Community Protocols of indigenous communities when there is clearly an identified need to do so. Article 12 proclaims that States 'shall' take into consideration customary laws and Community Protocols in the implementation of their obligations under the Nagoya Protocol and the obligations to do so are therefore mandatory in nature. States are only granted flexibility with regards to the extent they wish to take such governance mechanisms into account. ⁵⁶⁰ The provisions of Article 12 therefore

⁵⁵⁸ Article 12, Nagoya Protocol

⁵⁵⁹ Bavikatte, K & Robinson, DF (n.30) at 52.

⁵⁶⁰ Greiber, T et al (n. 11) at 140.

constitute a significant achievement for community rights and communal control over natural resources. ⁵⁶¹

Although all of the biocultural rights set out above allow for limited Party involvement and none of such rights are completely unqualified, they nevertheless remain a major milestone in the recognition of the self-determination of indigenous communities. These biocultural rights, as established in the Nagoya Protocol, can therefore be seen as substantial gains for indigenous communities in their struggle against biopiracy. Notwithstanding the Nagoya Protocol's recognition of the rights of indigenous communities to self-determination and to manage their genetic resources and traditional knowledge, in order for indigenous communities to capitalize on the biocultural rights enshrined in the Nagoya Protocol, there must be improved exercise of community rights at local level. ⁵⁶²

The current intellectual property systems are founded on the western notion of individualism, in terms of which the focus is on knowledge produced from individual effort. ⁵⁶³ However, traditional knowledge does not fit this mold and is as a result of communal rather than individual effort. ⁵⁶⁴ Traditional knowledge is not static and it evolves over time, thereby making it ill-designed for an intellectual property system which is designed for individualism and exclusivity. ⁵⁶⁵ Such knowledge focuses on the bio-cultural relationship between self and culture, whereby indigenous communities are more concerned with their obligations to each other and their natural resources, rather than in their ability to assert interest in property against the world. ⁵⁶⁶

Biocultural Community Protocols, ⁵⁶⁷ as advanced in the Nagoya Protocol, constitute a response to the implementation challenges facing indigenous communities in the protection of their genetic resources and associated traditional knowledge. A Biocultural Community Protocol

⁵⁶¹ n.:

⁵⁶² Bavikatte, K & Robinson, DF (n.30) at 54.

⁵⁶³ Cross, JT, 'Property rights and Traditional Knowledge' in *PER*, Vol.13 No. 4, 2010, 12 at 12.

⁵⁶⁴ Ihid

⁵⁶⁵ *Ibid*.

⁵⁶⁶ Du Plessis, E, 'Protection of Traditional Knowledge in South Africa: Does the "commons" provide a solution? Social Science Research Network, September 10, 2011, 1 at 7. Available at http://ssrn.com/abstract=1997992. Accessed on 12th October 2012.

⁵⁶⁷ Community Protocols constitute Charters of rules and responsibilities, in which indigenous communities set out their customary rights to natural resources, in accordance with customary, national and international law.

promotes the indigenous community's way of life, which is based on the customary sustainable use of biodiversity and such a Protocol is community led. 568

5.5 The Development of Biocultural Community Protocols

The development and use of Community Protocols gives indigenous communities the opportunity to reflect on their ways of life, values and customary laws and it further empowers such communities to make use of international and national laws, in the furtherance of their right to self-determination. Such Protocols can assist indigenous communities to:

- (i) assert and defend their customary rights when faced with external threats;
- (ii) gain recognition from policy makers and negotiate access to their customary resources;
- (iii) promote effective dialogue and equitable partnerships with other parties;
- (iv) improve organization, representation and cohesion between communities; and
- (v) establish local processes and institutions with regards to ABS arrangements, in accordance with their customary laws.⁵⁷⁰

By making use of Community Protocols, indigenous communities are given the opportunity to establish guidelines and procedures based on custom and values, for the future management of their natural resources. These Protocols also provide a means to establish procedural and substantive guidelines pertaining to decision-making, with particular regards to the principle of prior informed consent, within the ABS context.⁵⁷¹ Biocultural Community Protocols therefore enable indigenous communities to become pro-active with regards to matters with which they would ordinarily have been reactive, and such Protocols accordingly have the potential to ensure that indigenous communities are legally empowered by locally appropriate processes.⁵⁷²

⁵⁶⁸ Bavikatte K & Robinson, DF (n.30) at 62.

⁵⁶⁹ Ihid

⁵⁷⁰ Swiderska, K *et al* (n. 157) at 27.

⁵⁷¹ *Ibid*.

⁵⁷² *Ibid*.

5.6 Law 27811 of Peru

The first country to adopt a legal framework for the protection of traditional knowledge related to biodiversity was Peru, 573 which, as explained below, also provides a good example of the development and benefits of Community Protocols in practice. In August 2002, Law 27811 was established to protect the rights of indigenous communities over their traditional knowledge pertaining to biological diversity and, being declaratory in nature, such Law requires the PIC of indigenous communities for access to and use of traditional knowledge. ⁵⁷⁴ In addition, the Law establishes measures to ensure the fair and equitable sharing of benefits arising from the access to and use of traditional knowledge, as well as measures to preclude and limit acts of misappropriation.⁵⁷⁵ Of significance is that, although the Peruvian Law recognizes traditional knowledge to be cultural patrimony, it permits any single indigenous community to enter into an ABS agreement. 576 This has the potential to cause tension between collective cultural patrimonial rights and the rights of individual communities to enter into agreements for the commercial use of traditional knowledge. 577 The Peruvian ABS legislation does contain a provision to the effect that indigenous communities may look to customary law with a view to resolving internal conflicts, but this provides only a partial solution. ⁵⁷⁸

The Peruvian Law was formed on the basis that many indigenous communities in Peru lacked any central authority and their existing political organization constituted various local and regional, as well as national, organizations, which were diverse and not unified, ⁵⁷⁹ as we have seen from the case study pertaining to the Peruvian Medicinal Plant Sources of New Pharmaceuticals, under Chapter Four. Accordingly, requiring PIC from all custodians of traditional knowledge prior to negotiating an ABS agreement would in all probability prove to be a futile exercise and may in fact lead to a virtual moratorium on bioprospecting involving traditional knowledge. 580 Hence, in circumstances where there is a lack of central decisionmaking authority or established processes to resolve inter-community disputes among indigenous

⁵⁷³ Tobin, B (n. 550) at 112.

⁵⁷⁴ Law No. 27811 (Published in the Official Journal 'El Peruano' on August 10, 2002). See Article 6, Law 27811. English version available at http://www.wipo.int/wipolex/en/text.jsp?file_id=179597. Accessed on 28 October 2013. ⁵⁷⁵ Article 7 & 42, Law 27811.

⁵⁷⁶ Article 6 & 10, Law 27811.

⁵⁷⁷ Tobin, B (n. 552) at 113.

⁵⁷⁸ Article 46, Law 27811.

⁵⁷⁹ Tobin, B (n. 550) at 113.

⁵⁸⁰ *Ibid*.

communities, customary law is unlikely to offer a solution.⁵⁸¹ The Peruvian Law's provision pertaining to indigenous communities resorting to customary law to resolve their internal conflicts is, therefore, unfortunately not an answer to the problem.

Customary law and traditional decision-making forums were utilized by the indigenous communities of Peru in the development of a number of ABS agreements, including an agreement for the repatriation of native potato varieties between the Andean communities and the International Potato Centre, and a bioprospecting agreement involving Aguaruna communities of the northern Peruvian Amazon, negotiated within the International Biodiversity Group (ICBG) Program. While participating in a series of workshops to review the ABS and traditional knowledge Law of Peru, the Aguaruna communities came to the conclusion that indigenous communities with shared traditional knowledge should ideally work together in the development of Community Protocols, which would set out the agreed procedures for PIC, benefit-sharing and dispute resolution. S83

A Biocultural Protocol was established as a framework for the equitable sharing of benefits arising out of an ABS Agreement amongst five communities in the case of Peru's Potato Park. The process to develop the Protocol took approximately fifteen months and it was negotiated and designed by the communities themselves. The Protocol determines the way benefits are shared and used and it ensures a contribution to biodiversity conservation, as well as poverty reduction. It has ensured that the communities have an enhanced capacity for PIC and the negotiation of BSAs in ABS matters and it is representative of an ABS Biocultural Community Protocol actually functioning in practice, as it applies to benefits that are already being derived and distributed. S87

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⁵⁸¹ *Ibid*.

⁵⁸² *Ibid* at 113-114.

⁵⁸³ *Ibid* at 114.

⁵⁸⁴ Swiderska, K *et al* (n. 157) at 37.

⁵⁸⁵ *Ibid*.

⁵⁸⁶ *Ibid*.

⁵⁸⁷ *Ibid*.

5.7 The Biocultural Community Protocol of the Traditional Health Practitioners of Bushbuckridge

Community Protocols essentially have the potential to change the status quo in ABS matters from processes of merely attempting to secure communities' participation to becoming inclusive, locally appropriate processes driven by legally empowered communities. The Biocultural Community Protocol of the Traditional Health Practitioners of Bushbuckridge highlights the benefits of Community Protocols in the South African context. The Kruger to Canyons Biosphere Region (KZC) in the Limpopo and Mpumalanga Provinces in South Africa is part of UNESCO's World Network of Biosphere Reserves. The KZC spans over four million hectares and contains two national parks, the Kruger National Park and Blyde River Canyon Nature Reserve. This biosphere reserve is not only extremely biodiverse, but is also culturally diverse, yet many of the indigenous communities that reside within it are economically poor. An area in this region, known as Bushbuckridge, has many traditional healers who provide primary health care for many people in the region. Such healers also play a vital role in the promotion of traditional values and in acting as the custodians of the traditional knowledge of plants growing in the biosphere region.

The healers hold various forms of traditional knowledge with regards to the uses of the local medicinal plants, and they further support the conservation and sustainable use of such plants through their traditional practices of sustainable harvesting. Many of these plant species were being threatened due to the commercial level harvesting for use in South Africa's cities. As a result, access to protected areas under government control was severely restricted and traditional healers were struggling to harvest the plants they needed. In addition, the healers were concerned

⁵⁸⁸ *Ibid* at 63. Biosphere Reserves participate in UNESCO's man and Biosphere Programme and seek to find and demonstrate innovative solutions in reconciling biodiversity conservation and sustainable development. ⁵⁸⁹ *Ibid* at 64.

⁵⁹⁰ Du Plessis, E (n. 566) at 1.

⁵⁹¹ Jonas, H *et al* (n. 6) at 64.

⁵⁹² Sibye, R, Uys, M-T, Cocchiaro, G and Lorenzen, J, 'The Bushbuckridge BCP: Traditional health practitioners organize for ABS in South Africa' in *Participatory Learning and Action* 65, 101 at 103. Available at http://pubs.iied.org/pdfs/G03403.pdf. Accessed on 13th May 2013.

about the use of their traditional knowledge without PIC due to the historical misappropriation of traditional knowledge without any benefit accruing to indigenous communities. 594

As holders of traditional knowledge, the traditional healers acquired new rights once the South African Biodiversity Act was promulgated in 2004, together with the Bioprospecting Access and Benefit-Sharing Regulations in 2008. However, few health practitioners actually knew their rights and, in March 2009, the Biosphere Committee, which was responsible for the KZC's overall management, began assisting a group of traditional healers, based at Vukuzenzele Medicinal Plants Nursery in Bushbuckridge, who wanted to meet with other groups of healers with a view to discussing and establishing their rights.⁵⁹⁵ The Bushbuckridge Traditional Healers came from two different language groups, known as the Sepedi and Tsonga, but they viewed themselves as a single group due to their knowledge and use of the same medicinal plants. 596

The various groups of traditional healers thereafter met regularly to discuss and learn more about South African ABS legislation and law concerning the conservation of medicinal plants and protection of traditional knowledge. 597 This resulted in more than 80 healers forming a governance structure under the name of Bushbuckridge Traditional Healers (now known as the Kukula Traditional Health Practitioners' Association), with an Executive Committee being authorized to present their views to stakeholders. This structure then worked with the Biosphere Committee and Natural Justice, an NGO of lawyers who advise communities on environmental issues, to finalize a Biocultural Community Protocol which was presented to local authorities and other stakeholders in the KZC in September 2009. 598 The seven page Biocultural Community Protocol⁵⁹⁹ includes, *inter alia*, the biocultural values of the traditional healers, some detail of their traditional knowledge, the threats to their livelihoods posed by biodiversity loss and the taking of their traditional knowledge without the sharing of benefits, how the community plans to improve conservation and sustainable use of medicinal plants, and information for people wanting to access their traditional knowledge and medicinal plants. 600 With regards to access to

⁵⁹⁴ *Ibid*.

⁵⁹⁵ Jonas, H *et al* (n. 6) at 64.

⁵⁹⁶ *Ibid*.

⁵⁹⁷ *Ibid*.

⁵⁹⁸ *Ibid*.

⁵⁹⁹ The Biocultural Community Protocol of the Traditional Health Practitioners of Bushbuckridge. Available at www.naturaljustice.org. Accessed on 15th April 2013.

Biocultural Community Protocol of the Traditional Health Practitioners of Bushbuckridge: p 1.

their medicinal plants and use of their traditional knowledge, the Biocultural Community Protocol stipulates that commercial bioprospectors are expected to apply to the Executive Committee at the preliminary stage in the negotiation of a benefit-sharing agreement, whether such agreement be monetary or otherwise. ⁶⁰¹ The Protocol therefore makes clear to bioprospectors what the leadership and representative structure is and who to approach in the PIC and BSA negotiation processes.

The international and national rights of the traditional healers were unknown to them until negotiations towards a Biocultural Protocol brought them to light. The process of developing the Protocol encouraged the community to learn about ABS legislation and policy frameworks in their own context and according to their own timeframe. The process was not driven by outside influences and it enabled the community to consider inter-related issues, which, in turn, helped the traditional healers to articulate their opinions, concerns and forward-looking strategy in the form of a Protocol. Accordingly, for the traditional healers, the concluded Protocol constitutes an interface with government and the private sector about their values and it further embodies the resilience and vulnerabilities of their endemic ways of life. In so doing, the traditional healers are using national and international laws as a strong basis to make a moral and legal claim to their biocultural rights.

The traditional healers combined their respective individual knowledge by engaging in a participatory and non-time bound process, which resulted in them defining themselves as an Association committed to protecting their local biological resources and traditional knowledge. Through the establishment of a Community Protocol, the traditional healers defined the terms and conditions on which they were prepared to share their traditional knowledge. A local cosmetic company responded to the Protocol and approached the traditional healers on their terms, regarding the use of their medicinal plants and traditional knowledge. ⁶⁰³ This is a refreshing change to the usual case of bioprospecting, where the indigenous communities are required to respond to terms set out by bioprospectors. In 2011, the Association entered into a Non-disclosure Agreement with the said cosmetic company in order to research the use of certain

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⁶⁰¹ Biocultural Community Protocol of the Traditional Health Practitioners of Bushbuckridge: p 5.

⁶⁰² Jonas, H et al (n. 6) at 67.

⁶⁰³ *Ibid* at 68.

of their genetic resources and associated traditional knowledge. 604 If the research results in the development of cosmetic products, the Association is hoping to negotiate an access and benefitsharing agreement, with benefits to return to the group as a whole. 605 The Biocultural Community Protocol has undoubtedly empowered the traditional healers of Bushbuckridge, as it has enabled an endogenous response to the implementation challenges of ABS legislation in South Africa.

5.8 Potential Challenges in developing Biocultural Community Protocols

The development of Biocultural Community Protocols is, however, not without its own challenges. Natural Justice and its partners conducted consultation on Biocultural Community Protocols in India, Sri Lanka and South Africa during 2010, and during such consultations, various challenges and potential weaknesses were raised. ⁶⁰⁶ One potential challenge or weakness is that the process of developing a Biocultural Community Protocol could be open to abuse by outsiders or even from within the community itself. 607 In addition, the development process may in fact reinforce or perpetuate existing power injustices or inequalities in existence within the community, such as women and youth being excluded from decision-making processes. 608 It was further argued that the development industry may use Biocultural Community Protocols as yet another top-down imposition and it was also highlighted that community-based monitoring and evaluation of such Protocols was not emphasized enough. 609

As discussed above, although the Nagoya Protocol makes specific reference to the inclusion of Community Protocols, Parties have the discretion to decide whether to support the development of Community Protocols, in relation to access to traditional knowledge associated with genetic resources and the fair and equitable sharing of benefits arising out of the utilization of such knowledge. The use of the terms 'in accordance with domestic law' and 'as applicable' under Article 12 of the Nagoya Protocol offers Parties significant flexibility and discretion with regards to their consideration and support of customary laws and Community Protocols. It is unfortunate that the Nagoya Protocol fails to impose a stronger obligation in this regard. Nevertheless,

⁶⁰⁴ Sibuye, R et al (n. 592) 106.

⁶⁰⁵ *Ibid*.

⁶⁰⁶ Jonas, H et al (n. 6) at 68.

⁶⁰⁷ *Ibid*.

⁶⁰⁸ Ibid.

⁶⁰⁹ *Ibid*.

notwithstanding the weakness of the provisions of Article 12 of the Nagoya Protocol, it remains a major step in the right direction.

With the Nagoya Protocol increasing emphasis on Community Protocols, the potential challenges or weaknesses highlighted above could fast become a reality. Hence, there is a growing need for assistance to be provided to communities when developing Community Protocols. Jonas *et al* suggest that such assistance could take the form of inter-community lesson-sharing, good practice guidelines and tested methodologies and resources; ⁶¹⁰ while Swiderska *et al* highlight that a participatory process would be essential in the development of Community Protocols, so as to ensure that such Protocols represent the majority view or common interest of the community as a whole. ⁶¹¹ A participatory process is also critical to building up the capacity and confidence of indigenous communities to negotiate with the more powerful bioprospectors, so that their rules and rights, as enshrined in their Community Protocols, are recognized. ⁶¹² There must be a concerted effort to increase understanding of Community Protocols, how they can be effectively supported in practice and the benefits they can provide to the various stakeholders, including indigenous communities, government and bioprospectors. ⁶¹³ Community-based monitoring and evaluation will also be critical in improving the effects of such Protocols and achieving external recognition. ⁶¹⁴

Notwithstanding the aforesaid potential challenges, Biocultural Community Protocols have proved a vital tool in assisting indigenous communities to define themselves as a community and to establish their combined views on conservation and the sustainable use of their genetic resources, as well as the use of their traditional knowledge. The Biocultural Community Protocol of the Traditional Healers of Bushbuckridge, by way of example, has enabled the traditional healers to develop greater capacity in asserting their rights over their genetic resources and associated traditional knowledge, through the development of their Biocultural Community Protocol. The agreement by the traditional healers to combine their traditional knowledge is now widely seen as a leading example of traditional knowledge commons, whereby benefits

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⁶¹⁰ Jonas, Het al (n. 6) at 68.

⁶¹¹ Swiderska, K *et al* (n. 157) at 34.

⁶¹² *Ibid*.

⁶¹³ *Ibid* at 38.

⁶¹⁴ *Ibid* at 37.

⁶¹⁵ Sibuye, R et al (n. 592) at 107.

from the use of traditional knowledge return to the group as a whole. 616 The success of the Biocultural Community Protocol of the traditional healers of the Bushbuckridge has been linked to the integrity of the process and tools of community engagement and representation. ⁶¹⁷

The traditional healers acknowledge that their established Biocultural Community Protocol is not an end in itself, but is a step in the process towards their goal of conservation and sustainable livelihoods. 618 Ultimately, the continued revision and expansion of their Biocultural Community Protocol will be critical in this process. The undeniable benefit of a Protocol of this nature is that it provides a framework for the management of and access to genetic resources and associated traditional knowledge of the relevant indigenous community.

5.9 **Concluding Remarks**

The development of Community Protocols, setting out procedures regarding applications for access to genetic resources and traditional knowledge and identifying the relevant authorities within indigenous communities entitled to receive applications and make decisions on PIC, invariably provides the basis of building functional interfaces between indigenous communities, bioprospectors and government. As highlighted by Jonas et al, Community Protocols assist communities to provide a basis for the development of the future management of their natural resources by establishing their values and customary procedures which govern the management of their natural resources. 619 Such Protocols also assist communities in setting out their substantive and procedural requirements regarding decision-making in accordance with the principle of PIC. This will provide clarity to bioprospectors in ABS matters and will aid indigenous communities to gain recognition for their community-based natural resource management systems. Community Protocols enable indigenous communities to balance their customary management of their biocultural heritage with the external requirements, as established by legal frameworks. Such Protocols promote a more participatory approach to the

⁶¹⁶ Ihid

⁶¹⁷ *Ibid*.

⁶¹⁹ Jonas, H et al (n. 6) at 63.

governance of natural resources and biodiversity, thereby minimizing the power asymmetries that are normally characteristic of community-government relations.⁶²⁰

The Nagoya Protocol represents a significant instrument in the advancement of biocultural jurisprudence and the establishment of Biocultural Community Protocols. A Biocultural Community Protocol constitutes an interface document developed by an indigenous community, as a result of extensive consultations within the community and is intended to disclose to government and potential bioprospectors the process of engaging with such community. Although South Africa's ABS legislation makes no provision for Community Protocols, South Africa's Bioprospecting Guidelines have recognized that such Protocols can assist in ensuring that the indigenous community resolution, as required under Annexure 8 of the BABS Regulations, is not an impromptu decision but is instead a decision based on good community process. ⁶²¹ More significantly, South Africa's Bioprospecting Guidelines recognize that Community Protocols will provide government with a clear way of verifying the integrity of the community resolution obtained and in addition, will provide potential bioprospectors with well-defined steps to follow, when engaging with indigenous communities. ⁶²² Accordingly, Community Protocols have been identified as a crucial implementation tool that can assist indigenous communities in the protection of their rights, in relation to bioprospecting matters.

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⁶²⁰ Ihid

⁶²¹ Department of Environmental Affairs, 'South Africa's Bioprospecting, Access and Benefit-Sharing Regulatory Framework: Guidelines for Providers, Users and Regulators' July 2012 (n. 353) at 21.

⁶²² *Ibid*.

Chapter Six: Conclusion and Recommendations

6.1 International Law

The CBD was welcomed as the panacea against rampant biopiracy that had persisted long before it was established. 623 However, since the coming into force of the CBD in 1993, user countries have done little to meet their obligations under the CBD and an international ABS regime became critical in preventing biopiracy. 624 Although the Nagoya Protocol emerged as a partially negotiated text, it nevertheless remains a significant achievement for indigenous communities as it represents a high-water mark in international jurisprudence. 625 Unfortunately transparency, legal certainty and balance appear to have been sacrificed 626 and the critical demands of provider countries have been substantially watered down in the process of finalizing the Nagoya Protocol. The very general nature of the provisions of the Protocol does, however, offer the necessary flexibility to enable Parties to exercise a variety of options available to them at the crucial implementation stage. Notwithstanding its drawbacks, the Nagoya Protocol ultimately advances the rights of the indigenous communities holding genetic resources and associated traditional knowledge and encourages stronger involvement by such communities in bioprospecting matters.

6.2 South Africa

South Africa, now having ratified the Nagoya Protocol, must be prepared to meet its international obligations when the Nagoya Protocol does come into force. As present, the gaps and inconsistencies in South Africa's ABS legislation limit the achievement of a coherent legal framework that facilitates access to the genetic resources and associated traditional knowledge of indigenous communities, with a view to ensuring the fair and equitable sharing of benefits derived from the use of such genetic resources or traditional knowledge.

⁶²³ Kamau, EC, Fedder, B & Winter, G (n. 50) at 248.

⁶²⁴ *Ibid* at 249.

⁶²⁵ Jonas, H *et al* (n. 6) at 49.

⁶²⁶ Jospeh, RK (n. 10) at 92.

6.2.1 Capacity Building

From an implementation perspective, there are undoubtedly numerous challenges, with capacity development being critical. Capacity needs to be developed at national level in order to ensure firm leadership, to provide strategic guidance and to furnish technical assistance to bioprospectors, indigenous communities and provincial government. The relevant expertise cannot be easily or quickly gained due to the complex nature of ABS, bioprospecting and indigenous communities. It will therefore be essential for national government to include as part of its staff, individuals with the relevant scientific, commercial and other relevant expertise so as to ensure that well-informed decisions are made in the context of ABS. Although an expert ABS task team was established to advise the national government on the implementation of ABS measures, such task team was confined to government representatives only and failed to include the various other stakeholders involved in bioprospecting. 627

Capacity building is necessary not only within government but also among indigenous communities and supporting organizations affected by bioprospecting. From a practical perspective, this could involve the creation of a package of translated and simplified information or material that is relevant to the interests and rights of the various indigenous communities. 628

6.2.2 NGO's and Civil Rights Organizations

Having regard to the fact that indigenous communities depend largely on the support of NGOs and civil rights organizations, to be legally and financially empowered in ABS matters, the lack of provision for public participation in South Africa's ABS legislation, with particular regard to the bioprospecting permitting process, requires redress. It is suggested that the bioprospecting and ABS provisions of the Biodiversity Act be amended to the effect that they are brought within the ambit of Sections 99 and 100 of the Act, thereby requiring the Minister of Environmental Affairs to follow a consultative and public participation process, when dealing with bioprospecting permit applications. This would ensure that adequate notice containing sufficient information relating to the proposed bioprospecting is given, and it would, more importantly,

⁶²⁷ Wynberg, R & Taylor, M (n. 269) at 220.

⁶²⁸ *Ibid* at 220-221.

enable NGOs and civil rights organizations to make more informed representations and objections on behalf of the relevant indigenous communities.

6.2.3 Database of Permits

Due to the range of laws that are impacted by the Biodiversity Act and the variety of permits required by these laws, Wynberg and Taylor recommend that a single electronic database be created for permit applications for the use of biodiversity, which would cover ABS, research permits and permits relating to threatened and protected species. 629 Such database could include information pertaining to the application, its current status and details regarding permits already granted, which could assist in avoiding conflict between permits being granted in terms of provincial and national legislation, respectively. 630 This type of information could further assist in determining the volumes of genetic material being traded, which in turn would help in determining the benefits due to the indigenous communities who control such genetic resources or traditional knowledge. 631 The lack of such information has the potential to prevent compliance with, and negatively impact on, the implementation of benefit-sharing agreements. Adequate monitoring, enforcement and compliance are essential to ensure the effective implementation of an ABS system.

Overlapping Authorities

Notwithstanding the strides South Africa has taken in establishing ABS legislation, it would appear that the wider implementation challenges pertaining to traditional knowledge use and protection have not adequately been dealt with in the ABS framework. In this regard, although the Department of Arts and Culture has been a strong leader in the development of policy and laws relating to the protection of indigenous knowledge systems, the Department of Environmental Affairs, which has limited knowledge of working with indigenous communities, is responsible for determining whether indigenous communities are adequately compensated for the use of their genetic resources and traditional knowledge associated with such genetic resources. 632 Accordingly, from a practical perspective issues relating to traditional knowledge,

⁶²⁹*Ibid* at 221. ⁶³⁰*Ibid*.

⁶³¹Wynberg, R (n. 494) at 138.

⁶³² *Ibid* at 137.

indigenous communities and biodiversity in South Africa are often dealt with by overlapping Departments, which aggravates the already insurmountable implementation challenges.

6.2.5 Prior Informed Consent and Benefit-Sharing Agreements

The South African ABS regulatory framework for the first time obligates bioprospectors to obtain PIC from indigenous communities, who are custodians of genetic resources and the holders of the associated traditional knowledge, prior to the commercialization phase of bioprospecting. It further requires the various stakeholders to enter into a benefit-sharing agreement so as to ensure that the indigenous communities in control of the genetic resources or the holders of traditional knowledge are adequately compensated. Although the PIC and benefit-sharing provisions in South Africa's ABS legislation constitute a major advancement in addressing the historic exploitation of the rights and knowledge of indigenous communities, the failure of the Biodiversity Act to vest ownership of genetic resources in the State invariably has the potential to marginalize indigenous communities, as communal land-owners.

The South African land system applicable in communal areas is not well understood by western society and this could result in bioprospectors being more inclined to seek out resource owners whose ownership is more clear cut. This has negative connotations not only for indigenous communities, but for South Africa as a whole. The amending of the Biodiversity Act to vest ownership of genetic resources in the State has the potential to remedy this challenge. The suggested amendment to the Biodiversity Act must, nevertheless, impose certain basic requirements for access, which will oblige bioprospectors to obtain the PIC of indigenous communities for bioprospecting activities that fall within their communally owned land and to ensure the fair and equitable sharing of benefits that derive therefrom, with the relevant indigenous communities.

6.2.6 Implementation Challenges

More importantly, the implementation of South Africa's ABS legislation remains a major challenge. Legal clarity and specificity in PIC and benefit-sharing procedures is critical, particularly with regards to the complexity and multiplicity of indigenous communities in South Africa. From an implementation perspective, there nevertheless remains a need for flexibility and adaptability, having regard to the varying nature of indigenous communities. However,

specificity is vital in ensuring adequate information disclosure for the purposes of enabling compliance and accountability. A delicate balance between flexibility and specificity is therefore required. 633

Communication, cooperation and consultation is critical to ensure that indigenous communities receive clear and honest information regarding the proposed bioprospecting, enabling them to make informed decisions during the ABS negotiations. In addition, communication, cooperation and consultation are equally important to ensure that government establishes simple and clear information channels, as well as transparent and fair consultation processes in ABS matters. Comprehensive integration of the approaches and processes adopted by indigenous communities and those adopted by government and bioprospectors is vital.⁶³⁴ Such integration can be achieved by means of laws and policies, consultative processes or Biocultural Community Protocols.⁶³⁵

6.2.7 Addressing the Power Imbalances

The internationally approved legal requirements, such as PIC and BSAs, are still capable of circumvention and the injustices perpetuated by high-powered resource-extractive companies reveals the power imbalance between the stakeholders involved in bioprospecting. Accordingly, mechanisms to enable indigenous communities to engage on a more equal footing are essential. Notwithstanding international Conventions and Protocols, as well as progressive domestic ABS legislation, indigenous communities need to pro-actively assert their rights so as to ensure the equality and fairness advanced by the law.

While South Africa has developed a comprehensive ABS regime, which not only aligns with its obligations under the CBD, as well as most of the provisions of the Nagoya Protocol; but in fact goes beyond the scope of what is required, implementation measures remain lacking in South Africa's fight against the misappropriation of the biological resources and traditional knowledge of its indigenous communities. It would appear that, although progressive ABS laws, which offer recognition of the rights of indigenous communities, are necessary, they are, on their own, insufficient in ensuring that the rights of indigenous communities are in fact asserted and

⁶³³ Wynberg, R, Chennells R and Schroeder, D (n. 393) at 349.

⁶³⁴ *Ibid*.

⁶³⁵ *Ibid*.

⁶³⁶ *Ibid* at 348.

protected, in relation to bioprospecting matters. Having regard to bioprospecting in South Africa being influenced by the country's Apartheid history, the complex dynamics of cultural diversity, as well as the economic aspirations of the various parties involved and the emerging economy of South Africa, there is a need for an entirely new approach.

The Nagoya Protocol has presented a new era of biocultural rights. However, the ability of indigenous communities to adequately exercise their rights in the protection of their traditional knowledge and genetic resources, as well as the protection of their customary uses of their biological resources, will depend largely on whether they understand the ABS legal framework, in the context of their biocultural rights. In addition, such communities will need to understand the practical implementation challenges of engaging in ABS and they will need to be empowered to overcome the power inequalities inherent in their interactions with government and bioprospectors.

6.2.8 Biocultural Community Protocols

Community Protocols can undoubtedly assist indigenous communities in ABS matters, as such Protocols are community-led instruments which have the potential to provide a useful framework, with which communities can make informed decisions on whether ABS will benefit their local endogenous development aspirations. In so doing, such Protocols invariably assist in minimizing the implementation challenges of national ABS law and policy. While Community Protocols can provide a useful tool in combating the implementation challenges of South Africa's ABS legislation, such Protocols are not a panacea. They can assist in mobilizing and equipping indigenous communities to become more pro-active in bioprospecting matters. However, they will have a reduced impact if they are not recognized in national legislation. Notwithstanding the recognition of Community Protocols in the Nagoya Protocol, such tools provided for the advancement of the customary rights of indigenous communities, will fail to achieve their objectives, until there is a fundamental change, and such Protocols are given recognition at national level. Act is to 'give effect to ratified international agreements relating to

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⁶³⁷ *Ibid*.

⁶³⁸ Swiderska, K *et al* (n.157) at 37.

biodiversity which are binding on the Republic, 639 it is accordingly suggested that Biocultural Community Protocols can be given specific recognition in South Africa by way of amendments to the Biodiversity Act and its related Regulations. The recognition of such Protocols under South African national law will compel adherence with the provisions of Biocultural Community Protocols of indigenous communities, thereby strengthening their legitimacy and empowering indigenous communities, in bioprospecting matters.

6.3 **Concluding Remarks**

As ABS processes mature and implementation mechanisms, such as Biocultural Community Protocols, are put in place, ABS policies and procedures relating to indigenous communities are likely to become more streamlined and workable. Ultimately, however, even with good implementation policies and laws in place, regulating ABS in the context of indigenous communities is likely to remain a challenging process due to its cross-cutting nature.

⁶³⁹ Lewis, M (n. 114) at 89.

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