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UNIVERSITY OF CAPE TOWN



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The Effectiveness of Access and Benefit-Sharing Legislation in South Africa: Practical Considerations for National Regimes

by Michael Lowman

Submitted in partial fulfilment of the Masters of Philosophy in Environmental Management course from the Department of Environmental and Geographical Sciences at the University of Cape Town

May 2012

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University

Table of Contents

List of Acronyms	i
Abstract	.ii

Chapter 1 Background and Context. 1 1.1) Introduction 1 1.2) Rationale for Study 3 1.3) Methods. 5 1.4) Limitations 9 1.5) Thesis Structure 10

Chapter	2 Literature Review	11
2.1)	Introduction	11
2.2)	Scope of Bioprospecting and Access to Genetic Resources	11
2.3)	Academic Research and Research for Commercialization	13
2.4)	Prior Informed Consent	14
2.5)	Benefit-Sharing Agreements	16
2.6)	Mutually Agreed Terms	18
2.7)	Intellectual Property Rights	19
2.8)	Traditional Knowledge	20
2.9)	Interface between Traditional Knowledge and Intellectual Property Rights	22
2.10)	Benefit Distribution Mechanism	23
2.11)	Institutional Coordination	25
2.12)	Conclusion	26

Chapter	3 Legislation and Policy Overview	28
3.1)	Introduction	28
3.2)	Convention on Biological Diversity	29
3.2.1)	Progress Implementing the CBD	31
3.3)	Bonn Guidelines	32

3.4)	Nag	oya Protocol3	3
3.5)	Trac	le Related Aspects of Intellectual Property Rights (TRIPS)3	5
3.6)	Inter	rnational Treaty on Plant Genetic Resources for Food and Agriculture	6
3.7)	Sout	th Africa3	6
3.7.	1)	Policy Process	6
3.7.	2)	Constitution of the Republic of South Africa	7
3.7.	3)	NEMBA and National Environment Laws Amendment Act (NEA) 14 of 20093	8
3.7.	4)	Patents Amendment Act 20 of 20054	5
3.7.	5)	Indigenous Knowledge Systems Policy4	5
3.8)	Con	clusion4	6
hanter	4 Re	sults A	7

Chapter	r 4 Results	47
4.1)	Introduction	47
4.2)	The Scope of Bioprospecting and Definitional Implications	47
4.3)	Accessing Indigenous Biological Resources and Traditional Knowledge	49
4.4)	PIC and Challenges of Linking Indigenous Communities with TK	53
4.5)	The Function of Material Transfer Agreements	57
4.6)	Negotiating Benefit-Sharing Agreements	60
4.7)	Benefit Distribution Mechanism	63
4.8)	Institutional Arrangements	65
4.9)	Conclusion	68

4.9)	Conclusion	68
Chapter	r 5 Discussion	69
5.1)	Scope of Bioprospecting and its Definition	69
5.2)	Access to Indigenous Biological Resources and Traditional Knowledge	70
5.3)	PIC and Challenges Linking Indigenous Communities with TK	71
5.4)	The Function of Material Transfer Agreements	73
5.5)	Negotiating Benefit-Sharing Agreements	74
5.6)	Benefit-Sharing Mechanisms	76
5.7)	Institutional Arrangements	77
5.8)	The Effective Implementation of ABS Legislation	78

Chapter 6 Conclusion and Recommendations	82
References	86
Legislation	94
Appendices	95
Appendix A: Interview Questions for Industry	96
Appendix B: Interview Questions for NGO Representatives	98
Appendix C: Interview Questions for Researchers	99
Appendix D: Interview Questions for DEA	
Appendix E: Interview Questions for the Provincial Department	

List of Tables

Table 1. List of Interviews Conducted	6
Table 2. List of Conventions, Agreements and Statutes	28
Table 3. Permits Granted for Bioprospecting Purposes	51
Table 4. Assessing the Effectiveness of Implementing Chapter 6 of NEMBA	

200

Table 4. Assessing the Effectiveness of Implementing Chapter 6 of NEMBA 80
List of Figures
Figure 1. Bioprospecting Application Procedure for Commercial Purposes
Figure 2. Governing Structure for the Commercialization of Indigenous Biological Resources 43

List of Acronyms

ABS	Access and Benefit-Sharing
ASEAN	Association of South-East Asian Nations
CBD	Convention on Biological Diversity
CITES	Convention on International Trade in Endangered Species of Wild Fauna and Flora
CoGTA	Department of Cooperative Governance and Traditional Affairs
COP	Conference of the Parties
CSIR	Council for Scientific and Industrial Research
DEA	Department of Environmental Affairs
DST	Department of Science and Technology
DTI	Department of Trade and Industry
EU	European Union
FAO	Food and Agriculture Organization
IBR	Indigenous Biological Resource
ICBG	The International Cooperative Biodiversity Groups
IKS	Indigenous Knowledge Systems
IPR	Intellectual Property Right
MAT	Mutually Agreed Terms
MEC	Member of the Executive Council
MTA	Material Transfer Agreement
NEA	National Environmental Laws Amendment Act
NEMBA	National Environment Management: Biodiversity Act
PIC	Prior Informed Consent
PGRFA	Plant Genetic Resources for Food and Agriculture
SANBI	South African National Biodiversity Institute
TK	Traditional Knowledge
TRIPS	Trade Related Aspects of Intellectual Property Rights
UPOV	International Union for the Protection of New Varieties of Plants
WIPO	World Intellectual Property Organization
WTO	World Trade Organization

Abstract

The Convention on Biological Diversity provides an international regulatory framework for countries to develop their own access and benefit-sharing (ABS) legislation. This international convention governs the utilization of a country's genetic resources and associated traditional knowledge. Due to increased capabilities and demand from industry for these resources, a market is created over which ABS legislation is to govern. This is based on the realization of the objectives of the convention that provide for state sovereignty over a country's indigenous biological resources. This dissertation presents the results from an evaluation of ABS legislation and its implementation within South Africa. Key objectives are to analyze the implementation of regulations and procedures governing access to indigenous biological resources and traditional knowledge, and associated institutional arrangements. The legislation provides a mechanism that recognizes traditional knowledge, and seeks to develop equitable partnerships with indigenous and local communities through the utilization and development of indigenous biological resources and traditional knowledge. Current procedures are characterised by unclear definitions that do not facilitate an environment conducive for the effective implementation of the legislation. Complexities surrounding the linking of traditional knowledge and indigenous communities have not been properly considered by the legislators, and this results in applicants experiencing difficulties when attempting to obtain prior informed consent and develop material transfer agreements and benefit-sharing agreements. Policy-makers need to consider the practicalities of obtaining prior informed consent, and to develop a procedure that enables its effective realisation, yet still allowing for the development of equitable partnerships. The governance and implementation of ABS legislation needs to be coherent and efficient. Through the effective implementation of ABS legislation the ability to generate and distribute benefits may contribute to the formation of equitable partnerships between industry, researchers and indigenous and local communities.

Keywords: Convention on Biological Diversity, Traditional Knowledge, Indigenous Biological Resources, Genetic Resources, Access and Benefit-Sharing, Indigenous Communities, National Environment Management: Biodiversity Act.

Chapter 1 Background and Context

1.1) Introduction

The gathering and collecting of indigenous biological resources (IBRs) from different regions of the world has been occurring for centuries. These natural resources and associated traditional knowledge (TK) have been directly used for food, medicine, and other valuable products and have led to significant scientific and economic prosperity for many countries (Robinson, 2010). This exchange of TK and natural resources in the past was done without fair compensation for the country or community that initially provided the resource and TK (Schroeder, 2009). The use of IBRs and TK in commercially focused research or sale occurred throughout colonial history by foreign botanists, this was based on the principle of the 'common heritage of mankind', and interpreted as a free for all on a first come first serve basis (Wynberg, *et al*, 2009).

The past 18 years has seen significant growth in regulatory and policy development governing the use of genetic resources, and bioprospecting, which is defined as the exploration of biological material for commercially valuable genetic and biochemical properties (Wynberg and Taylor, 2008). In 1992, the world convened at the Earth Summit in Rio De Janiero where participating countries negotiated what was to become known as the Convention on Biological Diversity (CBD). There are 193 signatory contracting parties to the CBD (Schroeder and Pisupati, 2010). The CBD through its objectives seeks to promote the conservation of biological diversity, the sustainable use of its components as well as the fair and equitable distribution of benefits arising out of the utilization of genetic resources and TK (Reid, *et al*, 1993). Countries in return for conserving their natural resources and promoting the sustainable use of their components receive benefits in exchange for the utilization of their natural resources and TK.

Since the introduction of the CBD, contracting parties have developed Access and Benefit-Sharing (ABS) legislation in order to regulate the relationships between key stakeholders involved in bioprospecting activities. This has been pursued to varying degrees of success throughout the world and presents contrasting challenges for each contracting party. The complexities associated with bioprospecting activities and commercial stakeholders are not fully recognized and often policies have lagged behind the practice of bioprospecting (Wynberg and Laird, 2009). Issues that have been raised have had to deal with the broader concerns of

globalization, corporate activities and inequity between developing and developed countries (Wynberg and Laird, 2009). These national regulatory models must take into consideration the delicate and often sensitive issues that arise when utilizing IBRs and the TK of an indigenous community. It is important that these regulatory models provide legal certainty for potential stakeholders to gain access to these valuable resources (Barber, *et al*, 2002).

South Africa developed ABS legislation and enacted Chapter 6 of the National Environmental Management: Biodiversity Act (NEMBA or Biodiversity Act) in 2004. South Africa plays host to a region that is rich in biodiversity (Visconti, 2001). The Cape Floristic Kingdom found at the southern tip of Africa is home to 9000 plant species, and 1406 of these species are protected in the Red Data Book (Rouget, et al, 2003). South Africa is also home to other areas of high biodiversity including the Tongaland-Pondoland, and the Namaqualand. Excluding the Cape Floristic Kingdom southern Africa still has 1732 genera and 12280 species occurring outside the Cape Region (Rouget, 2003). It is important that this biodiversity is not exploited and decimated through over-harvesting. It is also important to protect this biodiversity from misappropriation, and requires that benefits generated from the utilization of biodiversity in fact flows back to the wider community from where it originates. Thus there is potential for interested industries to develop this biodiversity for commercial gain and the legislation requires that this is done on a sustainable basis and in a fair and equitable manner. Exploitation can occur where developed countries misappropriate valuable TK and IBRs, there is therefore a need for legislation that adequately protects potential beneficiaries and ensures equitable sharing of benefits materializes (Crouch, et al, 2008). The Biodiversity Act provides an overarching framework that provides the platform from which stakeholders are to begin developing IBRs and TK.

The succulent *Hoodia* plant is used by the San people of southern Africa, and it provides an example of why it is important to have legislation that adequately protects the holders of IBRs and TK. The Council for Scientific and Industrial Research (CSIR) identified the potential benefit of the succulent plant from a publication on the medicinal and poisonous plants of southern Africa (Wynberg and Chennells, 2009). Development of the succulent led scientists to discover the appetite suppressant potential of the plant, and subsequent technological advances led the CSIR to isolate and identify the active ingredients (Wynberg and Chennells, 2009). In 1995 a patent application was filed in South Africa for the use of these active components (Wynberg and Chennells, 2009). Subsequent agreements were entered into by various stakeholders to further

develop the succulent, without any acknowledgment of the San people for their contribution and intellectual property surrounding the use of the *Hoodia* plant (Wynberg and Chennells, 2009).

It must be noted that at the time of the development of the *Hoodia* plant there was no legislation governing the utilization of IBRs and TK within South Africa. This example occurred in a legislative vacuum and through laudable work undertaken by Biowatch and Action Aid awareness was raised about this situation. The Working Group of Indigenous Minorities in Southern Africa (WIMSA) was then mandated by the Southern African San Council to negotiate with the CSIR (Wynberg and Chennells, 2009). In 2003, a benefit-sharing agreement was signed between the South African San Council and the CSIR. The payment of royalties and milestone payments were made in acknowledgment of the contribution made by the San people (Wynberg and Chennells, 2009). This case study provides an example of the issues inherent in developing IBRs and TK within South Africa.

1.2) Rationale for Study

South Africa has developed ABS legislation in accordance with the CBD. This study provides an opportunity to assess how this legislation is implemented practically, so that issues that may arise within the South African regulatory framework can be taken into consideration by other countries developing ABS policies. It also provides an opportunity to assess these issues and develop South Africa's legislation further so that ABS can be effectively implemented within South Africa. South Africa is rich in biodiversity and this presents an opportunity to promote the development of these resources for economic gain as well as the capacity development of interested stakeholders. Indigenous communities provide valuable information that ABS legislation must accommodate. With efficient legislation the utilization of this knowledge could lead to investment, which could in turn contribute to capacity development within South Africa.

South Africa's biodiversity has inextricable links to the indigenous communities of the region. It is through identifying the practical implications of the ABS regime, that one can understand its implications for the providers of these resources. This study thus hopes to elicit the implications this legislation has for the rights of indigenous communities within South Africa. The utilization

of South Africa's biodiversity provides an opportunity for the dignity of marginalized communities to be restored.

The main initiators of bioprospecting are found within various industries namely, the pharmaceutical industry, biotechnology, seed, crop protection and plant biotechnology industries and ornamental horticulture industry. These stakeholders look to utilize natural resources for scientific research and economic prosperity. In trying to unlock the potential that a country has for bioprospecting opportunities it is important to understand the limitations that ABS legislation has on these stakeholders. Benefits can materialize from partnerships that are enabled through precise and efficient legislation that promotes the development of IBRs and TK. Thus it is important to understand where the legislation is effective and safeguard the development of partnerships between industry and indigenous communities in a manner that is socially acceptable.

The overall aim of this thesis is to critically review the implementation of Chapter 6 of NEMBA, and therefore provide information on the practical implications of NEMBA. The experiences of stakeholders provide an opportunity to ascertain how the legislation is implemented and to ascertain anomalies, constraints and potential. This thesis thus aims to elucidate how stakeholders perceive the implementation of ABS legislation in South Africa. This understanding is integral to promoting the social and economic upliftment of the people of South Africa, and ensuring that the equitable exchange of benefits is achieved between contracting parties.

More specifically, the objectives of this thesis are:

- To understand the implementation and interpretation of ABS legislation in South Africa.
- To identify and discuss the implications of current access procedures governing the utilization of genetic resources and traditional knowledge for stakeholders.
- To identify and discuss the implications of the institutional arrangements supporting these concepts.

Understanding how stakeholders interact and comply with the governing ABS legislation will indicate the effectiveness with which this legislation is implemented. This will be measured against the following criteria that serve as reference points to determining the effectiveness of ABS legislation and its implementation. These principles include:

- equity established between stakeholders,
- the ease with which the legislation can be complied with by the relevant stakeholders,
- environmental sustainability,
- the coherence and efficiency of the governing structure implementing the legislation, and
- the ability of the legislation to promote the generation of benefits and the equitable distribution thereof.

1.3) Methods

A qualitative research approach was adopted to enhance understanding about the beliefs, opinions, emotions, and contradictory behaviors and relationships of stakeholders to this research question. This provides information from the 'human side' of the issue at hand. The strength of qualitative research is its ability to provide complex textual descriptions of how people experience a given research issue (Miles, 1979). The flexibility of qualitative research entails open ended questions which, in an informal environment may be asked to gain an in depth look into the experiences and perspectives of the individual. It also allows the researcher to make sure subsequent questions are tailor-made to elicit information and gain a deeper understanding of the issues at hand.

Focus areas were formulated by looking at Chapter 6 of NEMBA and the regulations thereto, and extracting key features out of the text. These key features include: institutional arrangements of competent authorities, access/ownership of biological resources, prior informed consent (PIC), benefit-sharing agreements, material transfer agreements (MTAs), bioprospecting trust fund, coordination of national departments, research for academic purposes and research for bioprospecting activities.

Qualitative data was obtained through semi-structured interviews. These questions were generated around the above mentioned focus areas, and two way communications between the interviewer and interviewee generated information that was analyzed and critically evaluated against the relevant legislative procedures. These questions were adapted to each stakeholder depending on how they interacted with the legislation.

A list of respondents was compiled, using snowballing to develop this list. Snowballing samples emerge through a process of reference from one person to the next (Cooke, *et al*, 2004). Each participant interviewed allows the researcher to build on those experiences and pursue other participants with credibility (Cooke, *et al*, 2004). Through this method different stakeholders were identified, including national regulating authorities, provincial departments, non-governmental organizations (NGOs), industry, research institutions, national research institutions, universities, and community representatives.

A diverse number of stakeholders were interviewed and various aspects of the legislation discussed.

NAME	CAPACITY	EMPLOYER	DATE
Crouch, N	Ethnobotanist	South African National Biodiversity Institute	11/04/2011
Baart, E	Senior Manager, scientific services	Cape Nature, Provincial Department	6/05/2011
Gericke, N	Director	HGH Pharmaceuticals	12/05/2011
Mulder, M	Manager	Medical Research Council	10/05/2011
Eloff, K	Director of Research	University of Pretoria	23/05/2011
Mayeng, I	Traditional Healer	National Department of Health	23/05/2011
Maharaj, V	Research Group Leader	Council for Industrial and Scientific Research	23/05/2011
Malherbe, C	Deputy Director	Department of Environmental Affairs	24/05/2011
van Wyk, B-E	Lecturer	University of Johannesburg	25/05/2011
Sechaba, B	Deputy Director, Biotechnology Unit	Department of Science and Technology	25/05/2011

Table 1. List of Interviews Conducted

Hendriks, H	General Manager	SANParks	25/05/2011
Nel, D	Managing Director	Afriplex	31/05/2011
Von Braun, J	Staff Member	Natural Justice	7/06/2011
Bailey, A	Intellectual Property Manager	University of Cape Town	7/06/2011
Feiter, U	CEO	Parceval (Pty) Ltd	8/06/2011
Chennells, R	Human Rights Lawyer	Albertyn Chennells Attorney	15/06/2011
Gass, R	Owner	Zizamele Herbs	15/06/2011
Swart, E	Staff Member	Northern Cape Provincial Department	21/06/2011
Bam, N	Biodiversity Conservation Manager	Eastern Cape Provincial Department	21/06/2011
Chimanzi, A	Staff Member	Department of Economic Development, Environment and Tourism, Limpopo	21/06/2011
McKean, S	Resource Ecologist	KZN Wildlife	22/06/2011
Williams, R	Director	Biowatch	23/06/2011
Schleen, A	Staff Member	DEA, Free State	1/11/2011

The Department of Environmental Affairs (DEA) was interviewed as the designated issuing or competent authority with respect to NEMBA. This department forms part of the institutional arrangements that grant or refuse bioprospecting permit applications. The DEA forms the center with which all stakeholders interact and must approach when submitting permit applications. The provincial departments provide a link within the bioprospecting chain and their inclusion allowed for insight into the administrative functions performed by these authorities.

Interviewing individuals at research institutions allow for an understanding of the nature of interaction experienced with ABS legislation from an academic viewpoint as well as a commercial level. They also provide technical information with respect to the complexities associated with genetic resources and the difficulties of defining this term within the ABS system.

Industry members provide experiences that have arisen through direct interaction with the legislation, and are thus aware of the complexities associated with complying with ABS provisions. Their views provide ground level perspectives of the effectiveness of the administrative functions of the legislation.

NGOs act as representatives of indigenous people and local communities. It is important to understand how these local communities are provided for within the legislation and the challenges experienced by these groups.

These diverse stakeholders cover the institutional components of ABS legislation. The collection of these experiences enabled a holistic impression to be obtained of the practical implementation of ABS legislation in South Africa with respect to all stakeholders concerned.

Contact was made with the stakeholders identified, either telephonically or through e-mail. A date and time was then set to conduct the interview. The interviews were between half an hour, and an hour and a half depending on the depth at which the participant engaged with the legislation. A total of 23 interviews were conducted. Where the PIC of the interviewee was gained the interviews were recorded using a dictaphone. This information was later transferred onto a computer. This allowed for interviews to be transcribed, enabling accurate information gathering. Both telephonic and one-on-one interviews were conducted. Telephonic interviews were conducted in cases where the stakeholders where based in another province. In one case an interview was conducted through correspondence via e-mail.

The stakeholder was asked to introduce him or herself and describe in what capacity he/she was giving the interview. The open ended questions generated from the focus areas identified in the legislation were then introduced and discussed. Samples of the questionnaires can be found in Appendices A - E to this paper.

Qualitative research is an umbrella term to decode and come to terms with the meaning of phenomena occurring in the social world (Van Maanen, 1979). The transcribed texts were decoded into relevant sections from which a document analysis could be done and phenomena of

this social world could be ascertained. The decoded sections included the following: scope of bioprospecting, access/ownership of biological resources, linking indigenous and local communities with TK, PIC, benefit-sharing agreements, MTAs, the bioprospecting trust fund, provincial departments, the role of the DEA, negotiating capacity, and coordination of national departments.

Other case studies and literature serve as a reference point from which the South African legislative framework can be anchored and compared to. A method known as triangulation was used to prevent inclusion of results that are inaccurate and validate the process used to ensure that the variance reflected that of the trait and not the method used (Todd, 1979). Through this process the decoded texts and the experiences of the stakeholders were presented.

The findings shall be measured against certain principles that will highlight how effective the legislation is in its implementation.

C'36

1.4) Limitations

The nature of human beings is that we all come from different backgrounds and shaped by different experiences, and so our value systems differ from one person to the next. Different perspectives were conveyed through this analysis. When conducting only qualitative research it is important to prevent self-delusion and present an analysis that is accurate and reliable (Miles, 1979). A main criticism of qualitative research is that such research is a collection of anecdotes and subjective impressions that are strongly subject to researcher bias (Mays and Pope, 1995). Another criticism is that the research lacks the characteristic of reproducibility and could differ between researchers on the same topic (Mays and Pope, 1995).

The Promotion of Access to Information Act 2 of 2000 (PAIA) needed to be used to gain access to confidential information. This information refers to particulars of the MTAs and benefit-sharing agreements. Certain information is confidential and therefore industry is reluctant to divulge information that could compromise the success or failure of a permit application and product development. As such, details of bioprospecting permits are not divulged unless the parties to the permit have agreed to release information either through the DEA or through personal interactions. Sensitive information would not be divulged where such information could

be misappropriated and used for other purposes or compromise the granting of an application. A PAIA application to the DEA is still pending. This is to gain access to the specifics of the four bioprospecting permits granted by the Department.

To gain a true holistic impression from all stakeholders and represent an objective view is challenging. Stakeholders as well as researchers come with their own agendas and seek to present an argument suggesting compliance with the legislation or seeking justification for their actions. It is thus important to ascertain as much of an objective opinion from the interviewee as possible. This was done by asking open ended questions so that the interviewer did not direct the interviewee in gaining the answer that was most beneficial to the interviewer. This allowed the interviewee to express him/herself without being directed by leading questions. This would hopefully elicit an answer that was generated through the interviewee's own experiences.

1.5) Thesis Structure

This thesis is broken down into six chapters. This introductory chapter provides a conceptual framework of the ABS system and the reasoning for introducing ABS policies into a national framework, as well as the rationale for the research and the manner in which the research aim has been achieved. The second chapter provides the literature review of the relevant concepts and describes how these are dealt with in various countries. The third chapter deals with the legislative framework in South Africa that governs the utilization of IBRs and TK. The fourth chapter presents the results. Chapter five is a discussion of the results obtained, contextualizing these findings within the greater ABS spectrum. The sixth and final chapter presents the conclusion and recommendations.

Chapter 2 Literature Review

2.1) Introduction

This literature review describes the concepts embraced by countries implementing ABS legislation, and summarises key discussions in the literature about the topic. The CBD provides an important policy framework from which different mechanisms attempt to achieve the treaty's objectives. These concepts range from issues relating to: access/ownership of genetic resources, research for academic purposes and commercial activities, PIC, benefit-sharing agreements, MTAs, the bioprospecting trust fund, intellectual property rights, TK and institutional coordination. These concepts shall form the basis of this review.

To realize the objectives of the CBD and implement an ABS regime presents various challenges for many countries. A country has to weigh up the importance and the potential benefits that can actually be realized before instituting an ABS regime. The way in which countries have established ABS concepts within their own regulatory framework is discussed in this chapter.

2.2) Scope of Bioprospecting and Access to Genetic Resources

Prior to the CBD, there was no international legal framework that regulated access to genetic resources, nor was there a legal instrument that promoted the sharing of benefits produced through their scientific and commercial utilization (Schroeder and Pisupati, 2009). Before the negotiation of the CBD, the concept of the 'common heritage of mankind' included genetic resources, and so industrialized states had unrestricted access to genetic resources (Kiss, 1985). This unrestricted access based on a first-come first-serve principle was rejected by developing countries that contained the bulk of the biodiversity (Barber, *et al*, 2002). These developing countries argued that benefits derived from natural resources and TK had to be shared equitably with the country that provided access to the resource.

Article 15(1) of the CBD recognizes the sovereign rights of states over their natural resources with the authority to determine access to genetic resources resting with the national governments and subject to national legislation. By confirming the state's sovereignty over access to biological resources the open access status of biodiversity has been abolished, and the CBD designates the conservation and sustainable use of biodiversity to the responsibility of the countries that provide the resource (Richerzhagen and Holm-Mueller, 2005).

Acquiring access can often be a confusing, long and cumbersome process, with permits to specific resources obtained from a vast array of regional and local agencies (Carrizosa, 2004). This can have the effect of bioprospectors having to negotiate with several providers of genetic resources (Carrizosa, 2004). Overlapping of functions between various agencies can lead to overly bureaucratic procedures that result in high transaction costs and long processing times (Richerzhagen and Holm-Mueller, 2005). One of the more cumbersome and costly processes is said to be found in the Philippines, where the processing timeframe for most local scientists and researchers is seen as a deterrent for the growth and development of research (Medaglia and Silva, 2007).

In Fiji, local communities have property rights over resources that may be found on their territories, and are therefore able to engage and negotiate rights of access through their own deliberations (Tobin, 2002). However, this type of access comes with its own set of difficulties that must be negotiated. Tobin (2002), remarks that to reach an amicable solution fewer parties to an agreement is better. The negotiation of access with the correct community is said to be a tedious and burdensome process, especially in the Philippines, where it takes a minimum of 60 days to secure a credible access certificate (Medgalia and Silva, 2007). This has implications for the cost of obtaining access to the desired resource - especially where that resource is found in different regions across the country (Medaglia and Silva, 2007). Thailand requires bioprospectors to approach only government officials for access to genetic resources, this not only reduces the length of the access process, but also the costs of the transaction involved (Carrizosa, 2004).

Defining the utilization of genetic and biological resources has consequences for certain sectors of an economy, and it has not always been easy to establish which activities constitute access to biological resources and those to genetic resources (Medaglia and Silva, 2007). A lack of clarity between the two concepts creates practical difficulties for ABS implementation. If the law states that ABS provisions apply to all biological resources then this implies that every market transaction involving agricultural products would be an 'ABS transaction' (Medaglia and Silva,

2007). In some cases ABS laws have made the distinction between biological and genetic resources (Carrizosa, 2004). The precision with which these two concepts are defined is an important first step in developing ABS legislation that is efficient and precise in its application.

Access procedures that are overly bureaucratic, unclear, time consuming and expensive tend to deter research activities, and result in organizations approaching countries with less burdensome ABS legislation (Richerzhagen and Holm-Mueller, 2005). Organizations tend to move away from over-regulated countries to reduce administrative costs that hamper the development of a product.

2.3) Academic Research and Research for Commercialization

The use of biodiversity for academic research may evolve into bioprospecting, or through publications, databases and other vehicles that place information and research results in the public domain, may indirectly lead to commercialization (Laird, 2002). Many research institutions, as part of a wider trend in the scientific community, conduct both commercial and academic research through the formation of partnerships with a diverse range of public and private actors (Laird and Wynberg, 2002). Governments, institutions and other groups have tried to grapple with the difficulty of trying to differentiate between research for academic purposes, and research for commercialization (Laird and Wynberg, 2002).

The distinction between commercial and academic research is blurred as many academic researchers collect resources and knowledge for commercial companies (Laird and Noejovich, 2002). It is important that countries make the distinction between research for academic purposes and research for bioprospecting activities. This distinction allows groups to feel more comfortable because the governing institutions have acknowledged the difficulties in distinguishing between research for academic purposes and research for bioprospecting activities. (Laird and Posey, 2002).

Academia is an important stakeholder regarding access to genetic resources, and a major generator of knowledge for the attainment of the CBD objectives (Martinez and Biber-Klemm, 2010). The ABS system is said to complicate access to these resources for researchers by introducing concepts such as PIC, benefit-sharing agreements and MTAs (Martinez and Biber-

Klemm, 2010). Some researchers react to this by calling for more accessible procedures, and some even for the abolishment of the ABS system (Martinez and Biber-Klemm, 2010).

The objective of the Philippine ABS system is supported by the scientific community, even where those seeking genetic resources are individuals or foreign entities (Barber, *et al*, 2002). However, the impact of this system has had a negative effect on scientific research activities within the country (Barber, *et al*, 2002). The regime adopted represented a radical shift from past practices, when state intervention of taxonomic collection and other activities were at a minimum (Barber, *et al*, 2002). Thus, overly bureaucratic systems can have severe consequences for the development of IBRs within a country.

The conclusion of a commercial research agreement must be with the Philippine government, in accordance with certain requirements of the Philippine government's application process (Barber, *et al*, 2002). Stakeholders that seek to conclude an academic research agreement are given greater flexibility and self-regulation, depending on the type of activities and stakeholders involved, compared to that of commercial research agreements (Barber, *et al*, 2002).

If the process of obtaining permits becomes too complex for basic academic research, some researchers may avoid working in those areas (Laird and Lisinge, 2002). It is this type of scenario that researchers trying to exploit their biodiversity must avoid if they hope to attract foreign investment. Overly bureaucratic procedures may hinder research and development, and thus countries will seek resources that are more accessible.

2.4) Prior Informed Consent

The concept of informed consent has been extracted from the medical profession and adapted as a procedural requirement in accessing TK and IBRs (Schroeder, 2009). Schroeder (2009) notes that PIC is the voluntary, un-coerced decision made by a subgroup that legitimately represents an indigenous community, on the basis of adequate information and deliberation, to accept rather than reject some proposed course of action that will affect the community.

The requirements for PIC are based in the CBD and some enacted laws may only require PIC from the government authority, while others may seek it from different levels including local, indigenous and marginalized communities (ICCBD, 2000). It is essential for equity that clear legal mechanisms for obtaining PIC from local communities are put in place (Laird and Noejovich, 2002). It must also be noted that in the past efforts to instill PIC into national ABS legislation have proven difficult to implement (Laird and Noejovich, 2002).

Parties wishing to access the biological resource of a community must ensure that PIC is acquired to facilitate this access, and ensure the continued and legitimate exchange of these genetic resources (ten Kate and Laird, 2002). The consent is based on the premise that the information supplied about the use of the genetic resources is truthful, and is sufficient for the community to make an informed decision (Berlin and Berlin, 2003). Consent is to be given on receiving full disclosure regarding the extent and reasons for the activity, the specific procedure to be followed, the potential risks involved and the foreseeable implications of the activity (Laird and Noejovich, 2002).

Bioprospectors appear to avoid community owned areas intentionally where obtaining consent involves lengthy, complicated and often frustrating negotiations with community members (Crouch, *et al*, 2008). They rather choose to collect biological resources from state owned land and privately held farms where acquiring PIC is much easier and less time consuming (Lewis-Lettington and Mwanyiki, 2006). A major assumption of PIC is that communities, or groups of communities, are politically bounded organizations with governance structures designed for deal making and negotiating (Dutfield, 2009). Frustration can develop between the parties concerned during these deliberations.

In the Philippines there is strong political support for the concept of PIC to be obtained from local communities, and it is promulgated through the country's ABS regulations. This has become a major obstacle and has dampened interest in commercial bioprospecting in the Philippines (Laird, *et al*, 2002). The principle of PIC mandated by the 1995 regulations of the Philippines has been described as overly bureaucratic, time consuming, costly and does not take into consideration the realities of scientific research; whilst no one in particular is against the concept, it is the manner in which it is obtained that creates cause for concern amongst interested stakeholders (Barber, *et al*, 2002). For example, public awareness amongst local officials and community members within the Philippines is so low that to acquire truly 'informed' consent, requires time-consuming

educational effort, which is not considered the responsibility of scientific researchers (Barber, *et al*, 2002).

Moreover, the process can be foreign and invasive for some traditional, local or indigenous communities. Culturally sensitive approaches and respect for local traditions must be observed (Dutfield, 2009). People cannot always understand or be aware of the value systems or world views of other people, especially those most sacredly held (Schroeder, 2009). In the Philippines, PIC is obtained in accordance with the customary laws of the community concerned (Barber, *et al*, 2002). This looks to negate the possibility of engaging with an indigenous community without adhering to the customary practices held by the indigenous community with respect to PIC.

Where PIC is implemented, it is essential that the procedures of gaining PIC take into account the values of a particular community from which the consent is to be obtained (Schroeder, 2009). What is considered perfectly normal in one culture might be in complete contrast to practices in another culture. In recent years a number of communities, such as the Inuit Tapirisat in Canada and the Kuna in Panama, have articulated and developed codes for culturally suitable behaviour in which PIC is obtained for consultations undertaken inside their territories (Laird and Noejovich, 2002).

2.5) Benefit-Sharing Agreements

Benefit-sharing is a concept that is articulated by objective three of the CBD. The CBD aims to ensure that benefits that are derived from the utilization of genetic resources are distributed in a fair and equitable manner. Benefit-sharing aims to ensure that the appropriation of natural resources and TK from developing countries and communities by bioprospecting companies results in some type of transfer of resources for communities. It thus aims to ensure that whatever accrues out of the utilization of biological resources, TK, innovations and community practices are shared between the parties (ICCBD, 2000). The CBD through benefit sharing has provided a small step to redress the imbalances inherent between developing and developed countries (Schroeder, 2009).

Benefit sharing can come in a variety of forms ranging from non-monetary to monetary exchanges. Where natural resources or TK are given to another entity, they need to be

compensated in an appropriate form that is fair and equitable (Schroeder, 2009). The Nagoya Protocol and Bonn Guidelines provide examples of non-monetary and monetary benefits appropriate for exchange between users and providers of genetic resources. Some of these benefits include upfront payments, milestone payments, royalties, access fees, participation in product development, institutional capacity-building, collaboration, cooperation and contribution s to education and training.

Given the political, economic, cultural and social variations within a society, what is an 'equitable' exchange of benefits will vary significantly on a case by case basis (Barber, *et al*, 2002). This makes it difficult to determine the type of benefits to be exchanged between the parties - what is 'fair and equitable' to one may not be to another. Different sectors of the economy have different uses for natural resources and as such the size of the contribution from the natural resource will vary, as will the question of what is a fair and equitable benefit-sharing agreement (Laird and ten Kate, 2002).

Benefit-sharing agreements can take time to develop and negotiate. In the case of the cultivation and development of *Eragrostis tef (tef)* found in Ethiopia, it took 10 years to complete because of a lack of understanding of ABS provisions and implementation within Ethiopia (Wynberg, 2008). These protracted negotiations led to an array of long term benefits ranging from royalties to direct profits, contributions to a fund for local farmers, to scientific and technical capacity development (Wynberg, 2008). However, no benefits had been distributed up until 2008 despite 438 000 Euros available in the fund (Wynberg, 2008). This benefit-sharing agreement was further complicated by a decision from the Ethiopian government to ban all exports of tef (Wynberg, 2008). Contrasting opinions around the reasons for the ban are provided - ranging from tef shortages due to demand and it being a staple diet of the population of Ethiopia, to concerns of modernization of farming methods; as such Ethiopia needed to protect local markets (Wynberg, 2008). This example highlights the complex and lengthy deliberations that arise when trying to determine a suitable benefit-sharing agreement. A holistic approach to benefit-sharing is needed as commercialization is far from certain, and benefit-sharing should thus not be dependent only on successful development, and should provide for immediate and tangible benefits to be realized (Wynberg, 2004).

2.6) Mutually Agreed Terms

The successful negotiation of access agreements can be found in the form of a contract, MTA, benefit-sharing agreement or a research agreement. The primary ambition of these agreements is to authorize access to genetic resources, control their subsequent uses and establish terms and procedures for the sharing of benefits (Barber, *et al*, 2002). These agreements are negotiated according to the national legislative framework, and based on whether entities are indigenous communities, private persons, research institutions, or sub-national government units (Barber, *et al*, 2002). The role of the state might be to approve minimum conditions and approve each agreement, or alternatively the state might conclude a separate contract with the entity and form a third party in a tripartite agreement (Barber, *et al*, 2002). Depending on the ABS framework, the state is entitled to delegate rights to other entities whilst still retaining ownership over those rights (Barber, *et al*, 2002).

Article 15(7) of the CBD provides that the sharing of benefits should be on mutually agreed terms (MAT) between the party accessing the resources, and the party providing the resources. It refers to the variety of authorizations defining the requirements for ABS, by means of which users obtain access to genetic resources, or permission to collect, study, or utilize genetic resources commercially (ICCBD, 2000). One such implementation of MAT is expressed in s 84 of NEMBA and takes the form of an MTA.

Material transfer agreements can serve as a tool to clarify rights and responsibilities between stakeholders and the organizations supplying them with samples (Laird and ten Kate, 2002). It implies that bilateral negotiations entered by both parties have determined the terms for transfer of genetic resources (Chambers, 2003). It thus provides a standardized system that protects providers of genetic resources who may not have adequate measures to protect from exploitation. Parties are held legally accountable to the agreement (Chambers, 2003). It is common for these agreements to include monetary and non-monetary benefits.

The focus of the MTA is to provide a format in which parties are able to determine terms and conditions necessary for the exchange of resources. The determination of the MTA elicits the notion of equity, and entrenches equality amongst weak providing nations or indigenous and local communities and strong commercial parties (Tobin, 2002). These agreements seek to provide

legal certainty, and to guide negotiations between the provider of the genetic resource or TK and the researcher seeking to exploit the resource (Tobin, 2002).

2.7) Intellectual Property Rights

Protecting intellectual property rights (IPRs) in modern societies has become an integral driver of business competitiveness in the international arena of trade (Dutfield, 2006). Certain knowledge is referred to as intellectual property to which societies assign specific property rights, and these rights have semblance to ownership rights over physical property (Gibson, 2008). This knowledge takes on novel and innovative qualities that are not obvious and are supported by complete and adequate descriptions that are legally enshrined as patents (Gibson, 2008). Patents are a form of protecting IPR and are held by states for a limited period of time, and are exclusive; they prevent exploitation of the proprietor's invention (Gibson, 2008). Intellectual property rights can also be found in the form of copyrights and trade secrets (Gibson, 2008). Each mechanism has its own benefits that can be used by the entity creating the IPR.

Patents are the main mechanisms countries use to exercise control over an invention. For a fixed period of years it gives owners monopoly control over their inventions (Barber, *et al*, 2002). Patent protection has predominantly occurred within industrialized states and is much weaker in non-existent in developing states (Barber, *et al*, 2002). Appropriate capacity-building will be crucial for developing countries to implement intellectual property related treaties, and will be a necessity if these countries are to effectively use intellectual property and other tools in pursuit of sustainable development goals (Dutfield, 2006).

Many patent offices throughout the world have begun issuing patents for discoveries of information existing in the natural world, like the genetic sequence of living organisms (Barber, *et al*, 2002). This privatization of life forms and TK has evoked numerous ethical debates (Brush, 1993). The IPR system that is intended to look after commercial innovations has been deemed unsuitable for the safeguarding of TK and biological resources (Dutfield, 2004). It has been suggested that intellectual property systems have evolved primarily to serve industrial commercial interests that emphasizes private ownership, this is in contrast to many indigenous and local communities that employ collective and communal property traditions of ownership (Laird and ten Kate, 2002).

The patent system has undergone a process of regulatory harmonization, and the scope of what is patentable has increased (Drahos, 1999). The World Trade Organization (WTO) administers a trade agreement on Trade Related Aspects of Intellectual Property Rights (TRIPS) that incorporates a trend to extend patent rights for the discovery of information already existing in the natural world, such as the genetic sequences of living organisms (Laird, 2002). This valuable information is viewed as a proprietary asset and illustrates a trend towards privatization and commodification of biological and genetic information, instead of viewing these resources as part of the 'common heritage of mankind' (Barber, *et al*, 2002). This is relevant for member states, which are now obligated to phase in IPR standards over a period of time, allowing patents to enter the realm of agriculture, food production and health care (Wynberg, 2004).

Countries seek to protect IPRs of indigenous and local communities through the enactment of ABS provisions. These laws aim to recognize TK and through negotiations TK can be developed into a product and benefits generated. Communities are acknowledged and in some instances contribute to the development of their resource.

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2.8) Traditional Knowledge

It is difficult to define TK as it presents itself in different shapes and sizes. The World Intellectual Property Organization (WIPO) suggests that the term TK manifests itself as literary, artistic, scientific works, inventions, performances, marks, scientific discoveries, designs, names, symbols, undisclosed information, and all other tradition-based innovations and creations resulting from intellectual activities in the industrial, scientific, literary, or artistic fields (ICCBD, 2000).

The concept of TK refers to be a body of knowledge built up by a group of people through generations of living in close contact with nature (Berkes, 2009). This knowledge is traditional not because it is old or un-technical in nature, but because it is created in a manner that reflects the traditions of the originating communities and the way in which knowledge is created, preserved, and disseminated, and therefore does not relate to the knowledge itself (Hansen and Van Fleet, 2007).

The complexities associated with protecting TK are numerous (Robinson, 2010). The bulk of this information or TK is not written down and is communicated orally, often encoded in practical everyday non-technical language and sometimes as mythology, and it is passed onto the next generation of people who occupy the same places (Dutfield, 2006). It is increasingly acknowledged that TK is not out of date, obsolete or limited, but can be extremely evolutionary, adaptive, creative and even novel (Dutfield, 2004). Traditional knowledge is important for the maintenance of identity and culture (Robinson, 2010).

Given the orally transmitted and changeable nature of TK, problems are created when identifying truly local TK (Dove, 2000). For instance, trying to narrow down the exclusive users of certain *Hoodia* species encounters complexities because of its wide distribution. Minority communities known as the Nama, Damara, and Topnaar in Namibia have used it as a substitute for water and food as well as a medicinal remedy (Wynberg and Chennells, 2009). Given the nature of the San's history of resettlement and dislocation through marginalization and nomadic tendencies, establishing those groups that do have a definitive record of use has been nearly impossible (Wynberg, 2004). It is important to facilitate an ABS environment where the existence of knowledge and the custodians of such knowledge can be identified effectively (Barber, *et al*, 2002).

Traditional knowledge can be extremely important for developing IBRs into commercial products. Of approximately 120 pharmaceutical products developed from plants in 1985, two thirds were discovered from the study of their traditional medical use (Laird and ten Kate, 2002). This illustrates the importance and potential of TK to contribute to the development of a marketable product and highlights the value inherent in TK and the benefits that it can bring to stakeholders.

Indigenous and local groups have customary norms, laws and protocols that surround TK in order to maintain and regulate it (Robinson, 2010). The recognition of these practices and protocols can form a crucial component for the protection of TK (Robinson, 2010). The protection of these customary norms, laws and protocols have proven complex to resolve, because of concerns over secret or sacred knowledge that has spiritual connections to nature and the protection of the rights of these groups more broadly (Robinson, 2010). The complexities surrounding the preservation and utilization of TK are extremely delicate to balance. However, there is scope for innovative local and national initiatives to promote and safeguard TK, in accordance with attempts made in the CBD (Robinson, 2010).

2.9) Interface between Traditional Knowledge and Intellectual Property Rights

The international community through Article 8 (j) seeks to respect, preserve and maintain traditional knowledge and traditional lifestyles that are relevant for the conservation and sustainable use of biodiversity (Gibson, 2008). The value of TK has been widely recognized and includes domesticated seeds, traditional food products, alternative medicines, cosmetics, crafts and textiles (Dutfield, 2006). However, because of the multifaceted nature of TK, there is rigorous debate as to how best to protect such knowledge and the implications it has for various policy issues and sustainable development (Dutfield, 2006).

Intellectual property rights are considered incapable of co-existing with TK systems because they are privately or individually held and monopolistic in characteristic (Wynberg, 2004). A fundamental concept of traditional societies relates to communal ownership of property and communally shared concepts, thus the privatization of these concepts is contrary to the belief systems of indigenous people and local communities (Posey and Dutfield, 1996). These contradictions manifest within the community scenario and have led to conflict within communities over whether TK should be commoditized (Vermeylen, 2009). Indigenous peoples and local communities have become increasingly involved in the market and deliberate over IPR as a system of protection for their TK (Posey and Dutfield, 1996).

Intellectual property rights are formed on the premise that a patent protects some type of innovation made at a particular moment in time, but traditional innovations can be developed over generations and may result from incremental contributions from individuals (Barber, *et al*, 2002). This in turn makes it difficult to pinpoint a particular community as well as the individual responsible for developing the 'innovation'. A lot of knowledge surrounding medicinal plants and food crops arise from this collective innovation, and patent laws view this knowledge as in the public domain and t herefore incapable of being protected by patents (Barber, *et al*, 2002). Biotechnology and pharmaceutical companies who develop new products based on genetic resources and TK obtained from indigenous communities receive protection in the form of a patent, however the knowledge, innovations and rituals that allowed for the discovery to occur are not patentable (Barber, *et al*, 2002).

It was argued that for the effective protection of genetic resources and TK, the requirement for patent applicants to disclose the origin of genetic material and TK must be incorporated within TRIPS (Wynberg and Laird, 2009). Concerns range from uncertainty that the disclosure will bring about any real protection, the creation of uncertainties for industry and researchers that might develop as a result of the disclosure, cost implications to identify what should and what shouldn't be disclosed and concerns that approval of the proposal could condone the practice of patenting life forms (Wynberg and Laird, 2009). Despite these concerns both users and providers of genetic resources have incorporated this disclosure requirement within their legislation, in countries that include India, South Africa, Norway, Denmark and Costa Rica (Wynberg and Laird, 2009). However, the requirement is less effective unless it is applied on an international level, as the requirement is only enforceable within the country that has incorporated this into its legislation.

2.10) Benefit Distribution Mechanism

The sharing of benefits generated through the utilization of biological resources is executed through a number of different models. A trust fund is one such model that is adopted throughout the world. It has certain features that make it a suitable candidate as the mode of distribution of benefits to a range of stakeholders. The trust fund originates from Anglo-American legal tradition and it involves setting aside a sum of money, which is to be used for specific purposes for the benefit of the designated beneficiaries (Laird, *et al*, 2002). A trust fund can accommodate the long period that it takes to develop a product that can encompass several years and stretch into decades; it thus provides a stable and enduring structure from which funds can be constantly distributed (Laird, *et al*, 2002).

A primary requirement of a fund relates to the composition of the board, and its representation of the interests of all stakeholders, including the community, government, NGO members and industry (Laird, *et al*, 2002). This governance structure plays a crucial part in determining whether the fund will be a success or not. These stakeholders make decisions concerning the fund that are integral to its effective functioning, such as defining the guiding principles for proposal selection and grant-making (Laird, *et al*, 2002). A range of stakeholders that can evenly represent the diverse interests at hand must generate guiding principles. Where a trust is formed these

stakeholders form a board of trustees that are overseen by these guiding principles, and look to protect the long term interests of a group or country rather than the short term gains of individuals (Laird, *et al*, 2002).

Applicants with respect to benefit-sharing agreements can make payments into a mechanism such as a fund either as milestone payments, or as royalties for when the biological resource is commercialized into a product (Laird, *et al*, 2002). Where an overarching plan or framework for the distribution of benefits for the use of monetary payments is not set in place, this can potentially lead to several problems for the distribution of these benefits (Laird, *et al*, 2002).

The International Cooperative Biodiversity Groups (ICBG) project created the Forest People Fund in Suriname in 1994 and provided a mechanism for long-term compensation and distribution of revenues arising out of the utilization of genetic resources and ethnobotanical knowledge (Laird, *et al*, 2002). The stakeholders' main focus is to discover biologically active plants for drug development and biodiversity conservation, as well as to ensure that the source country and communities therein receive maximum benefits for their resources and intellectual input (Laird, *et al*, 2002). These are guiding principles that determine the focus of a fund. The Forest People Fund Foundation administers the Forest People Fund according to the foundation's by-laws that were written by Surinamese participants and regulated by the laws of Suriname (Laird, *et al*, 2002).

The by-laws require that the board of the Forest People Fund convene at least four times a year and that the day-to-day operational and financial requirements of the fund are administered effectively (Laird, *et al*, 2002). A diverse range of board members are represented and are to be retained for a maximum period of 5 years and may cast one vote in the boards decisions (Laird, *et al*, 2002). The Forest People Fund aid projects involve community development, health care and biodiversity conservation (Laird, *et al*, 2002). This is important to improve the livelihoods of the local people and involve these communities in project development and capacity-building.

This mechanism thus provides ABS legislation with a secure vehicle into which monetary benefits are paid into. Through its board of trustees, funds can be distributed with benefits to entitled beneficiaries. The trust deed dictates to the trustees how to go about distributing the funds. In the case of a trust the board of trustees shall undertake this task through special meetings and the terms of reference established in the trust deed. The trustees are therefore left to distribute the funds in a fair and equitable manner.

2.11) Institutional Coordination

The institutional arrangements designed to implement ABS legislation are crucial to its successful implementation. An institutional framework must be strong and robust with a committed and sensitive staff (Chaturvedi, 2009). No single institution can be expected to master the complex and extremely involved policy dialogue relating to ABS issues (Laird and Wynberg, 2002). These institutions must take into consideration and be well aware of the predicaments and apprehensions of indigenous communities towards formal research and development processes and administrative systems (Chaturvedi, 2009). Follow-up strategies must be pursued where a comprehensive institutional framework has been adopted to ensure implementation and acceptance of the relevant policy and further adaptation to the issues can be obtained (Barber, *et al*, 2002).

The multi-disciplinary nature of ABS requires an inter-agency approach that benefits from the experiences and expertise of each agency and allows staff, financial resources and other administrative support to be pooled together (Barber, *et al*, 2002). This multi-sectoral approach, however, can have its disadvantages. The Philippines created an inter-agency committee, known as the Inter-Agency Committee on Biological and Genetic Resources (IACBGR) that developed problems related to unavailability of members, lack of quorum, endless briefings and updates for absentee members, and a lack of continuity (Barber, *et al*, 2002). One of the obstacles that had to be contended with by the IACBGR was a lack of funding (Barber, *et al*, 2002). The IACBGR had to rely on member agencies to contribute operating funds, because the IACBGR and its technical secretariat did not have their own budget (Barber, *et al*, 2002).

The capacity of government is central to the successful implementation of ABS policy within a country. Governments, in order to facilitate effective and efficient implementation of ABS policy, need to build local capacity (Brush and Carrizosa, 2004). Delay in project applications could be the result of an absence of suitably qualified and trained evaluators or negotiators as was demonstrated by the Philippines and Columbian experiences (Brush and Carrizosa, 2004). A form of responsive regulation within developing countries develops where there are limited capacities to enforce ABS provisions, this type of governance mobilizes a cost effective method of social control as opposed to authoritarian command and control governance (Braithwaite, 2006). This

form of regulation relies on NGOs and other role players to ensure that key stakeholders are complying with the legislation (Braithwaite, 2006).

The example of Costa Rica suggests that ABS implementation is best achieved in a decentralized system where the organization seeking access to the resources negotiates directly with the empowered authority (Brush and Carrizosa, 2004). This reduces the number of parties involved in the negotiation and permitting process, which facilitates an environment conducive for successful policy implementation (Brush and Carrizosa, 2004).

Malaysia presents a duel system of governance - the state and federal governance systems are the current governing structures used in Malaysia over land resources and marine biodiversity. The state government has legislative control over land-based resources up to 3 km offshore, with the federal government having jurisdiction over the zone of economic exclusivity (Osman, 2004). This problem is compounded where island resources are governed by state structures and federal government exercises jurisdiction over the marine resources of marine parks (Osman, 2004). This situation creates conflicts of interest when developing policies governing natural resources.

2.12) Conclusion

The legislation that is enacted within a country should indicate to stakeholders a clear and certain path to gain access to valuable resources. The more stakeholders that are involved in the process of acquiring a bioprospecting permit contributes to further negotiations and interaction that can elicit further difficulties. Thus the process must be streamlined to minimize stakeholder interaction. This will ease the process of obtaining access to the resources.

The scope of the legislation determines what activities would require a permit to develop TK or IBRs. It is important that the scope distinguishes between the manner in which IBRs and genetic resources are accessed, and by including genetic resources within the definition of IBRs this will have serious consequences for all activities involving the use of IBRs.

The manner in which the legislation implements PIC is important for the fulfillment and protection of communities' rights. Given the sensitive and often delicate nature of the exchange

of information between stakeholders it is important to maintain a level of trust and take cognizance of cultural sensitivities within a community. This is seen to be a complex task and can be designated to the state to minimize bureaucracy and ensure protection of communities' rights, and limit the amount of stakeholders involved in the process. Where communities are left to negotiate PIC, this often leads to complicated negotiations, and can hamper research and development of IBRs and TK.

Regulating the exchange of resources between parties is done through an MTA. Legislation provides for the safeguarding of interests between all parties to this agreement, and is a cornerstone in the future exchange of resources. It provides certainty and legally binds stakeholders so that recourse can be had where parties fail to fulfill the agreement.

The protection of TK is an important element that needs to be considered by governing legislation. The manner in which countries protect TK is an important step to safeguard the interests of indigenous and local communities. Conflict between the western held notion of individual rights versus the collective communal idea of knowledge leads to a clash of ideologies. These ideologies need to be harmonized in a manner that recognizes the importance of both, and in particular provide for the protection of TK held by indigenous and local communities. Failure to recognize the importance of TK will lead to the further marginalization of indigenous and local communities.

The institutional arrangements provide the platform within which the above concepts are implemented. Consideration of the multi-disciplinary nature of developing IBRs and TK is needed when instituting the governing structure thereof. Certain countries have designated a focal point or competent authority to deal solely with the consideration of permit applications. Other countries have amended legislation to incorporate bioprospecting within already existing legislation.

The capacity of designated institutions is central to the successful implementation of ABS legislation. It is thus important that the necessary expertise and personnel are developed to implement ABS within a country. The financial impetus provided for the implementation of ABS legislation is a crucial factor in determining successful implementation thereof.
Chapter 3 Legislation and Policy Overview

3.1) Introduction

This chapter looks at the relevant statues, conventions and policies that have guided the formation of South Africa's ABS legislation. It describes the key provisions that guide companies seeking to gain access to genetic resources and TK. The provisions of international legislation provide the fundamental principles that are enshrined in chapter 6 of the National Environment Management: Biodiversity Act. It is important to understand the guiding framework to attain a greater understanding of the practicalities in complying with the formalities of these provisions. There is no single all-encompassing international treaty that captures all the issues surrounding the regulation of bioprospecting (Robinson, 2010). Below is a table outlining the various legislative guidelines developed internationally and in South Africa.

International Statutes, Conventions, Policy	Year Adopted
Convention on Biological Diversity, Rio De Janiero	1992
Governs the interaction between countries with high biodiversity and countries with technology to access this biodiversity. Promotes the conservation and sustainable utilitzation of IBRs in exchange for fair and equitable sharing of benefits.	
World Trade Organization Agreement on Trade-Related Aspects of Intellectual Property Rights (TRIPS), Morocco, 1994	1994
Promotes the patenting of IBRs and genetic material.	
International Treaty on Plant Genetic Resources for Food and Agriculture	2004
Governs the manner in which plant genetic resources are used for food and agricultural purposes and are considered and used by countries.	
Bonn Guidelines	2002
Provides guidelines for the utilization of TK and IBRs, provides a governing framework from which countries are able to develop access and benefit-sharing legislation.	
Nagoya Protocol	2010
Provides further Articles of what should be considered by contracting parties when	

Table 2. List of Conventions, Agreements and Statutes

developing and implementing ABS legislation.	
South African National Statutes and Policies	
Constitution of Republic of South Africa 108 of 1996	1996
The Constitution is an overarching framework to which other pieces of legislation fall under its ambit.	
National Environmental Management: Biodiversity Act 10 of 2004	2004
This Act was introduced to give effect to the CBD. It promotes the three objectives of the CBD and determines the manner in which applicants must proceed in order to legally utilize TK and IBRs.	
Indigenous Knowledge Systems Policy	2004
Grounding framework for the recognition and development of Indigenous Knowledge Systems within South Africa.	
Patents Amendment Act 20 of 2005	2005
South African piece of legislation that aims to protect holders of TK by disclosing the origin of IBRs used in a patent application.	
Regulations for Bioprospecting, Access and Benefit-Sharing legislation	2008
The Regulations give effect to NEMBA and provide guidance on how to practically comply with the legislation.	
National Environment Laws Amendment Act 14 of 2009	2009
The Amendment Act was promulgated to rectify anomalies inherent within NEMBA.	

3.2) Convention on Biological Diversity

The CBD is hard law and is legally binding on the contracting parties. This convention is an overarching framework for signatory countries to adopt. Its principle objectives as expressed in Article 1 provides for the conservation of biological resources diversity, the sustainable use of its components and the fair and equitable sharing of the benefits arising out of the utilization of genetic resources. The CBD has 42 Articles to guide the contracting parties in pursuit of these objectives.

The CBD provides for the cooperation between contracting parties. Environmental problems largely do not respect international borders or boundaries, thus a cooperative relationship between contracting parties is needed to safeguard the interests of other contracting parties. Contracting

parties are entrusted with sovereignty over biological resources if these policies do not cause damage to the environment of other states or of areas beyond national jurisdiction. This reenforces cooperation between nation states and is important in creating unity.

The protection of IPR of indigenous people and local communities is a complex and delicate matter, and through the CBD Article 8(j), indigenous and local communities TK and cultural practices that maintain TK and traditional lifestyles are to be respected and preserved. This paves the way for contracting parties to develop legislation in accordance with these principles and recognize the importance of TK and to ensure that cultural identity is maintained whilst utilizing such knowledge, innovations and practices.

Authority to determine access to genetic resources rests with the national governments, and is subject to national legislation. Article 15 provides the grounding from which access to genetic resources are regulated, and provides for provisions from which national legislative making bodies are able to promulgate their legislation. This insists on the state's autonomy when determining access provisions to biological resources; however, this article provides for provisions that include MAT, PIC, cooperation of contracting parties, as well as fair and equitable benefit sharing.

Article 16 of the CBD facilitates an environment that promotes access to and transfer of technology between contracting parties. This includes biotechnology, and that both access to and transfer of technology among contracting parties are essential elements for the attainment of the objectives of the CBD. The CBD also takes cognizance of patents and other IPRs to which national legislation and international law must cooperate to ensure that such rights are supportive of and do not run counter to its objectives. Given the high biodiversity of plant and animal species found in developing countries, this provision ensures that benefits are exchanged between the contracting parties that look to address the capacity differentiation between developed and developing parties in exchange for access to these natural resources.

The CBD through these articles is a major legal instrument safeguarding the biological resources of the world, they guide member states to achieve the objectives as set out in the CBD. South Africa has implemented concepts from the CBD through the enactment of NEMBA, described below in section 3.7.

3.2.1) Progress Implementing the CBD

Countries throughout the world have implemented ABS legislation to varying degrees, each reflecting their own national administrative structures, and each placing different emphasis on cultural and social priorities (Medaglia and Oliver, 2010). Currently over 50 countries have developed or are developing ABS laws (Vernooy and Ruiz, 2012). This low number can be attributed to a lack of technical expertise to legislate provisions, financial constraints, weak governmental structures and political support, social conflict and conflict over ownership of the genetic resources (Medaglia and Oliver, 2010). Some contracting parties have yet to promulgate legislation that effectively deals with concerns surrounding the utilization of natural resources and TK and rely on existing modes of governance for the utilization of natural resources (Braithwaite, 2006). Chile is one Pacific Rim country where several bioprospecting groups operate; however, there has not been significant incentive for legislators to promulgate a formal ABS framework (Carrizosa, 2004). This is because the benefits derived therefrom are not considered to be significant enough to warrant developing a comprehensive regime.

Various countries have adopted an approach whereby ABS is considered in the country's national biodiversity strategy or environmental or biodiversity legislation but have not yet regulated ABS in any detail. It allows countries to quickly set up general enabling legislation and it prepares a country for developing more detailed and descriptive processes in the future (Barber, *et al*, 2002).

Other countries have sought to modify existing biodiversity or environmental law with some general provisions on ABS or access to biological resources and may include a provision for the establishment of regulation on ABS (Medaglia and Rukundo, 2010). This limits the need to alter existing institutional structures and administrative processes, and is seen to be a more efficient and cost effective way of addressing ABS within a country (Barber, *et al*, 2002). However, within the existing institutional structures significant capacity-building is required to effectively deal with ABS particularities to ensure effective implementation (Braithwaite, 2006).

Regional framework legislation establishing common principles were promulgated by Bolivia, Columbia, Ecuador, Peru and Venezuela in the Andean Pact Decision 391 (Carrizosa, 2004). Links between eco-regions, ethnic and cultural beliefs contributed to the establishment of the Andean Pact Decision 391, which determines access to the genetic resources of these communities (Carrizosa, 2004). The Association of South-East Asian Nations (ASEAN) in 1998

aimed at promulgating a common ASEAN policy framework on access to genetic resources and TK (Barber, *et al*, 2002). The African Union has also developed a Model Law on the rights of local farmers, breeders and access, which regulates access to biological and genetic resources and the traditional knowledge of local communities and small farmers, as well as access to and use of seeds by breeders. There are 53 African states that are African Union members and support the Model Law (Vernooy and Ruiz, 2012).

3.3) Bonn Guidelines

The Bonn Guidelines look to operationalize the provisions of the CBD. The conference of the parties to the CBD eventually adopted the guidelines at its sixth meeting, held at The Hague in April 2002 (Secretariat of the Convention on Biological Diversity, 2002). The guidelines are voluntary and thus none of the contracting parties are obligated to implement these provisions. This is a key feature of the guidelines and in should no way to be construed as changing the rights and obligations of Parties under the CBD (s 7).

The primary intention of these guidelines is to provide parties and other relevant stakeholders with a transparent framework to facilitate ABS, and to assist states in establishing and implementing necessary policy, administrative and legal measures to achieve the objectives of the CBD (Wynberg and Taylor, 2008).

The guidelines outline important features to be implemented to ensure the effective utilization of genetic resources. The guidelines elicit roles and responsibilities of users and providers of genetic resources and encourage stakeholders to use a bilateral approach to facilitate ABS goals (Carrizosa, 2004). Key issues outlined include the involvement of relevant stakeholders and capacity building, steps in the ABS process, PIC, types of benefits to be exchanged, incentives, monitoring, reporting and accountability (Carrizosa, 2004).

3.4) Nagoya Protocol

In 2004, the 7th meeting of the CBD COP was held, and the contracting parties were mandated at its Ad Hoc Open-ended Working Group on ABS to elaborate and develop an international regime in order to implement Articles 15 (Access to Genetic Resources) and 8(j) (Traditional Knowledge). In 2010, after 6 years of negotiations, the Nagoya Protocol was signed in Japan to further the objectives of CBD, and provide both users and providers of genetic resources with greater transparency and legal certainty with respect to Article 15 and 8 (j) of the CBD (Nagoya, 2010).

The Nagoya Protocol hopes to achieve legal certainty, clarity and transparency, however the exact criteria of how this is to be achieved are not spelt out and there is still uncertainty inherent within the ABS system (Nijar, 2011). However, the Nagoya Protocol places emphasis on compliance and monitoring measures to be adopted by the contracting parties and this is said to be at the core of its objectives (Nijar, 2011). Articles 15, 16 and 18 of the Protocol, state that where resources have been pirated in violation of domestic laws, the state whose rights have been violated are entitled to seek redress and oblige other states to cooperate and provide appropriate opportunities for such redress (Zainol, *et al*, 2011). This is an important stepping-stone for facilitating an environment that has effective monitoring and compliance measures. Norway has adopted these provisions by providing that import of genetic material into the country from a state requires consent for collection or export of such material may only take place in accordance with such consent obtained from that provider country (Nijar, 2011). The state may bring legal action within another state that sets the conditions for the ABS interaction, and requires that organization to comply with those regulatory requirements (Nature Diversity Act No. 100, 2009).

Article 5 of the Protocol provides that benefits from the use of genetic resources and TK be shared in a fair and equitable manner based on MAT between providers and users in accordance with Article 15 of the CBD. Furthermore, each party is to take legislative, administrative and policy measures to implement these provisions (Zainol, *et al*, 2011). This article therefore reenforces the CBD Article 15. The Protocol further emphasizes the concept of PIC and through Article 6 of the Protocol ensures that this is implemented through legislative means. Contracting parties are thus obliged to enact legislation that takes into consideration the core principles as outlined in the CBD and the Bonn Guidelines.

An important supportive structure to Article 15 and 16 includes compliance provisions involved in the formation of designated checkpoints. Article 17 provides that one or more checkpoints be designated to ensure effective monitoring of activities. The disclosure of information to these checkpoints serves as a tool to ensure compliance, however some have argued that to impose sanctions on companies failing to comply with disclosure requirements could in fact deter the effectiveness of such a provision (Nijar, 2011).

The Protocol further defines the utilization of genetic resources to include the use of derivatives and pathogens (Nijar, 2011). The scope of the definition has been widened through the introduction of the Protocol. Where a resource is used, for example, to produce vitamins, benefits would have to be shared (Nijar, 2011). Should South Africa ratify the Protocol this definition would have to be incorporated within NEMBA. Derivatives are already included within South Africa's legislation, however the utilization of pathogens would have to be incorporated within the NEMBA.

Article 31 provides for an evaluation of the effectiveness of the Protocol four years after the entry into force of the Protocol. This re-emphasizes the commitment by contracting parties to promote effective compliance with ABS policies and legislation. Article 18.2 provides that each party must ensure that they give an opportunity to seek recourse to the courts of their country. This is to ensure that legal recourse is made accessible to all countries party to the Protocol (Nijar, 2011). This would ensure the enforcement of ABS provisions and together with the establishment of an ombudsman would ensure that stakeholders comply with ABS policies and legislation. The provision for an international ombudsman was deleted from earlier versions of the Protocol, however it can form part of developing countries' pursuit when the first review of the effectiveness of the protocol takes place (Nijar, 2011). This would protect indigenous communities' rights and developing countries that have been violated by unscrupulous actors.

On 10 January 2012, Somalia became the 73rd country to sign the Nagoya Protocol; a list of signatories is available at <u>www.cbd.int/abs/nagoya-protocol/signatories.</u>¹

^{1 50} countries must adopt and ratify the Nagoya Protocol before the agreement becomes legally binding on the contracting parties.

3.5) Trade Related Aspects of Intellectual Property Rights (TRIPS)

There is a conflict between the CBD and TRIPS - the CBD promoting the interests of developing countries and TRIPS supporting corporations and mainly developed countries (Zainol, *et al*, 2011). The TRIPS agreement administered by the WTO offers protection through Article 27.3 (b) for discoveries and inventions involving genetic resources of the natural world. With this trend there is strong support, particularly from developing countries, to disclose the origin of IBRs and TK associated with the development of a patent (Hoare and Tarasofsky, 2007). Ongoing discussions within the agendas of the CBD, WTO and the World Intellectual Property Organization (WIPO) have centered on the need to include this disclosure of origin requirement, however no consensus has yet been reached (Hoare and Tarasofsky, 2007). Various countries have nonetheless taken it upon themselves to include this requirement within national legislation, for example, the geographic origin for inventions based on biological material has been incorporated within EU countries' legislation for example, Belgium, Denmark and Sweden (Hoare and Tarasofsky, 2007).

South Africa has adopted this agreement through the Patents Amendment Act, which allows for the patenting of biological resources provided the origin of the resource has been given within the patent application. This Act thus seeks to protect the misappropriation of IBRs by ensuring the holders of such resources are disclosed, and duly acknowledged for their contribution.

A vital question concerning Article 27.3 (b) of the TRIPS agreement is whether or not the modification of plants are inventive enough to warrant patent protection (Zainol, *et al*, 2011). Until recently, these applications were considered incapable of meeting the criteria of inventiveness, non-obviousness, and it was thought improper to grant monopoly rights over plant varieties in view of their communal significance (Llewelyn, 1997). Rights under the Protection of New Varieties of Plants (UPOV) were thought to cater for the interests of new plant varieties (Rimmer, 2003). However the threats faced by breeders as a result of the UPOV regime, and the influence of biotechnology has led to the steady inclination toward patenting of plants, microorganisms and transgenic animals (Edelman, 1988).

3.6) International Treaty on Plant Genetic Resources for Food and Agriculture

The International Treaty on Plant Genetic Resources for Food and Agriculture (ITPGRFA) is the foremost legally binding international agreement focusing specifically on the conservation and sustainable use of Plant Genetic Resources for Food and Agriculture (PGRFA) (Gerstetter, *et al*, 2007). It seeks to ensure the conservation of, access to and sustainable use of PGRFA. In November 2001, the Treaty was adopted at the Conference of the Food and Agriculture Organization of the United Nations (FAO) after 7 years of negotiations (Gerstetter, *et al*, 2007). On 29 June 2004, the treaty finally entered into force after its fortieth ratification.

The ITPGRFA provides legal certainty with respect to the conditions under which an array of plant genetic resources for food and agriculture can be accessed and used, and the manner in which benefits derived and associated from their use must be shared (Gerstetter, *et al*, 2007). The legal mechanism creates a multilateral system of exchange for key crops and forages identified in Annex 1 to the treaty (Wynberg, *et al*, 2008).

Indigenous biological resources listed in terms of the ITPGRFA have been excluded in terms of s 80 (2) (b) from the definition of indigenous biological resources described in NEMBA. South Africa has excluded listed IBRs of the ITPGRFA through Chapter 6 of NEMBA s 80 2(b)(iii).

3.7) South Africa

3.7.1) Policy Process

South Africa became a contracting party to the CBD in 1995. The 1997 Biodiversity White Paper, through a two year public consultation process emerged as one of the first policies to incorporate ABS in South Africa (Wynberg, *et al*, 2001). The White Paper recognizes a need to establish legislative and administrative mechanisms to control access to South Africa's genetic resources (Wynberg and Taylor, 2008). Access and benefit sharing is included as one of six goals of the Biodiversity White Paper, and aims to 'ensure that benefits derived from the use and development of South Africa's genetic resources serve national interest' (DEAT, 1997).

Two objectives support this goal. The first objective supports legislative development to govern access to IBRs, and set up institutional arrangements to regulate this access (Wynberg and Taylor, 2008). The second objective is a commitment by South Africa to participate in the revision of the International Undertaking on Plant Genetic Resources; commitments to commence the national development of legislation on farmers' rights; and supporting activities for the safeguarding of indigenous and traditional livestock breeds and plant varieties (Wynberg and Taylor, 2008).

In furtherance of the White Paper South Africa developed the National Environment Management: Biodiversity Act 10 of 2004 (NEMBA), which was enacted by Parliament in 2004. This piece of legislation was the first in South Africa to comprehensively deal with the concept of ABS. Chapter 6 provided for the legislative framework that would guide the process of bioprospecting and commercialization of IBRs in South Africa.

It was not until 2008 that the Regulations to NEMBA were promulgated and came into force. The regulations provide for the actual implementation of NEMBA. The National Environment Laws Amendment Act 14 of 2009 (NEA) was promulgated to rectify problems inherent in NEMBA, although associated regulations have not yet been gazetted.

3.7.2) Constitution of the Republic of South Africa

The Constitution of the Republic of South Africa 108 of 1996 is the supreme law of the land and all legislation promulgated by legislators must fall within the ambit of the Constitution. The Constitution through its various sections protects the interests of the people of South Africa. These rights are a cornerstone in South African law.

Section 24 of the Constitution provides an extremely important right that entitles people to an environment that is not detrimental to their health or well-being, as well as to have measures implemented that prevent ecological degradation. These rights are extremely important when considering the implementation of NEMBA.

The Constitution also prescribes the institutional structure that governs the manner in which national legislation and provincial legislation is implemented. The schedule 4 listing of the Constitution provides for the concurrent jurisdiction of national and provincial government with respect to matters concerning the environment (Fuggle and Rabie, 2009). Thus in terms of s 146

of the Constitution, the provincial government may enact provincial legislation that contains the detailed regulations of the matter concerned, which must be aligned to the national legislative framework according to s 146 of the Constitution.

3.7.3) NEMBA and National Environment Laws Amendment Act (NEA) 14 of 2009

South Africa's NEMBA was promulgated in light of the CBD. The preamble of NEMBA provides for the sustainable use of indigenous biological resources and the fair and equitable sharing of benefits arising from bioprospecting involving indigenous biological resources. NEMBA also provides for the management and conservation of South Africa's biodiversity within the framework of the National Environmental Management Act 107 of 1998 (NEMA). Chapter 6 of NEMBA provides for the broad framework of ABS, the details of implementation to be left to national regulations. NEMBA also creates the South African National Biodiversity Institute (SANBI) that plays an advisory role to the Minister, and performs other functions in terms of s 11 of NEMBA.

3.7.3.1) Bioprospecting

An applicant wishing to engage in bioprospecting must approach the competent authority established in terms of s 97 of NEMBA, which is the Department of Environmental Affairs (DEA) (See Figure 1 below). NEMBA defines bioprospecting in relation to IBRs, as any research on, or development or application of, IBRs for commercial or industrial exploitation. It also includes the application, development or modification of any traditional uses for commercial or industrial exploitation.

A bioprospector in terms of this definition must apply for a permit to the competent authority. These competent authorities are designated as organs of states that may be issuing authorities for permits referred to in s 81. No person may engage in bioprospecting activities involving any IBRs without a permit, or is allowed to export from the Republic any IBRs for the purpose of bioprospecting or any other kind of research without a permit.

NEMBA through s 82 and the regulations as well as the NEA provide that where an applicant wishes to use IBRs or TK, that applicant must approach either a person, organ of state,

indigenous community or an individual holder of TK. The applicant must lodge a notification of interest to bioprospect with the competent authority when conducting the discovery phase of a project. Once the applicant reaches a point where he/she is about to begin commercialization as defined within the regulations, that applicant must ensure that the requisite PIC is obtained, and that MTAs and/or benefit-sharing agreements have been entered into.

Bioprospecting commercialization chain





3.7.3.2) Indigenous Biological Resources

The utilization of IBRs excludes genetic material of human origin; any exotic animals, plants, or other organisms, other than exotic animals, plants or other organisms referred to in paragraph s 80 (2)(a)(iii) of NEMBA, and IBRs listed in terms of ITPGRFA s 80 (2)(b)(iii). Section 80(2) of NEMBA include any plants, animals or other organisms of an indigenous species cultivated, bred or kept in captivity or cultivated, or altered in any way by means of biotechnology; any genetic material of such animal, plant or other organism; any cultivar, variety, strain, derivative, hybrid or fertile version of any indigenous species or of any animals, plants or other organisms referred to in subparagraph (i); and any exotic animals, plants or other organisms, whether gathered from the wild or accessed from any other source which, through the use of biotechnology, have been altered with any genetic material or chemical compound. It is important to note genetic resources have been included within the definition of IBRs, and are not presented as a distinct concept to IBRs.

3.7.3.3) Prior Informed Consent

Within s 82 (2) and s 82 (3) PIC requires the applicant to disclose all material information relating to the bioprospecting to be conducted by the stakeholder and on this basis obtain the prior consent of the stakeholder for the provision of, or access to, the resource. There are no attached forms to the Act or regulations stipulating a prescribed format of PIC that must be entered into.

The legislation requires PIC to be obtained once the commercialization phase of the bioprospecting project commences. Without PIC, the activity will not be allowed to continue. The manner in which PIC is to be pursued requires a cultural sensitivity towards the community being approached. The legislation does not prescribe how this approach is to be achieved. It merely requires that all material information relating to the activity be disclosed.

3.7.3.4) Benefit-Sharing Agreements

The applicant that wishes to commercialize an IBR, in terms of the definition as laid down in the regulations, must comply with the provisions of NEMBA before a permit will be issued. The applicant must approach the stakeholder(s) to which the IBR or TK relates. These stakeholders include a person, including any organ of state, community or an indigenous community and in terms of s 83, the applicant must approach the stakeholder (stakeholder concerned and enter into a benefit-

sharing agreement. The National Environment Amendment Laws Act 14 of 2009 (NEA) provide that benefit-sharing agreements are to be entered once the commercialization of IBR commences.

The regulations to NEMBA also provide a tick box benefit-sharing agreement template. This is to be completed and sent with the application for a bioprospecting permit. The types of benefits to be exchanged are either monetary or non-monetary. This includes acknowledgment of parties giving access, research results and copies of papers, support for conservation, student training and support, equipment and infrastructure, technology transfer, upfront payments, royalties, milestone payments, grants for development and environmental education projects. The agreement also requires the parties' names, contact details and in what capacity these parties enter into the agreement. The benefit-sharing agreement is then submitted to the Minister for approval or rejection.

3.7.3.5) Material Transfer Agreements

The MTA is formulated within s 84 of NEMBA. NEMBA provides the prescribed format to be entered into by the relevant stakeholders. The MTA is to accompany the application for a bioprospecting activity at the commercialization stage of the activity. It is attached to the regulations to NEMBA and governs the relationship between the stakeholders. It provides for the particulars of the suppliers of the IBR, what type of materials are being supplied, the area from where the resource comes from, the purpose for which the material is being collected, the present potential uses of the IBR and the conditions under which the material is being collected.

The MTA aims to regulate the exchange and the manner in which IBRs are to be used by the relevant parties. The MTA is to be completed with the benefit-sharing agreement at the commencement of the commercialization phase as presented within NEMBA.

3.7.3.6) Permitting

Certain sections governing the permitting system were amended through the introduction of the NEA. The amendments look to correct the anomalies within the NEMBA regulations. One such element was regulating the discovery phase of a bioprospecting activity the same as the commercialization phase. The amendments allowed a notification procedure to be lodged with the issuing authority whilst bioprospecting was in the discovery phase of its activities. Prior to the amendments, the regulations to NEMBA prescribed that PIC, MTA and benefit-sharing

agreements were to be entered into at the start of the discovery phase. The amendment now prescribes that the MTA and benefit-sharing agreements must be entered into at the beginning of the commercialization phase. Commercialization within NEMBA is a broad all-encompassing definition that includes activities conducted with respect to IBRs and includes; the filing of IPR, obtaining or transferring of any IPR or other rights, commencement with clinical trials and product development, market research and seeking pre-market approval for the sale of resulting products, multiplication of IBRs through cultivation, propagation, cloning or other means to develop and produce products such as drugs, industrial enzymes, food flavours, fragrance, cosmetics, emulsifiers, oleoresins, colours and extracts.

A designated competent authority or the DEA is the focal point to which all permit applications are to be sent. Once a competent authority has assessed the documents submitted by the applicant, a decision will be taken as to whether a permit should be granted, refused or sent back for amendments. The competent authority also has the power to cancel the permit because of misleading or false representations. See Figure 2 below for a schematic representation outlining the governing structure to approach when applying for a bioprospecting permit.

Where a permit has been granted by the DEA for a bioprospecting activity, the applicant must then approach the provincial department and apply for a collecting permit. This permit is to be obtained in terms of the provincial ordinance that governs the collection of IBRs from the province in which the bioprospecting permit has been granted for.

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Figure 2. Governing Structure for the Commercialization of Indigenous Biological Resources

3.7.3.7) Research for Academic Purposes

This is an intricate stage of the process as research for academic and commercial purposes often overlap. The legislation has separated the research for academic and commercialization purposes. Provincial authorities and ordinances regulate the collection permits for research on IBRs. The provincial authorities ensure collecting permits are granted for research purposes, as well as export permits for purposes other than bioprospecting. Research for commercialization purposes are conducted in the discovery phase of a project and governed by the regulations to NEMBA. The competent authority is responsible for the issuing of bioprospecting permits, which are then assessed by the provincial department. The provincial department then issues the collecting permit for a bioprospecting activity in accordance with the permit issued from the DEA.

The provincial department is empowered through the regulations to grant an export permit where the IBR is to be used for academic purposes.

3.7.3.8) Integrated Permits

Where an activity mentioned in s 90 of NEMBA is also regulated in terms of other law, for instance the provisions governing Convention on International Trade in Endangered Species of Wild Fauna and Flora (CITES) permits, the authority empowered under that law and the issuing authority empowered under NEMBA may exercise their respective powers jointly and issue an integrated permit.

Where NEMBA and other laws have been complied with the competent authority may grant an integrated permit. A bioprospecting activity will need to comply with NEMBA where only a CITES permit has been granted.

3.7.3.9) The Bioprospecting Trust Fund

The bioprospecting trust fund is created through s 85 of NEMBA and through its regulations which provide for the distribution of benefits to the relevant stakeholders to a benefit-sharing agreement. The fund, managed by the Director General of DEA, is the fund into which all money raised from benefit-sharing agreements that is due to stakeholders must be paid, and from which all payments to or for the benefit of stakeholders must be made with respect to s 85 of NEMBA. The NEA allows for the Director General or trustee to manage the bioprospecting trust fund.

3.7.4) Patents Amendment Act 20 of 2005

The Patents Amendment Act was developed to safeguard IBRs from misappropriation. It requires the applicant to furnish information, where a patent is applied for, with respect to any part played by TK or an IBR that may form part of the submitted patent and where so, submit evidence that the applicant has acquired the permission of the indigenous people or local communities to utilize that TK or IBR (Crouch, 2008). The impact of this amendment is limited when applicants seek wider protection that goes beyond the borders of South Africa. Applicants often do not limit the patent to South Africa and the amendment does not offer protection outside of South Africa's borders (Taylor and Wynberg, 2008). This requires a reliance on international agreements to enforce disclosure of origin of IBRs and TK used in a patent application which is not forthcoming within the TRIPS agreement.

The effectiveness of the patents office is also limited as it is a non-examining office, which does not carry out a substantive investigation into a patent application (Taylor and Wynberg, 2008). In other larger patent offices this would include a novelty search into 'prior art' and a decision on the merits of the invention (Wynberg and Taylor, 2008). With emphasis placed on the formalities associated with an application, a patent is granted as a matter of course with a rebuttable presumption of validity (Taylor and Wynberg, 2008).

3.7.5) Indigenous Knowledge Systems Policy

The Indigenous Knowledge Systems policy was developed and adopted by the Department of Science and Technology (DST) in 2004. The aim of this policy was to recognize, affirm, develop, promote and protect Indigenous Knowledge Systems (IKS) in South Africa. This policy is thus complementary to Chapter 6 of NEMBA and provides a road map to safeguard IKS within South Africa.

3.8) Conclusion

South Africa has developed legislation in accordance with the CBD and Bonn Guidelines, this reenforces South Africa's commitment to the objectives of the CBD. The practical implementation of these concepts will determine the success of the ABS regime in South Africa. The legislation provides a comprehensive platform from which bioprospecting activities are guided, and equitable partnerships can be established. The effectiveness with which this legislation is implemented will be determined in chapter 4.



Chapter 4 Results

4.1) Introduction

Through insight from some of the key industry representatives and stakeholders involved in the use of South Africa's natural resources, one can begin to understand some of the central issues surrounding bioprospecting and implementation of NEMBA. Access to these resources plays a central role in determining how IBRs and TK are utilized, and NEMBA prescribes certain provisions to be implemented in order to facilitate an environment conducive for bioprospecting. The attainment of PIC from an indigenous and local community is a cornerstone of this implementation and, together with benefit-sharing agreements and MTAs, it forms the procedural backbone of NEMBA. The designated institutional arrangements provide the platform that stakeholders must engage with and ensure that the provisions are complied with. This governing structure plays an integral part in the implementation of NEMBA by facilitating an environment within which stakeholders may pursue bioprospecting activities.

4.2) The Scope of Bioprospecting and Definitional Implications

South Africa through ABS legislation has defined what will be considered a bioprospecting activity. This includes the research, development or application of an IBR for commercial or industrial exploitation. The manner in which this definition is structured has consequences for various industries involved in the utilization of IBRs and TK. This is pertinent for cultivators and bulk traders of IBRs. If a stakeholder is conducting a bioprospecting activity then that stakeholder must apply for a bioprospecting permit in accordance with NEMBA.

It is important to note that the utilization of IBRs and genetic resources is regulated identically within NEMBA. Where a stakeholder has access to IBRs, that stakeholder also has access to the genetic resources they contain. The lack of distinction between the concepts was a key issue for the majority of stakeholders interviewed. For example, farmers and cultivators of IBRs are affected by this definition by virtue of their activities. These stakeholders are involved in the cultivation of IBRs and supply of IBRs and must comply with the legislation, even though these

activities are not considered bioprospecting activities. Cultivators are farmers that prepare land for growing IBRs that are used in bioprospecting activities. Some industry representatives argue that their activities do not specifically fall within the definition of bioprospecting as outlined in NEMBA, and as such they should not have to comply with the prescribed agreements (Gass, Zizamela Herbs, pers. comm., 2011):

I am not a prospector, I am a cultivator, with knowledge on how to cultivate, I'm a processor, I'm a trader, I don't do prospecting - so strictly speaking I shouldn't need a bioprospecting permit.

The current definition of bioprospecting within NEMBA includes the utilization of IBRs, which in the case of a farmer, would effectively force him to comply with NEMBA. The Department of Environmental Affairs (DEA) acknowledged that there is a distinction between how some applicants use IBRs and how others use the genetic resources (Malherbe, DEA, pers. comm., 2011). Where traders are trying to sell the IBR it is immaterial whether they have access to the genetic resource as long as they have the actual plant or resource. Where bioprospecting companies want to narrow down a compound and focus on the properties of a specific chemical within a plant, then those companies would want access to the genetic resource, but would not necessarily need the raw commodity. The legislation in its current form does not specifically outline this distinction, and therefore there are opportunities for misinterpretations (Malherbe, DEA, pers. comm, 2011).

Bulk traders of IBRs are compelled to adhere to ABS legislation when they trade in IBRs. The bulk trade of IBRs would include for example the buying and selling of raw material from one trader to the next. Every one of these traders, from grower to the eventual market, is according to NEMBA involved in bioprospecting activities and therefore must comply with NEMBA. One NGO representative noted that (Von Braun, Natural Justice, pers. comm., 2011):

You could interpret (the definition of bioprospecting) in a way that includes all trade in biological material and that certainly would be inefficient with respect to a whole lot of ongoing important commercial activities for South Africa.

The uniqueness of each resource and the manner in which they are utilized needs to be taken into account. There is a definite need to distinguish between the utilization of IBRs and genetic resources and dispense different policy approaches to access each resource, with one NGO representative suggesting that only the genetic resources should be regulated (Von Braun, Natural Justice, pers. comm., 2011).

Other research representatives felt there was no need to distinguish between genetic resources and IBRs. In some cases it is the actual genetics that contain the value and it is the utilization of these genetics that a party is interested in, and in other cases it is the biological material that an organization would be interested in. A NGO representative, however, stated (Williams, Biowatch, pers. comm., 2011):

I don't think one needs to distinguish between the two; they are still resources that are found within South Africa.

These experts emphasized that if you start to distinguish between genetic resources and IBRs then it could be argued that you might need to start distinguishing on a chemical or enzyme level, which could make it extremely complicated and even more difficult to administer (van Wyk, University of Johannesburg, pers. comm., 2011). There are thus contrasting views on the need to regulate the utilization of genetic resources and IBRs separately.

4.3) Accessing Indigenous Biological Resources and Traditional Knowledge

Countries have prescribed various methods to allow access to IBRs and TK. Each method comes with its positive and negative attributes. In South Africa, access providers have been divided into four different categories ranging from a private person, organ of state, indigenous community or individual holder of TK. This creates a situation within South Africa where a private person can allow access to an IBR if that resource is found on his/her land, and is entitled to benefits that are generated from the utilization thereof. This has effectively led to the privatization of IBRs where those resources are found on a private landowner's property, state property or on indigenous community land. Indigenous communities are provided with the opportunity to exploit their resources and negotiate access to their IBRs in accordance with the ABS provisions.

Industry has expressed the position that it would rather choose the path of least resistance in obtaining access to, and developing IBRs (Nel, Afriplex, pers. comm, 2011). The distinctions that are created between access providers within the legislation, allow this preference to manifest

itself in the conduct of the applicants. The objective of fair and equitable distribution of benefits arising from the utilization of genetic resources as outlined within the CBD is at risk. Industry members find themselves in a position where they are able to choose who should directly benefit from the exploitation of IBRs within South Africa. This idea was criticized by an NGO representative who stated that (Von Braun, Natural Justice, pers. comm., 2011):

There is an assumption that I as a landowner can give access to the plants in my garden for research, and I just don't think that is appropriate, it should be understood as the general ownership of the people of South Africa rather than me as the landowner who happens to have the plant on my land.

There are thus contrasting views surrounding who should be entitled to give access to IBRs. Some researchers insist on access procedures that do not hinder the pursuit of science and discovery (van Wyk, University of Johannesburg, pers. comm., 2011). Prior to the NEMBA amendments, research in the discovery phase was regulated identically to research in the commercialization phase. This had the effect of bringing the science community to a standstill (Eloff, University of Pretoria, pers. comm., 2011). Over-regulation of research at the beginning stages of a project is thought to hinder scientific and project development and was rejected by the research community (Eloff, University of Pretoria, pers. comm., 2011). The amendments have gone some way to protect the freedom of research institutions and other institutions to explore potential uses of IBRs and TK, and the legislation now provides only for a notification to be lodged with the competent authority where the discovery part of a project is pursued. These notifications are lodged by research institutions sometimes as a precaution to avoid further complexities that may ensue (Bailey, University of Cape Town, pers. comm., 2011). Institutions can then continue with research without having to obtain PIC, and only need to enter benefit-sharing agreements and MTAs when the commercialization phase of a project is reached.

The DEA is designated as the competent authority responsible for assessing permit applications. When an application for a bioprospecting permit is received by the DEA, it must ensure that the correct forms of PIC, MTA and benefit-sharing agreements have been obtained and entered into. The DEA thus aims to regulate the utilization of IBRs and TK. The DEA since 2008 has received 43 bioprospecting permit applications and granted only one. The DEA has granted a further three integrated export permits for bioprospecting activities (See Table 3 below). This illustrates the small number of permits granted with the intention to commercialize IBRs and TK, and is indicative of legislation that is not functioning to its full potential. The applicant on receipt of

permission to continue with the activity would then have to approach the provincial department to apply for a collection permit in terms of provincial ordinances.

Table 3. Permits Granted for Bioprospecting Purposes

Export Permit for Bioprospecting Activity: Sceletium tortuosum

Export permit granted to HGH Pharmaceuticals, PLT Thomas and the San Council. The benefits agreed to were upfront payments and royalties from profits generated through the sale of the product developed. *Sceletium* is a plant resource developed because of its mood enhancing abilities.

Export Permit for Bioprospecting Activity : Permit 2

Resource collected from the Western Cape, Mpumalanga and Limpopo.

Type of Agreements: Material Transfer Agreements, Benefit-Sharing Agreement.

Export Permit for Bioprospecting Activity: Permit 3

Resource collected from Northern Cape, Limpopo, North West, KwaZulu-Natal and Eastern Cape.

Type of Agreements: Material Transfer Agreements, Benefit-Sharing Agreement.

Bioprospecting Permit

Resource collected from KwaZulu-Natal.

Type of agreements: Material Transfer Agreements, Benefit-Sharing Agreements.

One permit includes the South African San Council, which in partnership with other stakeholders, entered into benefit-sharing agreements for the utilization of a plant called *Sceletium tortuosom*. The parties include the South African San Council, HGH Pharmaceuticals and PLT Thomas. This plant was developed as a mood enhancer and a benefit-sharing agreement was entered into by the relevant stakeholders. This included upfront payments and subsequent royalties (Gericke, HGH Pharmaceuticals, pers. comm., 2011). These agreements form an integral part in distributing benefits back to where the IBRs and/or TK originate from.

A researcher intimated that having a provincial framework as well as a national framework makes ABS legislation more complicated to comply with. Suggestions were made for streamlining, by possibly ensuring that one center is responsible for everything (Bailey, University of Cape Town, pers, comm., 2011). A practical example of the difficulties of complying with two frameworks arises where industry has to collect a plant species from another province and have it transferred to a different province that is technically capable of identifying that plant species (Maharaj, CSIR, pers. comm., 2011). However, a collecting permit will not be granted until national legislation has been fulfilled, and the plant species has been identified and filled into the application forms. This can result in slowing down research. For postgraduate students, research institutions, pharmaceutical companies or other potential stakeholders, this can cause unnecessary delays and add to financial burdens (Maharaj, CSIR, pers. comm., 2011). One industry representative noted that the logistics of obtaining an unidentified plant, and bringing it to another province to have it identified so that the stakeholder can fulfill the requirement of identifying the species to be utilized under national legislation, has not been thought through and at present is impractical (Maharaj, CSIR, pers. comm., 2011). This type of difficulty is created because of the way the application process is structured; the restructuring of application mechanisms and permitting processes would eliminate unnecessary costs and unwarranted delays.

One applicant noted a sense of frustration with the governance structures, in an example where the applicant had received permission to proceed with a bioprospecting activity pending the granting of the bioprospecting permit. On approaching the provincial government, however, he was refused a collecting permit because a bioprospecting permit had only been provisionally granted. This representative remarked (Maharaj, CSIR, pers. comm., 2011):

So typically national government will say you may continue with your research because we do not want to stop the research, so as long as you made your application you can continue with your research, fair enough. You go to the provincial government and then apply to harvest the plant; they come back and say we can only give you this when your bioprospecting permit is issued.

The applicant has to go back to the DEA and elicit relevant documentation in order to proceed, and this takes unnecessary time and effort. There is a need for the two departments to be communicating effectively to avoid this type of situation. In the above situation, the applicant had to stop research and request further information from the DEA to forward to the provincial authority, essentially taking on the roles of applicant and go-between. This is highlighted as one of the disconnections found between national and provincial government that hampers research.

4.4) PIC and Challenges of Linking Indigenous Communities with TK

Gaining access to IBRs and TK is achieved through obtaining PIC from the relevant provider. This is provided for within NEMBA in accordance with international law. The concept provides a certain amount of protection to stakeholders. In South Africa, PIC provides for the full disclosure of all material information relevant to a bioprospecting project. Identifying the parties to whom this information is presented and the mechanism to facilitate this exchange are central components to its success.

The identity of indigenous and local communities has been transformed through the exchange of genetic and cultural information over thousands of years. Linking these communities with specific TK and IBRs can be a complex task as one expert explained (van Wyk, University of Johannesburg, pers. comm., 2011):

For a long time in South Africa there has been cultural and genetic interchanges between different communities, thus, you can be part of one community, and also part of another community and it therefore makes it difficult to identify and separate communities.

This makes it difficult to ring-fence a homogenous community and gain PIC when there has been a convergence and exchange of cultural and genetic information (Nel, Afriplex, pers. comm., 2011). From a linguistic point of view, the San people of southern Africa have integrated Afrikaans into their language, and an amalgamation of languages and exchange of information has occurred between Afrikaners and the San. This has been occurring for centuries and has merged the lines of cultural identity between the two communities. It is not to say that one cannot identify the differences between San heritage and Afrikaner heritage, but people caught in the middle of this cultural interchange can theoretically identify with both communities, and be part of both. Industry has also explained that given the complexity of this task, the onus should rest with the state to determine the identification of a particular community (Feiter, Parceval, pers. comm., 2011). The competent authority has also remarked that applications are not approved because in the majority of cases the indigenous community cannot be identified (Malherbe, DEA, pers. comm., 2011).

Determining the exact origin of TK can be problematic. One industry representative made the point that (Mulder, MRC, pers. comm., 2011):

If it is a fairly common plant and ailment that it treats, you will probably find that all indigenous communities in South Africa have at some point or another used it.

Often, references made to the use of IBRs and TK are found in the form of a few written references made by western ethnobotanists (Feiter, Parceval, pers. comm., 2011). These written references are generally made on a very generic level within ethno-medicinal texts, by stating, for example, that the resource was used by the Tswana people (Crouch, SANBI, pers. comm., 2011). It is therefore very difficult to prove ownership of TK because of a lack of written evidence and should the courts be asked to decide who the original holders of that knowledge are, they would be placed in a difficult position (Chennells, Albertyn Chennells Attorneys, pers. comm., 2011).

One of the biggest challenges highlighted by a research institution is that IBRs and TK are not restricted by any borders, and may be associated with groups of people within several provinces, or even across national boundaries (Maharaj, CSIR, pers. comm., 2011). A single IBR can be used across various communities spanning several hundred years. For example, an IBR utilized by one community 50 years ago could have been used by a completely different community 500 years ago and yet another community 5,000 years ago (Nel, Afriplex, pers. comm., 2011). The question is how far back in time do you go to determine who the original holders of the TK are (Chennells, Albertyn Chennells Attorneys, pers. comm., 2011)?

The legislation defines an indigenous community as having a leadership structure within a distinct geographical area within the Republic of South Africa. The legislation does not provide a mechanism to obtain consent and relies on the applicant's own interpretation of what an indigenous community is. The Department of Cooperative Governance and Traditional Affairs (CoGTA) provides a framework from which a community can be identified, however, this is not without controversy. As the competent authority explained, certain individuals may claim to be the leaders of a specific community, but if that leader is not recognized by CoGTA this leads to further disputes over the legitimacy of those individuals (Malherbe, DEA, pers. comm., 2011). Thus, confrontations occur between various 'leaders' and CoGTA as to who should in fact be recognized as the true leaders of specific groups.

Indigenous communities can also decide for themselves who they are as a community. For example a group of traditional healers and herbalists in Mpumalanga, refer to themselves as a community for the purpose of sharing TK with outsiders in a bioprospecting framework (Malherbe, DEA, pers. comm., 2011); they don't include other people in this definition (Von Braun, Natural Justice, pers. comm. 2011). The current legislation makes no allowance for this method of identification, and this would have to be facilitated by the applicants.

The identification of indigenous communities is central to obtaining PIC. Without the identification of the source community, the applicant is unable to obtain PIC, and is therefore unable to proceed with its activities. The competent authority responsible for assessing permit applications emphasized this point (Malherbe, DEA, pers. comm., 2011):

The most critical issue is that applicants do not know who to engage with when trying to obtain PIC.

This was further confirmed by a number of industry representatives who expressed difficulties in determining who the correct people were to engage with (Nel, Afriplex, pers. comm., 2011). The practicalities of securing PIC lead to complexities that the legislation does not appear to accommodate. As a result, industry is left stuck at the first obstacle in the procedural requirements of NEMBA. The difficulties of obtaining PIC and the lack of prescribed procedures can result in industry proceeding to acquire this consent through dubious methodology. It was suggested by one industry member that stakeholders in some instances chose to arrange a 'front' refers to a stakeholder making contact with an individual, paying him a sum of money, getting that individual to sign a PIC related document, and using that document as part of the applicant's permit application (Hendriks, SANParks, pers. comm., 2011). This type of abuse can be avoided through effective and clear procedures.

These methods employed by industry result in unnecessary time and administrative costs for government who has to assess these types of applications. It has been suggested by industry that a suitable framework or procedure would guide industry more effectively and cut down on wasteful applications. It is imperative that industry has a clear structure within which to pursue PIC, otherwise industry itself is left to decide what is acceptable. This leads to further frustrations when applications are rejected based on inadequate attainment of PIC.

Acquiring the requisite PIC is a complex task that can take much time, resources and organization. Where PIC is to be obtained from an indigenous community directly this increases the length of time to obtain the required consent as confirmed by one industry representative (Feiter, Parceval, pers. comm., 2011):

These sorts of issues don't take days, weeks, or months to discuss but can take years...it's not like a business where you can just pick up the phone and speak to the chief about a certain agenda, it takes time to build up trust between the parties.

Industry is concerned that these intricate concepts cannot be explained in one sitting, and it can take multiple meetings to effectively communicate the applicant's intentions to the resource holder. Industry emphasized that a substantial amount of resources must be used to conduct meetings and administer appropriate PIC deliberations. In some cases airplane flights have to be arranged, hotel accommodation and other expenses for a single meeting (Mulder, MRC, pers. comm., 2011). If these deliberations turn into more than one or two meetings it results in a heavy financial burden for a small company. This could have negative impacts on the company staying solvent, and could possibly result in the project not reaching commercialization because of the intense financial burdens experienced by small to medium sized companies. This has a negative effect on the development of IBRs and could result in a halt to any further commercialization.

It was emphasized by representatives of indigenous and local communities that the issue of language is pertinent to the acquisition and implementation of effective PIC (Williams, Biowatch, pers. comm., 2011). This is not provided for within NEMBA and can result in unequal deliberations and misunderstandings between the parties concerned. This compounds the challenges of ensuring that the community is fully aware of the implications of granting access to an applicant for the utilization of their IBRs and/or TK. These communities at times are unable to fully comprehend scientific and legal terminology. It is important to bridge this gap through communication in a language that is accessible to both parties.

Some respondents representing marginalized communities believe that the legislation fails to address culturally sensitive issues when approaching indigenous and local communities, and it does not provide any culturally sensitive methods to be adopted when an applicant attempts to obtain PIC (Williams, Biowatch, pers. comm., 2011). The subsequent cultural misinterpretations that may occur could have a detrimental effect for the negotiations. Groups representing local communities urged current legislation to take cognizance of the disparities between different

stakeholders. At the same time it can be an unfamiliar process for organizations to approach communities and obtain PIC. The process of PIC is not the mindset of many organizations, and they do not realize the importance of fulfilling this requirement (Williams, Biowatch, pers. comm., 2011). It was stated by a member of industry that (Nel, Afriplex, pers. comm., 2011):

It is not our business to conduct a study on who the holders of traditional knowledge are, to try and find a chief in a rural area and sit down in the kraal with an interpreter.

This above statement indicates the feeling industry representatives have towards the process of identifying communities and obtaining the required PIC, who feel that this process is beyond the ambit of their business activities. It is also indicative of the uneasiness industry have when placed in this type of situation. Thus industry players feel out of their depth with respect to conducting these activities.

The task of identifying the correct community is made more difficult where a benefit-sharing agreement has been signed. In such cases there is a very real chance that many other parties will want to be beneficiaries to that agreement (Maharaj, CSIR, pers. comm., 2011). This was described by one industry representative as the 'me too' syndrome that arises from individuals who claim to have an interest in the IBR and who therefore believe they should be entitled to benefits (Feiter, Parceval, pers. comm., 2011). This illustrates the complexities of identifying and negotiating benefit-sharing agreements with the correct community. Industry wants to avoid these types of complexities that take up valuable time and money to negotiate.

4.5) The Function of Material Transfer Agreements

Material transfer agreements are an important legal instrument to safeguard the exchange of IBRs between the applicant and a stakeholder. Legally the agreements are concluded between the relevant stakeholders at the beginning of the commercialization phase of a bioprospecting activity. The MTAs promote an important function by establishing legal certainty between the stakeholders. The agreement thus allows the competent authority to determine who has in fact complied with the legislation, and so the MTA thus serves as an instrument whereby the competent authority can identify and monitor stakeholders who have not complied with NEMBA. Whilst there have been MTAs concluded between various stakeholders there seems to be some

confusion surrounding the implementation of these agreements and their intended use within industry.

The MTAs protect parties to the agreement by not allowing information generated within the agreement to be divulged to other parties (Gericke, HGH Pharmaceuticals, pers. comm., 2011). It has been noted by one industry representative that MTAs serve an important protective function by ensuring that the IBRs are only used for the intended purposes and that the exchange of IBRs only occurs between the relevant parties (Gericke, HGH Pharmaceuticals, pers. comm., 2011). The MTA thus provides clear lines of exchange between parties and that development of the IBR is maintained according to the provisions thereof.

The particulars of the provider, and the exporter or recipient, of the IBRs provide a rough representation of the supply chain of IBRs used for bioprospecting within South Africa (Crouch, SANBI, pers. comm., 2011). By attaching these conditions to the MTA the applicant is compelled to reveal his/her interactions and commercial activities between numerous stakeholders. This also allows the competent authority to monitor the stakeholders involved in this network, and pinpoint stakeholders not complying with NEMBA. This is a sensitive aspect of the legislation. One industry representative remarked that it is not the government's business to know the clients of the supplier and as such some stakeholders are reluctant to divulge this information to the competent authority (Gass, Zizamele Herbs, pers. comm., 2011).

The MTAs allow for monitoring of the extraction of these resources from the environment, and ensure it is done on a sustainable basis. This important conservation function ensures that plant populations are not decimated by wild harvesting (Eloff, University of Pretoria, pers. comm., 2011). It therefore provides a mechanism for the relevant authorities to monitor, and manage specific areas where the resource is being extracted (Eloff, University of Pretoria, pers. comm., 2011). The agreements in essence serve to regulate the exchange of IBRs between the applicant and the other stakeholders, and ensure that the material is used in a sustainable manner.

Research institutions perceive MTAs to have a restrictive element as they prohibit a stakeholder from using the IBR beyond the stipulated scope. The use of these resources and MTAs as provided for within NEMBA has been expressed as problematic (van Wyk, University of Johannesburg, pers. comm., 2011):

There is a danger of such mechanisms being misused to benefit the few and exclude others and I think again this goes against the modern idea of freedom of expression and of individuality.

The MTA has been viewed by parts of the scientific community as an instrument that can hinder scientific development. Scientists focus on discovery and exploring the elements of nature, and they feel uncomfortable about restrictions to explore the potential uses of IBRs.

It has also been suggested that the MTA does not necessarily benefit indigenous communities, as an applicant would sooner deal with a farmer than a community because an MTA can be arranged more simply (Crouch, SANBI, pers. comm., 2011). In the vast majority of cases the resource is not sourced from an indigenous community but rather from a cultivator or farmer (Crouch, SANBI, pers. comm., 2011). This attitude expressed towards MTAs has the effect of by-passing indigenous communities in the bioprospecting chain, and the exchange of IBRs is rather facilitated by farmers and more organized entities.

There seems to be a lack of understanding within industry concerning the process of MTAs and how the information divulged in an MTA can be used. Representatives feel that MTAs only add to already exorbitant administration costs (Nel, Afriplex, pers. comm., 2011). Industry often finds itself frustrated, and believes that the agreement only fits in a specific situation where you have an isolated community, and you want to regulate the exchange and use of resources between those two parties (Gass, Zizamele Herbs, pers. comm., 2011). It has been said that the MTA does not fit into a situation where a farmer is already growing an existing list of determined medicinal plants (Gass, Zizamele Herbs, pers. comm., 2011). There is thus a sense of frustration and confusion from industry about the relevance and purpose that an MTA serves unless it fits into a very specific situation. Other members of industry have totally rejected the notion of MTA as adding to already burdensome administration, a waste of time and amounting to further unwarranted costs (Nel, Afriplex, pers. comm., 2011).

Each stakeholder along the bioprospecting chain is expected to comply with NEMBA. This has financial implications for subsequent holders of IBRs as these stakeholders will have to incur the costs already priced into the IBRs that are being sold, and furthermore will have to comply with the legislation themselves. The first stakeholder has to comply with NEMBA, and therefore that stakeholder will have to recover the costs associated with negotiating, and concluding MTAs in the sale of the product or resource. This adds to the price at which the resource will be sold to the

next stakeholder. That new stakeholder, if conducting a bioprospecting activity, will also have to comply with the legislation and so the costs involved with identifying communities and negotiating further agreements will have to be recovered from the sale of the product. The local markets have to absorb these costs which will be recovered in the sale of the resource and therefore local products may be priced out of the market, with negative effects for the development of IBRs within South Africa (Gass, Zizamele Herbs, pers. comm., 2011).

One NGO representative remarked that the MTA does not take cognizance of the technical nature of language to be used for the negotiation of an MTA (Williams, Biowatch, pers. comm., 2011). The parties need to understand the agreement being entered into, and ordinary language must be used. This point was also highlighted by a representative of indigenous and local communities, who emphasized that local communities were unable to fully comprehend the legal intricacies of important documents, and could find themselves lost within the text (Chennells, Chennells Albertyn Attorneys, pers. comm., 2011).

4.6) Negotiating Benefit-Sharing Agreements

Benefit sharing is the utilization of IBRs and TK in exchange for monetary and/or non-monetary benefits. The current legislation provides the format with which this exchange occurs through a text box checklist template. Some of these benefits include technology transfer, workshops and skills development, upfront payments, royalties, and acknowledgments. Key issues that arise when negotiating these agreements relate to the protection afforded to stakeholders by the legislation, the point at which these agreements are to be entered into, raised expectations, and financial input associated with developing the agreement.

Legislation affords protection to stakeholders entering into benefit-sharing agreements, by seeking to ensure that these negotiations are conducted on an equal footing and are fair and equitable. From an industry perspective the question of what is fair and equitable plays a role in the formation of these agreements. There is very little precedence that dictates what is fair and equitable and it largely depends on the context in which these agreements are negotiated (Mulder, MRC, pers. comm., 2011). You may have a situation where company A and company B both approach the same community, and you get two completely different benefit-sharing agreements (Nel, Afriplex, pers. comm., 2011). This raises the question of whether this scenario leads to

benefit-sharing agreements that are fair and equitable to all stakeholders concerned as prescribed by the legislation. The other scenario that arises involves the same company approaching two communities with respect to the same IBR. The formation of two completely different benefitsharing agreements may not be the true intention of the legislators and may not fall within the ambit of what is fair and equitable to all parties concerned.

A benefit-sharing agreement must be entered into at the stage of commercialization as defined within NEMBA, however at this stage there is a very real chance that the product might not reach the market (Maharaj, CSIR, pers. comm., 2011). The realizing of monetary benefits throughout the product development is not realistic and is a difficult task to achieve. Industry is of the opinion that there are no real monetary benefits generated until the product is developed and goes on sale. One industry representative confirmed this opinion (Mulder, MRC, pers. comm., 2011):

It is very unlikely that there will be any tangible benefits during the commercialization phase, it only happens once you have commercialized and the product is on the market.

The benefits to be derived from the resource are often unknown and the dangers of raising expectations without any return are high. The definition of commercialization is so broad, and there are a few key steps in the commercialization chain that still need to be fulfilled. These steps, as defined in NEMBA, are critical to the success or failure of a product reaching the market.

Commercialization as defined in NEMBA occurs at a stage of the product development where it is still unclear or certain whether the product will in fact make it to the market and monetary benefits realized. The IBR may still have to go through further cultivation, clinical trials, product development, and market research. This was the case with HGH Pharmaceuticals and the San Council where the IBR and TK was taken right up to the point of a patent before any benefitsharing agreement was entered into (Chennells, Chennells Albertyn, pers. comm., 2011). A legal representative of the San Council expressed the opinion that HGH pharmaceuticals had in fact done the right thing by being secretive about their work for seven years, taking the development of the plant right up to the point of commercialization. By beginning to consult with different stakeholders at an earlier stage, the idea could have been misappropriated and then the company would have suffered commercially and no one would have benefited (Chennells, Chennells Albertyn Attorneys, pers. comm., 2011). Although criticism was leveled at HGH pharmaceuticals for being secretive in the development of their product, had they been politically correct and talked to other potential stakeholders there might not have been any product that was developed (Chennells, Chennells Albertyn Attorneys, pers. comm., 2011).

Due to the nature of product development some products can take months, years or decades before a product finally reaches the market (Maharaj, CSIR, pers. comm., 2011). Industry appears to place a lot of emphasis on monetary benefits and it has been expressed by an NGO representative involved in these negotiations this is usually the first benefit to be discussed (Chennells, Chennells Albertyn, pers. comm., 2011). Non-monetary benefits can however be undertaken by industry and can provide a sustainable form of benefit exchange. Industry can for example undertake to develop capacity within a community that contributes to improved and sustainable livelihoods (Feiter, Parceval, pers. comm., 2011). One industry representative noted that this type of benefit exchange also resulted in having control over how the benefits develop and help the community (Feiter, Parceval, pers. comm., 2011).

Non-monetary benefits are clearly beneficial to a community or access provider, especially in light of the low likelihood of financial returns. They however can become expensive as it costs money to go to a community and implement a capacity-building program (Feiter, Parceval, pers. comm., 2011). Although industries are willing to exchange non-monetary benefits and in some cases are actively involved in community upliftment projects, this is viewed as the primary responsibility of the state. One industry representative believed such projects should be undertaken by the state through the taxes contributed by industry in developing these products (Feiter, Parceval, pers. comm., 2011). Non-monetary benefits are labour intensive in nature and take time that could be spent elsewhere, like for instance getting the product to the market so that profits can be generated (Feiter, Parceval, pers. comm., 2011).

A further concern for both industry and representatives of indigenous communities is the financial burden associated with negotiating these benefit-sharing agreements. These burdens include lawyers to attend these meetings and actual costs incurred by traveling to the destination where meetings are to be held (Gericke, HGH Pharmaceuticals, pers. comm., 2011). This combined with the time consumed by the negotiations of these agreements, leads to a resource intensive process that perhaps small companies and communities are not equipped for at such an early stage of development. With the relatively small chance of commercialization the resources invested into the negotiations could be in vain as benefits are not guaranteed to materialize at this stage.

The costs associated with bringing a product to the market are increased because of time and energy associated with negotiating these benefit-sharing agreements (Feiter, Parceval, pers. comm., 2011). In the view of industry these input costs result in making South African products uncompetitive both locally and internationally (Gass, Zizamele Herbs, pers. comm., 2011). It was further expressed by one industry member that where the volumes of IBRs are small in terms of bulk export it becomes even more uncompetitive because industry is already dealing with small profit margins (Gass, Zizamele Herbs, pers. comm., 2011). As a result of these extra costs this can place a massive financial burden on industry and the indigenous communities who are involved in negotiating these agreements, which can in turn decrease the chance of the product being successful in both local and international markets.

Benefit-sharing as provided for within NEMBA is an important mechanism to promote the fair and equitable exchange of benefits. The manner it is applied for within NEMBA gives rise to certain complexities. The point at which these benefits are considered is of particular interest given the broad definition of commercialization as described within NEMBA. The raised expectations of communities in anticipation of benefits is a delicate issue that is compounded when the IBR and TK does not reach the market. Together with the financial impetus associated with developing an IBR and TK these issues need to be considered and dealt with effectively by NEMBA and the legislators.

4.7) Benefit Distribution Mechanism

The bioprospecting trust fund has been designated as the benefit distribution mechanism into which all benefits generated from bioprospecting activities must be paid into. These funds are then distributed to the relevant stakeholders. The structure and function of the mechanism empowered to distribute funds has come under scrutiny, and various stakeholders have challenged the purpose of it.

To date the benefit distribution fund in South Africa has made three upfront payments with respect to a benefit-sharing agreement (Malherbe, DEA, pers. comm., 2011). These payments were made to the San community as part of the benefit-sharing agreement established between HGH Pharmaceuticals and the San Council as well as two other communities from Paulshoek and Nou Rivier for the utilization of TK associated with the use of *Sceletium tortuosum* (Gericke,
HGH Pharmaceuticals, pers. comm., 2011). The Bioprospecting Trust Fund acts as an ATM and channels money paid into the fund to the designated stakeholders (Crouch, SANBI, pers. comm., 2011). The fund therefore has control over the distribution of funds and must enforce benefit-sharing agreements accordingly (Malherbe, DEA, pers. comm., 2011). Through this fund the competent authority is able to monitor payment of benefits to relevant stakeholders preventing unscrupulous actors from not paying entitled beneficiaries.

A representative from the competent authority was of the opinion that from a legal and functional point of view the fund will have to be reviewed (Malherbe, DEA, pers. comm., 2011). The manner in which the fund is administered is an important aspect to consider. The name of the bioprospecting trust fund is 'misleading' as it is not administered by a board of trustees empowered by a trust deed, but rather by the Director General (Malherbe, DEA, pers. comm., 2011).

The function of the trust fund has been challenged by industry representatives. Some question the idea of paying money destined to suppliers through the fund. These industry representatives are reluctant to rely on the fund to pay the suppliers of an applicant in connection with a bioprospecting project. As one representative explained (Nel, Afriplex, pers. comm., 2011):

I think people should rather be trusted to deal directly with the beneficiaries than through a fund which is going to add such a massive administration burden and it's just completely impractical. I think it should be reserved strictly for areas where there is an indigenous biological resource being used and they don't know who specifically the beneficiaries should be.

Stakeholders prefer to be responsible to beneficiaries on their own terms and not through the fund. It was also contended by certain industry members that the fund should have discretionary powers to distribute the benefits when the communities are unidentifiable (Mulder, MRC, pers. comm., 2011). At present the fund does not have this discretionary power. If the fund was empowered to distribute the benefits at its own discretion it would be ill-equipped to perform this function because of a lack of structure and representativeness.

4.8) Institutional Arrangements

The DEA is responsible for the assessment of bioprospecting permit applications but this has led to certain challenges. For example, the nature of bioprospecting entails that it crosses different disciplines and for this reason the coordination and integration of national and provincial departments is needed to effectively implement ABS. Expertise associated with assessing bioprospecting applications resulted in the formation of the bioprospecting expert group to deal with the scientific details associated with assessing bioprospecting applications. The DEA in order to successfully implement ABS legislation needs to have the financial and personnel capacity to implement the current legislation.

One representative of the DST noted that in order to maximize South Africa's IBRs and associated TK it is crucial that institutional coordination is implemented (Sechaba, DST, pers. comm., 2011). By involving and integrating the DST into determining the effectiveness of certain IBRs and TK, this would give credibility to products developed from these resources (Gass, Zizamele Herbs, pers. comm., 2011). The utilization of the IBR could also be done under one policy to avoid confusion between the different departments, and a uniform application of policy would result in the maximization of IBR and reduce duplication of work (Sechaba, DST, pers. comm., 2011).

It was suggested by industry that there is a disconnect between the different national departments. As one representative put it (Gass, Zizamele Herbs, pers. comm., 2011):

Our agricultural department says one thing and our biodiversity department (DEA) says another, they are not speaking the same language, it doesn't make sense. The one hand doesn't know what the other hand is doing, and the hands all belong to the same government, it's a bit of a problem.

For example, the control of resources exiting and entering the country represents the point at which the physical exchange of resources between countries occurs. The Department of Trade and Industry (DTI) is responsible for monitoring this exchange and therefore need to provide mechanisms to regulate this. There needs to be dialog between these two departments to ensure that resources used within the ABS realm are effectively monitored through exit and entry points throughout South Africa. The DTI needs to be in communication with the DEA and systems put in place to ensure that the correct IBRs are in fact being exported.

A necessity to integrate national departments is illustrated through interactions between departments. Currently through bilateral meetings of the different Director Generals in particular DST, the Department of Agriculture and the DEA discuss issues that jointly affect these departments (Malherbe, DEA, pers. comm., 2011). These structures have been developed to organize their activities more effectively. The national departments have been brought together and have expressed a need for a collaborating structure (Malherbe, DEA, pers. comm., 2011). The establishment of a bioprospecting colloquium has been proposed whereby all the departments are brought together to discuss these issues of cooperation and collaboration. This would provide an opportunity for the different department to discuss issues and the way forward with respect to regulating bioprospecting. So at present these structures have been set up to organize and better align the departments' activities (Malherbe, DEA, pers. comm., 2011). These processes and meetings attempt to coordinate the different disciplines and develop a holistic strategy towards ABS regulation.

The complexities associated with assessing bioprospecting permit applications led to the formation of the bioprospecting expert group. This group comprises different experts that give input as to whether or not the permit should be granted. The group was not established in terms of an Act of Parliament but was a reaction to the complexities that arose through the implementation of the ABS legislation. This group comprises representatives from all nine provincial departments, the DST, Department of Agriculture, Department of Health, DTI, as well as the South African National Parks and SANBI as advisors to the Minister (Malherbe, DEA, pers. comm., 2011). This diverse group of representatives contributes expert opinions from their various disciplinary fields that contribute to assessing bioprospecting applications, and the manner in which these activities are to be conducted. These diverse views thus contribute to the ability of the competent authority to make an informed decision regarding the proposed activity. This expert group performs an advisory function to the DEA so that an informed decision can be made (Hendriks, SANParks, pers. comm., 2011).

The DEA has expressed concerns about its capacity to implement NEMBA. Due to the scope of the current legislation state capacity is not sufficient to effectively implement ABS legislation (Malherbe, DEA, pers. comm., 2011). This has repercussions for the processing of applications. Industry representatives remarked that (Nel, Afriplex, pers. comm., 2011):

Some applicants who have handed in their applications in 2008 have not been granted bioprospecting permits and it is difficult to operate within this vacuum as industry.

This unreasonable delay could be attributed to capacity issues as well as to the difficulty associated with complying with ABS legislation. The DEA has four employees dedicated to implementing ABS legislation and this complement of staff are expected to implement NEMBA throughout South Africa (Malherbe, DEA, pers. comm., 2011). The problem is compounded when a staff member at the DEA leaves his or her post and a replacement has to be found. Due to the complex nature of the legislation the replacement staff have to be informed and training provided to ensure that they are proficient in the legislation (Malherbe, DEA, pers. comm., 2011). This again consumes more time and resources which affects the implementation of ABS legislation.

Limited resources also affect the provinces' ability to effectively monitor permits and other illegal bioprospecting activities. With such a broad reaching definition of bioprospecting the enormity of regulating all those affected is daunting. For instance, in the province of KwaZulu-Natal there is one district conservation office covering 200 square kilometers (McKean, KZN Wildlife, pers. comm., 2011). This is not an ideal situation to combat the illegal use of plant and animal species used in bioprospecting activities, and only through re-enforced capacity building will effective processing and monitoring of activities occur.

In addition, there is a considerable amount of financial resources required to effectively implement ABS legislation within South Africa (Malherbe, DEA, pers. comm., 2011). The scope of bioprospecting compels various applicants to follow NEMBA procedures, and the capacity to assist these applicants must be able to support this demand. There needs to be further capacity development within these governing structures so that the provisions can be adequately implemented and made easier for stakeholders to comply with (Bailey, University of Cape Town, pers. comm., 2011). However, the process of developing capacity is resource intensive.

The legislation according to most stakeholders is extremely onerous in its application and results in a high level of non-compliance (Malherbe, DEA, pers. comm., 2011). The DEA does not have the capacity to implement and monitor bioprospecting activities. Non-compliance is a major issue and this needs to be addressed through awareness workshops and other informative deliberations between the governing structure and industry to ensure compliance.

4.9) Conclusion

The ABS legislation is an important instrument because it secures the rights of indigenous communities by recognizing TK and the utilization of IBRs. It also attempts to establish equitable partnerships between relevant stakeholders to address inequalities that may be present between the different stakeholders. The legislation provides effectively for requiring that the sustainable harvesting of a resource is achieved. Through MTAs the exchange of benefits and the amount of the resource to be exchanged is monitored. Through DEA interactions with the provincial departments and provincial ordinances regulating the collection of resources, this provides for the safeguarding of resources.

However, the legislation is vague in providing for the fundamental task of identifying indigenous and local communities, this hinders the development of an environment conducive to establishing equitable partnerships. This affects how stakeholders are able to obtain PIC, establish MTAs and develop benefit-sharing agreements. Without providing effectively for the task of identifying communities or catering for the situation where the community is unidentifiable, industry are unable to advance with respect to developing IBRs and TK, and therefore the industry has become stagnate. The result is little or no benefits being generated through the implementation of NEMBA which can be seen by the limited benefits which have been distributed by the bioprospecting trust fund to date.

The governing structure is not financially equipped as well as in terms of personnel to ensure the effective implementation of NEMBA. At present given the scope of NEMBA, the DEA is unable to effectively implement and monitor the implementation of NEMBA. The links between national departments and the role each department must play to ensure the effective implementation of the legislation is not provided for within NEMBA. Many challenges present themselves through the implementation of NEMBA, through discussing these challenges a greater understanding can be ascertained and solutions implemented.

Chapter 5 Discussion

5.1) Scope of Bioprospecting and its Definition

The CBD links three definitions of biological resources, genetic resources and genetic material, however it does not provide an objective means of determining the difference between genetic resources and biological resources (Bhatti and Young, 2009). Access and benefit-sharing policies and laws that are precise in their definition of scope, facilitate the successful implementation of ABS policies (Carrizosa, 2004). The legal status of genetic resources should distinguish between rights over the physical entity and the genetic information embodied in the physical entity (Glowka, 1998).

In countries like the Philippines and Columbia the broad scope of bioprospecting has caused some difficulties (Carrizosa, 2004). These experiences have shown that regulating the utilization of IBRs and genetic resources identically are problematic for certain sectors of the economy, particularly the agricultural sector (Medaglia and Silva, 2007). In South Africa the utilization of these resources has been regulated identically and this creates difficulties for farmers, bulk traders of IBRs and other stakeholders that deal with IBRs. This illustrates the importance of precise definitions and the utilization of these resources in the same manner has detrimental effects for stakeholders not concerned with the utilization of genetic resources and the search for new products. This aspect of the South African legislation needs careful consideration to ensure that the correct stakeholders comply with the legislation and that it achieves its objectives.

The utilization of IBRs and genetic resources has been swept into one concept in NEMBA and it is important for South Africa to recognize the distinction between the different utilizations. Some countries have made the distinction between genetic resources, which are owned by the state, and biological resources, which are owned by private parties (Medaglia and Silva, 2007). In the Andean Pact, for example, biological resources are subject to private or collective rights and genetic resources are considered inalienable and cannot be appropriated (Barber, *et al*, 2002). Such differentiation is critical as it forms the basis for creating distinct ABS regimes for different categories of genetic resources, like for instance those used for agriculture and food versus other purposes (Barber, *et al*, 2002). South Africa's policies do not take into consideration the manner

in which the two resources are to be utilized, rather they exercise control over these resources identically with respect to the physical aspect of the resource. However, the intangible genetic information should be regulated in a different manner to accommodate these distinct differences.

5.2) Access to Indigenous Biological Resources and Traditional Knowledge

A state can develop access procedures to genetic resources and TK in various ways. A clear and systematic process needs to be established to review and act upon applications for access (Barber, *et al*, 2002). Where access permits have to be obtained from regional and local agencies which administer the same resource, as well as negotiate with the provider of TK and genetic resources, this may become a long, confusing and cumbersome process (Carrizosa, 2004). This can lead to long processes and high transaction costs for obtaining permits, which deters applicants from using resources from a particular country.

South Africa has empowered private persons, organs of states as well as indigenous communities by designating any one of these entities as access providers of the resource. The applicant must then approach the competent authority for the permit to be granted and once the permit has been granted the applicant must approach the provincial department to obtain a collecting permit. This is long and cumbersome for many stakeholders trying to gain access to valuable resources. Since 2008, the competent authority has only granted one bioprospecting permit and three integrated export permits for bioprospecting activities. This is indicative of access procedures that are not functioning appropriately, as it does not create an environment conducive for gaining access to IBRs and TK and converting these into tangible benefits.

Access procedures require the applicant to obtain PIC, and enter MTAs and benefit-sharing agreements. Implementing these important concepts to legitimize access to IBRs and TK not only takes lengthy communications, but can amount to costly transactions as is the case in the Philippines (Carrizosa, 2004). All these processes, although they have good intention, need to be efficiently implemented to ensure that the TK and IBRs are developed without burdensome legislation. This requires administrative procedures that do not restrict the development of IBRs and TK.

5.3) PIC and Challenges Linking Indigenous Communities with TK

The concept of PIC is important as it provides an indigenous community with an important right and empowers communities to grant access to their valuable resources, thus preventing unscrupulous actors from misappropriating their resources. The manner in which it is implemented however needs to take cognizance of certain complexities surrounding its attainment so that ABS can be effectively implemented.

In Brazil, there is a requirement that PIC is obtained from each of the concerned indigenous groups, and this has caused delays and confusion in the process, as resources and knowledge are often shared across communities and regions (Hirakuri and Tobin, 2005). The distribution of TK across many different communities means that the identification of a community can become arbitrary (Rosenthal, 2006). South African ABS legislation is vague in the implementation of this task, and this has contributed to delaying bioprospecting projects. The attainment of PIC was highlighted by the competent authority as the most critical aspect and major stumbling block for applicants trying to gain access to resources (Malherbe, DEA, pers. comm., 2011). The legislation does not effectively provide for this concept, and expresses a vague concept that can be interpreted differently by each stakeholder.

In Thailand the time it takes to complete the PIC process is significantly reduced by requiring applicants to acquire PIC only from the government (Carrizosa, 2004). This has the effect of reducing administrative costs and time taken to pursue a bioprospecting project. Costs and the time taken to obtain PIC was seen by industry as prohibiting the development of TK and IBRs in South Africa. Companies are likely to seek countries that were more efficient, thereby reducing costs involved with such activities.

Where PIC is to be obtained that consent must be specified in ABS legislation or in the regulations, as is the case in the Philippines (Barber, *et al* 2002). Industry has explained that given the complexity of the task of identifying indigenous and local communities and linking TK with these communities, the onus should rest with the state to determine the identification of a community (Feiter, Parceval, pers. comm., 2011). In South Africa, this might reduce the length of time associated with this task and reduce the costs involved, which can be substantial for stakeholders. It would also foster an environment that facilitates the exploration of TK and IBRs that could potentially lead to development that would be beneficial to the people of South Africa.

This point does not come without contention as the state may not be able to undertake this task, and could be hindered by a lack of resources available and/or technical expertise to effectively implement this idea, or the state not being completely legitimate in facilitating this environment.

The state also does not provide clear guidelines on how to practically obtain this consent, which could lead to the lengthy delays experienced by industry. It has been found that a key barrier to accessing genetic resources may not lie in the lack of PIC procedure, but rather in an overly bureaucratic and complex process involved with implementing ABS legislation (Hirakuri and Tobin, 2005). In South Africa's case, the lack of clarity surrounding the attainment of PIC could lead to an increase in the time taken to implement this provision.

It has been suggested that self-autonomy and letting groups decide for themselves who they are as a group is an appropriate method to be adopted. The idea of self-autonomy would give indigenous and local communities the power to decide for themselves who they were as a group. This however does come with its own problems, as the group that is to receive the benefits might for example leave women out of the decision making process, and thus the researcher must decide to either inject his/her notion of fairness into the deliberations (Schuklenk and Kleinsmidt, 2006).

When dealing with access and PIC related issues, the process can be foreign and invasive for some traditional, local or indigenous communities, as a result, culturally sensitive approaches and respect of local traditions must be observed (Robinson, 2010). In the Philippines, PIC is obtained in accordance with the customary laws of the community concerned to avoid a clash of cultures (Barber, *et al*, 2002). In South Africa, the legislation fails to acknowledge cultural sensitivities around gaining this consent. It is important during consultations that the information transferred is packaged into a form that can be interpreted by the community receiving the information (Laird and Noejovich 2002). The lack of acknowledgment of language differences expresses a lack of understanding regarding communication between two culturally different groups. This approach would go a long way to addressing the sensitive issue that might be associated with certain TK and IBRs within South Africa.

Whilst South Africa has implemented the concept of PIC, and recognized the importance of TK and IBRs contributed by indigenous and local communities, the manner in which it is implemented within South Africa complicates the process of gaining access to IBRs and TK. Benefits may not necessarily flow back to the wider community as envisaged within NEMBA.

The legislation needs to be structured and provide effective guidelines to promote the efficient implementation of ABS.

5.4) The Function of Material Transfer Agreements

The functions of MTAs are important because they provide legal certainty for the exchange of IBRs between stakeholders within South Africa, and serve as a very important platform to solidify the respective rights. They are important because they lay down details on benefit sharing, access, IPRs and the law regulating the agreement (Gebreselassie, 2009).

Material transfer agreements provide a standardized system that protects providers of genetic resources who may not have adequate representation that could prevent exploitation (Chambers, 2003). The MTAs within South Africa fulfil this function and further safeguard prospecting companies from other parties divulging information and resources to third parties.

The MTAs within South Africa provide a platform from which the exchange of IBRs can take place. It sets out the terms and conditions of exchange, which is very important in any commercial transaction. It allows the competent authority to effectively monitor what type of benefits are being exchanged, with whom are they being exchanged, and for what purposes they are being exchanged. This certainty is especially crucial for foreign investors who run the risk of losing money should stakeholders move outside of an agreement, and pursue their own interests with respect to the same IBR.

The MTAs also serve an important conservation function; the competent authority is able to monitor how much of the resource is in fact being harvested. Given the importance of biodiversity, this looks to ensure that the resource is harvested on a sustainable basis, which is an objective of NEMBA and the CBD.

The greatest advantage of developing MTAs may lie in the negotiations with local partners and the process that enables and empowers communities to take part in these negotiations. Communities through direct dealings with international collaborators have the potential to increase intellectual resources and the local valuation of IBRs, through the development of a product (Rosenthal, 1997). This process leads to increased awareness within communities, and these communities need to understand the processes that guide the development of their IBRs and

TK. The San Council provides an excellent example of a community that have grown their capacities through negotiations and increased the value of their resources. The MTAs developed between communities and industry provides valuable opportunity to develop and exchange IBRs that ultimately results in economic stimulus and establishes equitable partnerships. Further opportunities have been born out of the experience with *Hoodia* and development of *Sceletium* that could result in further benefits being generated from the Sans' TK and IBRs.

The competent authority has only approved four MTAs and this may indicate the difficulties surrounding the implementation of ABS provisions. Although MTAs have many benefits they are not being practiced by industry, and therefore the intended benefits of MTAs do not materialize. The Act and its provisions are therefore merely a 'white elephant' that is in some respects not achieving the desired objectives.

The administration associated with MTAs and the costs involved are a deterrent for industry, which gives rise to an unwillingness to enter into these agreements by industry. The avenues of access to IBRs and TK may entail that a different approach be adopted depending on the entity granting access to the resource, and in South Africa this results in industry moving away from entities or organizations where the negotiating of these agreements can be complicated. They nevertheless provide an important function by providing an important sustainable utilization mechanism and legal foundation to ensure the fair and equitable exchange of the IBR is achieved.

5.5) Negotiating Benefit-Sharing Agreements

South Africa has provided an excellent platform from which to negotiate benefits. The legislation provides for both monetary and non-monetary benefits to be exchanged between stakeholders. This ultimately results in capacity development of stakeholders. The exchange of benefits is formalized in an agreement and the benefits are usually distributed within the structure of a trust fund. Within South Africa these agreements are to be entered into at the commercialization phase of a bioprospecting project.

Some countries have adopted a baseline for the sharing of benefits. The Costa Rican biodiversity law mandates bioprospectors to pay 50% royalties, as well as 10% of the research budget either to the national system of protected areas, the landholder that provided the genetic resource or the

indigenous representative (Carrizosa, 2004). This is in stark contrast to South Africa where a general template for the exchange of benefits is to be fulfilled and a more flexible approach to benefit sharing exists. This is to secure a fair and equitable exchange of benefits between the stakeholders. South Africa's approach can thus be seen to be more flexible in the type of benefits to be exchanged compared to that of the mandatory approach adopted by Costa Rica which is more rigid and focuses on monetary benefits.

The timing of entering into benefit-sharing agreements is important to consider because of the time that can elapse before a product is developed from TK or an IBR. There is still a long way to go in terms of product development before actual benefits are realized, and there is still a good chance that the potential product will not realize any benefits (Wynberg, 2004). This was emphasized by certain sectors of industry that are reluctant to enter benefit-sharing agreements before actual commercialization begins and profits are realized from the TK or IBR. The definition of commercialization within NEMBA provides that a benefit-sharing agreement be entered before key steps in the development of the product are concluded. This includes conducting clinical trials, the cultivation of IBRs, propagation, cloning of IBRs to develop or produce products, filing of intellectual property rights and market research.

The fair and equitable distribution of benefits arising out of the utilization of IBRs and TK is a broad definition set out within the CBD and national legislation. What is fair and equitable is subjective and varies depending on the value system in which the stakeholders operate (Vermeylen, 2007). Therefore what is just for one community might not be just for another, and a situation can arise where a stakeholder can have different benefit-sharing agreements with respect to the development of the same resource. The concept of what is fair and equitable can therefore be difficult to determine because of the differentiation and contrast between value systems and expertise of the different stakeholders and communities. The competent authority in South Africa must assess the benefit-sharing agreement and may if necessary enter deliberations to ensure that a fair and equitable agreement is reached. This is an important function of the competent authority and provides a level of protection for stakeholders that may not be able to adequately facilitate negotiations.

The fairness of benefit-sharing agreements depends largely on the expertise of the negotiating stakeholders concerned (Carrizosa, 2004). This crucial aspect is covered within NEMBA. Protection is afforded to groups through the assessment of benefit-sharing agreements by the competent authority by ensuring that negotiations are conducted on an equal footing. The

competent authority will not grant a bioprospecting permit where the benefit-sharing agreement is not fair and equitable.

In the case of the succulent plant *Hoodia* the CSIR argued that the expectations of the San would be raised and the promises might not ever materialize (Wynberg, 2004). However, given the real possibility that the development of IBR might not result in any benefits being generated from the sale of a product, it would be in South Africa's best interest to guard against raising expectations because the possibility of the product not reaching the market is very real.

Developing benefit-sharing agreements with respect to bioprospecting permits is a delicate and complex task. Industry finds they have to commit financially where the benefits that they are attempting to generate have not materialized yet. The legislation provides a comprehensive list of monetary and non-monetary benefits that are to be decided on between the parties. This allows negotiations between the parties to reach a variety of agreements.

5.6) Benefit-Sharing Mechanisms

Some countries have adopted a trust fund as the mechanism to distribute benefits generated from the utilization of IBRs and TK (Carrizosa, 2004). The nature of a trust fund provides a model of keeping and distributing funds that suits the indeterminable period associated with the development of a project (Laird, *et al*, 2002). South Africa has adopted a trust fund as its preferred mechanism of distributing benefits.

For the successful implementation of the fund it is important that the composition of the board represents a diverse range of stakeholders, however this is not a mainstay of a successful distribution method as a diverse board may result in other issues (Guerin-McManus, *et al*, 2002). One of the reasons South Africa has failed to implement the necessary structure of a trust fund is because of financial constraints as confirmed by the competent authority (Malherbe, DEA, pers. comm., 2011). This has led to further questions over the effectiveness of the fund and the purpose for which it was created. A board of trustees has not been set up because of the lack of financial resources.

There is little information regarding the experiences of implementing funds and their effectiveness (Carrizosa, 2004). In South Africa the fund has only made three upfront payments

with respect to a benefit-sharing agreement and some have questioned the effectiveness of the fund and whether it is achieving the purpose for which it was created. This lack of benefit generation and distribution through the fund indicates that the ABS laws governing the utilization of IBRs and TK have not had the desired effect. The legislation was ratified in 2008 and there are only a handful of payments as evidence of South Africa's ability to develop IBRs and TK and generate benefits.

5.7) Institutional Arrangements

The institutional arrangements are central to how ABS legislation is implemented. The multidisciplinary nature of bioprospecting requires a suitable arrangement to accommodate this aspect. This entails a certain amount of financial impetus to enforce this legislation and to develop capacity at a national and provincial level to effectively implement ABS within South Africa.

It is crucial that procedures clearly identify the competent authority so that those who wish to seek access know to whom they must apply (Barber, *et al*, 2002). Coordination of legislation and policies need to be adopted and integrated to ensure that the regulation of bioprospecting is adequately provided for. South African legislation does not provide for this aspect, and it has resulted in expert groups being formulated to accommodate this element of ABS. In promulgating ABS, it is important that an integrated approach that does not isolate existing institutions is developed (Barber, *et al*, 2002). South Africa's approach makes the DEA the central department responsible for bioprospecting where in fact it requires expertise from other departments like DST, DTI and the Department of Agriculture to be effective.

Capacity related issues could give rise to what has been described as responsive regulation (Braithwaite, 2006). It is suggested that this poses a solution to the limitations expressed about capacity related issues experienced by developing countries (Braithwaite, 2006). It utilizes governmental and NGOs to coordinate social pressures to get a desired result (Braithwaite, 2006). In South Africa organizations like for instance Natural Justice, African Center for Biosafety (ACB) and Biowatch apply pressure on organizations that appear to be in breach of legislation. In the case of Schwabe and *Pelargonium sidoides*, a plant used for flu and chest ailments, the patent was successfully opposed by ACB and other commercial parties. This is an example of how

NGOs, other commercial interests and social pressure can affect the outcome of certain processes where the institutional capacities are unable to perform effectively.

Suitable financial resources and personnel must be provided for the successful implementation of ABS legislation (Barber, *et al*, 2002). In South Africa, there is a lack of funding to implement ABS legislation effectively and in accordance with its provisions. This brings into question the seriousness with which South Africa views the commitments adopted by ratifying the CBD.

Enforcement and monitoring of ABS legislation is very difficult to implement because of the nature of genetic resources and how they are used by certain organizations (Carrizosa, 2004). In South Africa, monitoring these activities is extremely difficult given the financial and capacity resources allocated for this task. Some provinces are also of the view that financial resources should be allocated to other areas of more importance.

5.8) The Effective Implementation of ABS Legislation

The effective implementation of NEMBA is dependent on whether the legislation is able to secure indigenous and local communities rights, promote sustainability of resources utilized by industry, the ease with which industry is able to comply with NEMBA, establish a governing structure that operates in an efficient and coherent manner, and the ability of the legislation to generate benefits. The above-mentioned criteria have been separated into effective and non-effective aspects of the legislation, and illustrate the characteristics that promote and hinder the effective implementation of NEMBA (See Table 4 below).

The legislation is a mechanism that facilitates an environment that recognizes TK and the utilization of IBRs. It creates a platform within which relevant stakeholders must create fair and equitable partnerships that facilitates the utilization of IBRs and TK. The legislation is important because it promotes the rights of indigenous and local communities, and it provides an opportunity to establish partnerships and develop relationships in an equitable manner. Through identifying the correct community and developing MTAs and benefit-sharing agreements, the legislation has provided a platform that should promote the development of equitable partnerships, and secure the rights of indigenous and local communities.

The sustainable utilization of IBRs is a core objective of NEMBA, and is provided for by the structures that govern the utilization of these resources. Provincial departments ensure that the resource is harvested on a sustainable basis by granting collecting permits relevant to the resource being collected. This ensures that the degradation of South Africa's biodiversity does not occur, and that future generations will also be able to appreciate and utilize the diversity of today. The MTAs control the exchange of IBRs between relevant stakeholders, this provides the competent authority with an opportunity to analyze the exchange of IBRs, and effectively monitor this exchange.

The intention of the legislation is good; however, its execution does not facilitate an environment as envisioned by the CBD and NEMBA. The legislation is not structured in a way that promotes compliance; the manner in which it has attempted to deal with specific tasks has not been effective. Clarity of definitions and procedures would result in more bioprospecting permits granted. The legislation does not effectively guide the applicants in an efficient manner, and this results in delays in granting bioprospecting permits. With just four bioprospecting permits granted out of a total of 43 applications received, this indicates the difficulty experienced by industry in trying to comply with the legislation. The legislation does not provide clear and direct mechanisms to identify indigenous and local communities, and it does not provide for the situation where the indigenous and local community is unidentifiable. This contributes to the difficulties experienced by industry in trying to comply with the legislation, and ultimately results in non-compliance from industry.

Without the financial support of the treasury the effective implementation of the legislation will not occur. Given the enormity of implementing NEMBA at present the DEA does not have the capabilities to ensure effective implementation. Without the financial resources, the DEA is unable to train and recruit the skills necessary to implement the legislation, and so the DEA is unable to develop the capacity needed to effectively implement NEMBA. The governing structures are handicapped because they do not have the financial muscle to implement NEMBA.

The legislation is one-dimensional in that it does not integrate important national departments. The legislation if arranged coherently has the potential to benefit South Africa. The involvement of the DTI for instance would provide insight into how the export of IBRs could/should be regulated at South African borders. This is a crucial component because this is where the resource leaves the country, and through effective organization and collaboration with the DTI the monitoring of legal and illegal exports could be achieved. National coordination is not provided

for within the legislation, given the multi-disciplinary nature of bioprospecting it should not be confined to one department. A more collaborative approach could refine the implementation process and promote a more effective approach to developing IBRs and TK.

The governing structure in place requires national and provincial departments to have clear lines of communication to ensure permits are granted efficiently. The two tier approach at present can result in misunderstandings occurring between national and provincial departments, and the legislation should look to reduce interactions between stakeholders and governance structures. This would minimize the potential risk posed by having to apply for two permits.

The generation and exchange of benefits between the relevant stakeholders can result in the empowerment of marginalized communities. This is important because it promotes the third objective of the CBD, which is the fair and equitable distribution of benefits. The legislation at present has not seen significant generation of benefits. The bioprospecting trust fund has had minimal payments to make as confirmed by the competent authority (Malherbe, DEA, pers. comm., 2011). The legislation is ineffective in generating benefits to be distributed to relevant stakeholders.

Table 4. Assessing the Effectiveness of Implementing Chapter 6 of NEMBA

Effective Characteristics of NEMBA Implementation

Secure indigenous and local community rights (Equity)

- Effective in that it secures valuable recognition of the holders of TK and IBRs.
- Provides for the valuable exchange of benefits that helps to empower indigenous and local communities and create equitable partnerships.
- Creates and exchanges skills between parties which supports and affirms the independence of indigenous and local communities.

Environmental sustainability

- The harvesting of resources is managed through the implementation of NEMBA.
- The provincial departments assess the sustainability of harvesting the resources.

Ineffective Characteristics of NEMBA Implementation

Ease of compliance

- Lack of clear effective procedures to identify correct communities, which is central to the idea of the fair and equitable exchange of benefits.
 - Lack of compliance from industry because of unclear, cumbersome and arduous legislation.
- Lack of guidance with respect to language used by bioprospectors results in associated knowledge and procedures being inaccessible to indigenous and local communities.
- Industry not complying with ABS provisions.
- Lack of clear effective guidance from the definitions provided within NEMBA i.e. bioprospecting, IBRs, genetic resources, commercialization, indigenous community.

Coherent and efficient governing structures

- Lack of coordination between national departments to effectively implement legislation.
- Disconnection between National and Provincial departments hinders the effective implementation of ABS in South Africa.
- Unreasonable time taken to assess and approve permits.
- Lack of financial and capacity resources results in the ineffective implementation of legislation.
- Unable to effectively monitor the current situation.

Ability to generate and distribute benefits

- Product development can take up to 10 to 15 years to begin generating benefits. However, only three upfront payments have been made by the bioprospecting trust fund.
- Low number of transactions made to beneficiaries suggests ineffective implementation of ABS provisions.
- Given the biodiversity present within South Africa the bioprospecting trust fund should be distributing more benefits and therefore legislation has been ineffective in generating benefits.

Chapter 6 Conclusion and Recommendations

The ABS legislation provides an excellent platform that recognizes TK as well as the rights of indigenous and local communities. This platform enables communities and industry to interact and develop equitable partnerships. The legislation however does not achieve this desired result through its implementation. This can be attributed to unclear definitions, unclear access procedures and a governing structure that is not equipped to implement NEMBA.

Where the TK of communities is exchanged, equitable partnerships can be formed between the relevant stakeholders. These agreements are intended to be mutually beneficial, and through effective legislation that promotes these relationships all parties concerned can benefit. The legislation thus begins to create a platform where stakeholders can engage and begin to fairly and equitably exchange ideas, skills and knowledge.

The exchange of IBRs is safeguarded to some extent by the utilization of MTAs, and these agreements perform an important function by legally securing the utilization and exchange of these resources, and requiring the activity to be conducted on a sustainable basis. The sustainability of the activity attempts to fulfil the second objective of the CBD, which focuses on sustainable use. The provincial department aims to achieve sustainable use by overseeing and regulating collecting permits for IBRs. The MTAs also play a pivotal role in detailing what type of resources can be collected, and the amount to be harvested. This allows the competent authority to monitor the harvesting of IBRs, and to help ensure that it is done on a sustainable basis.

For ABS to be more effective in its implementation greater emphasis must be given to the definitions that guide a potential bioprospector. There is a lack of clarity over the definition of bioprospecting and the implications this definition has for the stakeholders concerned. This applies in particular to those involved in trading raw material – the so-called biotraders. The situation where biotraders are unsure of whether the legislation applies to them indicates that the legislation is not specific enough in this regard, requiring amendment to the accurately define what is bioprospecting and who must apply. This would provide certainty to those individuals and organizations that find themselves uncertain about whether to comply with ABS legislation or not especially in the case of biotraders. Consideration should be given to amending NEMBA to reduce the scope of IBRs, and excluding biotrade from its purview.

Amnesty from the provisions of ABS legislation could also provide relief to certain individuals, including sangomas (traditional healers) and cultivators of IBRs, where the competent authority is of the opinion that in specific situations ABS legislation should not apply. The competent authority, on receiving an application, could then determine where reasonable to grant amnesty to those individuals or organizations to whom the legislation is not specifically directed at.

The ABS regime creates burdensome and unclear procedures for stakeholders particularly when trying to obtain PIC. Greater focus and attention must be given to the manner in which PIC is obtained. Highlighting a specific method or framework within ABS legislation would provide greater clarity to applicants and remove frustrations felt towards the difficulties of attaining PIC. A prescribed method would result in greater compliance with legislation. It would reduce time wasted on the interpretation of legislation of what constitutes PIC and avoid unnecessary costs for non-compliance. It could also potentially promote foreign interest by providing legal certainty and clarity with respect to the demands of this important aspect of ABS legislation, and promote the ease with which industry can comply with the legislation.

The ABS regime provides access procedures that have to deal with various challenges associated with PIC, MTAs and benefit-sharing agreements. The onus of identifying the correct community should perhaps not lie with the applicant, because the complexities associated with this task are beyond the scope and mandate of industry and researchers. Given the complexities surrounding this process, due acknowledgment of the situation where indigenous and local communities are unidentifiable is needed. The Department should develop procedures to allow for industry to continue with their activities while the holder of the TK is being identified, including a likely reconceptualization of the Bioprospecting Trust Fund. Where the holder of the TK cannot be identified, the revised Trust Fund could provide a road map as to how these funds are to be distributed. Checks and balances would clearly need to be put in place to avoid misappropriation by unscrupulous actors. This would help industry continue with the development of TK and IBRs where the community is unidentifiable, resulting in the generation of benefits for the wider South African public.

The ability of government to effectively implement ABS legislation is determined by the resources dedicated to this task and there is a need for greater human and financial capacity.. Low capacity could affect the safeguarding of TK and IBRs within South Africa, which could result in

further cases of exploitation. Through a greater commitment South Africa could gain greater good from its resources, and develop necessary skills that could empower impoverished communities. The attainment of the necessary expertise would also result in the effective implementation of the legislation.

There is a lack of coherency between the governing structures and their rules and modes of operation. The multi-disciplinary nature of bioprospecting needs to be taken into account when setting up such structures. Through the bioprospecting expert group an acknowledgment of these complexities allows for further insights from various sectors and role players. Further and strengthened collaboration between national structures could achieve the management of this complex industry.

The provincial departments provide an important conservation function by ensuring that targeted species are not decimated by over-harvesting. This however, should be synchronised more effectively with the DEA during the initial bioprospecting application phase to avoid further delays for the applicant once the bioprospecting permit has been granted. The DEA through the bioprospecting expert group elicits the expertise of provincial departments and therefore the sustainability of harvesting could be deliberated at that point, and communicated between the DEA and provincial departments to avoid further administration and delays at provincial level. At present the process is structured as a two-tier approach with the DEA being the focal point and the provincial departments need to be sufficiently resourced and clear lines of communication need to exist between national and provincial departments.

The ABS regime within South Africa is a first step towards securing the rights of indigenous and local communities, however there is still a need to refine the legislation for effective and more efficient implementation. The access procedures that guide industry fail to take into account the complexities involved in the process of obtaining PIC, MTAs and benefit-sharing agreements. Providing clear mechanisms that facilitate PIC and identifying communities to enter benefit-sharing agreements would enable the development of much-needed partnerships. Providing a mechanism to deal with the situation where communities cannot be identified will also allow for continued growth and development of resources that could potential lead to economic development and contribute positively to livelihoods. Empowering the governing structure, through financial and capacity related commitments, would contribute to the ability of the DEA to successfully implement the legislation. This, together with enhanced collaboration with other

national departments and the further development and amendment of legislation through the involvement of all affected departments would enhance the effectiveness of ABS legislation within South Africa.

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Appendices

University of Cape

Appendix A: Interview Questions for Industry

1. Please could you state the capacity and name of the organisation in which you work?

2. In your capacity at the organisation that you work for are you mandated to engage in bioprospecting activities?

3. How do you interpret the definition of bioprospecting in the Biodiversity Act? Do you understand this definition to be clear in its interpretation?

4. What constitutes an indigenous community and how is it identified or established according to the Biodiversity Act and regulations? Do you understand this definition to be clear in its interpretation?

5. What are the practical implications of linking particular traditional knowledge with a specific indigenous community?

6. Have you had to obtain PIC under any circumstances and if yes what were the practical steps in obtaining this consent?

7. How did you deal with a situation where communities in possession of traditional knowledge/biological resources are found across national or provincial boundaries?

8. Should the community of South Africa as a whole benefit from the development of South Africa's biological resources?

9. Is the notion of granting access to biological resources through either private person, organs of state or indigenous communities practical in ensuring that benefits flow back to the wider community of South Africa?

10. Should there be a distinction between access to genetic resources and access to biological resources? Please explain your answer.

11. What difference has the introduction of the notification procedure made to the way you implement the Biodiversity Act during the discovery phase of a bioprospecting activity?

12. Have you entered any benefit-sharing agreements with private persons, indigenous communities or organs of state, and what have been your experiences with regards to developing these benefit-sharing agreements?

13. What function do Material Transfer Agreements serve? Are they a useful tool? Elaborate please?

14. Why is there a need to distinguish between academic research and research for bioprospecting activities with respect to the recent amendments to the Biodiversity Act?

15. What is the difference between biotrading and the commercialisation of biological resources; and should they be regulated separately?

16. What mechanisms are in place to ensure that where an export permit for bioprospecting activities has been granted that the regulations of the exporting country are upheld in that user country?

17. How does the Nagoya protocol regulate the providers and users of biological resources when exporting those biological resources?

18. In respect to the issuing authorities of bioprospecting permits and the separation of powers between national and provincial spheres of government, is there a need to separate these national and provincial issuing authorities?

19. What purpose does the trust fund achieve?

20. How does the patents amendment Act address or protect the misappropriation of traditional knowledge and/or biological resources in South Africa?

21. Are there any other issues with respect to the practical implementation of access and benefit-sharing legislation that you would like to raise?

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Appendix B: Interview Questions for NGO Representatives

1. Please could you state your capacity and the name of the organisation in which you work?

2. What are you mandated to do in this capacity?

3. What are the practical difficulties in identifying or establishing these communities with respect to the Biodiversity Act?

4. What are the practical difficulties in linking these indigenous communities with the use of specific TK?

5. Looking at the concept of PIC, have you had to obtain this PIC before and if you have what were the practical issues and challenges experienced in obtaining this PIC.

6. Do you think the Act takes into consideration the difficulties associated with gaining this PIC?

7. Looking at ownership and access to biological resources should there be a distinction between granting access to these two resources, or should they be regulated under one heading?

8. What have been your experiences and challenges with regards to developing benefitsharing agreements?

9. How does the Act take into consideration, or should it take into consideration the different negotiation capacities between stakeholders?

10. What function do these MTAs serve and are they a useful tool?

11. The bioprospecting trust fund - what purpose does this fund achieve?

12. Is there a need to coordinate national and provincial departments with respect to issuing bioprospecting permits?

Appendix C: Interview Questions for Researchers

1. Please could you state the capacity and name of the organisation in which you work?

2. What are you mandated to do in this capacity?

3. Have you ever been involved in bioprospecting activities?

4. Looking at the concept of indigenous communities, how do you understand the concept of indigenous communities within the definition of the Biodiversity Act and do you understand it to be clear in its interpretation?

5. Looking at the concept of traditional knowledge or indigenous knowledge how do you understand this definition of traditional knowledge within the Biodiversity Act and regulations?

6. What are the practical implications or challenges of linking particular traditional knowledge with a specific indigenous community?

7. Have you had to obtain PIC under any circumstances, if yes what were the practical used in obtaining this consent?

8. What concerns and issues have you experienced with obtaining PIC in a practical situation?

9. Looking at ownership and granting access to these biological resources, within the legislation there is a distinction between private persons, organs of state and communities, how does this affect the manner in which stakeholders engage with these entities?

10. Should there be a distinction between granting access to genetic resources and access to IBRs?

11. Have you had to enter any benefit-sharing agreements and what have been your experiences with respect to developing these benefit-sharing agreements?

12. What function do MTAs serve and are they a useful tool?

13. Why is there a need to distinguish between academic research and research for bioprospecting activities, with respect to the recent amendment to the Biodiversity Act?

14. Looking at your interactions with the provincial departments in terms of academic research do you have any interactions with the provincial departments in terms of collecting materials or are you free to go out and conduct academic research on any plants?

15. Are there any other issues that you would like to raise with respect to the practical implementation of ABS legislation?
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Appendix D: Interview Questions for DEA

1. Please could you state your name and capacity of the organisation in which you work?

2. What are you mandated to do in this capacity?

3. How do you interpret the definition of bioprospecting in the Biodiversity Act? Do you understand this definition to be clear in its interpretation? Please elaborate if not?

4. What is considered a recognised leadership structure within an indigenous community? And how is it identified in a practical situation?

5. What practical difficulties are there in linking indigenous communities with specific traditional knowledge?

6. What is considered a sufficient form of PIC when issuing a bioprospecting permit?

7. When determining the extent to which PIC has been obtained what issues and concerns have you experienced with respect to applications for bioprospecting permits?

8. Does the current ABS legislation effectively deal with the concept of PIC?

9. How does the distinction, that is made between granting access to biological resources through either private persons, organs of state or indigenous communities, affect the manner in which stakeholders engage with these entities?

10. What motivated the change to include individual holders of traditional knowledge to the recent amendments?

11. Is there a need to effect any legislative changes with respect to access to genetic resources and access to IBRs?

12. How has the introduction of the notification procedure affected the way in which the Act is implemented?

13. What have been your experiences in assessing benefit-sharing agreements, how are applicants complying with this legislation?

14. What measures do you take to ensure that the applicant has identified all potential beneficiaries to an agreement?

15. What function do material transfer agreements serve? Are they a useful tool?

16. How are conditions attached to the approval of material transfer agreements monitored?

17. How does the legislation take into consideration the situation of informal traders, in for instance rooibos tea, how are they affected by the current Access and Benefit-Sharing regime?

18. Is there a need to differentiate between biotrading and actual commercialisation of biological resources?

19. How many biotraders out there are aware that they are conducting a bioprospecting activity?

20. What type of punishment could they expect?

21. What user measures will be put in place to regulate bioprospecting activities by South African companies in other countries?

22. Is there a need to link the Department of agriculture, DTI, DST and DEA? Is there a need to coordinate all those departments into one entity?

23. What type of interaction does the DEA have with other provincial departments, and how do these different departments coordinate the issuing of permits?

24. What purpose does the trust fund achieve?

25. Are there any issues that you would like to raise with respect to the implementation of this legislation in South Africa?

26. In terms of DTI, why would there be a need to integrate the departments?

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Appendix E: Interview Questions for the Provincial Department

1. As Cape Nature are you mandated to engage in bioprospecting activities?

2. How do you interpret the definition of bioprospecting in the Biodiversity Act? Do you understand this definition to be clear in its interpretation?

3. Identifying indigenous communities - is it clear in the interpretation of the ABS legislation?

4. What is your understanding of PIC as defined in the ABS legislation?

5. Have you ever had to obtain PIC in any circumstances?

6. What effect is created by granting ownership right of biological resources to private persons, organs of state, or indigenous communities?

7. Is it appropriate in your opinion that individuals within the community should be rewarded for holding the traditional knowledge? Why?

8. How do you understand ownership of genetic resources in South Africa?

9. Should ownership of a genetic resource be vested in the state?

10. Has Cape Nature entered into any benefit-sharing agreements before?

11. Have you had any experience in developing benefit-sharing agreements?

12. Have you had any experience in material transfer agreements?

13. Why is there a need to distinguish between research for academic purposes and research or bioprospecting activities with respect to the recent amendments to the Biodiversity Act?

14. How does the provincial department deal with the distinction between research for academic purposes and research for bioprospecting activities and how does it monitor organizations that cross over from academic research to research for bioprospecting activities?

15. In respect to the issuing authorities of bioprospecting permits and the separation of powers between national, provincial and local spheres of government, does this separation of powers affect the department's ability to grant permits? If yes, please elaborate?

16. Are there any other issues with respect to the legislation that you would like to raise?