

THE TRADITIONAL KNOWLEDGE ASPECT OF INTELLECTUAL  
PROPERTY AND BIOPROSPECTING WITHIN THE SOUTH AFRICAN  
TERRITORIAL SEA AND EXCLUSIVE ECONOMIC ZONE

by

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## SUMMARY

Bioprospecting has proven to be an essential component in the process of biological product development. Of notable interest is the pharmaceutical industry, within which billions of dollars are generated annually from the sales of drugs derived from natural biological resources. Most of the natural biological resources are obtained from the developing countries where local/indigenous people in these communities play a crucial role in helping bioprospectors to identify biogenetic resources with active compounds that could be of interest to the pharmaceutical researchers. The knowledge that is obtained from these local communities is referred to as Traditional Knowledge.

In a bid to try and avoid the unlawful exploitation and expropriation of both local indigenous resources and local communities' knowledge, several international and regional instruments as well as national legislation has been adopted to ensure that the relations between all interested parties are balanced in as far as its reasonably possible. The research conducted in this treatise seeks to look at the protection that is currently provided for by the relevant laws and policies in place with specific focus being placed on the local communities whom, without adequate protection, will be the most vulnerable. The subject of the research has also been limited to the South African territorial waters and the exclusive economic zone.

A practical example of the effect and relevance of regulated bioprospecting will be discussed in a matter relating to the *Hoodia* plant and the indigenous San communities that had initially been unduly excluded from benefitting from the knowledge that was obtained from them.

## ABBREVIATIONS

ABNJ	Areas Beyond National Jurisdiction
ABS	Access Benefit Sharing
AU	African Union
CBD	Convention on Biological Diversity
CSIR	Council of Scientific & Industrial Research
EEZ	Exclusive Economic Zone
GDP	Gross Domestic Product
GNP	Gross National Product
IP	Intellectual Property
IPR	Intellectual Property Rights
MAT	Mutually Agreed Terms
OECD	Organization for Economic Cooperation and Development
PIC	Prior Informed Consent
TK	Traditional Knowledge
TRIPS Agreement	Trade-Related Aspects of Intellectual Property Rights
UNCLOS	United Nations Convention on the Law of the Sea
WIPO	World Intellectual Property Organization
WTO	World Trade Organisation



## CHAPTER 1: INTRODUCTION

Current systems established to protect intellectual property were formulated at a time when industrialization was picking up in the Western States.<sup>1</sup> As a result, the system was structured in a manner that perceived the needs of the technologically advanced societies such as the United States of America and the United Kingdom.<sup>2</sup> These technologically advanced states had the means and the opportunities to harness resources and use them to their benefit without giving due recognition to the areas where they extracted the resources from. This background has led to various indigenous peoples, local communities and governments, mostly in the developing countries,<sup>3</sup> to demand more protection and reasonable benefit sharing systems. These are aimed at benefitting local communities which provide traditional knowledge (TK) that is acquired by bioprospectors. Bioprospectors are people performing the act of bioprospecting. Bioprospecting can be defined as the systematic search for and development of new sources of chemical compounds, genes, micro-organisms, macro-organisms, and other valuable products from nature. It entails the search for economically valuable genetic and biochemical resources from nature.<sup>4</sup> It entails the search for economically valuable genetic and

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<sup>1</sup> Reference to Western States in this context relates to developed countries. Developed countries are defined as a sovereign state that has a highly developed economy and advanced technological infrastructure relative to other less industrialized nations. Most commonly, the criteria for evaluating the degree of economic development are gross domestic product (GDP), gross national product (GNP), the per capita income, level of industrialization, amount of widespread infrastructure and general standard of living according to International Monetary Fund Working Paper on Classifications of Countries Based on Their Level of Development: How it is Done and How it Could be Done accessed at <https://www.google.com/url?sa=t&rct=j&q=&esrc=s&source=web&cd=10&ved=0CF4QFjAJahUKEwixkMLrnezIAhWDvBoKHRX5Ak4&url=https%3A%2F%2Fwww.imf.org%2Fexternal%2Fpubs%2Fft%2Fwp%2F2011%2Fwp1131.pdf&usq=AFQjCNGV5WIXah5n4rbAJ9WnbYufs0XpPQ&sig2=lbOviHOLFVU2yKnd-FSkxQ&cad=rja> on 28 October 2015.

<sup>2</sup> Visser *Biodiversity, Bioprospecting, and Biopiracy: A Prior Informed Consent Requirement for Patents* 2006 429.

<sup>3</sup> Developing country is a nation with an underdeveloped industrial base, and a low Human Development Index (HDI) relative to other countries to International Monetary Fund Working Paper on Classifications of Countries Based on Their Level of Development: How it is Done and How it Could be Done accessed at <https://www.google.com/url?sa=t&rct=j&q=&esrc=s&source=web&cd=10&ved=0CF4QFjAJahUKEwixkMLrnezIAhWDvBoKHRX5Ak4&url=https%3A%2F%2Fwww.imf.org%2Fexternal%2Fpubs%2Fft%2Fwp%2F2011%2Fwp1131.pdf&usq=AFQjCNGV5WIXah5n4rbAJ9WnbYufs0XpPQ&sig2=lbOviHOLFVU2yKnd-FSkxQ&cad=rja> on 28 October 2015.

<sup>4</sup> Essential Medicines and Health Products Information Portal available at <http://apps.who.int/medicinedocs/en/d/Jh2996e/6.3.html> accessed on 14 November 2015.

biochemical resources from nature.<sup>5</sup> These bioprospectors are generally from developed economies<sup>6</sup> that have advanced technologies to conduct the required screening<sup>7</sup> and sampling.<sup>8</sup>

Over the last four decades, it has been established that oceans hosts enormous wealth of biodiversity. Deep sea habitat alone is estimated to contain between 500,000 and 10 Million species.<sup>9</sup> Although the ocean contains about 95% of the world's biosphere, only a tiny fraction of it has been explored<sup>10</sup> and most of this biosphere is located in the southern hemisphere.

There is considerable knowledge that lies within the local indigenous populations which has been shared among communities for generations. Often, this knowledge is transmitted by word of mouth and is seldom documented. Without proper legal framework in place, such knowledge can be exploited to the detriment of the local indigenous people and as such, laws and regulations must be put in place to protect these individuals.<sup>11</sup>

The focus of this treatise is on TK and the conservation of biodiversity within the territorial waters as well as the exclusive economic zone (EEZ). The principle source of legislation in this context is the United Nations Convention on Law of the Sea (UNCLOS), which intends to regulate "all uses of the oceans and their resources."<sup>12</sup> However, because UNCLOS does not expressly deal with biogenetic resources and biodiversity, the Convention on Biological Diversity (CBD) will be referred to extensively. The CBD covers matters concerning sustainable use of biodiversity as well as the equitable benefit sharing

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<sup>5</sup> *Ibid.*

<sup>6</sup> Also referred to as developed countries defined in footnote 1 *Supra*.

<sup>7</sup> Screening is defined by the medical dictionary as the process by which candidate substances for active compounds are evaluated in a battery of assays (screens) designed to detect a specific biological property or activity. Screening can be conducted randomly or can be targeted screening. Accessed at <http://medical-dictionary.thefreedictionary.com/screening> on 14 November 2015.

<sup>8</sup> Sampling in bioprospecting is the process whereby samples from various areas are selected and tested for screening. Found in *IP Handbook of Best Practices* accessed at <http://www.iphandbook.org/handbook/ch09/p04/eo/> on 14 November 2015.

<sup>9</sup> Secretariat on the Convention on Biological Diversity, Marine and Coastal biodiversity, available at <http://www.cbd.int/undb/media/factsheets/undb-factsheet-marine-en.pdf>.

<sup>10</sup> *Ibid.*

<sup>11</sup> Harvey & Gericke Bioprospecting: Creating value for Biodiversity 2008 323.

<sup>12</sup> UN Convention on the Law of the Sea of 10 December 1982, Overview and full text, available at [http://www.un.org/depts/los/convention\\_agreements/convention\\_overview\\_convention.htm](http://www.un.org/depts/los/convention_agreements/convention_overview_convention.htm) accessed 14 September 2015.



of products and benefits obtained from genetic resources. In order to provide more protection and give more effect to the CBD, the Nagoya Protocol on Access to Genetic Resources and the Fair and Equitable Sharing of Benefits Arising from their Utilization (the Nagoya Protocol) was adopted in Japan in 2010.<sup>13</sup>

In addition to these instruments, the World Trade Organisation (WTO) Agreement on Trade-Related Aspects of Intellectual Property Rights (TRIPS)<sup>14</sup> provides the legislative framework of bioprospectors rights and obligations in connection with innovations derived from marine biological resources. South Africa has enacted legislation to deal with matters regarding bioprospecting and access to genetic resources, in accordance with the CBD. To this end, the National Environmental Management: Biodiversity Act<sup>15</sup> (Biodiversity Act) will be discussed in subsequent chapters. There are other pieces of legislation in South Africa that regulate the subject matter of this treatise. An example of such legislation is the Marine Living Resources Act<sup>16</sup> which has its objectives as, *inter alia*: the need to conserve marine living resources for both present and future generations; the need to apply precautionary approaches in respect of the management and development of marine living resources; and the need to preserve marine biodiversity. Section 8 of the Biodiversity Act provides that in a matter where two or more pieces of legislation apply, the Biodiversity Act will take precedence. As such, without disregarding the value of other pieces of legislation, the focus of this treatise will be restricted to the Biodiversity Act.

Chapter 2 will focus on the concept of bioprospecting with reference to various legal instruments, both national and international.

In Chapter 3, marine bioprospecting is examined in relation to the existing legal framework and international agreements that regulate the extent to which bioprospecting is done within territorial waters.

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<sup>13</sup> Parties to the Nagoya Protocol <https://www.cbd.int/abs/nagoya-protocol/signatories/> accessed 17 September 2015.

<sup>14</sup> Agreement on Trade-Related Aspects of Intellectual Property Rights (TRIPS) -adopted 15 April 1994, entered into force 1 January 1995.

<sup>15</sup> 10 of 2004.

<sup>16</sup> 18 of 1998.

In Chapter 4, an analysis of intellectual property (IP) and TK is conducted. The relationship between IP and TK is analyzed in light of the current legal framework and how indigenous communities, the custodians of TK, are legally protected from exploitation. The promotion of mechanisms, such as access to benefit sharing (ABS), that are designed to benefit local indigenous communities, will also be referred to.

In Chapter 5, the practical application of bioprospecting within territorial waters and the EEZ will be discussed.

Chapter 6 contains the conclusion.

## CHAPTER 2: BIOPROSPECTING

### 2.1 Introduction

Over the years, several definitions of bioprospecting have been advanced by various authors, academics as well as organizations, such as the World Trade Organisation (WTO). The most appropriate definition is the exploration of biological material or biological diversity for commercially viable genetic and biochemical properties.<sup>17</sup> A more comprehensive definition of bioprospecting is “the exploration, extraction and screening of biological diversity and indigenous knowledge for commercially valuable genetic and biochemical resources.”<sup>18</sup>

In the definitions section, the Biodiversity Act described bioprospecting in relation to indigenous biological resources as any research on, or development or application of, indigenous biological resources for commercial or industrial exploitation.<sup>19</sup> The Act provides that bioprospecting is a systematic search, collection or gathering of such resources; utilization for purposes of such research or development of any information regarding any traditional uses of indigenous biological resources by indigenous communities, among other things.<sup>20</sup> Biological diversity, commonly referred to as biodiversity, has been described as an over-arching term for the degree of nature’s variety and is a concept understood to cover three facets, namely the diversity of ecosystems; the diversity of species; and genetic diversity within species.<sup>21</sup> Also provided for in the Act is a fairly broad definition for indigenous biological resources namely the variability among living organisms from all sources, *inter alia*, terrestrial, marine and other aquatic

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<sup>17</sup> United Nations Environment Programme- Division of Environmental Law and Conventions Environmental Law and Governance Branch found at [https://www.wto.org/english/forums\\_e/ngo\\_e/posp62\\_apec\\_e.pdf](https://www.wto.org/english/forums_e/ngo_e/posp62_apec_e.pdf) accessed 5 October 2015; Harvey & Gericke “Bioprospecting: Creating a Value for Biodiversity” 2008 *Research in Biodiversity – Models and Applications* 323.

<sup>18</sup> World Health Organisation in Essential Medicines and Health Products Information Portal found at <http://apps.who.int/medicinedocs/en/d/Jh2996e/6.3.html> accessed 25 October 2015; Sandhu “Bioprospecting: Pros and Cons” 2004 1.

<sup>19</sup> s1(1) of the National Environment Management: Biodiversity Act 10 of 2004 (the Biodiversity Act).

<sup>20</sup> *Ibid.*

<sup>21</sup> Article 2 Convention on Biological Diversity (CBD); Visser “Biodiversity, Bioprospecting, and Biopiracy: A Prior Informed Consent Requirement for Patents” 2006 18 *South African Mercantile Law Journal* 431.

ecosystems.<sup>22</sup> This includes ecological complexes and recognizes inclusion of diversity within species, between species and of the ecosystems.<sup>23</sup>

In this Chapter, the concept of bioprospecting as well as the various legal instruments that are in place to regulate the activities of the contracting parties in this regard will be investigated. To this end, the CBD and the Nagoya Protocol, which are international instruments will be looked at. Thereafter the Biodiversity Act, which is the relevant national legislation of South Africa, will be discussed.

## 2 2 Parties Involved in Bioprospecting

Developed countries have seen the successful development of large corporations, especially in the pharmaceutical industries which have invested large amounts of resources into their research and development programs over the decades. As a result, their research has shown that natural biogenetic resources are rich in active ingredients.<sup>24</sup> The outcome of this realization had a huge impact in the pharmaceutical industry because most active ingredients in medicines are being derived from natural products. As a result, these natural products continue to be a source of new drugs.<sup>25</sup>

The biggest challenge however, has been that, although the developed countries have advanced research facilities and technology, most biodiversity is not located in these countries. In fact, it has been estimated that 90% of the world's genetic resources are situated in developing countries whereas more than 90% of the world's research is conducted in the developed countries.<sup>26</sup> This means that there has to be a way with which access to biodiversity by multi-national corporations is possible under terms and

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<sup>22</sup> *Ibid.*

<sup>23</sup> *Ibid.*

<sup>24</sup> Harvey & Gericke "Bioprospecting: Creating value for Biodiversity" 2008 323. Accessed at <http://cdn.intechopen.com/pdfs/21540.pdf> on 17 September 2015.

<sup>25</sup> Harvey & Gericke 2008 323; Crouch *et al* "South Africa's bioprospecting, access and benefit sharing legislation: current realities, future complications, and proposed alternative." 2008 *South African Journal of Science* 355.

<sup>26</sup> Visser 2006 429.

conditions that are mutually acceptable with the local inhabitants from where the biogenetic resources are sourced from.<sup>27</sup>

For the purpose of this treatise, the contracting parties,<sup>28</sup> will be restricted to the bioprospectors. These could be a research institute, a pharmaceutical company or an organization that could be working in its own capacity or on behalf of any other interested party;<sup>29</sup> the governments usually acting through a designated cabinet minister heading the portfolio covering environmental matters, for example, the Minister of Trade & Industry in the context of South Africa, who has the authority to issue or delegate the issuing of the permit required for bioprospecting;<sup>30</sup> as well as the traditional/indigenous community that is the custodian of the traditional knowledge transferred, or their representatives thereof.<sup>31</sup>

## 2 3 International Framework

### 2 3 1 Convention on Biological Diversity

Following decades of such unregulated collection of samples for a variety of purposes, the United Nations created a framework for preserving the world's biodiversity while encouraging the sustainable use of biodiversity,<sup>32</sup> namely the CBD. This was enacted during the Earth Summit in Rio de Janeiro in June 1992 and has been signed and ratified by several states.<sup>33</sup> South Africa became a signatory to the CBD on 4 June 1993 and ratified the CBD on 2 November 1995.

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<sup>27</sup> Harvey & Gericke 2008 323.

<sup>28</sup> Contracting parties will be the persons, natural or juristic, who have invested interests in the biogenetic resources sought - <http://www.wipo.int/patents/en/> accessed 28 October 2015.

<sup>29</sup> Quezada "Status and Potential of Commercial Bioprospecting Activities in Latin America and the Caribbean" 2007 14 United Nations Publications.

<sup>30</sup> S81 of Act 10 of 2004.

<sup>31</sup> S1 of Act 10 of 2004.

<sup>32</sup> Harvey & Gericke 2008 323.

<sup>33</sup> 192 countries as well as the European Union have ratified the CBD since 1992 with the notable exception being the United States of America according to the CBD website accessed at <https://www.cbd.int/information/parties.shtml> on 27 October 2015.

The CBD has three main goals which are the conservation of biodiversity, the sustainable use of the components of biodiversity and the sharing of benefits arising from the commercial and other utilization of genetic resources in a fair and equitable way.<sup>34</sup> The preamble of the CBD provides, *inter alia*: that the goals set out in the Convention are based on the notion that conservation and sustainable use of biological diversity is critical for meeting the food and health needs of the expanding global population; that states have sovereign rights over their own biological resources; and recognizing that there is close and traditional dependence of many indigenous and local communities embodying traditional lifestyles on biological resources; and the desirability of sharing equitably benefits arising from the use of traditional knowledge. The states that have ratified the CBD recognize and acknowledge that countries have sovereign rights over their genetic and biological resources which is within their respective boundaries. They further agree to the conditions that are laid down in the CBD for the preservation and sustainable use of biodiversity for the benefit of present and future generations.<sup>35</sup>

Article 15 of the CBD has provided for various mechanisms to allow access to biogenetic resources. The provisions provided in Article 15 are:

- States' Sovereign Rights;
- Mutually Agreed Terms; and
- Prior Informed Consent.

These will be discussed forthwith.

## 2 3 1 1 States' Sovereign Rights

The first provision provides that national governments have authority over genetic resources within their territorial space as part of their sovereign rights. Such genetic resources are subject to national legislation. It is submitted that these must be respected

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<sup>34</sup> The Preamble of the CBD.

<sup>35</sup> Harvey & Gericke 2008 323.

by bioprospectors.<sup>36</sup> This means that contracting states have a right to determine the conditions under which access to genetic resources is conducted, which in turn implies that countries with biogenetic resources have a legal entitlement with which they can negotiate compensation for granting access to genetic resources. This can take the form of profit sharing if the biogenetic resources are commercialized.<sup>37</sup>

It is, however, imperative to note that the right provided for by the above mentioned provision is not an intellectual property right since it refers to the access of the phenotype<sup>38</sup> of the genetic resources and thus relates to the tangible goods which, in this case, are genetic resources in the form of natural plants and animals.<sup>39</sup>

## 2.3.1.2 Mutually Agreed Terms

The CBD stipulates that in cases where access is granted, it must be on mutually acceptable terms and in accordance with the provisions in question.<sup>40</sup> Mutually agreed terms also, in principle, ensure that there must have been full disclosure by the party that intends to engage in bioprospecting in terms of the project they want to conduct. Such disclosure should clearly specify, *inter alia*, the impact such conduct will have on the environment; the sustainability of the biogenetic resources that will be exploited; and the sharing of the resulting products, either in terms of monetary value or non-monetary value.<sup>41</sup> Non-monetary benefits that can be shared with or gained by the local

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<sup>36</sup> Article 15(1) of the CBD.

<sup>37</sup> Visser 2006 433.

<sup>38</sup> According to the Oxford Online Dictionary, phenotype is the set of observable characteristics of an individual resulting from the interaction of its genotype with the environment. Genotype is the genetic constitution of an individual organism.

<sup>39</sup> Visser 2006 433; Crouch *et al* 2008 357.

<sup>40</sup> Article 15(4) of the CBD.

<sup>41</sup> *Ibid.*

communities can include transfer of technology<sup>42</sup> as well as the participation by the contracting parties in the results and benefits of genetic resources.<sup>43</sup>

### 2 3 1 3 Prior Informed Consent

Unless the contracting parties agree otherwise, access to genetic resources shall be subject to prior informed consent from the party that is providing the biogenetic resources.<sup>44</sup> This is subject to the provisions of the CBD<sup>45</sup> and entails that bioprospectors should include information that is accurate in as far as why they need the biogenetic resources concerned. This information must be provided before consent can be granted.<sup>46</sup> Bioprospectors cannot seek permission from the government alone. They must also consult and obtain consent from the local or indigenous people who own the knowledge that is critical to the utilization of the biogenetic resources that are being sought.<sup>47</sup>

### 2 3 1 4 Benefit Sharing

The source country is expected to be involved in the collaborative research and development project relating to its biodiversity.<sup>48</sup> That country must furthermore, benefit from the technology transfer,<sup>49</sup> from the results of the research and from the sharing of the commercial benefits resulting from the use of its biodiversity.<sup>50</sup> The section on benefit

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<sup>42</sup> Transfer of technology is the process of transferring skills, knowledge, technologies, methods of manufacturing, samples of manufacturing and facilities among governments and other institutions to ensure that scientific and technological developments are accessible to a wider range of users who can then further develop and exploit the technology into new products, processes, applications, materials or services.

<sup>43</sup> Steenkamp *Benefits sharing in accordance with the Convention on Biological Diversity*. (Unpublished Masters Dissertation, North-West University) 2006 11.

<sup>44</sup> Article 15(5) The CBD.

<sup>45</sup> *Ibid.*

<sup>46</sup> Visser 2006 435.

<sup>47</sup> *Ibid.*

<sup>48</sup> Article 15(6) of the CBD.

<sup>49</sup> Article 16(2) of the CBD.

<sup>50</sup> Article 15(7) of the CBD.



sharing will be discussed in depth in Chapter Four below in light of Article 8(j) of the CBD which also makes it mandatory on the states that have ratified the CBD to preserve traditional knowledge of indigenous and local people.

One of the main challenges facing the CBD at the time of its inception was that the CBD stipulated what was meant to be achieved but did not provide sufficient guidelines on how the ideals in the CBD could be achieved.<sup>51</sup> In a bid to try and assist with the implementation of bioprospecting under the CBD, the Conference of the Parties, which is the official CBD body, adopted the Bonn Guidelines on Access to Genetic Resources and Fair and Equitable Sharing of the Benefits Arising out of their Utilization (the Bonn Guidelines) in 2002.<sup>52</sup> These guidelines were intended to guide all the CBD ratifying states to follow best practices in setting up bioprospecting agreements.<sup>53</sup>

The Bonn Guidelines has been superseded by the Nagoya Protocol on Access to Genetic Resources and the Fair and Equitable Sharing of Benefits Arising from their Utilization to the Convention on Biological Diversity (the Nagoya Protocol) which was adopted in Japan in October 2010.<sup>54</sup> The Nagoya Protocol will be discussed below.

## 2 3 2 The Nagoya Protocol

The Nagoya Protocol is an international agreement which is aimed at-

“shar[ing] the benefits arising from the utilization of genetic resources and by appropriate transfer of relevant technologies, taking into account all the rights over those resources and to technologies, and by appropriate funding, thereby contributing to the conservation of biological diversity and the sustainable use of its components.”<sup>55</sup>

It entered into force on the 12 October 2014. South Africa signed the Nagoya Protocol on 11 May 2011 and ratified it on 10 January 2013.<sup>56</sup>

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<sup>51</sup> Harvey & Gericke 2008 324.

<sup>52</sup> Harvey & Gericke 2008 324.

<sup>53</sup> Harvey & Gericke 2008 324.

<sup>54</sup> The CBD website (<https://www.cbd.int/abs/>)

<sup>55</sup> The CBD website (<https://www.cbd.int/abs/>)

<sup>56</sup> The CBD website (<https://www.cbd.int/abs/nagoya-protocol/signatories/>)

The Nagoya Protocol aims to provide greater legal certainty in aspects regarding bioprospecting. It deals more clearly with the use of traditional knowledge associated with genetic resources in the sense that contracting parties have to ensure that the local communities have provided prior informed consent and there is fair and equitable benefit sharing with the relevant communities.<sup>57</sup>

## 2.4 Regional Framework

In a bid to strengthen the position of developing countries in the process of bioprospecting, the former Organisation of African Unity (now renamed the African Union) developed the African Model Legislation for the Protection of the Rights of Local Communities, Farmers and Breeders, and for the Regulation of Access to Biological Resources 2000 (the Model Legislation).<sup>58</sup>

In terms of these agreements, obligations are placed on the applicant seeking access to biogenetic resources namely that the applicant would not only reveal their identity, or the representee where applicable, but must also disclose the planned bioprospecting project. They also have to disclose, *inter alia*: the nature of the resources to which access is sought; the sites where they will be collected from; their present uses, as well as its potential uses; its sustainability thereof; and the associated risks of accessing it.<sup>59</sup> In addition, they have to advise whether any collection of the resource endangers any component of biological diversity and if so, to what extent. Furthermore, the purpose for which the access of the resource is sought has to be disclosed. This includes the type and extent of the research as well as teaching or commercial use expected from it.<sup>60</sup>

In terms of the Model Legislation, the local communities are entitled to withdraw their consent or to restrict the activities relating to access where such activities are likely to be

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<sup>57</sup> Harvey & Gericke 2008 324.

<sup>58</sup> African Model Legislation For The Protection Of The Rights Of Local Communities, Farmers And Breeders, and For The Regulation Of Access To Biological Resources 2000; Visser 2006 435.

<sup>59</sup> Part 1 of African Model Legislation For The Protection Of The Rights Of Local Communities, Farmers And Breeders, And For The Regulation Of Access To Biological Resources 2000; Visser 2006 435.

<sup>60</sup> Article 3 of the African Model Legislation For The Protection Of The Rights Of Local Communities, Farmers And Breeders, And For The Regulation Of Access To Biological Resources 2000.

detrimental to their socio-economic life, or their natural or cultural heritage.<sup>61</sup> Local or indigenous communities also retain, and thus can at any time exercise, their right to access, use, and exchange or share their biological resources to sustain their livelihood systems as regulated by their customary practices and laws.<sup>62</sup> This model was aimed at promoting benefit sharing.<sup>63</sup>

## 2.5 National Framework

On the African continent, only a few countries have developed comprehensive policies and laws that are relevant, as well as being in support of, access to biogenetic resources and benefit sharing. These are the relatively more developed states on the continent. South Africa is one such country and has enacted the Biodiversity Act<sup>64</sup> which will be examined below.

In South Africa, bioprospecting is regulated mainly by Chapter 6 of the Biodiversity Act which also regulates access to biological resources and benefit sharing.<sup>65</sup> The Chapter has a threefold application, namely: to regulate bioprospecting that involves indigenous biological resources; to regulate the export from South Africa of indigenous biological resources; and to provide for a fair and equitable sharing by stakeholders in benefits arising from bioprospecting involving indigenous biological resources.<sup>66</sup> The Act prohibits the engagement in bioprospecting or exporting of such resources unless a permit is issued in accordance with Chapter 7 of the Act.<sup>67</sup>

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<sup>61</sup> Article 21 of the Recognition and Protection of Right of Local Communities, Farmers and Breeders, and for Regulation of Access to Biological Resources, 2000.

<sup>62</sup> Visser 2006 436.

<sup>63</sup> Benefit sharing refers to a commitment to channel some kind of returns, whether monetary or non-monetary, back to the range of designated participants: affected communities, source communities or source nations according to Article 1 of African Model Legislation for the Protection of the Rights of Local Communities, Farmers and Breeders, and for the Regulation of Access to Biological Resources 2000.

<sup>64</sup> 10 of 2004.

<sup>65</sup> Visser 2006 437.

<sup>66</sup> S80(1) of Act 10 of 2004.

<sup>67</sup> S81(1) of Act 10 of 2004.

The Biodiversity Act requires bioprospectors to obtain a permit from the Minister of Trade and Industry for bioprospecting involving indigenous biological resources as well as for the export of these resources.<sup>68</sup> Furthermore, the Act has made it mandatory that indigenous communities and landowners must provide prior informed consent, and for bioprospectors to enter into benefit sharing agreements with the indigenous communities who use the resources traditionally,<sup>69</sup> before a permit is issued by a competent body.<sup>70</sup> A more detailed discussion on how the Act regulates access to genetic resources will be discussed in Chapter Four.

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<sup>68</sup> S81 Act 10 of 2004.

<sup>69</sup> Harvey & Gericke 2008 325.

<sup>70</sup> S82 Act 10 of 2004.

## CHAPTER 3: MARINE BIOPROSPECTING

### 3 1 Introduction

The marine environment has been identified as a host of unprecedented wealth of biodiversity.<sup>71</sup> It is estimated that the deep sea habitat alone contains between 500,000 and 10 million species; and with the oceans carrying an estimated biosphere<sup>72</sup> of about 95%. To date, only a small fraction of that biosphere has been explored.<sup>73</sup> Advancements in technology have facilitated the exploration of the more remote and extreme spheres. These pristine areas appear to be particularly interesting to explore as the organisms living in such extreme conditions often embody distinctive and unique survival systems.<sup>74</sup> The states forming part of the Organisation for Economic Cooperation and Development (OECD) are diversifying their economies and have since identified and highlighted marine bioprospecting as a prioritized area with significant potential commercially.<sup>75</sup>

Currently, there is no internationally-agreed definition of marine bioprospecting. Various authors have described marine bioprospecting to basically consist of procuring and analyzing samples of marine genetic material in order to identify potentially marketable products to be developed from them.<sup>76</sup> Neither bioprospecting nor marine bioprospecting has been defined by the CBD or the United Nations Convention on Law of the Sea (UNCLOS). In a note prepared by the CBD Secretariat, marine bioprospecting has been

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<sup>71</sup> Secretariat on the Convention on Biological Diversity, Marine and Coastal Biodiversity, available at <http://www.cbd.int/undb/media/factsheets/undb-factsheet-marine-en.pdf> accessed 14 August 2015.

<sup>72</sup> According to World Biodiversity website biosphere is defined as the layer of the planet Earth where life exists. This layer ranges from heights of up to ten kilometers above sea level, used by some birds in flight, to depths of the ocean such as the Puerto Rico trench, at more than 8 kilometers deep. Accessed at [http://www.biodiversidad.gob.mx/v\\_ingles/planet/whatis\\_bios.html](http://www.biodiversidad.gob.mx/v_ingles/planet/whatis_bios.html) on 28 August 2015.

<sup>73</sup> J. F. Grassle and N. J. Maciolek, "Deep-sea species richness: regional and local diversity estimates from quantitative bottom samples" [1992] *The American Naturalist* 313; Secretariat on the Convention on Biological Diversity, Marine and Coastal Biodiversity, available at <http://www.cbd.int/undb/media/factsheets/undb-factsheet-marine-en.pdf> accessed 14 August 2015.

<sup>74</sup> Leary "Bioprospecting and the Genetic Resources of Hydrothermal Vents on the High Seas: What is the Existing Legal Position, Where are we heading and what are our Options?" 2004 *Macquarie Journal of International and Comparative Environmental Law* 137.

<sup>75</sup> OECD, Global Forum on Biotechnology: Marine Biotechnology – Potential and Challenges, available at <http://www.oecd.org/sti/biotech/oecdglobalforumonbiotechnologymarinebiotechnologypotentialandchallenges.htm> accessed 15 August 2015.

<sup>76</sup> N. Leroux and M.M. Mbengue, Deep-Sea Marine Bioprospecting under UNCLOS and the CBD, available at <http://www.gmat.unsw.edu.au/ablos/ABLOS10Folder/S3P1-P.pdf> accessed 28 July 2015.

defined as “the exploration of diversity for commercially valuable genetic and biochemical resources.”<sup>77</sup>

In the following sections, the legal framework for marine bioprospecting will be discussed in relation to existing legal rules.

### 3 2 UNITED NATIONS CONVENTION ON THE LAW OF THE SEA

UNCLOS does not make mention of “marine genetic resources”, or “marine bioprospecting”. This could have been as a result of the fact that at the time of drafting of UNCLOS, very little was known about the potential that lies within the seas. As Leroux and Mbengue put it; “the deep ocean was for long viewed as an immense, lifeless expanse of water with little to no interest to international lawyers.”<sup>78</sup> This could be the reason why UNCLOS failed to address such a crucial matter, despite efforts by the drafters to settle and regulate all matters relating to the law of the sea.<sup>79</sup>

Be that as it may, it will be counter-productive to all states aiming to promote peaceful, equitable and efficient utilization of the seas if one is to argue that UNCLOS fails to provide a legal regime for deep-sea marine bioprospecting.<sup>80</sup> In as much as UNCLOS fails to address these issues explicitly, it is submitted that many of the general provisions provided by the agreement can be applied to marine bioprospecting. In addition, used together with other relevant provisions of the various legal instruments, such as the CBD, they provide a comprehensive legal regime which can be applied to marine bioprospecting.<sup>81</sup>

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<sup>77</sup> “Progress Report on the Implementation of the Programmes of Work on the Biological Diversity of Inland Water Ecosystems, Marine and Coastal Biological Diversity, and Forest Biological Diversity - Information on Marine and Coastal Genetic Resources, Including Bioprospecting” (UNEP/CBD/COP/5/INF/7).

<sup>78</sup> Leroux and Mbengue <http://www.gmat.unsw.edu.au/ablos/ABLOS10Folder/S3P1-P.pdf> 1.

<sup>79</sup> Preamble of UNCLOS Paragraph 1.

<sup>80</sup> Leroux and Mbengue <http://www.gmat.unsw.edu.au/ablos/ABLOS10Folder/S3P1-P.pdf> 3.

<sup>81</sup> The CBD expressly refers to UNCLOS in Article 22(2) and provides that it should be implemented consistently with the rights and obligations of States under the Law of the Sea.

### 3 2 1 Marine Bioprospecting in the Territorial Waters and Exclusive Economic Zone

Article 56 (1) (a) of UNCLOS provides that states have:

“sovereign rights [in their EEZ] for the purpose of exploring and exploiting, conserving and managing the natural resources, whether living or non-living, of the waters superjacent to the seabed and of the seabed and its subsoil.”

It can therefore be implied, within reason, that marine genetic material extracted from marine living organisms clearly fall within the category of the “natural resources” as defined by Article 56(1)(a) of UNCLOS. It can therefore be implied that coastal states have sovereign rights to allow or prohibit the exploration and exploitation of marine genetic resources within their EEZs.<sup>82</sup> These sovereign rights are coupled with the crucial right to impose fares or royalties obtained as a result of the commercialization of the marine biotech products. A good example of this can be found in the Norwegian Law of Management of Living Marine Resources (the Marine Resources Act)<sup>83</sup> which provides that marine bioprospecting permits in the areas under its jurisdiction may lay down that a proportion will accrue to the State if the product arises from the use of Norwegian marine genetic material.<sup>84</sup>

UNCLOS also limits the way in which freedom is exercised by coastal States to explore and exploit the marine genetic resources in their EEZs. Article 192 of UNCLOS imposes upon states a general obligation to protect and preserve the environment. This automatically includes marine genetic resources that fall within their territorial jurisdictions. In essence, states have a duty to ensure that activities undertaken by private or public entities in the process of marine bioprospecting will not damage the environment.<sup>85</sup> Article 192 further compels states to introduce and implement a preservation framework that is applicable and relevant to marine bioprospecting activities that are carried out within their EEZ. In addition, Articles 194 to 196 of UNCLOS imposes more specific obligations to prevent, reduce and control pollution that arises from marine

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<sup>82</sup> Leary 2004 *Macquarie Journal of International and Comparative Environmental Law* 137.

<sup>83</sup> Norwegian Law of Management of Living Marine Resources Act 37 of 2008.

<sup>84</sup> S10 Norwegian Law of Management of Living Marine Resources Act 37 of 2008.

<sup>85</sup> Leroux and Mbengue <http://www.gmat.unsw.edu.au/ablos/ABLOS10Folder/S3P1-P.pdf> 3.

bioprospecting cruises<sup>86</sup> conducted within the EEZ. These Articles cover a variety of pollution forms, including light and noise pollution, which are of particular concern in the total darkness, and nearly absolute silence of the habitats where bioprospecting takes place.<sup>87</sup>

Article 77(1) of UNCLOS provides that coastal states may exercise sovereign rights for the purposes of exploring and exploiting the natural resources of their continental shelf. Article 77(4) further provides that such natural resources include living organisms belonging to sedentary species.<sup>88</sup>

### 3.3 Marine Bioprospecting and the Convention on Biological Diversity.

The environmental and conservation duties that are imposed on states by UNCLOS are complemented by several obligations that have also been imposed on states by the CBD.<sup>89</sup> The CBD obliges states to identify and monitor marine genetic resources in their areas of national jurisdiction under Article 7. The main focus is placed on any resources that require conservation measures. The main aim of the CBD is the conservation of biological diversity as well as the sustainable use thereof in a fair and equitable way that promotes access to genetic resources and the transfer of the relevant knowledge.<sup>90</sup> It adopts a holistic and ecosystem-based approach to the sustainable use and conservation of biological diversity. It also recognizes states' sovereignty over their natural resources.<sup>91</sup>

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<sup>86</sup> A bioprospecting cruise is the process where researchers go on an expedition in the seas in search of biogenetic resources. These cruises have led to the sampling and sometimes commercialization of new marine biotech products. Leary 2004 *Macquarie Journal of International and Comparative Environmental Law* 137-141.

<sup>87</sup> Leary 2004 *Macquarie Journal of International and Comparative Environmental Law* 165.

<sup>88</sup> Art 68 of UNCLOS defines sedentary species as organisms which, at the harvestable stage, either are immobile on or under the seabed or are unable to move except in constant physical contact with the seabed or the

Subsoil. It is noteworthy to recall that microorganisms found in hydrothermal vents and cold seeps are considered sedentary or not depending on their biology.

<sup>89</sup> Article 2 Convention on Biological Diversity.

<sup>90</sup> Article 1 & 2 CBD.

<sup>91</sup> Article 3 CBD.



The CBD does not define the phrase “areas of national jurisdiction” nor the term “bioprospecting” although it addresses the use of genetic resources and the sovereignty of individual states. This then implies that the jurisdictional scope of the CBD is somewhat limited to the components of biodiversity that are found in the areas within the limits of national jurisdiction.<sup>92</sup> In simple terms, this means that deep seabed genetic resources in areas beyond national jurisdiction (ABNJ) are not covered within the scope of the CBD.<sup>93</sup> Interestingly, the CBD applies to processes and activities within the jurisdiction of states or under the control of such states whether it’s within or beyond the national jurisdiction of the state in question.<sup>94</sup> It follows then that activities that are conducted in ABNJ, such as navigation, scientific research, bioprospecting, exploration and exploitation, will all fall within the scope of the CBD if they are conducted under the control of a CBD ratifying state.<sup>95</sup> In such cases, flag state<sup>96</sup> parties are obliged to cooperate in conserving and using biodiversity sustainably.<sup>97</sup>

Apart from the provisions that deal with the conservation and sustainable use of biodiversity, the CBD also provides measures addressing access to genetic resources, transfer of technologies, technical and scientific cooperation.<sup>98</sup> In respect of the jurisdiction set out by the CBD, these provisions are limited to genetic resources falling within the limits of the national jurisdiction. Some of these measures are adapted to apply in areas beyond national jurisdiction using appropriate frameworks.<sup>99</sup>

The CBD provides that the authority to determine access to genetic resources belongs to the national government of the state in question and will be subject to national legislation.<sup>100</sup> In addition, the CBD mandates states to facilitate access to genetic

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<sup>92</sup> Article 4 CBD.

<sup>93</sup> UNU-IAS Report: Bioprospecting of Genetic Resources in the Deep Seabed, Scientific, Legal and Policy Aspects 38 available at <https://www.cbd.int/doc/external/unu/unu-ias-mar-report-2005-en.pdf> accessed on 17 September 2015.

<sup>94</sup> Article 4 CBD.

<sup>95</sup> UNU-IAS Report 39 <https://www.cbd.int/doc/external/unu/unu-ias-mar-report-2005-en.pdf>.

<sup>96</sup> Art 217 of UNCLOS deals with flag state which by definition, is the state in which a vessel is registered. On the high seas, flag states hold sole jurisdiction over oceangoing vessels. In other words, ocean-going vessels on the high seas are required only to comply with globally agreed upon standards subject to enforcement by the flag state.

<sup>97</sup> Article 25.

<sup>98</sup> Articles 15 to 20.

<sup>99</sup> UNU-IAS Report 40 <https://www.cbd.int/doc/external/unu/unu-ias-mar-report-2005-en.pdf>.

<sup>100</sup> Article 15(1) CBD.

resources for environmentally-sound uses by other parties on mutually agreed terms.<sup>101</sup> Parties shall also carry out scientific research related to resources that are provided for by the other party with their full participation, and they must take measures to share the results of the research and commercial benefits thereof in a fair and equitable way.<sup>102</sup>

The CBD also deals with matters relating to access to, and transfer of technology, which includes biotechnology. Parties that are involved in access and transfer of such knowledge must ensure that it happens in a manner that takes cognizance of the conservation and sustainable use of biodiversity.<sup>103</sup> In developing countries, such access and transfer shall be provided for under fair and most favorable terms and, in the case of technologies that are subject to patents and other intellectual property rights (IPRs), on terms that recognize, and are consistent with, the adequate and effective protections of such IPRs.<sup>104</sup> The CBD further mandates states to apply measures to ensure that the private sector facilitates access and transfer of technology for the benefit of governmental institutions and the private sector of developing countries.<sup>105</sup>

Under Article 19, the CBD addresses the handling of biotechnology and the distribution of its benefits. It also deals with the measures that must be adopted to provide for the effective participation in biotechnology research by countries providing genetic resources.<sup>106</sup> In return, these parties are then supposed to be given priority access to the results and commercial benefits arising from such in a fair and equitable way.<sup>107</sup>

### 3 4 Intellectual Property Rights Framework on Marine Bioprospecting

Patents have been granted for inventions that are based on or are related to genetic resources.<sup>108</sup> Granting of such patents has, to some extent, sparked heated debates

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<sup>101</sup> Article 15(2) & (4) CBD.

<sup>102</sup> Article 15(6) CBD.

<sup>103</sup> Article 16(1) CBD.

<sup>104</sup> Article 16(2) CBD.

<sup>105</sup> Article 16(4) CBD.

<sup>106</sup> Article 19(1) CBD.

<sup>107</sup> Article 19(2) CBD.

<sup>108</sup> Eisenberg "The Story of *Diamond v Chakrabarty*: Technological Change and the Subject Matter Boundaries of the Patent System Intellectual Property Stories" (Foundation Press, 2006) 327.

which were generally linked to the gap that exists between developed and developing states with respect to access to and the sharing of benefits arising from the commercial utilization of biodiversity.<sup>109</sup>

IPRs, specifically patents, are a temporary monopoly on a specific invention or technology which satisfies the patentability criteria namely novelty, inventiveness and industrial applicability.<sup>110</sup> Patents are subject to national legal structures where the protection is awarded for a limited time period, often 20 years.<sup>111</sup> During this period, the patent owner has the exclusive right to commercially exploit the invention or technology while he/she prevents the unauthorized use of the said invention or technology. In as far as bioprospecting is concerned, patents are therefore considered the most powerful intellectual property protection. Global minimum standards for national regulation are established by the TRIPS and through this agreement the member States that have signed and ratified this agreement are obliged to issue patents to products and processes that are novel, inventive and have the capacity to be applied on an industrial scale.<sup>112</sup>

According to the CBD, biotechnology means “any technological application that uses biological systems, living organisms or derivatives thereof, to make or modify products or processes for specific use.”<sup>113</sup> From this definition, marine microorganisms cannot then be excluded from patenting and hence, can be patented under the TRIPS Agreement.<sup>114</sup> It is important at this point to make it clear that discoveries, as opposed to inventions, will not qualify for protection under the patent regime.<sup>115</sup> The logical question that then follows this is how does one differentiate between a discovery of new biological material from, for example microorganisms, that can be patented?

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<sup>109</sup> Marine Bioprospecting T

<sup>110</sup> Article 27 of TRIPS Agreement defines patents as any inventions, whether products or processes, in all fields of technology, provided that they are new, involve an inventive step and are capable of industrial application.

<sup>111</sup> *Ibid.*

<sup>112</sup> Article 27(1) TRIPS Agreement.

<sup>113</sup> Article 2 CBD.

<sup>114</sup> Drankier “Marine Genetic Resources in Areas beyond National Jurisdiction: Access and Benefit-Sharing.” 2012 *The International Journal of Marine and Coastal Law* 375.

<sup>115</sup> *Ibid.*

The development of biotechnology in the field of marine natural products has given rise to a range of legal questions, since, prior to the wave of patent applications in the biotechnological field that took place in the 1970s, living organisms were generally regarded as non-patentable.<sup>116</sup> However, genetically engineered organisms, although they are derived from nature, seem to involve substantial human effort and human intervention which has led to the development of the law to allow the patenting of living microorganisms.<sup>117</sup> A landmark decision on this particular matter was given in the United States Supreme Court judgment in the case of *Diamond v Chakrabarty*.<sup>118</sup> In this case,<sup>119</sup> Chakrabarty engineered a bacterium that broke down crude oil components. Upon application for a patent, it was denied and the decision was taken on appeal to the U.S. Supreme Court. Since no such bacterium existed in nature, the Court concluded that it was nothing short of human ingenuity and therefore could be patented.<sup>120</sup> From then onwards, numerous patents for engineered living organisms have been issued across the world in various jurisdictions.

### 3.5 National Environmental Management: Biodiversity Act 10 of 2004.

The Biodiversity Act does not implicitly refer to marine bioprospecting *per se*, but the definitions section does describe “bioprospecting” and “biodiversity” as the variability among living organisms from all sources including those that are derived from the marine environment.<sup>121</sup> The Act also defines the phrase “introduction from the sea” to refer to specimen or species obtained from ABNJ within the seas.<sup>122</sup> To that effect, since the Act

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<sup>116</sup> Eisenberg *the Story of Diamond v Chakrabarty: Technological Change and the Subject Matter Boundaries of the Patent System* Intellectual Property Stories (Foundation Press, 2006) 327.

<sup>117</sup> *Ibid.*

<sup>118</sup> [1980] 447 U.S. 303.

<sup>119</sup> In 1972, Ananda Chakrabarty filed a patent application, assigned to the General Electric Company, on a human-made, genetically engineered bacterium from *Pseudomonas*, which was capable of breaking down multiple components of crude oil and was believed to have significant value for the treatment of oil spills. The patent claims not only included the method of producing the bacteria but also the bacteria themselves. The patent examiner allowed the claims for the method but rejected claims for the bacteria on two grounds. Firstly, micro-organisms are products of nature, and secondly, as living things they are not patentable subject matter under the US patent regime.

<sup>120</sup> *Diamond v. Chakrabarty* [1980] 447 U.S. 303.

<sup>121</sup> S1 Act 10 of 2004.

<sup>122</sup> *Ibid.*

applies to all biogenetic resources found within the Republic, including those found in the marine environment, the principles that are applicable to terrestrial environment, as discussed in Chapter 2, will also apply to marine environment in as far as the territorial sea and the EEZ is concerned.

## CHAPTER 4: INTELLECTUAL PROPERTY AND TRADITIONAL KNOWLEDGE

### 4 1 Introduction

There is no universally accepted definition for TK. As a result, TK is either described or defined in a general sense or in the narrow sense. TK in a general sense refers to the content of knowledge inclusive of traditional cultural expressions,<sup>123</sup> like distinctive signs and symbols associated with TK. TK in the narrow sense refers to knowledge that has been acquired or produced as a result of intellectual activity in a traditional context and includes know-how, practices, skills and innovations.<sup>124</sup>

The World Intellectual Property Organization (WIPO) describes traditional knowledge as:

“a living body of knowledge that is developed, sustained and passed on from generation to generation within a community, often forming part of its cultural and spiritual identity.”<sup>125</sup>

Dutfield argues that TK refers basically to the knowledge that is associated with the environment and thus defines TK as;

“a body of knowledge built by a group of people through generations living in close contact with nature. It includes a system of classification, a set of empirical observations about the local environment, and a system of self-management that governs resource use.”<sup>126</sup>

### 4 2 The Need for Protection of Traditional Knowledge

The negotiations at WIPO relating to the protection of TK have been, to a greater extent, initiated by developing countries which have significant indigenous populations that possess or harbor the TK of those respective communities. TK is vulnerable to both

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<sup>123</sup> Traditional Cultural Expressions (TCEs) are also known as expressions of folklore and such may include signs and symbols, dance, art, handicrafts and narratives, designs, names or many other artistic or cultural expressions - Dutfield *Intellectual Property, Biogenetic Resources and Traditional Knowledge* 97.

<sup>124</sup> Traditional Knowledge and Intellectual Property – Background Brief from WIPO website [http://www.wipo.int/pressroom/en/briefs/tk\\_ip.html](http://www.wipo.int/pressroom/en/briefs/tk_ip.html) accessed 30 August 2015.

<sup>125</sup> *Ibid.*

<sup>126</sup> Dutfield *Intellectual Property, Biogenetic Resources and Traditional Knowledge* (2004) 91.

expropriation and exploitation. Access to traditional knowledge in unregulated circumstances has happened earlier and local communities have been exploited financially by global pharmaceutical companies, as illustrated earlier.

Apart from the international agreements and emerging international norms, some of which will be discussed below, there are a number of reasons why developing countries may feel motivated to protect TK.<sup>127</sup> TK based innovations can be protected successfully and subsequently benefit the local indigenous populations from the protection that is offered through patents, trademarks and geographical indication protection.<sup>128</sup> In the alternative, protection can be afforded by treating information as a trade secret or confidential information.<sup>129</sup> One of the greatest challenges confronting the protection of TK is that it is generally undocumented and is passed from generation to generation by word of mouth.<sup>130</sup>

Without doubt, policy issues involved in the protection of TK are quite broad and diverse. Nonetheless, issues relating to IP can be narrowed down to two key themes on which IP protection is being sought. These are defensive protection and positive protection.<sup>131</sup> Defensive protection refers to the provisions adopted in the law or by the regulatory authorities to prevent IPR claims to knowledge or a product being granted to unauthorized persons.<sup>132</sup> Positive protection refers to the acquisition by TK holders themselves of any IPR, such as a patent or an alternative right provided by a *sui generis* system.<sup>133</sup> Positive protection measures may also serve to provide defensive protection and *vice versa*.

TK has been recognized as an important component in the conservation of the environment and biodiversity. This is clearly illustrated by the way in which TK is protected

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<sup>127</sup> Dutfield *Intellectual Property, Biogenetic Resources and Traditional Knowledge* 97.

<sup>128</sup> *Ibid.*

<sup>129</sup> Traditional Knowledge <http://www.wipo.int/tk/en/tk/> accessed 30 August 2015.

<sup>130</sup> Traditional Knowledge and Intellectual Property – Background Brief from WIPO website [http://www.wipo.int/pressroom/en/briefs/tk\\_ip.html](http://www.wipo.int/pressroom/en/briefs/tk_ip.html).

<sup>131</sup> Dutfield *Protecting Traditional Knowledge and Folklore: A review of progress in diplomacy and policy formulation. International Trade & Sustainable Development Series* 2003 1; Traditional Knowledge and Intellectual Property – Background Brief from WIPO website [http://www.wipo.int/pressroom/en/briefs/tk\\_ip.html](http://www.wipo.int/pressroom/en/briefs/tk_ip.html).

<sup>132</sup> *Ibid.*

<sup>133</sup> Traditional Knowledge <http://www.wipo.int/tk/en/tk/> accessed 30 August 2015.

within various international instruments, such as the CBD, the TRIPS Agreement and the Bonn Guidelines.

#### 4 3 International Framework regulating Traditional Knowledge

As mentioned earlier, at the drafting of the CBD, developing states envisaged, as part of their goals, that they were going to participate in the restructuring of the global relations in as far as economy controlled by access to biogenetic resources was concerned.<sup>134</sup> The developing countries were, and still are, in full support of the proposed motion to compensate indigenous communities for the knowledge that was provided to the large multi-national corporations conducting research and development in developing countries. The protection and promotion of equitable exchange of traditional knowledge, as provided for in the CBD, will be discussed below in addition to the TRIPS Agreement.

##### 4 3 1 Convention of Biological Diversity and Traditional Knowledge.

In the Preamble of the CBD, specific recognition is given to how the indigenous and local communities are dependent on traditional lifestyles relying on biological resources as well as the desire with which the use of traditional knowledge, innovations and practices relevant to the conservation of biological diversity can be shared equitably among the parties involved.<sup>135</sup> The drafters of the CBD went further and emphasized the importance of encouraging equitable benefit sharing arising from the utilization of knowledge, innovations and practices of indigenous communities.<sup>136</sup> Article 8(j) of the CBD reads as follows;

“subject to its national legislation, respect, preserve, and maintain knowledge, innovations and practices of indigenous local communities embodying traditional lifestyles relevant for the conservation and sustainable use of biological diversity and

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<sup>134</sup> Masango *Indigenous traditional knowledge protection: prospects in South Africa's intellectual property framework?* 76 1 2010 74.

<sup>135</sup> The Preamble, CBD.

<sup>136</sup> Article 8(j) CBD.



promote their wider application with the approval and involvement of the holders of such knowledge and practices and encourage the equitable sharing of the benefits arising from the utilization of such knowledge, innovations and practices.”

This article takes notice of the fact that the implementation of the CBD, in as far as TK is concerned, is subject to the discretion of the parties and is regulated by the national legislation of the particular state. The provision made in article 8(j) that the transaction involving the exchange and equitable sharing of TK be subject to national legislation also provides that the application of that clause may not be uniform across various jurisdictions and the contracting parties have the discretion to decide how they conduct themselves.<sup>137</sup>

In article 10(c), the CBD provides that the contracting parties must try, where possible, to protect and encourage customary use of biological resources in a manner that is compatible with conservation and sustainability requirements.<sup>138</sup> In addition to such requirements, the CBD further promotes, in the same light, the sharing of benefits that are derived from such use of biological resources, inclusive of the customary or traditional knowledge derived thereof.<sup>139</sup>

The CBD gives recognition to the sovereignty that each country has over the resources found within its jurisdiction and the resulting authority to regulate and control access to such resources.<sup>140</sup> The CBD does not make specific mention of its application within the territorial waters, as discussed in Chapter 3. However, the jurisdiction of a coastal state extends to the EEZ of a state, as provided for in UNCLOS. Therefore, it is submitted that these provisions will equally apply in the EEZ the same way they apply on land.<sup>141</sup>

The CBD makes it clear that states with genetic resources have sovereign rights over their territories<sup>142</sup> and any material that is within that territory can only be expropriated or exploited by agreement between the parties on terms that the CBD describes as “mutually agreed terms” (MATs).<sup>143</sup> These MATs will, among other things, ensure that there is

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<sup>137</sup> *Ibid.*

<sup>138</sup> Article 10(c) CBD.

<sup>139</sup> Article 15 CBD.

<sup>140</sup> Article 15(1) CBD.

<sup>141</sup> Masango *Indigenous traditional knowledge protection: prospects in South Africa's intellectual property framework?* 76, 1 2010 74.

<sup>142</sup> Article 15(1) CBD.

<sup>143</sup> Article 15(7) CBD.

access to benefit sharing (ABS) that is equitable between the contracting parties, taking into consideration the resources bioprospectors have to dispose of during the sampling and screening phase of their research, as well as the TK that is supplied by the indigenous people of an area.

In an attempt to increase protection of TK and give more effect to the CBD, the Bonn Guidelines were drafted with the intention to assist CBD parties in the development and drafting of legislative, administrative and policy measures on ABS.<sup>144</sup>

#### 4 3 2 The Bonn Guidelines on Access to Genetic Resources and Fair and Equitable sharing of Benefits

The Bonn Guidelines were published by the Secretariat of the CBD in 2002. Guideline 9 provides the scope of the Bonn Guidelines in which they recognize comprehensively the matter of benefit sharing inclusive of the benefits derived of all genetic resources as well as those associated with traditional knowledge.<sup>145</sup>

The objectives of the Bonn Guidelines, *inter alia*, are to provide parties and stakeholders with a transparent framework to facilitate access to genetic resources and ensure fair and equitable sharing of benefits.<sup>146</sup> The benefits referred to in the Bonn Guidelines can either be monetary or non-monetary benefits.<sup>147</sup> The structure of these guidelines allows contracting parties to have flexibility in terms of the agreements they will come to. These will be recognized as legally binding MATs or, in the alternative, a contract or agreement between the contracting parties that will be legally enforceable.<sup>148</sup> The Bonn Guidelines has given the CBD more effect in ensuring that ABS is possible. The framework provides

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<sup>144</sup> Paragraph 1 The Bonn Guidelines of the CBD; Keating *Access to Genetic Resources and Equitable Benefit Sharing Through a New Disclosure Requirement in the Patent System: An Issue in Search of a Forum* 2005 JPTOS 525.

<sup>145</sup> Guideline 9 the Bonn Guidelines of the CBD.

<sup>146</sup> Guideline 11(b) the Bonn guidelines of the CBD.

<sup>147</sup> Guideline 46 the Bonn Guidelines of the CBD.

<sup>148</sup> Guideline 41 the Bonn Guidelines of the CBD.

that full disclosure must be made, both to the contracting party and to the patent officer/registrar from where the patent will be subsequently applied from.<sup>149</sup>

#### 4 3 2 1 Disclosure Element and the Benefit Sharing Process

Part IV of the Bonn Guidelines provides for steps in the ABS process which has been recognized as a framework that can be available either at a national level or the regional level.<sup>150</sup> The steps that are often involved in the process of obtaining access to genetic resources and sharing of benefits may include the activities that are prior to access, research and commercialization.<sup>151</sup> Such steps will involve disclosure by bioprospectors of the intended screening and sampling processes they intend to employ and how their harvesting will ensure that access to such biological genetic resources is done in a conservative and sustainable manner. Such disclosure will form part of the process that is required in reaching MATs between the contracting parties.<sup>152</sup>

The MATs will also provide detailed intended specific use of the genetic material resources which will be an element of prior informed consent. Prior informed consent is a mechanism used by contracting parties to ensure that full disclosure must be made by the contracting parties. Should the specifications that were discussed at the point where prior informed consent was given have changed, any such changes may require the bioprospectors to lodge a new application for prior informed consent.<sup>153</sup> Permitted uses should be clearly stipulated and further prior informed consent for changes that were encountered, perhaps due to the fact that they were unforeseeable, should be required and has to be granted before the process of bioprospecting can proceed.<sup>154</sup>

The procedure for obtaining prior informed consent to a competent authority involves, *inter alia*: disclosure of the type and quantity of genetic resources that will be accessed

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<sup>149</sup> *Ibid.*

<sup>150</sup> Guideline 22 the Bonn Guidelines of the CBD.

<sup>151</sup> Guideline 23 the Bonn Guidelines of the CBD.

<sup>152</sup> *Ibid.*

<sup>153</sup> *Ibid.*

<sup>154</sup> Guideline 34 the Bonn Guidelines of the CBD.

and sought;<sup>155</sup> evaluation on how such activity may impact the conservation and sustainable use of biodiversity;<sup>156</sup> accurate information regarding the intended use;<sup>157</sup> information on how the research and development will be conducted;<sup>158</sup> and the purpose of the collection; research and expected results.<sup>159</sup> It is important to note that permission to access genetic resources does not in turn imply permission to use associated knowledge and the reverse is true.<sup>160</sup>

#### 4.3.2.2 Disclosure of Origin in Patent Applications

The second element of disclosure is the requirement that a patent applicant has to disclose the origin of the genetic material they intend to protect with the patent application. This is a form of defensive protection mechanism. This compulsory disclosure was initially started by civil society organizations and was strongly supported by developing states and the intention for such was to help realize fair and equitable benefit sharing that is required by the CBD.<sup>161</sup> This is supposed to be done to ensure that the TK has been acquired in line with the biodiversity access and benefit sharing regulations in the source countries.

Three distinct forms of proposals relating to disclosure of the origin of the biogenetic resources can be identified. These are either weak form, medium form or strong form. The weak form of such disclosure is whereby the disclosure by the patent applicant as to the origin of the biogenetic material is encouraged but not a requirement. Subsequently, failure to disclose, the omission thereof, would not disqualify the patent from being granted.<sup>162</sup> In contrast to the weak form, the medium form of disclosure makes it

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<sup>155</sup> Guideline 36(b) the Bonn Guidelines of the CBD.

<sup>156</sup> Guideline 36(e) the Bonn Guidelines of the CBD.

<sup>157</sup> Guideline 36(f) the Bonn Guidelines of the CBD.

<sup>158</sup> Guideline 36(h) the Bonn Guidelines of the CBD.

<sup>159</sup> Guideline 36(k) the Bonn Guidelines of the CBD.

<sup>160</sup> Guideline 37 the Bonn Guidelines of the CBD.

<sup>161</sup> Dutfield *Protecting Traditional Knowledge and Folklore: A review of progress in diplomacy and policy formulation. International Trade & Sustainable Development Series* 2003 33

<sup>162</sup> *Ibid*

mandatory that the origin of the biogenetic resources be disclosed at the time of application for a patent to be granted.<sup>163</sup>

The strong form goes way beyond the requirement of disclosure required by the medium form in that it actually requires that a patent applicant must comply with the CBD's access to benefit sharing provisions. This can be done by making it a strict requirement for a patent applicant to submit official documentation from the states where resources are harvested which proves that the biogenetic resources and the associated TK have been obtained in accordance with the requirements provided for ABS and prior informed consent was given.<sup>164</sup>

#### 4.3.3 Agreement on Trade-Related Aspects of Intellectual Property Rights and Traditional Knowledge.

The TRIPS Agreement requires that WTO Members to allow patents to be available for any inventions in all fields of technology. The requirements must be products or processes that must be new, involve an inventive step and are capable of industrial application. There are certain items that are listed in the TRIPS Agreement which cannot be patented and these include plants and animals other than microorganisms and essentially biological processes for the production of plants and animals other than non-biological and microbiological processes.<sup>165</sup>

Genetic biochemical resources are not expressly excluded or included from the TRIPS Agreement. It is therefore possible, in principle, to have patents be made available for genetic biochemical resources subject to the conditions that they may be new, involve an inventive step and are capable of industrial application.<sup>166</sup> It has been widely accepted across Europe and Northern American jurisdictions that one cannot claim, as an

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<sup>163</sup> *Ibid*

<sup>164</sup> Dutfield *Protecting Traditional Knowledge and Folklore: A review of progress in diplomacy and policy formulation. International Trade & Sustainable Development Series* 2003 34

<sup>165</sup> Article 27(3)(b) TRIPS Agreement

<sup>166</sup> Dutfield *Protecting Traditional Knowledge and Folklore: A review of progress in diplomacy and policy formulation. International Trade & Sustainable Development Series* 2003 30

invention, something that occurs naturally in nature. This means that what could be a simple discovery of nature cannot be patented. However, it is possible to extract elements of nature and make them available for industrial purposes or utilization for the first time and thereby claim a patent for such extraction.<sup>167</sup> This argument has been very difficult to prove to patent registrars or courts. Patents have however been issued where a certain change has been effected on a natural compound such as; an addition of a gene, or purifying a compound, or combining it with something else thereby giving it a better structural advantage as opposed to how its individually and naturally found in nature.<sup>168</sup> There is no clear indication as to whether being the first one to describe a product or invention in biochemistry terms will allow for a patent to be granted.

#### 4 4 The National Framework – The National Environmental Management: Biodiversity Act.

South Africa became a signatory of the CBD on 4 June 1993 and CBD was ratified on 2 November 1995, where South Africa became a party. South Africa enacted the Biodiversity Act which was fully operational on 1 January 2006.<sup>169</sup>

The Biodiversity Act has three main objectives that are aligned with those of the CBD which are conservation of biological diversity, the sustainable use of its components and fair and equitable sharing of benefits arising out of the utilization of genetic resources.<sup>170</sup> The benefit sharing envisioned by the Biodiversity Act includes the appropriate access to genetic resources and the appropriate transfer of relevant technologies.<sup>171</sup>

The Biodiversity Act provides specifically for bioprospecting, access to biological resources and benefit sharing in Chapter Six of the Act. Chapter Six was put in place in order to regulate bioprospecting involving indigenous biological resources for the

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<sup>167</sup> *Ibid.*

<sup>168</sup> Dutfield *Protecting Traditional Knowledge and Folklore: A review of progress in diplomacy and policy formulation. International Trade & Sustainable Development Series* 2003 34

<sup>169</sup> *Ibid.*

<sup>170</sup> S2 Act 10 of 2004.

<sup>171</sup> *Ibid.*

purposes of bioprospecting.<sup>172</sup> In addition to that, provision is made for the establishment of a fair and equitable sharing by stakeholders in benefits that arise from bioprospecting involving indigenous biological resources.<sup>173</sup>

The Biodiversity Act further makes provisions that protects certain stakeholders as well as their interests which must be kept in mind when the granting of a permit for a proposed bioprospecting project is being considered.<sup>174</sup> Section 82(1) of the Act identifies these stakeholders as;

“(a) A person, including any organ of state or community, providing or giving access to the indigenous biological resources to which the application relates; and

(i) whose traditional uses of the indigenous biological resources to which the application relates have initiated or will contribute to or form part of the proposed bioprospecting; or

(ii) whose knowledge of or discoveries about the indigenous biological resources to which the application relates are to be used for the proposed bioprospecting.”

In a situation where a person, community or an organ of state provides or gives access to biological resources to which such application relates, a permit will only be issued if certain conditions are met. These conditions are, *inter alia*: that the applicant has disclosed all material information relating to the relevant bioprospecting to other stakeholders on the basis of disclosure required to fulfill the elements of prior informed consent;<sup>175</sup> there is a material transfer agreement that regulates the provision of or access to such resources;<sup>176</sup> as well as a benefit sharing agreement that provides for sharing by the stakeholder in any future benefits that may be derived from the relevant bioprospecting.<sup>177</sup>

In cases where the stakeholder is an indigenous community<sup>178</sup> then the relevant authority may only issue a permit if-

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<sup>172</sup> S80 Act 10 of 2004.

<sup>173</sup> *Ibid.*

<sup>174</sup> S82(1) Act 10 of 2004.

<sup>175</sup> S82(2)(a) Act 10 of 2004.

<sup>176</sup> S82(2)(b)(i) Act 10 of 2004.

<sup>177</sup> S82(2)(b)(ii) Act 10 of 2004.

<sup>178</sup> S82(1)(b) Act 10 of 2004 defines indigenous community as a community-

(i) whose traditional uses of the indigenous biological resources to which the application relates have initiated or will contribute to or form part of the proposed bioprospecting; or

“(a) the applicant has disclosed all material information relating to the relevant bioprospecting to the stakeholder and on the basis of that disclosure has obtained the prior consent of the stakeholder to use any of the stakeholder's knowledge of or discoveries about the indigenous biological resources for the proposed bioprospecting;

(b) the applicant and the stakeholder have entered into a benefit-sharing agreement that provides for sharing by the stakeholder in any future benefits that may be derived from the relevant bioprospecting; and

(c) the Minister has in terms of section 83(2) approved such benefit-sharing agreement.”<sup>179</sup>

In this manner the Biodiversity Act ensures that the issuing authority<sup>180</sup> may further engage the contracting parties to reach an agreement that is more equitable and beneficial to all the parties that are involved.<sup>181</sup> In addition to this, the Biodiversity Act requires the Minister<sup>182</sup> to ensure that agreements reached between the parties are equitable and where necessary, can make recommendations before a permit is granted.<sup>183</sup>

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(ii) whose knowledge of or discoveries about the indigenous biological resources to which the application relates are to be used for the proposed bioprospecting.

<sup>179</sup> *Ibid.*

<sup>180</sup> The Minister (see footnote 183 below) or an organ of state in the national, provincial or local sphere of government designated by regulation in terms of section 97 as an issuing authority for permits of the kind in question.

<sup>181</sup> S82(4) Act 10 of 2004.

<sup>182</sup> The Cabinet member responsible for national environmental management.

<sup>183</sup> S82(4)(c) Act 10 of 2004.



## CHAPTER 5: APPLICATION OF BIOPROSPECTING WITHIN THE SOUTH AFRICAN TERRITORIAL WATERS AND THE EEZ.

### 5 1 Introduction

As noted earlier, all the international instruments and agreements that are used to regulate activities within the seas do not expressly mention the use of biogenetic resources and inferences must be made to extend protection where needed. Even the South African legislation, the Biodiversity Act does not deal with biogenetic resources within territorial waters and the EEZ and as such, it is established that the principles that apply on land will also apply within the territorial waters and EEZ since it is considered to be sovereign territory of the state in question.

In the field of seeking leads for new drugs from natural products, bioprospecting follows either of the two main approaches commonly used which are: the use of leads from traditional medical uses, also referred to as Ethnopharmacology,<sup>184</sup> and the use of natural products as a highly diverse set of chemicals for random screening.<sup>185</sup> Ethnopharmacology has been a source of some very notable medicinal discoveries including; morphine that was isolated in 1804, quinine isolated in 1820, ephedrine isolated in 1897 and tubocurarine that was isolated in 1935. All these compounds or their derivatives or analogues<sup>186</sup> are still widely used in the field of medicine today.<sup>187</sup>

There have been instances in which, in the process of ethnopharmacological discoveries, proper procedures were not adhered to in which the use of some of the policies and instruments was tested. The application of such policies have been proved to be helpful in favor of the indigenous communities. An example will be considered forthwith:

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<sup>184</sup> Ethnopharmacology is a related study of ethnic groups and their use of drugs. Ethnopharmacology is distinctly linked to plant use, ethnobotany, as this is the main delivery of pharmaceuticals.

<sup>185</sup> Harvey & Gericke 2008 328; Crouch *et al* 2008 356.

<sup>186</sup> Analogues is a chemical compound that is structurally similar to another but differs slightly in composition (as in the replacement of one atom by an atom of a different element or in the presence of a particular functional group).

<sup>187</sup> Harvey & Gericke 2008 328.

## 5.2 The *Hoodia* Case

A case in point is the development of an appetite suppressant from the traditionally used South African plants found in the *Hoodia* genus which, at some point, had to be stopped because in the process of the commercial development of the *Hoodia*. Inappropriate agreements were entered between the South African Research Organization, CSIR, and commercial development partners without the inclusion of the holders of traditional knowledge, the San people.<sup>188</sup> After intensive campaigning (by the San people and their legal representative), in what is regarded as a milestone in Africa and elsewhere, the patent holder and the San community entered into a benefit sharing agreement as contracting parties. The resultant effect of the above agreement led to a successful, acceptable agreement that was mutually beneficial to all the parties concerned.<sup>189</sup>

In brief, the facts of this case are as follows;

- CSIR developed an appetite suppressant derived from species of *Hoodia*, a succulent plant indigenous to Southern Africa and long used by the San, indigenous peoples of the region, to stave off hunger and thirst.
- CSIR used active constituents of the *Hoodia* plant which is responsible for suppressing appetite and was patented by CSIR. CSIR is one of the largest research organizations in Africa, accounting for about 10% of the entire African research and development budget
- The appetite suppressant has been commercialised into a food supplement and/or prescription medicine, with considerable financial potential. The current market potential for the dietary control of obesity is over \$3 billion per annum in the United States alone
- Up until 2001, the San remained unaware of the fact that their knowledge of *Hoodia* had commercial application. They were not aware that their knowledge had led to research, scientific validation, and the filing of international patents by the CSIR.

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<sup>188</sup> Harvey & Gericke 2008 328.

<sup>189</sup> Harvey & Gericke 2008 328.

Moreover, they were excluded from lucrative deals being struck between CSIR and Phytopharm (UK) to develop the drug.

- In 2003, however, following intense negotiations, an agreement was reached between the CSIR and the San, to give the San a share of royalties from potential drug sales; 6% of royalties received by CSIR; and 8% of all milestone payments. The San-Hoodia Benefit Sharing Trust was formed to administer the money for San welfare.

The *Hoodia* Patent (Patent No.198/3170) has 132 claims which includes *inter alia*:

- a) Process for preparing the Hoodia extract which has the appetite suppressant agent;
- b) An extract comprising an appetite suppressant agent when produced by the above process;
- c) A composition having appetite suppressant activity comprising the extract;
- d) Other processes for extracting appetite suppressant agent from plant material;
- e) An extract containing a particular chemical compound which is defined;
- f) A group of chemical compounds *per se* not limited by function or derivation from plant material.

The *Hoodia* Patent is both a process and a product patent. All *Hoodia* extracts containing appetite suppressants from any *Hoodia* plant (even species not known to San) are patented and any extract that contains the named chemical compound from any other plant is protected by the *Hoodia* patent.

As mentioned above, The *Hoodia* plant has been traditionally used by the San people for decades as an appetite suppressant. The CSIR was, without any doubt, the first to express the use of the compounds in the *Hoodia* plant in biochemical language but the intended use of such plant could not be identified as new/novel, at least not to the San people, who were not listed anywhere in the patent.<sup>190</sup> CSIR was held to have a legitimate claim to the patent according to the European Patent Convention's standards which state in their guidelines that:

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<sup>190</sup> *Ibid.*

“If a substance found in nature has first to be isolated from its surrounding and a process for obtaining it is developed, that process is patentable. Moreover, if the substance can be properly characterized either by its structure, by the process by which it is obtained or by other parameters ... and it is ‘new’ in the absolute sense of having no previously recognized existence, then the substance per se may be patentable.”

This presents a problem as it disregards the role played by the indigenous people who have been using the plant for decades. This position has not been challenged or raised in contention although the CSIR agreed to share the benefits with the San people after they were heavily criticized for initially failing to make such a commitment.<sup>191</sup>

In as much as the *Hoodia* case was based on land, it is submitted that the same principles that were employed on this case can be equally applied within the territorial waters as well as the EEZ.

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<sup>191</sup> Dutfield *Protecting Traditional Knowledge and Folklore: A review of progress in diplomacy and policy formulation. International Trade & Sustainable Development Series* 2003 31.

## CHAPTER 6: CONCLUSION

Bioprospecting is the exploration of biodiversity for commercially valuable genetic and biochemical resources. The process of bioprospecting often involves the screening and sampling of the genetic resources in search for active compounds that can be used in the manufacturing and production of chemicals. The process of acquiring information during sampling may involve engaging with the local indigenous communities that have been using certain plants and herbs for generations to cure ailments among their people.

There is considerable knowledge that lies within the local indigenous populations which has been shared among communities for generations. Often, this knowledge is transmitted by word of mouth and is seldom documented. Without proper legal framework in place, such knowledge can be exploited to the detriment of the local indigenous people and as such, laws and regulations have been put in place to protect these individuals. In some respects, these laws are not sufficient to give enough protection and often at times inferences have to be made to extend protection in cases where the legal framework does not expressly address a particular matter.

The focus of this treatise has been on TK and the conservation of biodiversity within the territorial waters and the EEZ. The UNCLOS is the principle source of law in this regard as it intends to regulate “all uses of the oceans and their resources.”<sup>192</sup> However, because UNCLOS does not expressly deal with biogenetic resources and biodiversity, one of the key instruments that is often applied is the CBD. The CBD covers matters concerning sustainable use of biodiversity as well as the equitable benefit sharing of products and benefits obtained from genetic resources. In order to provide more protection and give more effect to the CBD, the Nagoya Protocol was adopted in Japan in 2010.

Locally in South Africa, bioprospecting is regulated by Chapter 6 of the Biodiversity Act which also regulates access to biological resources and benefit sharing.<sup>193</sup> The Chapter has a threefold application, namely to regulate bioprospecting that involves indigenous

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<sup>192</sup> UN Convention on the Law of the Sea of 10 December 1982, Overview and full text, available at [http://www.un.org/depts/los/convention\\_agreements/convention\\_overview\\_convention.htm](http://www.un.org/depts/los/convention_agreements/convention_overview_convention.htm) accessed 14 September 2015.

<sup>193</sup> Visser 2006 437.

biological resources; to regulate the export from South Africa of indigenous biological resources; and to provide for a fair and equitable sharing by stakeholders in benefits arising from bioprospecting involving indigenous biological resources. The Act prohibits the engagement in bioprospecting or exporting of such resources unless a permit is issued in accordance with Chapter 7 of the Act.

The Biodiversity Act requires bioprospectors to obtain a permit from the Minister of Trade and Industry for bioprospecting involving indigenous biological resources as well as for the export of these resources. In addition to all this, the Act has made it mandatory indigenous communities and landowners must provide prior informed consent, and for bioprospectors to enter into benefit sharing agreements with the indigenous communities who use the resource traditionally, before a permit is issued by the Minister.

The Biodiversity Act has defined bioprospecting as process within which biogenetic resources are screened and sampled in search of active biological compounds that are essential in product developments. The Act does not implicitly refer to marine bioprospecting *per se*, but the definitions section does describe biodiversity as the variability among living organisms from all sources including those that are derived from the marine environment, hence by extension, the definition provided for bioprospecting can also be held to apply equally in the territorial waters.<sup>194</sup>

As established above, there is no express regulation of bioprospecting and biogenetic resources within the seas. It is therefore assumed that, since the Act applies to all biogenetic resources found within the Republic, including those found in the marine environment, the principles that are applicable to terrestrial environment, will also apply to marine environment in as far as the territorial sea and the EEZ is concerned.

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<sup>194</sup> S1 Act 10 of 2004.

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